InspireMD, Inc.
Form 10-KT
February 26, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM 10-K

£ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

R **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from July 1, 2013 to December 31, 2013

COMMISSION FILE NUMBER: 001-35731

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2123838**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
321 Columbus Avenue	
Boston, Massachusetts	**02116**

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(857) 453-6553**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.0001 par value	NYSE MKT

Securities registered pursuant to Section 12(g) of the Act: none

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes £ No R

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes £ No R

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes R No £

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes R No £

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. £

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 definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

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

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Act). Yes £ No R

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2013, based on the price at which the common equity was last sold on the NYSE MKT on such date, was approximately $56,816,075. For purposes of this computation only, all officers, directors and 10% or greater stockholders of the registrant are deemed to be affiliates.

Indicate the number of shares outstanding of each of the registrant’s classes of common stock as of the latest practicable date.

Class	**Outstanding at February 25, 2014**
Common Stock, $0.0001 par value	34,925,920

Documents incorporated by reference:

None

TABLE OF CONTENTS

PART I

In this Transition Report on Form 10-K/T, unless the context requires otherwise, the terms “we,” “our,” “us,” or “the Company” 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, taken as a whole, and the terms “we,” “our,” “us,” or “the Company” for periods subsequent to the closing of the share exchange transactions refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries, including InspireMD Ltd., taken as a whole.

Item 1. Business.

Change in Fiscal Year End

On September 16, 2013, our board of directors approved a change in our fiscal year-end from June 30 to December 31, effective December 31, 2013. This Transition Report on Form 10-K/T reports our financial results for the six month period from July 1, 2013 through December 31, 2013, which we refer to as the “transition period” throughout this report. Following the transition period, we will file annual reports for each twelve month period ended December 31 of each year beginning with the twelve month period ended December 31, 2014.

History

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

On March 31, 2011, we completed a series of share exchange transactions pursuant to which we issued the shareholders of InspireMD Ltd. 12,666,666 shares of common stock (as adjusted for the one-for-four reverse stock split of our common stock that occurred on December 21, 2012) in exchange for all of InspireMD Ltd.’s issued and outstanding ordinary shares, resulting in the former shareholders of InspireMD Ltd. holding a controlling interest in us and InspireMD Ltd. becoming our wholly-owned subsidiary. In addition, all options, warrants or other securities convertible into or exercisable for ordinary shares of InspireMD Ltd. were exchanged for options, warrants or other securities convertible into or exercisable for shares of our common stock.

Immediately following the share exchange transactions, we transferred all of our pre-share exchange operating assets and liabilities to our wholly-owned subsidiary, Saguaro Holdings, Inc., a Delaware corporation, and transferred all of Saguaro Holdings, Inc.'s outstanding capital stock to Lynn Briggs, our then-majority stockholder and our former president, chief executive officer, chief financial officer, secretary-treasurer and sole director, in exchange for the cancellation of 1,875,000 shares of our common stock (as adjusted for the one-for-four reverse stock split of our common stock that occurred on December 21, 2012) 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 designees of InspireMD Ltd.

Overview

We are a medical device company focusing on the development and commercialization of our proprietary stent platform technology, MGuard™. MGuard provides embolic protection in stenting procedures by placing a micronet mesh sleeve over a stent (see photograph below of an MGuard stent). Our initial products are marketed for use mainly in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). According to the TYPHOON STEMI trial (New England Journal of Medicine, 2006) and the SOS SVG Trial (Journal of the American College of Cardiology, 2009), of patients with acute myocardial infarction and saphenous vein graft coronary interventions, 7.5% to 44% experience major adverse cardiac events, including cardiac death, heart attack and restenting of the artery. When performing stenting procedures in patients with acute coronary symptoms, interventional cardiologists face a difficult dilemma in choosing, with the aim of ensuring adequate protection from distal embolization (the dislodgement of particles from the artery wall that results in blood clot), between bare-metal stents, which have a high rate of restenosis (formation of new blockages), and drug-eluting (drug-coated) stents, which have a high rate of late thrombosis (formation of clots months or years after implantation), require administration of anti-platelet drugs for at least one year post procedure, are more costly than bare-metal stents and have additional side effects. We believe that MGuard is a simple and seamless solution for these patients. For the six months ended December 31, 2013, our total revenue was approximately $3.1 million and our net loss was approximately $9.3 million. For the six months ended December 31, 2012, our total revenue was approximately $1.9 million and our net loss was approximately $9.4 million.

MGuard Sleeve – Microscopic View

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

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

In October 2007, our first generation product, the MGuard Coronary, received CE Mark approval for treatment of coronary arterial disease in the European Union. CE Mark is a mandatory conformance mark on many products marketed in the European Economic Area and certifies that a product has met European Union consumer safety, health or environmental requirements. We began shipping our product to customers in Europe in January 2008 and have since expanded our global distribution network to Southeast Asia, India, Latin America and Israel.

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

The MGuard Prime version of the MGuard Coronary product received CE Mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. We believe we can use and leverage the clinical trial results of our original stainless steel based MGuard Coronary to help market our new cobalt-chromium based MGuard Prime version of the MGuard Coronary product. In addition, MGuard Carotid received CE Mark approval in the European Union in March 2013.

4

However, we face a number of challenges to the further growth of our MGuard Coronary and other planned MGuard products. For example, we face competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. Most of our current and potential competitors have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. In addition, none of our products 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 products, including one that is underway, 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 or our products could be challenged in view of third party intellectual property rights. Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our MGuard products based on one or more of these patents. Additionally, there is a strong preference to use drug-eluting stents in some countries. Over the last decade, there has been an increasing tendency to use drug-eluting stents in percutaneous coronary intervention (PCI), commonly known as angioplasty (a therapeutic procedure to treat narrowed coronary arteries of the heart found in patients with heart disease), with a usage rate of drug-eluting stents in PCI approaching 70-80% in some countries, even though drug-eluting stents do not address thrombus management in acute myocardial infarction. Also, the use of other bare-metal stents is preferred over the use of MGuard products in certain circumstances, such as when placing the stent at the entrance to large side branches, known as “jailing large side branches.”

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

Our principal executive offices are located at 321 Columbus Avenue, Boston, MA 02116. Our telephone number is (857) 453-6553. We make available free of charge through our website at www.inspire-md.com our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports. You may also obtain any materials we file with, or furnish to, the U.S. Securities and Exchange Commission on its website at www.sec.gov.

Business Segment and Geographic Areas

For financial information about our one operating and reportable segment and geographic areas, refer to “Part II—Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Part II—Financial Statements and Supplementary Data—Note 12. Entity Wide Disclosures.”

Our Industry

According to Fact Sheet No. 310/updated June 2013 of the World Health Organization, approximately 7.0 million people worldwide died of ischaemic heart disease in 2011. 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 2014 MEDTECH OUTLOOK produced in December 2013 by BMO Capital Markets, revenues from the global coronary stent market are predicted to slightly decline, although in volume of stents the market is predicted to continue to grow. The growth in volume is due to the appeal for less invasive percutaneous coronary intervention procedures and advances in technology coupled with the increase in the elderly population, obesity rates and advances in technology.

Coronary artery disease is one of the leading causes of death worldwide. The treatment of coronary artery disease includes alternative treatment methodologies, that is, coronary artery bypass grafting or angioplasty (percutaneous coronary intervention) with or without stenting. According to the 2014 MEDTECH OUTLOOK produced by the BMO Capital Markets in December 2013, the percutaneous coronary intervention procedures involving stents used to treat coronary artery diseases had an estimated 68% market penetration rate in 2013.

Our Products

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

MGuard Deployed in Artery

The protective sleeve is designed to provide several clinical benefits:

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

MGuard – Coronary Applications

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

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

The results of the initial single arm trials (MAGICAL, PISCIONE and iMOS) for the MGuard Coronary stent suggest higher levels of reperfusion, lower rates of 30-day and 1-year major adverse cardiac events, and high levels of complete ST resolution, as compared to the levels and rates of other bare-metal and drug-eluting stents. MGuard Coronary demonstrated high levels of complete ST resolution (occurrence in 61% of patients in the MAGICAL study and 90% of patients in the PISCIONE study for the MGuard Coronary stent) and lower rates of 30 day and 1 year major adverse cardiac events (2.4% and 5.9%, respectively, for the MGuard Coronary stent), as compared to the levels and rates of other bare-metal and drug-eluting stents, as reported by Vlaar et. al. (Cardiac death and reinfarction after 1 year in the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS): a 1-year follow-up study, Lancet 2008; 371: 1915–20). As reported in the study by Vlaar et. al., complete ST resolution occurred in 44.2% of patients with a bare-metal stent and 56.6% of patients with a bare-metal stent preceded by an aspiration procedure, and the 30 day and 1 year major adverse cardiac event rates were 9.4% and 20.3%, respectively, for patients with a bare-metal stent and 6.8% and 16.6%, respectively, for patients with a bare-metal stent preceded by an aspiration procedure. Furthermore, results from the HORIZONS-AMI trial demonstrated that 1-year major adverse cardiac event rates were 10.5% for patients with drug eluting stents. Complete ST resolution is the evidence of a quick and adequate disappearance of the pathologic ST elevation in the patient's electrocardiogram, which is the clear marker of STEMI. The faster and more complete the resolution is, the better recovery of the myocardium and the better prognosis for the patient. Vlaar et. al. reported that a higher complete ST resolution correlates with lower mortality and/or reinfarction rates among affected patients (cardiac mortality was 1.4% for patients with complete ST resolution compared to 15.3% for patients with no ST resolution).

With respect to our MASTER I trial, 30 day, 6 month and 12 month results were reported on October 24, 2012, May 23, 2013 and October 19, 2013, respectively (See "— Clinical Trials — Completed Clinical Trials for MGuard Coronary Bare Metal Stent Plus Bio-Stable Mesh"). As described below, the MASTER I trial demonstrated superior rates of epicardial coronary flow, complete ST-segment resolution and a slightly lower mortality rate with the MGuard Coronary as compared to commercially-approved bare metal or drug-eluting stents. However, unlike the other trials described above, the MASTER I trial failed to show a statistically significant reduced rate of 30 day, 6-month or 12-month major adverse cardiac events with the MGuard Coronary compared to a conventional bare metal stent.

