InspireMD, Inc.
Form 10-K
March 13, 2012

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

FORM 10-K

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

For the fiscal year ended: December 31, 2011

OR

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

COMMISSION FILE NUMBER: 000-54335

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)
3 Menorat Hamaor St. Tel Aviv, Israel	67448
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 972-3-691-7691

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.0001 par value

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 £ Smaller reporting company R
(Do not check if a smaller reporting company)

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 the last business day of the registrant's most recently completed second fiscal quarter, based on the price at which the common equity was last sold on the OTC Bulletin Board on such date, was approximately $108,616,000. 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 March 12, 2012
Common Stock, $0.0001 par value	68,178,947

Documents incorporated by reference:

None

TABLE OF CONTENTS

PART I

In this Annual Report on Form 10-K, unless the context requires otherwise, all references to "we," "our" and "us" for periods prior to the closing of our share exchange transactions on March 31, 2011 refer to InspireMD Ltd., a private company incorporated under the laws of the State of Israel that is now our wholly-owned subsidiary, and its subsidiary, and references to "we," "our" and "us" for periods subsequent to the closing of the share exchange transactions refer to InspireMD, Inc., a publicly traded Delaware corporation, and its direct and indirect subsidiaries, including InspireMD Ltd.

Item 1. Business.

History

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

On March 31, 2011, we completed a series of share exchange transactions pursuant to which we issued the shareholders of InspireMD Ltd. 50,666,663 shares of common stock in exchange for all of InspireMD Ltd.'s issued and outstanding ordinary shares, resulting in the former shareholders of InspireMD Ltd. holding a controlling interest in us and InspireMD Ltd. becoming our wholly-owned subsidiary.

Immediately following the share exchange transactions, we transferred all of our pre-share exchange operating assets and liabilities to our wholly-owned subsidiary, Saguaro Holdings, Inc., a Delaware corporation, and transferred all of Saguaro Holdings, Inc.'s outstanding capital stock to Lynn Briggs, our then-majority stockholder and our former president, chief executive officer, chief financial officer, secretary-treasurer and sole director, in exchange for the cancellation of 7,500,000 shares of our common stock held by Ms. Briggs.

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

Overview

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

1

MGuardTM Sleeve – Microscopic View

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

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

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

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

Our principal executive offices are located at 3 Menorat Hamaor St., Tel Aviv, Israel 67448. Our telephone number is 972-3-691-7691. 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 13. Entity Wide Disclosures.”

Our Industry

According to Fact Sheet No. 310/June 2011 of the World Health Organization, approximately 7.3 million people worldwide died of coronary heart disease in 2008. Physicians and patients may select from among a variety of treatments to address coronary artery disease, including pharmaceutical therapy, balloon angioplasty, stenting with bare metal or drug-eluting stents, and coronary artery bypass graft procedures, with the selection often depending upon the stage of the disease. A stent is an expandable “scaffold-like” device, usually constructed of a stainless steel material, that is inserted into an artery to expand the inside passage and improve blood flow.

According to the January 3, 2011 2011 MEDTECH OUTLOOK produced by the Bank of Montreal Investment Banking Group, known as BMO Capital Markets, after registering a compounded annual growth rate from 2002 to 2009 of approximately 13%, the revenues from global coronary stents market is predicted to remain relatively constant, although in volume of stents the market is predicted to continue to grow. The growth in volume is due to the appeal for less invasive percutaneous coronary intervention procedures and advances in technology coupled with the increase in the elderly population, obesity rates and advances in technology.

Coronary artery disease is one of the leading causes of death worldwide. The treatment of coronary artery disease includes alternative treatment methodologies, that is, coronary artery bypass grafting or angioplasty (percutaneous coronary intervention) with or without stenting. According to the January 3, 2011 2011 MEDTECH OUTLOOK produced by the BMO (Bank of Montreal) Investment Banking Group, the percutaneous coronary intervention procedures involving stents are increasingly being used to treat coronary artery diseases with an 88.3% penetration rate in 2009.

Our Products

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

MGuardTM Deployed in Artery

The protective sleeve is designed to provide several clinical benefits:

- the mesh diffuses the pressure and the impact of deployment exerted by the stent on the arterial wall and reduces the injury to the vessel;
- it reduces plaque dislodgement and blocks debris from entering the bloodstream during and post procedure (called embolic showers);
- in future products, when drug coated, the mesh is expected to deliver better coverage and uniform drug distribution on the arterial wall and therefore potentially reduce the dosage of the active ingredient when compared to approved drug-eluting stents on the market; and

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

MGuardTM – Coronary Applications

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

MGuardTM Coronary and MGuard Prime™ with a bio-stable mesh. Our first MGuardTM product, the MGuardTM Coronary with a bio-stable mesh, is comprised of our mesh sleeve wrapped around a bare-metal stent. It received CE Mark approval in October 2007 and, in January 2008, we started shipping this product to customers and distributors in Europe. MGuard Prime™ with a bio-stable mesh is comprised of our mesh sleeve wrapped around a cobalt-chromium stent. In comparison to a conventional bare-metal stent, we believe the MGuardTM Coronary and MGuard Prime™ with a bio-stable mesh provide protection from embolic showers. Results of clinical trials on the MGuardTM Coronary stent, including the MAGICAL, PISCIONE and MGuard international registry (iMOS) clinical trials described below (see "Business – Product Development and Critical Milestones - Comparison of Clinical Trial Results to Date with Results Achieved Using Bare Metal or Drug-Eluting Stents in the STEMI population" below), indicate positive outcomes and safety measures, as explained below (see "Business – Product Development and Critical Milestones - Comparison of Clinical Trial Results to Date with Results Achieved Using Bare Metal or Drug-Eluting Stents in the STEMI population" below). The results of these clinical trials for the MGuardTM Coronary stent suggest higher levels of myocardial blush grade 3 (occurrence in 73% of patients in the MAGICAL study and 90% of patients in the PISCIONE study, for the MGuardTM Coronary stent) and lower rates of 30 day and 1 year major adverse cardiac event rates, (2.4% and 5.9%, respectively, for the MGuardTM Coronary stent), as compared to the levels and rates of other bare-metal and drug-eluting stents, as reported by Svilaas, et. al. ("Thrombus Aspiration during Primary Percutaneous Coronary Intervention," New England Journal of Medicine, Volume 358, 2008). As reported in the study by Svilaas, et. al., myocardial blush grade 3 occurred in 32.2% of patients with a bare-metal stent and 45.7% of patients with a bare-metal stent preceded by an aspiration procedure, and the 30 day and 1 year major adverse cardiac event rates were 9.4% and 20.3%, respectively, for patients with a bare-metal stent and 6.8% and 16.6%, respectively, for patients with a bare-metal stent preceded by an aspiration procedure. Furthermore, results from a recent HORIZONS-AMI trial demonstrated that 1 year major adverse cardiac event rates were 10.9% for patients with drug eluting stents. Myocardial blush grade refers to a 0-3 grade scale given to the adequacy of perfusion and blood flow through an area served by a coronary artery; the longer the blush persists, the poorer the blood flow and the lower the myocardial blush grade. Ndrepepa, et. al. ("5-Year Prognostic Value of No-Reflow Phenomenon After Percutaneous Coronary Intervention in Patients With Acute Myocardial Infarction," Journal of the American College of Cardiology, Volume 55, Issue 21, 2010) reported that high myocardial blush grades correlate with higher survival rates among affected patients. Sustained performance by the MGuardTM Coronary stent with respect to contributing to higher levels of myocardial blush grade 3 and lower rates of 30 day and 1 year major adverse cardiac event rates would differentiate the MGuardTM Coronary stent from other bare-metal and drug-eluting stents that do not offer such benefits.