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

onto various approved drug eluting stents is currently being evaluated, a proprietary MGuard Coronary with a drug-eluting bio-absorbable mesh is not yet under development. The bio-absorbability of MGuard Coronary with a drug eluting bio-absorbable mesh is intended to improve upon the bio-absorbability of other drug-eluting stents, in light of the large surface area of the mesh and the small diameter of the fiber. We intend to study whether the protective sleeve on the MGuard Coronary with a drug-eluting bio-absorbable mesh can improve uniform distribution of the applied drug to the vessel wall for improved drug therapy management compared to other drug-eluting stents, where the drug is distributed on the struts only. If this intended result is achieved with respect to the improved and uniform distribution of the applied drug to the vessel wall, the total dosage of the medication potentially could be reduced while increasing its efficacy. MGuard Coronary with a drug-eluting bio-absorbable mesh is expected to promote smooth and stable endothelial cell growth and subsequent attachment to the lumen of the vessel wall, which is essential for rapid healing and recovery.

MGuard – Carotid Applications

We intend to market our mesh sleeve coupled with a self-expandable stent (a stent that expands without balloon dilation pressure or need of an inflation balloon) for use in carotid-applications. We obtained CE Mark approval for our MGuard carotid stent in March 2013 and expect to commence our first clinical study of this product in the first half of 2014. We believe that our MGuard design will provide substantial advantages over existing therapies in treating carotid artery stenosis (blockage or narrowing of the carotid arteries), like conventional carotid stenting and endarterectomy (surgery to remove blockage), given the superior embolic protection characteristics witnessed in coronary arterial disease applications in high risk patient populations. We intend that the embolic protection will result from the mesh sleeve, as it traps emboli at their source. In addition, we believe that MGuard Carotid will provide post-procedure protection against embolic dislodgement, which can occur immediately after a carotid stenting procedure and is often a source of post-procedural strokes in the brain. Schofer, et al. ("Late cerebral embolization after emboli-protected carotid artery stenting assessed by sequential diffusion-weighted magnetic resonance imaging," *Journal of American College of Cardiology Cardiovascular Interventions*, Volume 1, 2008) have also shown that the majority of the incidents of embolic showers associated with carotid stenting occur immediately post-procedure.

MGuard – Peripheral Applications

We intend to market our mesh sleeve coupled with a self-expandable stent (a stent that expands without balloon dilation pressure or need of an inflation balloon) for use in peripheral applications. This product is currently under development, although we have temporarily delayed its development until additional funding is secured. Peripheral Artery Disease, also known as peripheral vascular disease, is usually characterized by the accumulation of plaque in arteries in the legs, need for amputation of affected joints or even death, when untreated. Peripheral Artery Disease is treated either by trying to clear the artery of the blockage, or by implanting a stent in the affected area to push the blockage out of the way of normal blood flow.

As in carotid procedures, peripheral procedures are characterized by the necessity of controlling embolic showers both during and post-procedure. Controlling embolic showers is so important in these indications that physicians often use covered stents, at the risk of blocking branching vessels, to ensure that emboli does not fall into the bloodstream. We believe that our MGuard design will provide substantial advantages over existing therapies in treating peripheral artery stenosis (blockage or narrowing of the peripheral arteries).

Product Development and Critical Milestones

Below is a list of the products described above and our projected critical milestones with respect to each. As used below, "CQ" stands for calendar quarter (e.g., "CQ1-2013" means January 1, 2013 through March 31, 2013). While we

currently anticipate seeking approval from the U.S. Food and Drug Administration for all of our products in the future, we have only outlined an estimated timetable to seek U.S. Food and Drug Administration approval for our MGuard Coronary with bio-stable mesh product in our current business plan. The use of the term “to be determined” in the table below with regard to certain milestones indicates that the achievements of such milestones is unable to be accurately predicted as such milestones are too far in the future.

Product	**Indication**	**Start Development**	**CE Mark**	**European Union Sales**	**FDA Approval**	**U.S. Sales**
MGuard Coronary Plus Bio-Stable Mesh	Bypass/ Coronary	2005	Oct. 2007	CQ1-2008	CQ2-2016	2016
MGuard Peripheral Plus Bio-Stable Mesh	Peripheral Arteries	CQ1-2011	To be determined	To be determined	To be determined	To be determined
MGuard Carotid Plus Bio-Stable Mesh	Carotid Arteries	CQ1-2011	March 2013	To be determined	To be determined	To be determined
MGuard Coronary Plus Bio-Absorbable Drug-Eluting Mesh	Bypass/ Coronary	To be determined	To be determined	To be determined	To be determined	To be determined

With respect to MGuard Carotid with bio-stable mesh and MGuard Peripheral with bio-stable mesh, we have determined that the expected commencement of sales in the European Union cannot be accurately predicted since (i) sales cannot commence for MGuard Carotid until we have further clinical data for this product and (ii) the development of MGuard Peripheral with bio-stable mesh has been postponed until we have additional funding.

We anticipate that our MGuard Coronary with bio-stable mesh will be classified as a Class III medical device by the U.S. Food and Drug Administration.

Pre-Clinical Studies

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

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

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

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

Clinical Trials

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

Product	Stent Platform	Clinical Trial Sites	Follow-up Requirement	Objective	Study Status No. of Patients	Start Enrollment	End Enrollment	End of Study
MGuard Coronary	Bare-Metal Stent Plus Bio-Stable Mesh	Germany – two sites	12 months	Study to evaluate safety and performance of MGuard system	41	CQ4-2006	CQ4-2007	CQ2-200
		Brazil – one site	12 months		30	CQ4-2007	CQ1-2008	CQ2-200
		Poland – four sites	3 years		60	CQ2-2008	CQ3-2008	CQ3-201
		International MGuard Observational Study – worldwide – 19 sites	12 months		550	CQ1-2009	CQ1-2013	CQ1-201
		Israeli MGuard Observational Study – Israel – 9 sites	6 months		87	CQ4-2009	CQ1-2013	CQ3-201
		Master randomized control trial – 9 countries, 50 centers in South America, Europe and Israel	13 months		433	CQ2-2011	CQ2-2012	CQ3-201
		Brazil Observational Study – 25 sites	12 months		Up to 500	CQ3-2010	To be determined	To be determin
		FDA Study – 70 sites, U.S. and out of U.S.	13 months	Pivotal study to evaluate safety and performance of MGuard system for FDA approval	1,114	CQ3-2013	CQ4-2014	CQ1-201
	Drug-Eluting Stent (Bare-Metal	South America and Europe – 10 sites	To be determined	Pilot study to evaluate safety and	To be determined	To be determined	To be determined	To be determin

	Stent + Drug Eluting Mesh)			performance of MGuard system for FDA and CE Mark approval				
		U.S. – 50 sites	To be determined		To be determined	To be determined	To be determined	To be determin
		Rest of World as an Observational Study	12 months to 3 years	Evaluation of safety and efficacy for specific indications	To be determined	To be determined	To be determined	To be determin
MGuard Peripheral	Self-Expanding System + Mesh	South America and Europe – four sites	12 months	Pilot study to evaluate safety and performance of MGuard system for CE Mark approval	To be determined	To be determined	To be determined	To be determin
MGuard Carotid	Self-Expanding System + Mesh	Rest of World as a registry study	12 months	Evaluation of safety and efficacy for specific indications post-marketing	30	CQ2-2014	CQ3-2014	CQ3-201

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

The MGuard Coronary clinical trials for the drug-eluting stent have been delayed from our previously announced target until additional funding is secured.

With respect to the MGuard Peripheral clinical trial for the self-expanding system plus mesh, the start date has been delayed from our previously announced start date until additional funding is secured.

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

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

As shown in the table above, we have completed six clinical trials with respect to our MGuard 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 MGuard Coronary rate of device success, meaning the stent was successfully deployed in the target lesion, was 100% and the rate of procedural success, meaning there were no major adverse cardiac events prior to hospital discharge, was 95.1%. At six months, only one patient (2.4% of participants) had major Q-wave myocardial infarction (QWMI) and 19.5% of participants had target vessel revascularization (an invasive procedure required due to a stenosis in the same vessel treated in the study). This data supports MGuard Coronary's safety in the treatment of vein grafts and native coronary legions.

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

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

Our observation study in Europe was an open registry launched in the first calendar quarter of 2009. This registry enrolled 550 patients in 19 sites, primarily in Austria, Czech Republic and Hungary, and was aimed at evaluating the performance of MGuard Coronary with bio-stable mesh in a "real world" population. Based upon the number of patients enrolled, we decided to close enrollment on January 10, 2013 and concentrate on clinical follow-up for this study. The primary endpoint that this registry evaluated was the occurrence of major adverse cardiac events at 30 days and six months following deployment of the stent. The clinical follow-up continued for a period of up to one year per patient. We expect to have a final report of the results from this study available in the first calendar quarter of 2014.

Our observational study in Israel was an open registry launched in the fourth calendar quarter of 2009. This registry enrolled 87 patients. Based upon the number of patients enrolled, we decided to close enrollment on February 6, 2013 and concentrate on clinical follow-up for this study. The primary endpoint that this registry evaluated was the occurrence of major adverse cardiac events at 30 days following deployment of the stent. The clinical follow-up was conducted six months following deployment of the stent. We expect to have a final report of the results from this study available in the first calendar quarter of 2014.

In the second calendar quarter of 2011, we began the MGuard for Acute ST Elevation Reperfusion Trial (which we refer to as our "MASTER I trial"), a prospective, randomized study in Europe, South America and Israel to compare the MGuard Coronary stent with commercially-approved bare metal and drug-eluting stents in achieving superior myocardial reperfusion (the restoration of blood flow) in primary angioplasty for the treatment of acute STEMI, the most severe form of heart attack. The MASTER I trial enrolled 433 subjects, 50% of whom were treated with an MGuard Coronary stent and 50% of whom were treated with a commercially-approved bare metal or drug-eluting stent. The detailed acute and 30 days results from the trial, which were presented at the Transcatheter Cardiovascular Therapeutics (TCT) conference on October 24, 2012, were as follows:

- The primary endpoint of post-procedure complete ST-segment resolution (restoration of blood flow to the heart muscle after a heart attack) was significantly improved in patients randomized to the MGuard Coronary stent compared to commercially-approved bare metal or drug-eluting stents (57.8% vs. 44.7%).

- The MGuard Coronary stent resulted in superior rates of thrombolysis in myocardial infarction (TIMI) 3 flow, which evidences normal coronary blood flow that fills the distal coronary bed completely, as compared to commercially-approved bare metal or drug-eluting stents (91.7% vs. 82.9%), with comparable rates of myocardial blush grade 2 or 3 (83.9% vs. 84.7%) and corrected TIMI frame count (cTFC) (17.0 vs. 18.1), markers of optimal blood flow to the heart.

- Angiographic success rates (attainment of <50% final residual stenosis of the target lesion and final TIMI 3 flow) were higher in the MGuard Coronary group compared to commercially-approved bare metal or drug-eluting stents (91.7% vs 82.4%).

- Mortality (0% vs. 1.9%) and major adverse cardiac events (1.8% vs. 2.3%) at 30 days post procedure were not statistically significantly different between patients randomized to the MGuard Coronary stent as opposed to commercially-approved bare metal or drug-eluting stents. All other major adverse cardiac event components, as well as stent thrombosis, were comparable between the MGuard Coronary and commercially-approved bare metal or drug-eluting stents.

The six month results from the trial, which were presented at EuroPCR, the official annual meeting of the European Association for Percutaneous Cardiovascular Interventions, on May 23, 2013, were as follows:

- Mortality (0.5% vs. 2.8%) and major adverse cardiac events (5.2% vs. 3.4%) at 6 months post procedure were not statistically significantly different between patients randomized to the MGuard Coronary stent as opposed to commercially-approved bare metal or drug-eluting stents. All other major adverse cardiac event components, as well as stent thrombosis, were comparable between the MGuard Coronary and commercially-approved bare metal or drug-eluting stents.

The twelve month results from the trial, which were presented at the Transcatheter Cardiovascular Therapeutics (TCT) conference on October 29, 2013, were as follows:

- Mortality (1.0% vs. 3.3%) and major adverse cardiac events (9.1% vs. 3.3%) at 12 months post procedure were not statistically significantly different between patients randomized to the MGuard Coronary stent as opposed to commercially-approved bare metal or drug-eluting stents. All other major adverse cardiac event components, as well as stent thrombosis, were comparable between the MGuard Coronary and commercially-approved bare metal or drug-eluting stents.

In sum, the MASTER I trial demonstrated that among patients with acute STEMI undergoing emergency PCI, or angioplasty, MGuard Coronary resulted in superior rates of epicardial coronary flow (blood flow within the vessels that run along the outer surface of the heart) and complete ST-segment resolution compared to commercially-approved bare metal or drug-eluting stents. In addition, MGuard Coronary showed a slightly lower mortality rate and a slightly higher major adverse cardiac event rate as compared to commercially-approved bare metal or drug-eluting stents six and twelve months following the procedure.

A detailed table with the results from the MASTER I trial is set forth below. In statistical significance testing, "p-Value" refers to the probability of obtaining a given test result. Anything less than 0.05 is considered statistically significant.

	MGuard Coronary	Bare Metal Stents/Drug Eluting Stents	p-Value
Number of Patients	217	216	—
TIMI 0-1	1.8	5.6	0.01
TIMI 3	91.7	82.9	0.006
Myocardial blush grade 0-1	16.1	14.8	0.71
Myocardial blush grade 3	74.2	72.1	0.62
ST segment resolution >70	57.8	44.7	0.008
30 day major adverse cardiac event	1.8	2.3	0.75
6 month major adverse cardiac event	5.2	3.4	0.34
12 month major adverse cardiac event	9.1	3.3	0.02

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

In the third calendar quarter of 2010, we launched a Brazilian registry to run in 25 Brazilian sites and enroll 500 patients. The primary endpoint that this registry will evaluate is the occurrence of major adverse cardiac events at six months following the deployment of the stent, and the clinical follow-up will continue for a period of up to one year per patient. As of February 25, 2014, 24 patients of the prospective 500 have been enrolled.

U.S. Food and Drug Administration Trial

Presently, none of our products may be sold or marketed in the U.S. In connection with our efforts to seek approval of our MGuard Coronary with bio-stable mesh by the U.S. Food and Drug Administration, we filed an investigational device exemption application with the U.S. Food and Drug Administration during the summer of 2012 in order to conduct a pivotal trial. On April 19, 2013, we received an approval with conditions from the U.S. Food and Drug Administration for our investigational device exemption application, which allowed us to initiate enrollment in the trial. This trial, which we refer to as our "MASTER II trial," is expected to be a multi-center, randomized study, consisting of up to 1,114 patients suffering from STEMI, throughout 35 sites in the U.S. and an additional 35 sites in

Europe. The MASTER II trial will have two co-primary endpoints: superiority in complete ST resolution and non-inferiority in death and target vessel myocardial infarction. In addition, a 356 patient sub-study will be conducted to assess the effect of the MGuard Coronary on infarct size, as measured by magnetic resonance imaging, and an additional 200 patient sub-study will be conducted to assess the late lumen loss, measured at 13 months. We expect that the clinical follow-ups for the subjects in the study will be at 30 days, six months and 12 months. The budget for the MASTER II trial is estimated to be up to $13.0 million and the enrollment phase for the study is expected to last 18 months. We began enrollment in the MASTER II trial on July 29, 2013.

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

13

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

- the MAGICAL study, a single arm study in which 60 acute ST-segment elevation myocardial infarction (the most severe form of a heart attack, referred to as STEMI) patients with less than 12 hours symptom onset were enrolled, as reported in "Mesh Covered Stent in ST-segment Elevation Myocardial Infarction" in *EuroIntervention*, 2010 and presented by D. Dudek, "Extended Follow-up of the MAGICAL Trial", EuroPCR 2012;

- the PISCIONE study, a single arm study in which 100 STEMI patients were enrolled, as reported in "Multicentre Experience with MGuard Net Protective Stent in ST-elevation Myocardial Infarction: Safety, Feasibility, and Impact on Myocardial Reperfusion" in *Catheter Cardiovasc Interv*, 2009 and presented by F. Piscione, "Multicentre Experience MGuard with MGuard net Protective Stent in ST-elevation Myocardial Infarction: Long-term Results", Transcatheter Cardiovascular Therapeutics (TCT) Conference 2010 and F. Piscione, "MGuard in Acute MI: Three-Year Follow-up", TCT Conference 2011;

- the iMOS study, a Registry on MGuard Coronary use in the "real-world" population, from a study whose data was not published; and

- the Jain study, which looks at a small group of 51 STEMI patients, as reported in "Prevention of Thrombus Embolization during Primary Percutaneous Intervention Using a Novel Mesh Covered Stent" in Catheter Cardiovasc Interv, 2009 and presented by R. Weermckody, "A Mesh Covered Stent Effectively Reduces the Risk of Digital Embolisation During Primary Percutaneous Intervention for ST Elevation Myocardial Infarction," EuroPCR 2010.

Our meta-analysis included data from the following trials:

- The CADILLAC (Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications) study, which found that primary stent implantation is a preferred strategy for the treatment of acute myocardial infarction, as reported in "A Prospective, Multicenter, International Randomized Trial Comparing Four Reperfusion Strategies in Acute Myocardial Infarction: Principal Report of the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications (CADILLAC) Trial" in *Journal of American College of Cardiology*, 2001, "Comparison of Angioplasty with Stenting, with or without Abciximab, in Acute Myocardial Infarction" in *New England Journal of Medicine*, 2002, "Frequency, Correlates, and Clinical Implications of Myocardial Perfusion After Primary Angioplasty and Stenting, With and Without Glycoprotein IIb/IIIa Inhibition, in Acute Myocardial Infarction" in *Journal of the American College of Cardiology*, 2004 and "Combined Prognostic Utility of ST-segment Recovery and Myocardial Blush After Primary Percutaneous Coronary Intervention in Acute Myocardial Infarction" in *European Heart Journal*, 2005;

- The EXPORT trial which was a randomized open-label study whose primary endpoint was to evaluate flow improvement in AMI patients using either conventional stenting or aspiration followed by stenting, as reported in "Systematic Primary Aspiration in Acute Myocardial Percutaneous Intervention: A Multicentre Randomised

Controlled Trial of the Export Aspiration Catheter" in *EuroIntervention*, 2008;

- The EXPIRA trial which was a single-center study aimed to explore pre-treatment with manual thrombectomy as compared to conventional stenting, as reported in "Thrombus Aspiration During Primary Percutaneous Coronary Intervention Improves Myocardial Reperfusion and Reduces Infarct Size: The EXPIRA (Thrombectomy with Export Catheter in Infarct-related Artery During Primary Percutaneous Coronary Intervention) Prospective, Randomized Trial" in *Journal of American College of Cardiology*, 2009;

- The REMEDIA trial, whose objective was to assess the safety and efficacy of the EXPORT catheter for thrombus aspiration in STEMI patients, as reported in "Manual Thrombus-Aspiration Improves Myocardial Reperfusion: The Randomized Evaluation of the Effect of Mechanical Reduction of Distal Embolization by Thrombus-Aspiration in Primary and Rescue Angioplasty (REMEDIA) Trial" in *Journal of American College of Cardiology*, 2005;

- The Horizons-AMI (Harmonizing Outcomes with RevascularIZatiON and Stents in Acute MI), which is the largest randomized trial which compared drug-eluting stents to bare metal stents in myocardial infarction patients, as reported in "Paclitaxel-Eluting Stents Versus Bare-Metal Stents in Acute Myocardial Infarction" in *New England Journal of Medicine*, 2009, "Bivalirudin in Patients Undergoing Primary Angioplasty for Acute Myocardial Infarction (HORIZONS-AMI): 1-Year Results of a Randomised Controlled Trial" in *Lancet*, 2009, and "Heparin Plus a Glycoprotein IIb/IIIa Inhibitor Versus Bivalirudin Monotherapy and Paclitaxel-eluting Stents Versus Bare-metal Stents in Acute Myocardial Infarction (HORIZONS-AMI): Final 3-year Results from a Multicentre, Randomised Controlled Trial" in *Lancet*, 2011; and

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

The non-randomized, pooled data analysis of MGuard Coronary outcomes in STEMI population show comparable rates of thrombolysis in myocardial infarction (TIMI) 3 flow with no significant difference of the historical control as compared to MGuard Coronary (87.8% and 91.7%, respectively), while the rates of myocardial blush grade score 3 (37.3% for the historical control and 81.6% for MGuard Coronary) and ST segment resolution>70% (53.6% for the historical control and 79.1% for MGuard Coronary) are significantly better with the MGuard Coronary. MGuard Coronary also appears consistently superior at the 30 days major adverse cardiac event (8.4% for the historical control and 2.4% for MGuard Coronary) and 1 year major adverse cardiac event (12.8% for the historical control and 5.9% for MGuard Coronary) endpoints. The data appears in the following tables.