MGuardTM Coronary with a drug eluting bio-absorbable mesh. Based upon the clinical profile of MGuardTM Coronary, we anticipate that the MGuardTM Coronary with a drug-eluting bio-absorbable mesh will offer both the comparable myocardial blush grade 3 levels and 30-day and 1-year major adverse cardiac event rates as the MGuardTM Coronary with a bio-stable mesh, as described above, and a comparative restenosis rate, which is the rate at which patients experience formation of new blockages in their arteries, when compared to existing drug-eluting stents. The bio-absorbability of MGuardTM Coronary with a drug eluting bio-absorbable mesh is intended to improve upon the bio-absorbability of other drug-eluting stents, in light of the large surface area of the mesh and the small diameter of the fiber. We intend for the protective sleeve on the MGuardTM Coronary with a drug-eluting

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

MGuardTM – Carotid Applications

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

MGuardTM – Peripheral Applications

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

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

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

Product Development and Critical Milestones

Below is a list of the products described above and our projected critical milestones with respect to each. As used below, "Q" stands for our fiscal quarter. While we currently anticipate seeking approval from the U.S. Food and Drug Administration for all of our products in the future, we have only outlined a timetable to seek U.S. Food and Drug Administration approval for our MGuardTM Coronary plus with bio-stable mesh product in our current business plan. The use of the term "to be determined" in the table below with regard to certain U.S. Food and Drug Administration trial milestones indicates that the achievements of such milestones is unable to be accurately predicted as such milestones are too far in the future.

Product	Indication	Start Development	CE Mark	European Union Sales	FDA Approval	U.S. Sales

MGuard™ Coronary Plus Bio-Stable Mesh	Bypass/ Coronary	2005	Oct. 2007	Q1-2008	Q3-2015-Q4-2015	2015
MGuard™ Peripheral Plus Bio-Stable Mesh	Peripheral Arteries	Q1-2011	Q1-2012	Q4-2012	To be determined	To be determined
MGuard™ Carotid Plus Bio-Stable Mesh	Carotid Arteries	Q1-2011	Q1-2012	To be determined	To be determined	To be determined
MGuard™ Coronary Plus Bio-Absorbable Drug-Eluting Mesh	Bypass/ Coronary	Q1-2013	Q3-2016	Q4-2016	To be determined	To be determined

With respect to the timetable for MGuard™ Coronary Plus Bio-Stable Mesh, the expected timing for the U.S. Food and Drug Administration approval and U.S. sales has been changed due to unanticipated delays in the U.S. Food and Drug Administration approval process. With respect to the timetable for MGuard™ Peripheral Plus Bio-Stable Mesh, the expected commencement of sales in the European Union has been delayed on account of our desire to provide extra time after obtaining CE Mark approval to promote our product and develop a proper launching program for it. With respect to MGuard™ Carotid Plus Bio-Stable Mesh, we have determined that the expected commencement of sales in the European Union can no longer be accurately predicted because we have delayed the further development of this product subject to obtaining additional funding for its development.

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

Pre-Clinical Studies

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

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

Product	Stent Platform	Approval Requirement	Start of Study	End of Study
MGuardTM Coronary	Bare-Metal Stent Plus Bio-Stable Mesh	CE Mark (European Union + Rest of World)	Q4-2006	Q3-2007
	Drug-Eluting Mesh (Bare-Metal Stent Plus Drug-Eluting Mesh)	CE Mark (European Union + Rest of World)	To be determined	To be determined
		FDA (U.S.)	To be determined	To be determined
	Cobalt-Chromium Stent Plus Bio-Stable Mesh	FDA	Q3-2012	Q3-2015 - Q4-2015
MGuardTM Peripheral/Carotid	Self Expending System Plus Mesh	CE Mark (European Union + Rest of World)	Q2-2012	Q2-2013
		FDA (U.S.)		

MGuardTM Carotid	Self Expending System Plus Mesh	Peripheral information on animals can be used

With respect to the preclinical studies for MGuardTM Coronary, the drug-eluting mesh trials have been indefinitely suspended due to our determination to focus our time and resources on other trials at this time and the start of the cobalt-chromium stent plus bio-stable mesh trial was delayed from our previously announced target due to the delay of the U.S. Food and Drug Administration approval process for MGuard™ Coronary Plus Bio-Stable Mesh.

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

Clinical Trials

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

						Study Status		
Product	Stent Platform	Clinical Trial Sites	Follow-up Requirement	Objective	No. of Patients	Start	End Enrollment	End of Study
MGuardTM Coronary	Bare-Metal Stent Plus Bio-Stable Mesh	Germany – two sites	12 months	Study to evaluate safety and performance of MGuardTM system	41	Q4-2006	Q4- 2007	Q2-2008
		Brazil – one site	12 months		30	Q4-2007	Q1-2008	Q2-2009
		Poland – four sites	6 months		60	Q2-2008	Q3-2008	Q2-2009
		International MGuardTM Observational Study - worldwide - 50 sites	12 months		1,000	Q1-2008	Q4-2013	Q4-2013
		Israeli MGuardTM Observational Study - Israel - 8 sites	6 months		100	Q2-2008	Q3-2011	Q3-2012
		Master randomized control trial - 7 countries, 50 centers in South America, Europe and Israel	12 months		430	Q2-2011	Q2-2012	Q2-2013
		Brazil – 25 sites	12 months		500	Q3-2010	To be determined	To be determined
		FDA Study - 40 sites, U.S.	12 months	Pilot study to	800	Q1-2012 - Q2-2012	Q3-2013 – Q1-2014	Q4-2014 - Q2-2015

	and out of U.S.		evaluate safety and performance of MGuardTM system for FDA approval				
	South America and Europe – 10 sites	8-12 months	Pilot study to evaluate safety and performance of MGuardTM system for FDA and CE Mark approval	500	To be determined	To be determined	To be determined
Drug-Eluting Stent (Bare-Metal Stent + Drug Eluting Mesh)	U.S. – 50 sites	12 months		2,000	To be determined	To be determined	To be determined
	Rest of World as a registry study	8-12 months	Evaluation of safety and efficacy for specific indications	400	To be determined	To be determined	To be determined

Product	Stent Platform	Clinical Trial Sites	Follow-up Requirement	Objective	No. of Patients	Study Status		
						Start	End Enrollment	End of Study
MGuardTM Peripheral	Self Expanding System + Mesh	South America and Europe – four sites	12 months	Pilot study to evaluate safety and performance of MGuardTM system for CE Mark approval	50	Q2-2012	Q1-2013	Q4-2014
		South America and Europe – six sites	6 months		150	Q2-2010	Q4-2010	Q2-2011
MGuardTM Carotid	Self Expanding System + Mesh	Rest of World as a registry study	6 months	Evaluation of safety and efficacy for specific indications post-marketing	100	Q2-2012	Q3-2013	Q3-2014

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

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

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

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

With respect to the MGuardTM Carotid clinical trial for the self expanding system + 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 MGuardTM Coronary Bare-Metal Stent Plus Bio-Stable Mesh

As shown in the table above, we have completed five clinical trials with respect to our MGuardTM Coronary with bio-stable mesh. Our first study, conducted at two centers in Germany, included 41 patients with either saphenous vein graft coronary interventions or native coronary lesions treatable by a stenting procedure (blockages where no bypass procedure was performed). The MGuardTM Coronary rate of device success, meaning the stent was successfully deployed in the target lesion, was 100% and the rate of procedural success, meaning there were no major adverse cardiac events prior to hospital discharge, was 95.1%. At six months, only one patient (2.5% of participants) had major myocardial infarction (QWMI) and 19.5% of participants had target vessel revascularization (an invasive procedure required due to a stenosis in the same vessel treated in the study). This data supports MGuardTM's safety in the treatment of vein grafts and native coronary legions.