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

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

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

Acute Binary Resteonosis 6 month,%													
1 year target vessel revascularization	—	8.7	5.8	12.9	11.2	—	—	—	—	—	—	8.0	—
Acute Binary Resteonosis 1 year,%	—	21	8.2	—	—	—	—	—	—	—	—	11.5	—

16

Future Clinical Trials for MGuard Coronary

We expect that post-marketing trials will be conducted to further evaluate the safety and efficacy of the MGuard Coronary with bio-stable mesh in specific indications. These trials will be designed to facilitate market acceptance and expand the use of the product. In other countries outside of the U.S., we believe that we generally will be able to rely upon CE Mark approval of the product, as well as the results of the MASTER II trial and MASTER I trial in order to obtain local approvals.

Growth Strategy

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

- ***Successfully commercialize MGuard Coronary with bio-stable mesh.*** We have begun commercialization of MGuard Coronary with a bio-stable mesh in Europe, Russia, Asia and Latin America through our distributor network and directed selling efforts and we are aggressively pursuing additional registrations and contracts in other countries such as Canada, South Korea and certain smaller countries in Latin America. By the time we begin marketing this product in the U.S., we expect to have introduced the MGuard Coronary technology to clinics and interventional cardiologists around the world, and to have fostered brand name recognition and widespread adoption of MGuard Coronary. We plan to accomplish this by participating in national and international conferences, conducting and sponsoring clinical trials, publishing articles in scientific journals, holding local training sessions and conducting electronic media campaigns.

- ***Successfully develop the next generation of MGuard stents.*** While we market our MGuard Coronary with bio-stable mesh, we intend to develop the MGuard Coronary with a drug-eluting mesh. We are also working on our MGuard stents for carotid, for which we received CE Mark approval in March 2013. In addition, we released our cobalt-chromium version of MGuard Coronary, MGuard Prime, in 2010, which has predominantly replaced, and we anticipate will entirely replace, the original stainless steel based version of MGuard Coronary over the next few years.

- ***Continue to leverage MGuard technology to develop additional applications for interventional cardiologists and vascular surgeons.*** In addition to the applications described above, we believe that we will eventually be able to utilize our proprietary technology to address imminent market needs for new product innovations to significantly improve patients' care. We have applied for intellectual property rights using our mesh technology in the areas of brain aneurism, treating bifurcated blood vessels and a new concept of distal protective devices. We believe these areas have large growth potential given, in our view, that present solutions are far from satisfactory, and there is a

significant demand for better patient care. We believe that our patents, and patent applications once allowed, can be put into practice and that they will drive our growth at a later stage.

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

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- ***Establish relationships with collaborative and development partners to fully develop and market our existing and future products.*** We are seeking strategic partners for collaborative research, development, marketing, distribution, or other agreements, which could assist with our development and commercialization efforts for MGuard Coronary and other potential products that are based on our proprietary mesh technology. We are in discussions with multiple potential partners and may enter into an arrangement to pursue further development and commercialization of these products.

- ***Continue to protect and expand our portfolio of patents.*** Our patents and their protection are critical to our success. We have filed nine separate patent applications for our MGuard technology in the U.S. and corresponding patent applications in Canada, China, Europe, Israel, India, and South Africa. We believe these patents and patent applications collectively cover all of our existing products, and may be useful for protecting our future technology developments. We intend to continue patenting new technology as it is developed, and to actively pursue any infringement covered by any of our patents. To date, we have secured patent protection in China for four patents and in each of the U.S. and South Africa for one patent. See "— Intellectual Property — Patents."

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

Competition

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

In the future, we believe that physicians will look to next-generation stent technology to compete with existing therapies. These new technologies will likely include bio-absorbable stents, stents that are customizable for different lesion lengths, stents that focus on treating bifurcated lesions, and stents with superior polymer and drug coatings. Some of the companies developing new stents are The Sorin Group, Xtent, Inc., Cinvention AG, OrbusNeich, Biotronik SE & Co. KG, Svelte Medical Systems, Inc., Reva Inc. and Stentys SA, among others. To address current issues with drug-eluting stents, The Sorin Group and Cinvention AG have developed stents that do not require a polymer coating for drug delivery, thereby expanding the types of drugs that can be used on their respective stents. OrbusNeich has addressed the problem differently, developing a stent coated with an antibody designed to eliminate the need for any drug at all. Xtent, Inc. has been concentrating on a stent that can be customized to fit different sized lesions, so as to eliminate the need for multiple stents in a single procedure. Biotronik SE & Co. KG is currently developing bio-absorbable stent technologies, and Abbott Laboratories is currently developing a bio-absorbable

drug-eluting stent. These are just a few of the many companies working to improve stenting procedures in the future as the portfolio of available stent technologies rapidly increases. As the market moves towards next-generation stenting technologies, minimally invasive procedures should become more effective, driving the growth of the market in the future. We plan to continue our research and development efforts in order to be at the forefront of the acute myocardial infarction solutions.

According to the 2014 MEDTECH OUTLOOK produced by the BMO Capital Markets on December 3, 2013, the worldwide stent market is dominated by three major players, with a combined total market share of approximately 92%. Within the bare metal stent market and drug-eluting stent market, the top three companies have approximately 71% and 97% of the market share, respectively. These three companies are Abbott Laboratories, Boston Scientific Corporation and Medtronic, Inc. To date, our sales are not significant enough to register in market share. As such, one of the challenges we face to the further growth of MGuard is the competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. Most of our current and potential competitors, including but not limited to those listed above, have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do.

In addition to the challenges from our competitors, we face challenges related specifically to our products. None of our products 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 products will be expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. Furthermore, our rights to our intellectual property with respect to our products could be challenged. Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our MGuard products based on one or more of these patents, and/or will allege misappropriation of their proprietary confidential information or other intellectual property.

We note that an additional challenge facing our products comes from drug-eluting stents. Over the last decade, there has been an increasing tendency to use drug-eluting stents in PCI, with a usage rate of drug-eluting stents in PCI approaching 70-80% in some countries, even though drug-eluting stents do not address thrombus management in acute myocardial infarction. The HORIZONS-AMI trial that compared drug-eluting stents to bare-metal stents in STEMI patients failed to show any benefit of drug-eluting stents as compared to bare-metal stents with regard to safety (death, re-infarction, stroke, or stent thrombosis), but showed the 1-year target vessel revascularization (TVR) rate for drug-eluting stent patients was only 5.8%, as compared to 8.7% for patients with bare-metal stents. However, based on data from over 350 patients across three clinical trials, the TVR rate for MGuard Coronary was 2.8%. (This data is comprised of: (i) a TVR rate of 2.3% for a 100-patient study, as reported in “Multicentre Experience with MGuard Net Protective Stent in ST-elevation Myocardial Infarction: Safety, Feasibility, and Impact on Myocardial Reperfusion” in *Catheter Cardiovasc Interv*, 2009; (ii) a TVR rate of 2.3% for a sub-group of 203 STEMI patients from the International MGuard Observational Study; and (iii) a TVR rate of 6.0% for a group of 51 heart attack patients, as reported in “Prevention of Thrombus Embolization during Primary Percutaneous Intervention Using a Novel Mesh Covered Stent” in *Catheter Cardiovasc Interv*, 2009).

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

Research and Development Expenses

During each of the six months ended December 31, 2013 and the twelve months ended June 30, 2013 and 2012, we spent approximately $3.3 million, $4.2 million and $4.0 million, respectively, on research and development.

Sales and Marketing

Sales and Marketing

In October 2007, MGuard Coronary with a bio-stable mesh received CE Mark approval in the European Union, and shortly thereafter was commercially launched in Europe through local distributors. We are also in negotiations with additional distributors in Europe, Asia and Latin America and are actively selling our MGuard Coronary with a bio-stable mesh in more than 20 countries.

Until U.S. Food and Drug Administration approval of our MGuard Coronary with a bio-stable mesh, which we are targeting for 2016, we plan to focus our marketing efforts primarily on Europe, Asia and Latin America. Within Europe, we have focused on markets with established healthcare reimbursement from local governments such as Russia, Italy, Germany, France, Austria, Poland, Czech Republic, Denmark, Holland, Spain, Sweden, Switzerland and the United Kingdom.

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

Product Positioning

The MGuard Coronary has initially penetrated the market by entering market segments with indications that present high risks of embolic dislodgement, notably acute myocardial infarction and saphenous vein graft coronary interventions. The market penetration of the MGuard Coronary for each of the twelve months ended June 30, 2013 and June 30, 2012 was minimal, with total sales of approximately $4.9 million and approximately $5.3 million, respectively each representing less than 1% of the total sales of the acute myocardial infarction solutions market. The market penetration for the six months ended December 31, 2013 was also minimal, with total sales in the six months ended December 31, 2013 of approximately $3.1 million representing less than 1% of the total sales of the acute myocardial infarction solutions market.

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

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

Insurance Reimbursement

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

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

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

Intellectual Property

Patents

We have filed nine patent applications that are pending in the U.S. covering aspects of our MGuard technology. We have filed corresponding patent applications in Canada, China, Europe, Israel, India and South Africa, for an aggregate total of 35 patents and pending applications. These patent rights are directed to cover percutaneous therapy, knitted stent jackets, stent and filter assemblies, *in vivo* filter assembly, optimized stent jackets, stent apparatuses for treatment via body lumens and methods of use, stent apparatuses for treatment via body lumens and methods of manufacture and use, and stent apparatuses for treatment of body lumens, among others. In lay terms, these patent applications generally cover three aspects of our products: the mesh sleeve with and without a drug, the product and the delivery mechanism of the stent. On October 27, 2010, our patent application pertaining to "Stent Apparatus for Treatment via Body Lumens and Method of Use", South African patent application 2007/10751, was issued as South African Patent No. 2007/10751. On October 25, 2011, our patent application pertaining to "In Vivo Filter Assembly", U.S. Patent Application 11/582,354, was issued as U.S. Patent 8,043,323. On June 13, 2012, our patent application pertaining to "Filter Assemblies," Chinese Patent Application No. 200780046659.9, was issued as Chinese Patent No. ZL200780046659.9. On September 26, 2012, our patent application pertaining to "Bifurcated Stent Assemblies," Chinese Patent Application No. 200780046676.2, was issued as Chinese Patent No. ZL200780046676.2. On October 10, 2012, our patent application pertaining to "Knitted Stent Jackets," Chinese Patent Application No. 200780046697.4, was issued as Chinese Patent No. ZL200780046697.4. On January 2, 2013, our patent application pertaining to "Optimized Stent Jacket," Chinese Patent Application No. 200780043259.2, was issued as Chinese Patent No. ZL200780043259.2. None of the other patent applications has been granted to date, although two more are now allowed and awaiting issuance. We believe one or more pending patent applications, upon issuance, will cover each of our existing products. We also believe that the patent applications we have filed, in particular those covering the use of a knitted micron-level mesh sleeve over a stent for various indications, if issued as patents with claims substantially in their present form, would likely create a significant barrier for another company seeking to use similar technology. There is no assurance, however, that our pending patent applications will issue as patents with such claims or that if issued, the patents will withstand challenges to their validity or enforceability that may arise.

There is also a risk that our products and commercial processes, as commercialized, will be found to infringe or in some way violate the intellectual property rights of third parties. To date, however, we are not aware of other companies that have patents directed to a micron fiber, releasable knitted fiber sleeve over a stent. However, larger, better funded competitors own patents relating to the use of drugs to treat restenosis, stent architecture, catheters to deliver stents, and stent manufacturing and coating processes and compositions, as well as general delivery mechanism patents like rapid exchange that might be alleged to cover one or more of our products. For example, we are aware of one public company that is pursuing patent protection directed to layered materials disposed over a particular stent configuration, however, these applications were generally filed after our core patent application filings. Stent manufacturers have historically engaged in significant litigation, and we could be subject to claims of infringement of intellectual property from one or more competitors. Although we believe that any such claims based on patents of which we are currently aware would be un-founded, such litigation would divert attention and resources away from the development and/or commercialization of MGuard stents and other product development, and could result in an adverse court judgment that would make it impossible or impractical to continue selling MGuard stents in

one or more territories. Furthermore, we may be subject to claims of infringement of patent rights of which we are currently unaware. Other manufacturers or other parties may also challenge the intellectual property that we own, or may own in the future. We may be forced into litigation to uphold the validity of the claims in our patent portfolio, as well as our ownership rights to such intellectual property, and litigation is often an uncertain and costly process.

Trademarks

We use the InspireMD and MGuard trademarks in connection with our products. We have registered these trademarks in Europe. The trademarks are renewable indefinitely, so long as we continue to use the mark in Europe and make the appropriate filings when required. We have also registered the name “MicroNet®” as a trademark in the U.S. and we are pursuing a similar trademark in Europe.

Government Regulation

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

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

As noted below, we currently have distribution agreements for our products with distributors, or are directly selling our products, in the following countries: Italy, Austria, Slovenia, Spain, Hungary, Estonia, Ukraine, Holland, Russia, Latvia, Brazil, Mexico, Argentina, Colombia, India, Sri Lanka, South Africa, Pakistan, Belarus, Croatia, Ireland, Lithuania, Malta, Malaysia, Venezuela, Australia, Belgium, the Czech Republic, Finland, Kazakhstan, Slovakia, Sweden, Denmark, Norway, Switzerland, Poland, Germany, Cyprus, France, Finland, Romania, the United Kingdom, Saudi Arabia, New Zealand and Israel. We are subject to governmental regulation in each of these countries and we are not permitted to sell all of our products in each of these countries. In addition, we have distribution agreements for our products in Uzbekistan, Taiwan, South Korea, Canada, Kuwait and Armenia, although we have not yet obtained regulatory approval to sell our products in those countries. While each of the European Union member countries accepts the CE Mark as its sole requirement for marketing approval, some of these countries still require us to take additional steps in order to gain reimbursement rights for our products. Furthermore, while we believe that each of the above-listed countries that is not a member of the European Union accepts the CE Mark as its primary requirement for marketing approval, each such country requires additional regulatory requirements for final marketing approval of the MGuard Prime version of the MGuard Coronary product. Additionally, in Canada, we are required to pass annual facilities audit inspections performed by Canadian inspectors. Furthermore, we are currently targeting additional countries in Europe, Asia, and Latin America. We believe that each country that we are targeting also accepts the CE Mark as its primary requirement for marketing approval. We expect that the results of the MASTER I trial will enhance our ability to satisfy any additional governmental regulatory requirements in each of the countries where we currently distribute or directly sell our products and in any countries that we are currently targeting for expansion. However, even if all governmental regulatory requirements are satisfied in each such country, we anticipate that obtaining marketing approval in each country could take as few as three months or as many as twelve months, due to the nature of the approval process in each individual country, including typical wait times for application processing and review, as discussed in greater detail below.

The MGuard Prime version of the MGuard Coronary product received CE Mark approval in the European Union in October 2010 and marketing approval in those countries listed in the table below. We are currently seeking marketing approval for the MGuard Prime version of the MGuard Coronary product in Brazil, Mexico, Argentina, South Korea, Taiwan, Australia, Belarus, Malaysia, Saudi Arabia, the U.S. and Canada. We are focused on seeking marketing approval in these countries because we believe that these countries represent the strongest opportunities for us to grow with respect to our sales. We have determined that other countries with better organized and capitalized healthcare systems may not present us the same opportunities for growth due to the lack of use of stents in treatment of cardiac episodes and less advantageous healthcare reimbursement policies, among other reasons. While we understand that

each of the countries in which we are seeking marketing approval for the MGuard Prime version of the MGuard Coronary product accepts the CE Mark as its primary requirement for marketing approval and does not to our understanding require any additional tests, each country does have some additional regulatory requirements for marketing approval. More specifically, for example, for the approval process in Mexico, where we already have approval for and sales of MGuard Coronary, we need to submit an application for regulatory approval for MGuard Prime, which we anticipate will be granted at least thirty months later. For the approval process in Argentina, we need to submit an application for regulatory approval, which we anticipate will be granted approximately at least sixteen months later. For the approval process in South Korea, we need to submit an application for regulatory approval and have in-house quality audit, which we anticipate will be granted in approximately two years. For the approval process in Canada, we need to submit an application for regulatory approval, which we anticipate will be granted approximately twelve months later. For the approval process in Australia, we need to submit an application for regulatory approval, to have in-house quality audit which we anticipate will be granted in approximately one year. For the approval process in Taiwan, we need to submit an application for regulatory approval, which we anticipate will be granted at least fifteen months later. In Israel, where we received marketing approval in September 2011, we are subject to annual renewal of our marketing approval. Regulators in Israel may request additional documentation or other materials and results of studies from medical device manufacturers as part of the renewal process. Generally, however, the annual renewal of marketing approval is given automatically, barring a material change in circumstances or results. In Russia, we received market approval in February 2012. In Chile, we received market approval for our previous distributor in December 2010. We have terminated our relationship with our previous distributor in Chile, however, and once we enter into a relationship with a new distributor, we will be required to submit a new application for regulatory approval in Chile, which we anticipate will be granted approximately twelve months after our submission for approval.

For the approval process in Brazil for MGuard Prime, where we already have approval for and sales of MGuard Coronary, we must comply with Brazilian Good Manufacturing Practice, or GMP, quality system requirements. ANVISA, Brazil's regulatory agency, must conduct an inspection of the manufacturing of the MGuard Prime version of the MGuard Coronary product to determine compliance with Brazil GMP regulations. Upon successful completion of an audit, ANVISA will then issue the GMP certificate necessary to register a medical device in Brazil, which can take approximately one year to complete. Based upon new legislation in Brazil, we intend to apply for regulatory approval while we await the results of the audit necessary to receive our GMP certificate. We anticipate that the approval process in Brazil will take between two and three years.

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

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

Countries	Original MGuard Approval		Original MGuard Sales	MGuard Prime Approval	MGuard Prime Sales	
Argentina	Y		Y	N	N	
Armenia	N		N	N	N	
Australia	N	(2)	Y	N	Y	(1)
Austria	Y		Y	Y	Y	
Belarus	Y		Y	N	Y	(3)
Belgium	Y		N	Y	Y	
Brazil	Y		Y	N	N	
Chile	N	(2)	Y	N	Y	(3)
Colombia	Y		Y	N	N	
Croatia	Y		Y	Y	Y	
Cyprus	Y		Y	Y	Y	
Czech Republic	Y		Y	Y	Y	
Denmark	Y		Y	Y	N	
Egypt	Y		N	N	N	
Estonia	Y		Y	Y	Y	
Finland	Y		N	Y	Y	
France	Y		Y	Y	Y	
Germany	Y		Y	Y	Y	
Greece	Y		Y	Y	N	
Holland (Netherlands)	Y		Y	Y	Y	
Hungary	Y		Y	Y	Y	
India	Y		Y	Y	N	
Ireland	Y		Y	Y	Y	

Israel	Y		Y		Y		Y	
Italy	Y		Y		Y		Y	
Kazakhstan	N	(4)	Y		N		N	
Latvia	Y		Y		Y		Y	
Lithuania	Y		Y		Y		Y	
Malaysia	N		N		N		Y	(3)
Malta	Y		N		Y		Y	
Mexico	Y		Y		N		N	
Norway	Y		N		Y		Y	
Pakistan	Y	(5)	Y		N		N	
Poland	Y		Y		Y		Y	
Portugal	Y		Y		Y		N	
Romania	Y		Y		Y		Y	
Russia	Y		Y		Y		Y	
Saudi Arabia	N		N		N		Y	(3)
Singapore	N		Y	(6)	N		N	
Slovakia	Y		Y		Y		Y	
Slovenia	Y		Y		Y		Y	
South Africa	Y	(5)	Y		Y		Y	
Spain	Y		Y		Y		Y	
Sri Lanka	Y	(5)	Y		N		N	
Sweden	Y		Y		Y		Y	
Switzerland	Y		Y		Y		Y	
Ukraine	Y		Y		N		N	
United Kingdom	Y		N		Y		Y	
Uzbekistan	N		N		N		N	
Venezuela	N	(2)	Y		N		N	

(1) We sold a limited quantity of our MGuard Prime products in Australia pursuant to a law that permits patients to purchase medical products that are not included on the Australian Register of Therapeutic Goods under certain limited circumstances, on case by case bases.

(2) We terminated our relationship with our previous distributor in this country, through which our product had market approval. As a result of such termination, we will be required to obtain regulatory approval upon our selection of a new distributor in such country.

(3) We have made sales to distributors in this country, but based upon information from such distributors, we believe that the product has not been sold to customers in this country.

(4) Our regulatory approval for sales in Kazakhstan expired in January 2014. We intend to renew our regulatory approval for Kazakhstan in the future.

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

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

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

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

We will also be required to register with the U.S. Food and Drug Administration as a medical device manufacturer. As such, our manufacturing facilities will be subject to U.S. Food and Drug Administration inspections for compliance with Quality System Regulation. These regulations will require that we manufacture our products and maintain our documents in a prescribed manner with respect to design, manufacturing, testing and quality control activities. As a medical device manufacturer, we will further be required to comply with U.S. Food and Drug Administration requirements regarding the reporting of adverse events associated with the use of our medical devices, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. U.S. Food and Drug Administration regulations also govern product labeling and prohibit a manufacturer from

marketing a medical device for unapproved applications. If the U.S. Food and Drug Administration believes that a manufacturer is not in compliance with the law, it can institute enforcement proceedings to detain or seize products, issue a recall, enjoin future violations and assess civil and criminal penalties against the manufacturer, its officers and employees.