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

The study in Poland included 60 patients with acute ST-segment elevation myocardial infarction (the most severe form of a heart attack, referred to as "STEMI"). The purpose of the study was to confirm the clinical performance of MGuardTM Coronary with bio-stable mesh when used in STEMI patients where percutaneous coronary intervention is the primary line of therapy. Perfect blood flow in the artery was achieved in 90% of patients, perfect blood flow into the heart muscle was achieved in 73% of patients and complete restoration of electrocardiogram normality was achieved in 61% of patients. The total major adverse cardiac events rate during the six-month period following the deployment of the stents was 0%.

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

Our ongoing observation study in Europe is an open registry launched in the first fiscal quarter of 2009. This registry is expected to enroll up to 1,000 patients and is aimed at establishing the performance of MGuardTM Coronary with bio-stable mesh in a "real world" population. To date, the primary countries to join are Austria, Czech Republic and Hungary. The primary endpoint that this registry will evaluate is the occurrence of major adverse cardiac events at six months following deployment of the stent, and the clinical follow-up will continue for a period of up to one year per patient. As of February 29, 2012, 527 patients of the prospective 1,000 have been enrolled in 28 sites.

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

deployment of the stent. As February 29, 2012, 86 patients of the prospective 100 have been enrolled.

In the third fiscal quarter of 2010, we launched a Brazilian registry to run in 25 Brazilian sites and enroll 500 patients. The primary endpoint that this registry will evaluate is the occurrence of major adverse cardiac events at six months following the deployment of the stent, and the clinical follow-up will continue for a period of up to one year per patient. As of February 29, 2012, 16 patients of the prospective 500 have been enrolled.

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

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

- The MAGICAL study, a single arm study in which 60 acute ST-segment elevation myocardial infarction (the most severe form of a heart attack, referred to as STEMI) patients with less than 12 hours symptom onset were enrolled, as reported in "Mesh Covered Stent in ST-segment Elevation Myocardial Infarction" in EuroIntervention, 2010;

- the PISCIONE study, a single arm study in which 100 STEMI patients were enrolled, as reported in "Multicentre Experience with MGuard Net Protective Stent in ST-elevation Myocardial Infarction: Safety, Feasibility, and Impact on Myocardial Reperfusion" in Catheter Cardiovasc Interv, 2009;

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

- the Jain study, which looks at a small group of 51 STEMI patients, as reported in "Prevention of Thrombus Embolization during Primary Percutaneous Intervention Using a Novel Mesh Covered Stent" in Catheter Cardiovasc Interv, 2009.

Our meta-analysis included data from the following trials:

- The CADILLAC (Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications) study, which found that primary stent implantation is a preferred strategy for the treatment of acute myocardial infarction, as reported in "A Prospective, Multicenter, International Randomized Trial Comparing Four Reperfusion Strategies in Acute Myocardial Infarction: Principal Report of the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications (CADILLAC)" Trial in Journal of American College of Cardiology, 2001;

- The EXPORT trial which was a randomized open-label study whose primary endpoint was to evaluate flow improvement in AMI patients using either conventional stenting or aspiration followed by stenting, as reported in "Systematic Primary Aspiration in Acute Myocardial Percutaneous Intervention: A Multicentre Randomised Controlled Trial of the Export Aspiration Catheter" in EuroIntervention, 2008;

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

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

- The Horizons-AMI (Harmonizing Outcomes with RevascularIZatiON and Stents in Acute MI), which is the largest randomized trial which compared DES to BMS in MI patients, as reported in "Paclitaxel-Eluting Stents Versus Bare-Metal Stents in Acute Myocardial Infarction" in New England Journal of Medicine, 2009; and

10

- 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.

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

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

Trial	CADILLAC	Horizons-AMI	Horizons-AMI	TAPAS	TAPAS	EXPORT	EXPORT	EXPIRA	EXPIRA	REM
Group	Stent + Abciximab	BMS	DES	Thrombus aspiration	control	control	TA	control	Thrombus aspiration	Thro aspir
Number of Patients	524	749	2257	535	536	129	120	87	88	5
Thrombolysis in myocardial infarction 0-1,%	--	--	--	--	--	3.9	2.4	1.1	0	-
Thrombolysis in myocardial infarction 3,%	96.9	87.6	89.8	86	82.5	76.9	82	--	--	-
Myocardial blush grade 0-1,%	48.7	--	--	17.1	26.3	31.6	27.6	40.2	11.4	3
Myocardial blush grade 3,%	17.4	--	--	45.7	32.2	25.4	35.8	--	--	-
ST segment resolution>70%,%	62	--	--	56.6	44.2	--	--	39.1	63.6	5

ST segment resolution>50%,%	--	--	--	--	--	71.9	85	--	--	-
30 day major adverse cardiac event,%	4.4	--	--	6.8	9.4	--	--	--	--	1
6 month major adverse cardiac events,%	10.2	--	--	--	--	--	--	--	--	-
1 year major adverse cardiac events,%	--	13.1	10.9	16.6	20.3	--	--	--	--	-
Acute Binary Resteonosis 6 month,%	20.8	--	--	--	--	--	--	--	--	-
1 year target vessel revascularization		7.4	4.6	12.9	11.2					
Acute Binary Resteonosis 1 year,%	--	21	8.3	--	--	--	--	--	--	-

Future Clinical Trials for MGuardTM Coronary

We anticipate that additional studies will be conducted to meet registration requirements in key countries, particularly the U.S. We have currently budgeted $8.5 million for the U.S. Food and Drug Administration trial. We expect that post-marketing trials will be conducted to further establish the safety and efficacy of the MGuardTM Coronary with bio-stable mesh in specific indications. These trials will be designed to facilitate market acceptance and expand the use of the product. We anticipate that the MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial), for which we have budgeted $2.0 million, will serve to promote market acceptance of the product and expand its usage. The MASTER Trial is a multinational, randomized controlled trial of the MGuard™ mesh protective coronary stent that includes 432 patients in a two-arm, parallel design, with the intention of testing the MGuard™ stent against commercially approved bare-metal stents or drug-eluting stents with respect to myocardial reperfusion in primary angioplasty for the treatment of acute ST-elevation myocardial infarction. In other countries, we believe that we generally will be able to rely upon the CE Mark approval of the product, as well as the results of the U.S. Food and Drug Administration trial and MASTER Trial in order to obtain local approvals.

In the second fiscal quarter of 2011, we began a prospective, randomized study in Europe, South America and Israel to demonstrate the superiority of the MGuard™ stent over commercially-approved bare-metal and drug-eluting stents in achieving better myocardial reperfusion (the restoration of blood flow) in primary angioplasty for the treatment of acute STEMI. We anticipate that this trial will enroll 432 subjects, 50% of whom will be treated with an MGuard™ stent and 50% of whom will be treated with a commercially-approved bare-metal or drug-eluting stent. The primary endpoint of this study is the occurrence of the restoration of normal electrocardiogram reading. As of February 29, 2012, 201 patients of the prospective 432 have been enrolled.