Customers

Our customer base is varied. We began shipping our product to customers in Europe in January 2008 and have since expanded our global distribution network to Southeast Asia, India, Latin America and Israel. For the six months ended December 31, 2013, 70% of our revenue was generated in Europe, 11% of our revenue was generated in Latin America, 7% of our revenue was generated in Asia and 4% of our revenue was generated in Israel, with the remaining 8% of our revenue generated in the rest of the world. Our major customers in the six months ended December 31, 2013 were Bosti Trading Ltd., a distributor in the Russian Federation that accounted for 24% of our revenues and Izasa Distribuciones Tecnicas SA, a distributor in Spain that accounted for 12% of our revenues. Our agreement with Bosti Trading Ltd. grants Bosti Trading Ltd. the right to be the exclusive distributor of MGuard products in the Russian Federation, the Republic of Uzbekistan and the Republic of Armenia until May 2014, subject to the achievement of certain order minimums. Under our agreement with Bosti Trading Ltd., Bosti Trading Ltd. is required to purchase 3,500 stents from us in 2012, 6,000 stents in 2013 and 4,000 stents in the first six months of 2014, respectively. Although Bosti Trading Ltd. did not adhere to its order minimum for 2012 and 2013, we did not terminate Bosti Trading Ltd.’s right to be the exclusive distributor of MGuard products in the Russian Federation, the Republic of Uzbekistan and the Republic of Armenia. Our agreement with Izasa Distribuciones Tecnicas SA grants Izasa Distribuciones Tecnicas SA the right to be the exclusive distributor of MGuard products in Spain until May 2014, with no order minimums currently in place. Izasa Distribuciones Tecnicas SA also agreed to partner with us in a study to be conducted in Spain entitled MGuard Prime Implementation in STEMI (acute myocardial infarction with ST elevation).

For the twelve months ended June 30, 2013, 71% of our revenue was generated in Europe, 12% of our revenue was generated in Latin America, 6% of our revenue was generated in Asia and 6% of our revenue was generated in Israel, with the remaining 5% of our revenue generated in the rest of the world. Our major customers in the twelve months ended June 30, 2013 were Bosti Trading Ltd., which accounted for 17% of our revenues, Izasa Distribuciones Tecnicas SA, a distributor in Spain that accounted for 14% of our revenues, and CMS Produtos Medicos Ltda., which accounted for 10% of our revenues. Our agreements with Bosti Trading Ltd. and Izasa Distribuciones Tecnicas SA are discussed above. Our agreement with CMS Produtos Medicos Ltda. grants CMS Produtos Medicos Ltda. the right to be the exclusive distributor of MGuard products in Brazil until April 2014, with no order minimums currently in place. Unless otherwise indicated below, all of the distribution agreements described under “Customers” are subject to automatic annual extensions unless affirmatively terminated.

For the six months ended June 30, 2012, 64% of our revenue was generated in Europe, 22% of our revenue was generated in Latin America and 8% of our revenue was generated in Israel, with the remaining 6% of our revenue generated in the rest of the world. Our major customers in the six months ended June 30, 2012 were Bosti Trading Ltd., which accounted for 22% of our revenues, Euromed Deutschland GmbH, our former distributor in Germany that accounted for 14% of our revenues, and Kardia Srl, a distributor in Italy that accounted for 9% of our revenues. For the twelve months ended June 30, 2012, our major customer was Bosti Trading Ltd., accounting for 15% of our revenues. Our agreement with Bosti Trading Ltd. is discussed above. Our agreement with Euromed Deutschland GmbH was terminated on January 28, 2013, in connection with Euromed Deutschland GmbH filing for insolvency protection on September 24, 2012. Our agreement with Kardia Srl grants Kardia Srl the right to be the exclusive distributor of MGuard products in Italy until August 2016, with no order minimums currently in place.

Manufacturing and Suppliers

We manufacture our stainless steel MGuard stent through a combination of outsourcing and assembly at our own facility. Third parties in Germany manufacture the base stent and catheter materials, and we add our proprietary mesh sleeve to the stent. Our current exclusive product supplier is QualiMed Innovative Medizinprodukte GmbH. QualiMed Innovative Medizinprodukte GmbH is a specialized German stent manufacturer that electro polishes and crimps the stent onto a balloon catheter that creates the base for our stainless steel MGuard stents. QualiMed Innovative Medizinprodukte GmbH has agreed to take responsibility for verifying and validating the entire stent system by performing the necessary bench test and biocompatibility testing. During the production process, QualiMed Innovative Medizinprodukte GmbH is responsible for integrating the mesh covered stent with the delivery system, sterilization, packaging and labeling. Our manufacturing agreement with QualiMed Innovative Medizinprodukte GmbH expires in September 2017, unless earlier terminated by either party in the event of breach of material terms of the agreement, liquidation of the other party, our failure to receive requested products for more than 60 days, a substantiated intellectual property claim is brought against the other party or the development agreement between the parties is terminated. The manufacturing agreement provides for a rebate program that rewards us for increases in sales of our products. Our proprietary mesh sleeve is supplied by Biogeneral, Inc., a San Diego, California-based specialty polymer manufacturer for medical and engineering applications. Natec Medical Ltd. supplies us with catheters that help create the base for our MGuard stents. Our agreement with Natec Medical Ltd., which may be terminated by either party upon six months’ notice, calls for non-binding minimum orders and discounted catheters upon reaching certain purchasing thresholds.

25

Our MGuard Prime cobalt-chromium stent was designed by Svelte Medical Systems Inc. We have an agreement with Svelte Medical Systems Inc. that grants us a non-exclusive, worldwide license for production and use of the MGuard Prime cobalt-chromium stent for the life of the stent's patent, subject to the earlier termination of the agreement upon the bankruptcy of either party or the uncured default by either party under any material provision of the agreement. Our royalty payments to Svelte Medical Systems Inc. are determined by the sales volume of MGuard Prime stents. Until October 20, 2012, we paid a royalty of 7% for all product sales outside of the U.S. and, for products sales within the U.S., a rate of 7% for the first $10.0 million of sales and a rate of 10% for all sales exceeding $10.0 million. We also shared with Svelte Medical Systems Inc. in the cost of obtaining the CE Mark approval, with its costs not to exceed $85,000, and the U.S. Food and Drug Administration approval, with its costs not to exceed $200,000. On October 20, 2012, we amended our agreement with Svelte Medical Systems Inc., pursuant to which Svelte Medical Systems Inc. reduced the royalty rate to 2.9% of all net sales both inside and outside the U.S. in exchange for (i) us waiving the $85,000 in regulatory fees for the CE Mark that were owed to us by Svelte Medical Systems Inc., (ii) us making full payment of royalties in the amount of $205,587 due to Svelte Medical Systems, Inc. as of September 30, 2012, and (iii) $1,763,000, payable in 215,000 shares of our common stock (as adjusted for the one-for-four reverse stock split of our common stock that occurred on December 21, 2012), that were valued at the closing price of our common stock on October 19, 2012 of $8.20 per share (as adjusted for the one-for-four reverse stock split of our common stock that occurred on December 21, 2012). On August 22, 2013, we further amended our agreement with Svelte Medical Systems Inc., pursuant to which (i) we agreed to pay Svelte Medical Systems Inc. an advanced payment of $192,000, representing a royalty rate of 2.0% of all net sales for the period from July 1, 2013 to June 30, 2015, assuming net sales of $1.2 million per quarter, (ii) we agreed to pay a royalty rate of 2.5% on any net sales exceeding $10.56 million for the period from July 1, 2013 to June 30, 2015 and (iii) the royalty rate was increased to 2.9% of all net sales beginning July 1, 2015. We have mutual indemnification obligations with Svelte Medical Systems Inc. for any damages suffered as a result of third party actions based upon breaches of representations and warranties or the failure to perform certain covenants in the license agreement, and Svelte Medical Systems Inc. will also indemnify us for any damages suffered as a result of third party actions based upon intellectual property or design claims against the MGuard Prime cobalt-chromium stent.

Our MGuard Prime cobalt-chromium stent is being manufactured and supplied by MeKo Laserstrahl-Materialbearbeitung. Our agreement with MeKo Laserstrahl-Materialbearbeitung for the production of electro polished L605 bare metal stents for MGuard Prime is priced on a per-stent basis, subject to the quantity of stents ordered. The complete assembly process for MGuard Prime, including knitting and securing the sleeve to the stent and the crimping of the sleeve stent on to a balloon catheter, is done at our Israel manufacturing site. Once MGuard Prime has been assembled, it is sent for sterilization in Germany and then back to Israel for final packaging.

Each MGuard stent is manufactured from two main components, the stent and the mesh polymer. The stent is made out of stainless steel or cobalt chromium. Both of these materials are readily available and we acquire them in the open market. The mesh is made from polyethylene terephthalate (PET). This material is readily available in the market as well, because it is used for many medical applications. In the event that our supplier can no longer supply this material in fiber form, we would need to qualify another supplier, which could take several months. In addition, in order to retain the approval of the CE Mark, we are required to perform periodic audits of the quality control systems of our key suppliers in order to insure that their products meet our predetermined specifications.

Distributors

We currently have exclusive distribution agreements for our CE Mark-approved MGuard Coronary with bio stable mesh with medical product distributors based in Italy, Austria, Slovenia, Spain, Hungary, Estonia, Ukraine, Holland, Russia, Latvia, Brazil, Mexico, Argentina, Colombia, India, Sri Lanka, South Africa, Pakistan, Belarus, Croatia, Ireland, Lithuania, Malta, Malaysia, Venezuela, Australia, Belgium, the Czech Republic, Finland, Kazakhstan, Slovakia, Sweden, Denmark, Norway, Uzbekistan, Armenia, Canada, Finland, Korea, Romania, the United Kingdom, Taiwan, Saudi Arabia and Israel. We are currently in discussions with multiple distribution companies in Europe, Asia, and Latin America.