We also plan to conduct a large clinical study for U.S. Food and Drug Administration approval in the U.S. We expect that this study will be a prospective, multicenter, randomized clinical trial. Its primary objective will be to compare the safety and the effectiveness of the MGuard™ stent in the treatment of de novo stenotic lesions in coronary arteries in patients undergoing primary revascularization (a surgical procedure for the provision of a new, additional, or augmented blood supply to the heart) due to acute myocardial infarction with the MultiLink Vision stent system from Abbott Vascular. We expect total enrollment of approximately 800 subjects, at up to 40 sites throughout the U.S. and Europe. The combined primary endpoint of this study will be the occurrence of Blush Score of 3, which would indicate that blood supply to the heart muscle is optimal, following the procedure, and the occurrence of target vessel failure (a composite endpoint of cardiac death, reoccurrence of a heart attack and the need for a future invasive procedure to correct narrowing of the coronary artery). This study is expected to start in 2012, and the enrollment phase is expected to last 18 months. We expect that subjects will be followed for 12 months with assessments at 30 days, six months and 12 months. This plan is tentative, and is subject to change to conform with U.S. Food and Drug Administration regulations and requirements.

Planned Trials for future MGuardTM Peripheral and Carotid Products

As shown in the table at the beginning of this section, we also plan to conduct clinical trials for our additional products in development in order to obtain approval for their use. We anticipate that local distributors in the countries in which such trials will take place will support many of these studies.

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 MGuardTM Coronary with bio-stable mesh. We have begun commercialization of MGuardTM Coronary with a bio-stable mesh in Europe, Asia and Latin America through our distributor network and we are aggressively pursuing additional registrations and contracts in other countries such as Russia, Canada, South Korea, Belgium, the Netherlands 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 MGuardTM technology to clinics and interventional cardiologists around the world, and to have fostered brand name recognition and widespread adoption of MGuardTM 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 MGuardTM stents. While we market our MGuardTM Coronary with bio-stable mesh, we intend to develop the MGuardTM Coronary with a drug-eluting mesh. We are also working on our MGuardTM stents for peripheral and carotid, for which we expect to have CE Mark approval by the first quarter of 2012. In addition, we released our cobalt-chromium version of MGuardTM, MGuard Prime™, in 2010, which we anticipate will replace MGuardTM over the next couple of years.

- Continue to leverage MGuardTM 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 secured intellectual property using our unique 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 a 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 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 MGuardTM portfolio of products. We intend to work closely with leading cardiologists to evaluate and ensure the efficacy and safety of our products. We intend that some of these prominent physicians will serve on our Scientific Advisory Board, which is our advisory committee that advises our board of directors, and run clinical trials with the MGuardTM Coronary stent. We believe these individuals, once convinced of the MGuardTM Coronary stent's appeal, will be invaluable assets in facilitating the widespread adoption of the stent. In addition, we plan to look to these cardiologists to generate and publish scientific data on the use of our products, and to present their findings at various conferences they attend. Dr. Gregg W. Stone, director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapy of New York Presbyterian Hospital/Columbia University Medical Center and the co-director of Medical Research and Education at The Cardiovascular Research Foundation is the study chairman for the MASTER Trial. Dr. Donald Cutlip, Executive Director of Clinical Investigation at the Harvard Clinical

Research Institute, will provide scientific leadership of the U.S. Food and Drug Administration trials. On October 4, 2011, InspireMD Ltd., our wholly-owned subsidiary, entered into a clinical trial services agreement with Harvard Clinical Research Institute, Inc., pursuant to which Harvard Clinical Research Institute, Inc. will conduct a study entitled "MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction" on our behalf. We will pay Harvard Clinical Research Institute, Inc. an estimated fee of approximately $10 million for conducting the study, subject to adjustment dependent upon changes in the scope and nature of the study, as well as other costs to be determined by the parties.

- Continue to protect and expand our portfolio of patents. Our patents and their protection are critical to our success. We have filed ten separate patents for our MGuardTM technology in Canada, China, Europe, Israel, India, South Africa and the U.S. We believe these patents cover all of our existing products, and can be useful for future technology. We intend to continue patenting new technology as it is developed, and to actively pursue any infringement upon our patents. On October 25, 2011, one of our patent applications, U.S. patent application 11/582,354, was issued as U.S. Patent 8,043,323.

- Develop strategic partnerships. We intend to partner with medical device, biotechnology and pharmaceutical companies to assist in the development and commercialization of our proprietary technology. Although we have not yet done so, we plan to partner with a company in the U.S. to guide products through U.S. Food and Drug Administration approval and to support the sale of MGuardTM stents in the U.S.

As noted above, we previously filed patents for our MGuardTM technology in China, as part of our intended growth strategy. However, upon further consideration of the cost and resources required to achieve 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 MGuardTM 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, due to less stringent regulatory approval requirements in Europe, 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 currently 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 January 3, 2011 2011 MEDTECH OUTLOOK produced by the BMO (Bank of Montreal) Investment Banking Group, the worldwide stent market is dominated by four major players, with a combined total market share of approximately 96%. Within the bare metal stent market and drug-eluting stent market, the top four companies have approximately 92% and 98% of the market share, respectively. These four companies are Abbott

Laboratories, Boston Scientific Corporation, Johnson & Johnson and Medtronic, Inc. To date our sales are not significant enough to register in market share. As such, one of the challenges we face to the further growth of MGuard™ is the competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. Most of our current and potential competitors, including but not limited to those listed above, have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do.

In addition to the challenges from our competitors, we face challenges related specifically to our products. None of our products are currently approved by the U.S. Food and Drug Administration. Clinical trials necessary to support a pre-market approval application to the U.S. Food and Drug Administration for our MGuard™ stent will be expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. Furthermore, our rights to our intellectual property with respect to our products could be challenged. Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our MGuard™ stent based on one or more of these patents.

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

Another challenge facing the MGuardTM products is that placing the stent at the entrance to large side branches, known as jailing large side branches, is not recommended with the MGuardTM Coronary stent, because there is 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 2011, 2010 and 2009, we spent approximately $2.5 million, $1.3 million and $1.3 million, respectively, on research and development.

Sales and Marketing

Sales and Marketing

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

Until U.S. Food and Drug Administration approval of our MGuardTM Coronary with a bio-stable mesh, which we are targeting for 2014, 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 Italy, Germany, Great Britain, France, Greece, Austria, Hungary, Poland, Slovenia, Czech Republic and Slovakia.

15

In addition to utilizing local and regional distributor networks, we are using international trade shows and industry conferences to gain market exposure and brand recognition. We plan to work with leading physicians to enhance our marketing efforts. As sales volume increases, we plan to open regional offices and manage sales activities more closely in each of our defined geographical regions, and to provide marketing support to local and regional distributors in each area.

Product Positioning

The MGuardTM 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 MGuardTM Coronary in 2011 was minimal, with total sales in the twelve months ended December 31, 2011 of approximately $6 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, MGuardTM, as a superior and cost effective solution to these currently unmet needs of interventional cardiologists. We believe our MGuardTM technology is clinically superior to bare-metal stents because it provides embolic protection during and post-procedure. We believe our MGuardTM 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 MGuardTM technology that we believe to exist, the MGuardTM technology maintains the deliverability, crossing profile, and dilatation pressure of a conventional stent, and interventional cardiologists do not have to undergo extensive 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 MGuardTM 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 MGuardTM 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., once the MGuardTM 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 MGuardTM will be eligible for reimbursement through both governmental healthcare agencies and most private insurance agencies in the U.S.

16

Intellectual Property

Patents

We have filed ten separate patents for our MGuardTM technology in Canada, China, Europe, Israel, India, South Africa and the U.S. for an aggregate of 35 filed patents. These patents 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 patents generally cover two parts of our products: the mesh sleeve, with and without a drug, and the delivery mechanism of the stent. On October 25, 2011, one of our patent applications, U.S. patent application 11/582,354, was issued as U.S. Patent 8,043,323. None of the other patents have been granted to date. We believe these patents, once issued, will cover all of our existing products and be useful for future technology. We also believe that the patents we have filed, in particular those covering the use of a knitted micron-level mesh sleeve over a stent for various indications, would create a significant barrier for another company seeking to use similar technology.

To date, we are not aware of other companies that have patent rights to a micron fiber, releasable knitted fiber sleeve over a stent. However, larger, better funded competitors own patents relating to the use of drugs to treat restenosis, stent architecture, catheters to deliver stents, and stent manufacturing and coating processes as well as general delivery mechanism patents like rapid exchange. 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 would be un-founded, such litigation would divert attention and resources away from the development of MGuardTM stents. Other manufacturers 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, an uncertain and costly process.

Trademarks

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

Government Regulation

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

Sales of medical devices outside the 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 an 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 in the following countries: Italy, Germany, Austria, Czech Republic, Slovakia, France, Slovenia, Greece, Cyprus, Portugal, Spain, Poland, Hungary, Estonia, Lithuania, Ukraine, United Kingdom, Holland, Russia, Latvia, Brazil, Chile, Costa Rica, Mexico, Argentina, Colombia, India, Sri Lanka, South Africa, Pakistan 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. 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 for MGuard Prime™. 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 intend that the results of the MASTER Trial will satisfy any additional governmental regulatory requirements in each of the countries where we currently distribute our products and in any countries that we are currently targeting for expansion. However, even if all governmental regulatory requirements are satisfied in each such country, we anticipate that obtaining marketing approval in each country could take as few as three months or as many as twelve months, due to the nature of the approval process in each individual country, including typical wait times for application processing and review, as discussed in greater detail below.

MGuard Prime™ received CE Mark approval in the European Union in October 2010 and marketing approval in Israel in September 2011. We are currently seeking marketing approval for MGuard Prime™ in Brazil, Malaysia, Mexico, Russia, Serbia, Singapore, Argentina, India, Sri Lanka and Pakistan. We are focusing 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 each of the countries in which we are seeking marketing approval for MGuard Prime™ accepts the CE Mark as its primary requirement for marketing approval and does not require any additional tests, each country does require some additional regulatory requirements for marketing approval. More specifically, for the approval process in Malaysia, we need to submit an application for regulatory approval, which we anticipate will be granted in three months. For the approval process in Mexico, we need to submit an application for regulatory approval, which we anticipate will be granted in twelve months. For the approval process in Serbia, we need to submit an application for regulatory approval, which we anticipate will be granted in twelve months. For the approval process in Singapore, we need to submit an application for regulatory approval, which we anticipate will be granted in six months. For the approval process in Argentina, we need to submit an application for regulatory approval, which we anticipate will be granted in approximately twelve months. For the approval process in India, we need to submit an application for regulatory approval, which we anticipate will be granted in approximately twelve months. For the approval process in Sri Lanka, we need to submit an application for regulatory approval, which we anticipate will be granted in six to twelve months. For the approval process in Pakistan, we need to submit an application for regulatory approval, which we anticipate will be granted in six to twelve months. In Israel, where we received marketing approval in September 2011, we will be subject to annual renewal of our marketing approval. Regulators in Israel may request additional documentation or other materials and results of studies from medical device manufacturers such as us 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.

For the approval process in Brazil, we must comply with Brazilian Good Manufacturing Practice, or GMP, quality system requirements. ANVISA, Brazil's regulatory agency, must conduct an inspection of MGuard Prime™ 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. Once we receive the necessary GMP certificate, we can apply for regulatory approval. We anticipate that the approval process in Brazil will take between one and two years.

For the approval process in Russia, we must first provide test samples of MGuard Prime™ and then conduct government-authorized testing. We must then submit the test results together with our application for regulatory approval to the Russian regulatory authority. We anticipate that the approval process in Russia will take between five to twelve months.

Please refer to the table below setting forth the approvals and sales for MGuard™ and MGuard Prime™ on a country-by-country basis.

Approvals and Sales of MGuard™ and MGuard Prime™ on a Country-by-Country Basis

Countries	MGuard™ Approval	MGuard™ Sales	MGuard Prime™ Approval	MGuard Prime™ Sales	Countries	MGuard™ Approval	MGuard™ Sales	MGuard Prime™ Approval	MGuard Prime™ Sales
Argentina	Y	Y	N	N	Italy	Y	Y	Y	Y
Austria	Y	Y	Y	Y	Latvia	Y	Y	Y	Y
Brazil	Y	Y	N	N	Lithuania	Y	Y	Y	N
Chile	Y	Y	N	N	Malaysia	N	N	N	N
Colombia	Y	Y	N	N	Mexico	Y	Y	N	N
Costa Rica	Y	Y	N	N	Pakistan	Y	Y	N	N
Cyprus	Y	Y	Y	N	Poland	Y	Y	Y	Y
Czech Rep	Y	Y	Y	N	Portugal	Y	Y	Y	N
UK	Y	N	Y	N	Russia	Y	Y	N	N
Estonia	Y	Y	Y	Y	Serbia	N	N	N	N
France	Y	Y	Y	Y	Singapore	N	Y1	N	N
Germany	Y	Y	Y	Y	Slovakia	Y	Y	Y	N
Greece	Y	Y	Y	Y	Slovenia	Y	Y	Y	N
Holland (Netherlands)	Y	Y	Y	Y	South Africa	Y	Y	N	N
Hungary	Y	Y	Y	Y	Spain	Y	Y	Y	Y
India	Y	Y	N	N	Sri Lanka	Y	Y	N	N
Israel	Y	Y	Y	Y	Ukraine	Y	Y	N	N

1 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 MGuardTM Coronary plus with bio-stable mesh product will be classified as a Class III medical device by the U.S. Food and Drug Administration.

A manufacturer may seek market authorization for a new medical device through the rigorous Premarket Approval application process, which requires the U.S. Food and Drug Administration to 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.

19

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 Canada, Southeast Asia, India and Latin America. In 2011, forty six percent (46%) of our revenue was generated in Europe, eighteen percent (18%) of our revenue was generated in Asia, sixteen percent (16%) of our revenue was generated in South America, twelve percent (12%) of our revenue was generated in the Middle East with the remaining eight percent (8%) of our revenue generated in the rest of the world.