We are in the process of replacing certain third party distributors with direct sales channels in key countries where end user average selling prices and the lack of strong distributors are limiting factors. While we believe that this transition to direct selling will ultimately lead to greater sales in these markets, the transition away from certain distributors adversely impacted revenue for the six months ended December 31, 2013 and the twelve months ended June 30, 2013, as we had fewer parties selling our products. In addition, we are in the process of appointing new distributors in certain territories, and believe that new incentives and broader responsibilities have strengthened arrangements with our partners in those territories.

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

Employees

As of February 25, 2014, we had 71 full-time employees. Except for some of our employees in Europe, our employees are not party to any collective bargaining agreements. We do not expect the collective bargaining agreements to which our employees are party to have a material effect on our business or results of operations. We consider our relations with our employees to be good. We believe that our future success will depend, in part, on our continued ability to attract, hire and retain qualified personnel.

Item 1A. Risk Factors.

There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. You should carefully consider the risks described below and the other information included in this Transition Report on Form 10-K/T, including the consolidated financial statements and related notes. 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. 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 have a history of net losses and may experience future losses.

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

We expect to derive our revenue from sales of our MGuard stent products and other products we may develop. If we fail to generate revenue from this source, our results of operations and the value of our business would be materially and adversely affected.

We expect our revenue to be generated from sales of our MGuard stent products and other products we may develop. Future sales of these products, if any, will be subject to the receipt of regulatory approvals and commercial and market uncertainties that may be outside our control. If we fail to generate such revenues, our results of operations and the value of our business and securities would be materially and adversely affected.

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

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

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the patentability of our pending patent applications. For example, some material references may be in a foreign language and may not be uncovered during examination of our patent applications. Additionally, patent applications in the 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, enforcing, and defending such rights in certain foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in any foreign jurisdictions, our business prospects could be substantially harmed.

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

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

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

We currently manufacture our MGuard stent at our facility 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 to meet market demand or for use in our current and planned clinical trials, or if our manufacturing process yields substandard stents, our development and commercialization efforts would be delayed.

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 meet potential future demand. If we are unable to manufacture a sufficient supply of our MGuard stent, our revenues, business and financial prospects would be adversely affected and we may suffer reputational harm, which could further adversely affect our revenues, business and financial prospects. In addition, if the scaled-up production process is not efficient or produces stents that do not meet quality and other standards, our future gross margins may decline. Also, our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth. If we are unable to manage our growth effectively, our business could be harmed.

Additionally, any damage to or destruction of our Tel Aviv facility 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 to the U.S. Food and Drug Administration for our products 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 products will be expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. In some trials, a greater number of patients and a longer follow up period may be required. Patient enrollment in clinical trials and the ability to successfully complete patient follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of our products, or they may be persuaded to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical events unrelated to or related to our products. Delays in patient

enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays or result in the failure of the clinical trial.

In addition, the length of time required to complete clinical trials for pharmaceutical and medical device products varies substantially according to the degree of regulation and the type, complexity, novelty and intended use of a product, and can continue for several years and cost millions of dollars. The commencement and completion of clinical trials for our 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 Boston Scientific Corporation, Medtronic Inc., Abbott Laboratories and others.

We cannot provide any assurance that the data collected from our current and planned clinical trials will be sufficient to demonstrate that the MGuard stents are an attractive alternative to other procedures. If we fail to demonstrate safety and efficacy that is at least comparable to other drug-eluting stents or bare-metal stents that have received regulatory approval and that are available on the market, our ability to successfully market the MGuard stent will be significantly limited. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with our MGuard stent will vary. Clinical trials conducted with the MGuard Coronary stent have involved procedures performed by physicians who are technically proficient and are high-volume stent users. Consequently, both short-term and long-term results reported in these clinical trials may be significantly more favorable than typical results of practicing physicians, which could negatively affect rates of adoptions of our products. We also believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our MGuard Coronary stent will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published.

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

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

Because our products are new and long-term success measures have not been completely validated, regulatory agencies, including the U.S. Food and Drug Administration, may take a significant amount of time in evaluating product approval applications. For example, there are currently several methods of measuring restenosis and we do not know which of these metrics, or combination of these metrics, will be considered appropriate by the U.S. Food and Drug Administration for evaluating the clinical efficacy of stents. Treatments may exhibit a favorable measure using one of these metrics and an unfavorable measure using another metric. Any change in the accepted metrics may result in reconfiguration of, and delays in, our clinical trials. Additionally, we have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals, and our clinical, regulatory and quality assurance personnel are currently composed of only eight employees. As a result, we may experience delays in connection with obtaining regulatory approvals for our products.

In addition, the products we and any potential licensees license, develop, manufacture and market are subject to complex regulatory requirements, particularly in the 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.

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 constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Moreover, any modification to a device that has received U.S. Food and Drug Administration approval that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new approval from the U.S. Food and Drug Administration. If the U.S. Food and Drug Administration disagrees with any determination by us that new approval is not required, we may be required to cease

marketing or to recall the modified product until approval is obtained. In addition, we could also be subject to significant regulatory fines or penalties.

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

The medical device market is highly competitive. We compete with many medical device 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 Boston Scientific Corporation, Guidant Corporation, Medtronic, Inc., Abbott Vascular Devices, Johnson & Johnson, Terumo Medical Corporation and others. Most of our current and potential competitors, including but not limited to those listed above, have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. There can be no assurance that we will have sufficient resources to successfully commercialize our products, if and when they are approved for sale. The worldwide market for stent products is characterized by intensive development efforts and rapidly advancing technology. Our future success will depend largely upon our ability to anticipate and keep pace with those developments and advances. Current or future competitors could develop alternative technologies, products or materials that are more effective, easier to use or more economical than what we or any potential licensee develop. If our technologies or products become obsolete or uncompetitive, our related product sales and licensing revenue would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

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

Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our MGuard stent based on one or more of these patents. It is also possible that a lawsuit asserting patent infringement, misappropriation of intellectual property, or related claims may have already been filed against us of which we are not aware. A number of stent-related patents are owned by very large and well-capitalized companies that are active participants in the stent market. As the number of competitors in the stent market grows, the possibility of patent infringement by us, and/or a patent infringement or misappropriation claim against us, increases.

These companies have maintained their position in the market by, among other things, establishing intellectual property rights relating to their products and enforcing these rights aggressively against their competitors and new entrants into the market. All of the major companies in the stent and related markets, including Boston Scientific Corporation 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 or if we experience an interruption of the supply of materials from suppliers, we may not be able to obtain materials that are necessary to develop our products.

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

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

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

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

We may be exposed to product liability claims based on the use of any of our products, or products incorporating our licensed technology, in clinical trials. We may also be exposed to product liability claims based on the sale of any such products following the receipt of regulatory approval. Product liability claims could be asserted directly by

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

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

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

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

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

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 multiple countries. Consequently, we face complex legal and regulatory requirements in multiple jurisdictions, which may expose us to certain financial and other risks. International sales and operations are subject to a variety of risks, including:

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

International markets are also affected by economic pressure to contain reimbursement levels and healthcare costs. Profitability from international operations may be limited by risks and uncertainties related to regional economic conditions, regulatory and reimbursement approvals, competing products, infrastructure development, intellectual property rights protection and our ability to implement our overall business strategy. We expect these risks will

increase as we pursue our strategy to expand operations into new geographic markets. We may not succeed in developing and implementing effective policies and strategies in each location where we conduct business. Any failure to do so may harm our business, results of operations and financial condition.

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

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

We believe that future reimbursement may be subject to increased restrictions both in the 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.

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

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act in the 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 levies a 2.3% excise tax, that began on January 1, 2013, on all sales of any U.S. medical device listed with the U.S. Food and Drug Administration under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Part 807, unless the device falls within an exemption from the tax, such as the exemption governing direct retail sale of devices to consumers or for foreign sales of these devices. If we commence sales of our MGuard Coronary stent in the 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 which started in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level in the 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 plan to introduce our products in the U.S.

In the European Union, on September 26, 2012, the European Commission proposed a revision of the legislation currently governing medical devices. If adopted by the European Parliament and the Council in their present form, these proposed revisions, which would be adopted in 2014 and would then gradually come into effect from 2015 to 2019, will impose stricter requirements on medical device manufacturers. Moreover, the supervising competences of the competent authorities of the European Union Member States and the notified bodies will be strengthened. The regulation of advanced therapy medicinal products is also in continued development in the European Union, with the European Medicines Agency publishing new clinical or safety guidelines concerning advanced therapy medicinal

products on a regular basis. Any of these regulatory changes and events could limit our ability to form collaborations and our ability to continue to commercialize our products, and if we fail to comply with any such new or modified regulations and requirements it could adversely affect our business, operating results and prospects.

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

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

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

We may have violated Israeli securities law.

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

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

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

- developing MGuard Carotid, MGuard Peripheral and MGuard Coronary with a drug eluting bio-absorbable mesh and any additional products;
- pursuing growth opportunities, including more rapid expansion;
- acquiring complementary businesses;

- making capital improvements to improve our infrastructure;
- hiring qualified management and key employees;
- developing new services, programming or products;
- responding to competitive pressures;
- complying with regulatory requirements such as licensing and registration; and
- maintaining compliance with applicable laws.

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

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

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

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

Risks Related to Operating in Israel

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

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

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

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

varying in degree and intensity, has caused security and economic problems in Israel. Although Israel has entered into peace treaties with Egypt and Jordan, and various agreements with the Palestinian Authority, there has been a marked increase in violence, civil unrest and hostility, including armed clashes, between the State of Israel and the Palestinians since September 2000. The establishment in 2006 of a government in the Gaza Strip by representatives of the Hamas militant group has created heightened unrest and uncertainty in the region. In mid-2006, Israel engaged in an armed conflict with Hezbollah, a Shiite Islamist militia group based in Lebanon, and in June 2007, there was an escalation in violence in the Gaza Strip. From December 2008 through January 2009 and again in November and December 2012, Israel engaged in an armed conflict with Hamas, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. Recent political uprisings and social unrest in Syria are affecting its political stability, which has led to the deterioration of the political relationship between Syria and Israel and have raised new concerns regarding security in the region and the potential for armed conflict. Similar civil unrest and political turbulence is currently ongoing in many countries in the region. The continued political instability and hostilities between Israel and its neighbors and any future armed conflict, terrorist activity or political instability in the region could adversely affect our operations in Israel and adversely affect the market price of our shares of common stock. In addition, several countries restrict doing business with Israel and Israeli companies have been and are today subjected to economic boycotts. The interruption or curtailment of trade between Israel and its present trading partners could adversely affect our business, financial condition and results of operations.