Our major customers in the twelve months ended December, 2011 were Kirloskar Technologies (P) Ltd., a distributor in India that accounted for 18% of our revenues, Tzamal Jacobsohn Ltd., a distributor in Israel that accounted for 12% of our revenues , and Izasa Distribuciones Tecnicas SA, a distributor in Spain that accounted for 9% of our revenues. Our agreement with Kirloskar Technologies (P) Ltd. grants Kirloskar Technologies (P) Ltd. the right to be the exclusive distributor of MGuardTM products in India until May 2013, subject to achievement of certain order minimums. Under our agreement with Kirloskar Technologies (P) Ltd., Kirloskar Technologies (P) Ltd. was required to purchase 15,000 stents from us in 2011 and is required to purchase 20,000 stents from us in 2012, at a price per stent of $600, for total minimum order values of $9,000,000 in 2011 and $12,000,000 in 2012, respectively. Kirloskar Technologies (P) Ltd. will also be eligible to receive free stents representing 15% or 20% of the total value of stents purchased, depending upon the annual volume of the purchases of our stents. Although Kirloskar Technologies (P) Ltd. did not achieve its order minimum for 2011, we did not terminate either our agreement with Kirloskar Technologies (P) Ltd. or Kirloskar Technologies (P) Ltd.'s right to be the exclusive distributor of MGuardTM products in India. Our agreement with Tzamal Jacobsohn Ltd. grants Tzamal Jacobsohn Ltd. the right to be the exclusive distributor MGuardTM products in Israel until December 2012, subject to achievement of certain order minimums. Under our agreement with Tzamal Jacobsohn Ltd., Tzamal Jacobsohn Ltd. must achieve at least 85% of the following order minimums: 1,400 stents during the twelve months ending March 31, 2012 and 1,600 stents during the twelve months ending March 31, 2013, at a price per stent, per an oral agreement, of 400 Euros, for total minimum order values of 560,000 Euros and 640,000 Euros, respectively. Tzamal Jacobsohn Ltd. will be granted options to purchase 8,116 shares of our common stock for each $100,000 in sales upon achievement of the order minimums. Our agreement with Izasa Distribuciones Tecnicas SA grants Izasa Distribuciones Tecnicas SA the right to be the exclusive distributor of MGuardTM products in Spain until May 2012, subject to achievement of certain order minimums. Under our agreement with Izasa Distribuciones Tecnicas SA, Izasa Distribuciones Tecnicas SA was required to purchase 4,000 stents from us in 2011, at a price per stent of 700 Euros, for a total minimum order value of 2,800,000 Euros in 2011. Izasa Distribuciones Tecnicas SA did not achieve its order minimum for 2011 and was not eligible to receive free stents pursuant to its agreement; however, we did not terminate either our agreement with Izasa Distribuciones Tecnicas SA or Izasa Distribuciones Tecnicas SA's right to be the exclusive distributor of MGuardTM products in Spain. In addition, pursuant to an amendment to our agreement with Izasa Distribuciones Tecnicas SA, Izasa Distribuciones Tecnicas SA, through its subsidiaries, was required to purchase 500 MGuard Prime™ stents from us at a price per stent of 700 Euros in February 2011. Izasa Distribuciones Tecnicas SA met its purchase requirement in February 2011 and received a bonus of 100 free stents. 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). In addition, other current significant customers are in Germany, Argentina, and Brazil.

Our major customer in 2010 was Hand-Prod Sp. Z o.o, a Polish distributor, that accounted for 29% of our revenues. We have an agreement with Hand-Prod Sp. Z o.o that grants Hand-Prod Sp. Z o.o the right to be the exclusive distributor of MGuardTM products in Poland until December 2012, subject to achievement of certain order minimums. Under our agreement with Hand-Prod Sp. Z o.o, Hand-Prod Sp. Z o.o was required to purchase 1,500 stents from us in 2011 and must purchase 2,500 stents from us in 2012, at a price per stent of 400 Euro, for total minimum order values of 600,000 Euro in 2011 and 1,000,000 Euro in 2012, respectively. Hand-Prod Sp. Z o.o did not achieve its order minimum for 2011 and therefore did not receive any free stents in 2011, but will be eligible to receive 500 free stents in 2012 if it achieves the minimum order values for that year. Although Hand-Prod Sp. Z o.o

did not achieve its order minimum for 2011, we did not terminate either our agreement with Hand-Prod Sp. Z o.o or Hand-Prod Sp. Z o.o's right to be the exclusive distributor of MGuardTM products in Poland. In addition, in 2011, we granted Hand-Prod Sp. Z o.o an option to purchase 48,697 shares of our common stock as consideration for its assistance in promoting our business in Poland.

Manufacturing and Suppliers

We manufacture our stainless steel MGuardTM 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 MGuardTM 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 MGuardTM 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.

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. We will pay 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 million of sales and a rate of 10% for all sales exceeding $10 million. We will also share with Svelte Medical Systems Inc. in the cost of obtaining the CE Mark approval, with our costs not to exceed $85,000, and the U.S. Food and Drug Administration approval, with our costs not to exceed $200,000. 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.

MGuardTM 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, Germany, Austria, Czech Republic, Slovakia, France, Slovenia, Greece, Cyprus, Portugal, Spain, Poland, Hungary, Estonia, Lithuania, Ukraine, United Kingdom, Holland, Russia, Latvia, Brazil, Chile, Costa Rica, Mexico, Argentina, Colombia, India, Sri Lanka, South Africa, Pakistan and Israel. We are currently in discussions with multiple distribution companies in Europe, Asia, and Latin America.

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 for a term of approximately three years and automatically renew for an additional three years unless modified by either party.

Employees

As of February 29, 2012, we had 66 full-time employees. Our employees are not party to any collective bargaining agreements. 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 Annual Report on Form 10-K, 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. In such case, the trading price and market value of our common stock could decline and you may lose part or all of your investment in our common stock. The risks and uncertainties described below include forward-looking statements and our actual results may differ from those discussed in these forward-looking statements.

Risks Related to Our Business

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

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

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

Our ability to protect our products from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering medical devices and pharmaceutical inventions and the

scope of claims made under these patents, our ability to enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any of our pending patents may not provide us with commercially meaningful protection for our products or afford a commercial advantage against our competitors or their competitive products or processes. In addition, patents may not be issued from any pending or future patent applications owned by or licensed to us, and moreover, patents that may be issued to us in the future may not be valid or enforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing products like ours, despite our patent rights.

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the patentability of our pending patent applications. For example, patent applications in the U.S. are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the U.S. are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office to determine priority of invention in the U.S. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the U.S. The laws of some foreign jurisdictions do not protect intellectual property rights to the same degree as in the U.S., and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

We may initiate litigation to enforce our patent rights on any patents issued on pending patent applications, which may prompt adversaries in such litigation to challenge the validity, scope or enforceability of our patents. If a court decides that such patents are not valid, not enforceable or of a limited scope, we may not have the right to stop others from using our inventions. Also, even if our patents are determined by a court to be valid and enforceable, they may not be sufficiently broad to prevent others from marketing products similar to ours or designing around our patents, despite our patent rights, nor provide us with freedom to operate unimpeded by the patent rights of others.

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

We have a history of net losses and may experience future losses

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

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

We currently manufacture our MGuard™ stent at our facilities in Tel Aviv, Israel, and we have contracted with QualiMed Innovative Medizinprodukte GmbH, a German manufacturer, to assist in production. If there were a

disruption to our existing manufacturing facility, we would have no other means of manufacturing our MGuard™ stent until we were able to restore the manufacturing capability at our facility or develop alternative manufacturing facilities. If we were unable to produce sufficient quantities of our MGuard™ stent for use in our current and planned clinical trials, or if our manufacturing process yields substandard stents, our development and commercialization efforts would be delayed.

We currently have limited resources, facilities and experience to commercially manufacture our product candidates. In order to produce our MGuard™ stent in the quantities that we anticipate will be required to meet anticipated market demand, we will need to increase, or "scale up," the production process by a significant factor over the current level of production. There are technical challenges to scaling-up manufacturing capacity, and developing commercial-scale manufacturing facilities will require the investment of substantial funds and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required scale-up in a timely manner or at all. If unable to do so, we may not be able to produce our MGuard™ stent in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, if at all. If we develop and obtain regulatory approval for our MGuard™ stent and are unable to manufacture a sufficient supply of our MGuard™ stent, our revenues, business and financial prospects would be adversely affected. In addition, if the scaled-up production process is not efficient or produces stents that do not meet quality and other standards, our future gross margins may decline. Also, our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth. If we are unable to manage our growth effectively, our business could be harmed.

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

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

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

Clinical trials necessary to support a pre-market approval application to the U.S. Food and Drug Administration for our MGuard™ stent will be expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. Clinical trials supporting a pre-market approval applications for the Cypher stent developed by Johnson & Johnson and the Taxus Express2 stent developed by Boston Scientific Corporation, which were approved by the U.S. Food and Drug Administration and are currently marketed, involved patient populations of approximately 1,000 and 1,300, respectively, and a 12-month follow up period. In some trials, a greater number of patients and a longer follow up period may be required. The U.S. Food and Drug Administration may require us to submit data on a greater number of patients or for a longer follow-up period than those for pre-market approval applications for the Cypher stent and the Taxus Express2 stent. Patient enrollment in clinical trials and the ability to successfully complete patient follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of our products, or they may be persuaded to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical events unrelated to or related to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays or result in the failure of the clinical trial.

In addition, the length of time required to complete clinical trials for pharmaceutical and medical device products varies substantially according to the degree of regulation and the type, complexity, novelty and intended use of a product, and can continue for several years and cost millions of dollars. The commencement and completion of clinical trials for our products under development may be delayed by many factors, including governmental or regulatory delays and changes in regulatory requirements, policy and guidelines or our inability or the inability of any potential licensee to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials.

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

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

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

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

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

Because our products are new and long-term success measures have not been completely validated, regulatory agencies, including the U.S. Food and Drug Administration, may take a significant amount of time in evaluating product approval applications. For example, there are currently several methods of measuring restenosis and we do not know which of these metrics, or combination of these metrics, will be considered appropriate by the U.S. Food and Drug Administration for evaluating the clinical efficacy of stents. Treatments may exhibit a favorable measure using one of these metrics and an unfavorable measure using another metric. Any change in the accepted metrics may result in reconfiguration of, and delays in, our clinical trials. Additionally, we have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals, and our clinical, regulatory and quality assurance personnel are currently composed of only 9 employees. As a result, we may experience a long regulatory process 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 constitutes promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or

penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

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

Additionally, we may be required to conduct costly post-market testing and surveillance to monitor the safety or efficacy of our products, and we will be required to report adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements, such as Quality System Regulation, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

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

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

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

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

The medical device market is highly competitive. We compete with many medical service companies in the U.S. and internationally in connection with our current product and products under development. We face competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. When we commercialize our products, we expect to face intense competition from Cordis Corporation, a subsidiary of Johnson & Johnson, Boston Scientific Corporation, Guidant, Medtronic, Inc., Abbott Vascular Devices, Terumo and others. Most of our current and potential competitors, including but not limited to those listed above, have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. There can be no assurance that we will have sufficient resources to successfully commercialize our products, if and when they are approved for sale. The worldwide market for stent products is characterized by intensive development efforts and rapidly advancing technology. Our future success will depend largely upon our ability to anticipate and keep pace with those developments and advances. Current or future competitors could develop alternative technologies, products or materials that are more effective, easier to use or more economical than what we or any potential licensee develop. If our technologies or

products become obsolete or uncompetitive, our related product sales and licensing revenue would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

We may be exposed to product liability claims based on the use of any of our products, or products incorporating our licensed technology, in clinical trials. We may also be exposed to product liability claims based on the sale of any such products following the receipt of regulatory approval. Product liability claims could be asserted directly by consumers, health-care providers or others. We have obtained product liability insurance coverage; however such insurance may not provide full coverage for our future clinical trials, products to be sold, and other aspects of our

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

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

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

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

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

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

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

- foreign currency exchange rate fluctuations;
- greater difficulty in staffing and managing foreign operations;
- greater risk of uncollectible accounts;
- longer collection cycles;
- logistical and communications challenges;
- potential adverse changes in laws and regulatory practices, including export license requirements, trade barriers, tariffs and tax laws;
- changes in labor conditions;
- burdens and costs of compliance with a variety of foreign laws;

- political and economic instability;
- increases in duties and taxation;
- foreign tax laws and potential increased costs associated with overlapping tax structures;
- greater difficulty in protecting intellectual property; and
- general economic and political conditions in these foreign markets.

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

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

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

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

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

The Patient Protection and Affordable Care Act and Health Care and Educational Reconciliation Act in the U.S. were enacted into law in March 2010. Certain provisions of these acts will not be effective for a number of years and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impacts will be from the legislation. The legislation does levy a 2.3%

excise tax on all U.S. medical device sales beginning in 2013. If we commence sales of our MGuard™ stent in the U.S., this new tax may materially and adversely affect our business and results of operations. The legislation also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the provisions include a reduction in the annual rate of inflation for hospitals starting in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level in the U.S., or the effect of any future legislation or regulation. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business and results of operations.

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

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

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

We may have violated Israeli securities law.

We may have violated section 15 of the Israeli Security Law of 1968. Section 15 to the Israeli Security Law of 1968 requires the filing of a prospectus with the Israel Security Authority and the delivery thereof to purchasers in connection with an offer or sale of securities to more than 35 parties during any 12 month period. We allegedly issued securities to more than 35 investors during certain 12-month periods, ending in October 2008. Our wholly-owned subsidiary, InspireMD Ltd., a private company incorporated under the laws of the State of Israel, applied for a no-action determination from the Israel Security Authority on February 14, 2011 in connection with the foregoing. To date, the Israel Security Authority has not responded to InspireMD Ltd.'s application for no-action determination and we are unable to predict when a response will be received. The maximum penalties for violating section 15 of the Israeli Security Law of 1968 are as follows: imprisonment of 5 years; a fine of up to approximately $317,000 to be paid by management of the violating company; and a fine of up to approximately $1,590,000 to be paid by the violating company, any of which penalties could result in a material adverse effect on our operations.

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

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

- pursuing growth opportunities, including more rapid expansion;
- acquiring complementary businesses;
- making capital improvements to improve our infrastructure;
- hiring qualified management and key employees;

31

- developing new services, programming or products;
- responding to competitive pressures;
- complying with regulatory requirements such as licensing and registration; and
- maintaining compliance with applicable laws.

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

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

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

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

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

All of our assets are located outside the U.S. and we do not currently maintain a permanent place of business within the U.S. In addition, most of our directors and all of our officers are nationals and/or residents of countries other than the U.S., and all or a substantial portion of such persons' assets are located outside the U.S. As a result, it may be difficult for investors to enforce within the U.S. any judgments obtained against us or any of our non-U.S. directors or officers, including judgments predicated upon the civil liability provisions of the securities laws of the U.S. or any state thereof. Consequently, you may be effectively prevented from pursuing remedies under U.S. federal and state securities laws against us or any of our non-U.S. directors or officers.