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

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

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

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

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

The majority of our assets are located outside the U.S. In addition, certain 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. officers, including judgments predicated upon the civil liability provisions of the securities laws of the U.S. or any state thereof. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the U.S. Israeli courts may refuse to hear a U.S. securities law claim because Israeli courts may not be the most appropriate forums in which to bring such a claim. Even if an Israeli court agrees to hear a claim, it may determine that the Israeli law, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, certain content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the Israeli law. Consequently, you may be effectively prevented from pursuing remedies under U.S. federal and state securities laws against us or any of our non-U.S. directors or officers.

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

The tax benefits that are available to us require us to continue meeting various conditions and may be terminated or reduced in the future, which could increase our costs and taxes. InspireMD Ltd. has been granted a “Beneficiary Enterprise” status by the Investment Center in the Israeli Ministry of Industry Trade and Labor which made us eligible for tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959. The main benefit is a two-year exemption and five years of a reduced tax rate of 25% from tax on income derived from beneficiary activities in facilities located in Israel. In order to remain eligible for the tax benefits of a “Beneficiary Enterprise”, we must continue to meet certain conditions stipulated in the Israeli Law for the Encouragement of Capital Investments, 1959 and its regulations, as amended, which may include, among other things, making specified investments in fixed assets and equipment, financing a percentage of those investments with our capital contributions, filing certain reports with the Investment Center, complying with provisions regarding intellectual property and the criteria set forth in the specific certificate of approval issued by the Investment Center or the Israel Tax Authority. If we do not meet these requirements, the tax benefits could be cancelled and we could be required to refund any tax benefits that we received in the past. Further, in the future, these tax benefits may be reduced or discontinued. If these tax benefits are cancelled, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies is 26.5% of taxable income. In the future, we may not be eligible to receive additional tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959. The termination or reduction of these tax benefits would increase our tax liability, which would reduce our profits.

Risks Related to Our Organization and Our Common Stock

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

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

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

The ongoing internal control provisions of Section 404 of the Sarbanes-Oxley Act of 2002 require us to identify of material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the U.S. Our management, including our chief executive officer and chief financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business

with us, cause downgrades in our future debt ratings leading to higher borrowing costs and affect how our stock trades. This could in turn negatively affect our ability to access public debt or equity markets for capital.

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

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

- technological innovations or new products and services by us or our competitors;
- additions or departures of key personnel;
- sales of our common stock, particularly under any registration statement for the purposes of selling any other securities, including management shares;
- limited availability of freely-tradable "unrestricted" shares of our common stock to satisfy purchase orders and demand;
- 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.

Delaware law, our corporate charter and bylaws and our stockholder rights plan, or poison pill, contain anti-takeover provisions that could delay or discourage takeover attempts that stockholders may consider favorable.

Our board of directors is authorized to issue shares of preferred stock in one or more series and to fix the voting powers, preferences and other rights and limitations of the preferred stock. Accordingly, we may issue shares of preferred stock with a preference over our common stock with respect to dividends or distributions on liquidation or dissolution, or that may otherwise adversely affect the voting or other rights of the holders of common stock. Issuances of preferred stock, depending upon the rights, preferences and designations of the preferred stock, may have the effect of delaying, deterring or preventing a change of control, even if that change of control might benefit our stockholders. In addition, we are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless (i) prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; (ii) the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (iii) on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 could delay or prohibit mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

In addition, on October 22, 2013, our board of directors adopted a rights agreement, implementing what is commonly known as a "poison pill," to protect and maximize the value of our outstanding equity interests in the event of an unsolicited attempt by an acquirer to take us over, in a manner or on terms not approved by our board of directors. The rights agreement may have the effect of rendering more difficult or discouraging an acquisition of our company

deemed undesirable by our board of directors and could cause substantial dilution to any such person or group that attempts to acquire us on terms or in a manner not approved by our board of directors, except pursuant to an offer conditioned upon the negation, purchase or redemption of the rights set forth in the rights agreement.

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. Our stockholders and the holders of our options and warrants may sell substantial amounts of our common stock in the public market. The availability of these shares of our common stock for resale in the public market has the potential to cause the supply of our common stock to exceed investor demand, thereby decreasing the price of our common stock.

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

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

We do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors as our board of directors may consider relevant. We are also subject to certain restrictions pursuant to our loan and security agreement with Hercules Technology Growth Capital, Inc., which prohibits us from paying dividends or distributions on our common stock. 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 Indebtedness

Our obligations under our term loan are secured by substantially all of our assets, so if we default on those obligations, the lender could foreclose on our assets. As a result of these security interests, such assets would only be available to satisfy claims of our general creditors or to holders of our equity securities if we were to become insolvent at a time when the value of such assets exceeded the amount of our indebtedness and other obligations. In addition, the existence of these security interests may adversely affect our financial flexibility.

The lender under our term loan has a security interest in substantially all of our assets and those of InspireMD Ltd., our wholly-owned subsidiary. As a result, if we default under our obligations to the lender, the lender could foreclose on its security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations.

In the event of a default in connection with our bankruptcy, insolvency, liquidation, or reorganization, the lender would have a prior right to substantially all of our assets to the exclusion of our general creditors. In that event, our assets would first be used to repay in full all indebtedness and other obligations secured by the lender, resulting in all or a portion of our assets being unavailable to satisfy the claims of any unsecured indebtedness. Only after satisfying the claims of any unsecured creditors would any amount be available for our equity holders.

The pledge of these assets and other restrictions may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged under the term loan, our ability to incur additional secured indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

Our loan and security agreement contains customary events of default. In addition, an event of default will include the occurrence of a circumstance that would reasonably be expected to have a material adverse effect upon (i) our business, operations, properties, assets, prospects or condition (financial or otherwise), (ii) our ability to perform our obligations under the agreement and any related loan documents or (iii) the collateral, the lender's liens on the collateral or the priority of such liens.

We have a substantial amount of indebtedness, which may adversely affect our cash flow and our ability to operate our business.

Pursuant to the terms of our loan and security agreement, the lender made a term loan to us and InspireMD Ltd. in aggregate amount of $10 million. We are required to make monthly payments of interest until August 31, 2014, monthly payments of principal and interest after such date, and repay the entire principal balance and any unpaid interest on February 1, 2017.

The terms of our term loan could have negative consequences to us, such as:

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

- the amount of our interest expense may increase because our term loan has a variable rate of interest at any time that the prime rate, as reported in the Wall Street Journal, is above 5.5%;

- we will need to use a substantial portion of our cash flows to pay principal and interest on our term loan, which will reduce the amount of money we have for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other business activities;

- we may have a higher level of debt than some of our competitors, which may put us at a competitive disadvantage;

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

- we may be more vulnerable to economic downturns and adverse developments in our industry or the economy in general.

Our ability to meet our expenses and debt obligations will depend on our future performance, which will be affected by financial, business, economic, regulatory and other factors. We will be unable to control many of these factors, such as economic conditions. We cannot be certain that our earnings will be sufficient to allow us to pay the principal and interest on our debt and meet any other obligations. If we do not have enough money to service our debt, we may be required, but unable to refinance all or part of our existing debt, sell assets, borrow money or raise equity on terms acceptable to us, if at all, and the lender could foreclose on its security interests and liquidate some or all of our assets.

Our loan and security agreement contains covenants that could limit our financing options and liquidity position, which would limit our ability to grow our business.

Covenants in our loan and security agreement impose operating and financial restrictions on us. These restrictions prohibit or limit our ability, and the ability of InspireMD Ltd., to, among other things:

- pay cash dividends to our stockholders;

- redeem or repurchase our common stock or other equity;

- incur additional indebtedness;

- permit liens on assets;

- make certain investments (including through the acquisition of stock, shares, partnership or limited liability company interests, any loan, advance or capital contribution)

- sell, lease, license, lend or otherwise convey an interest in a material portion of our assets; and

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Transition Report on Form 10-K/T 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," "estimates," and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and will probably not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or our management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;
- our ability to complete clinical trials as anticipated and obtain and maintain regulatory approvals for our products;
- our ability to adequately protect our intellectual property;
- disputes over ownership of intellectual property;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;
- the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that the MGuard technology is an attractive alternative to other procedures and products;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- entry of new competitors and products and potential technological obsolescence of our products;
- loss of a key customer or supplier;

- technical problems with our research and products and potential product liability claims;
- adverse economic conditions;
- adverse federal, state and local government regulation, in the U.S., Europe or Israel;
- price increases for supplies and components;
- inability to carry out research, development and commercialization plans; and
- loss or retirement of key executives and research scientists.

You should review carefully the risks and uncertainties described under the heading “Item 1A. Risk Factors” in this Transition Report on Form 10-K/T for a discussion of these and other risks that relate to our business and investing in shares of our common stock. The forward-looking statements contained in this Transition Report on Form 10-K/T are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our headquarters are located in Boston, Massachusetts, where we lease approximately 2,725 square feet of executive office space. In addition, in Tel Aviv, Israel, we currently have a 1,000 square meter office and manufacturing facility that has the capacity to manufacture and assemble 4,800 stents per month, based upon the production schedule of one shift per day. We believe that our current facility is sufficient to meet anticipated future demand by adding additional shifts to our current production schedule.

Item 3. Legal Proceedings.

From time to time, we may be involved in litigation that arises through the normal course of business. As of the date of this filing, we are not a party to any material litigation nor are we aware of any such threatened or pending litigation.

There are no material proceedings in which any of our directors, officers or affiliates or any registered or beneficial shareholder of more than 5% of our common stock is an adverse party or has a material interest adverse to our interest.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been quoted on the NYSE MKT since April 11, 2013 under the symbol “NSPR.” Prior to that date, it was traded on the OTC Bulletin Board since April 11, 2011. Prior to that date, there was no active market for our common stock.

The following table sets forth (i) the intra-day high and low sales price per share for our common stock, as reported on the NYSE MKT, for the period of April 11, 2013 to December 31, 2013, and (ii) the high and low bid prices for our common stock, as reported by the OTC Bulletin Board, for the period of April 11, 2011 to April 10, 2013. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. The OTC Bulletin Board quotations prior to December 21, 2012 are adjusted for the one-for-four reverse stock split of our common stock that occurred on such date.

Transition Period Ended December 31, 2013	High	Low
First Quarter	$2.68	$1.80
Second Quarter	$3.67	$2.27

Fiscal Year Ended June 30, 2013	High	Low
First Quarter	$10.00	$3.84
Second Quarter	$10.16	$3.01
Third Quarter	$4.25	$1.95
Fourth Quarter	$3.15	$1.88

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

Fiscal Year Ended December 31, 2011	High	Low
Second Quarter	$11.56	$7.00
Third Quarter	$	