Risks Related to Our Organization and Our Common Stock

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

On March 31, 2011, we became subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, including the requirements of Section 404 of the Sarbanes-Oxley Act. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting and to obtain a report by our independent auditors addressing these assessments. These reporting and other obligations will place significant demands on our management, administrative, operational, internal audit and accounting resources. We are

presently upgrading our systems; implementing financial and management controls, reporting systems and procedures; implementing an internal audit function; and we have hired additional accounting, internal audit and finance staff. If we are unable to accomplish these objectives in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired. Any failure to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price. Moreover, effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed.

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

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

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

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

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

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

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

We are subject to the Securities and Exchange Commission's "penny stock" rules since our shares of common stock sell below $5.00 per share. Penny stocks generally are equity securities with a per share price of less than $5.00. The penny stock rules require broker-dealers to deliver a standardized risk disclosure document prepared by the Securities

and Exchange Commission that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information must be given to the customer orally or in writing prior to completing the transaction and must be given to the customer in writing before or with the customer's confirmation.

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

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

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

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

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

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

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. Approximately 59,278,947 shares of our common stock will become saleable under Rule 144 following April 6, 2012. As these shares and as additional shares of our common stock become available for resale in the public market, the supply of our common stock will increase, which could decrease the price of our common stock.

In addition, if our stockholders sell substantial amounts of our common stock in the public market, upon the expiration of any statutory holding period under Rule 144, upon the expiration of lock-up periods applicable to outstanding shares, or upon the exercise of outstanding options or warrants, it could create a circumstance commonly referred to as an "overhang" and in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, could also make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

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

We do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investment in our common stock will only occur if our stock price appreciates.

Risks Related to Our Intended Reverse Stock Split

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

The Nasdaq Capital Market has numerous initial listing requirements applicable to the listing of our common stock and its continued listing thereafter. While we believe we currently meet these standards, other than the minimum bid price requirement of more than $4.00 per share, we cannot assure you that our common stock will be accepted for listing on the Nasdaq Capital Market following the reverse stock split or that we will maintain compliance with all of the requirements for our common stock to remain listed. Moreover, there can be no assurance that the market price of our common stock after the reverse stock split will adjust to reflect the decrease in common stock outstanding or that the market price following a reverse stock split will either exceed or remain in excess of the current market price.

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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:

- adverse economic conditions and/or intense competition;

- loss of a key customer or supplier;
- entry of new competitors and products;
- adverse federal, state and local government regulation, in the U.S., Europe or Israel;

- failure to adequately protect our intellectual property;
- inadequate capital;
- technological obsolescence of our products;
- technical problems with our research and products;
- price increases for supplies and components;
- inability to carry out research, development and commercialization plans;
- loss or retirement of key executives and research scientists and other specific risks; and
- the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives.

You should review carefully the risks and uncertainties described under the heading "Item 1A. Risk Factors" in this Annual Report on Form 10-K 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 Annual Report on Form 10-K 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 Tel Aviv, Israel where we currently have an 825 square meter facility that employs 34 of our manufacturing personnel and currently has a capacity to manufacture and assemble 3,000 stents per month. 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, except for the matters described below.

On November 2, 2010, Eric Ben Mayor, a former senior employee of InspireMD Ltd., filed suit in Regional Labor Court in Tel Aviv, claiming illegal termination of employment and various amounts in connection with his termination, including allegations that he is owed salary, payments to pension fund, vacation pay, sick days, severance pay, commission for revenues and other types of funds. In total, Mr. Mayor is seeking $428,000, additional compensation for holding back wages, and options to purchase 2,029,025 shares of our common stock at an exercise price of $0.001 per share. We have filed a notice in Regional Labor Court indicating that the parties have rejected a court proposal for mediation and a second preliminary hearing was held on November 3, 2011. The Company got an extension from court to file motions regarding the disclosure procedure between the parties until March 31, 2012. No further hearing date has been set.

Other than as set forth above, 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 Disclosure.

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 OTC Bulletin Board since April 11, 2011 under the symbol NSPR.OB. Prior to that date, there was no active market for our common stock. The following table sets forth the high and low bid prices for our common stock for the periods indicated, as reported by the OTC Bulletin Board. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

Fiscal Year 2011	High	Low
Second Quarter	$2.89	$1.75
Third Quarter	$2.74	$1.80
Fourth Quarter	$2.59	$1.60

The last reported sales price of our common stock on the OTC Bulletin Board on March 12, 2012, was $1.55 per share. As of March 12, 2012, there were approximately 233 holders of record of our common stock.

Dividend Policy

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

Item 6. Selected Financial Data.

The following selected consolidated financial data should be read in conjunction with "Part II—Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Part II—Financial Statements and Supplementary Data." The balance sheet data at December 31, 2011, 2010 and 2009 and the statement of operations data for each of the three years ended December 31, 2011, 2010 and 2009 have been derived from the audited Consolidated Financial Statements for such years, included in and "Part II—Financial Statements and Supplementary Data." The balance sheet data at December 31, 2008 and 2007, and the statement of operations data for each of the two years ended December 31, 2008 and 2007 have been derived from our books and records.

	Statement of Operations Data				
	2011	2010	2009	2008	2007
Revenues	6,004	4,949	3,411	-	-
Cost of Revenues	3,011	2,696	2,291	404	328
Gross Profit (Loss)	2,993	2,253	1,120	(404)	(328)
Gross Margin	50%	46%	33%	0	0
Total Operating Expenses	16,722	5,472	3,837	5,627	5,903
Net Loss	(14,665)	(3,420)	(2,724)	(6,495)	(6,138)
Basic and Diluted loss per common share	(0.24)	(0.07)	(0.06)	(0.14)	(0.14)
Basic and Diluted common shares outstanding	61,439,700	49,234,528	47,658,853	46,364,731	42,647,151

Balance Sheet Data					
	2011	2010	2009	2008	2007
Cash, Cash equivalents and short term deposits	5,094	636	376	1,571	2,717
Restricted Cash	91	250	302	30	34
Working Capital	6,389	(53)	(1,289)	589	2,625
Total Assets	10,465	4,355	4,509	4,448	3,923
Shareholder's Equity	6,754	(914)	(1,339)	134	2,949

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying condensed consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

Overview

We are a medical device company focusing on the development and commercialization of our proprietary stent platform technology, MGuard™. MGuard™ provides embolic protection in stenting procedures by placing a micron mesh sleeve over a stent. Our initial products are marketed for use mainly in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

On March 31, 2011, we completed a series of share exchange transactions pursuant to which we acquired all of the capital stock of InspireMD Ltd., a company formed under the laws of the State of Israel, in exchange for an aggregate of 50,666,663 shares of our common stock. As a result of these share exchange transactions, InspireMD Ltd. became our wholly-owned subsidiary, we discontinued our former business and succeeded to the business of InspireMD Ltd. as our sole line of business.

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

Recent Events

On October 31, 2011, our stockholders authorized our board of directors to amend our amended and restated certificate of incorporation to effect a reverse stock split of our common stock at a ratio of one-for-two to one-for-four, at any time prior to our 2012 annual stockholders' meeting, the exact ratio of the reverse stock split to be determined by the board. As of the date of this prospectus, we have not effected the reverse stock split and, as such, the information with respect to our common stock in this prospectus and the accompanying financial statements and related notes does not give effect to any reverse stock split.

On October 4, 2011, InspireMD Ltd., our wholly-owned subsidiary, entered into a clinical trial services agreement with Harvard Clinical Research Institute, Inc., pursuant to which Harvard Clinical Research Institute, Inc. will conduct a study entitled "MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction" on our behalf. We will pay Harvard Clinical Research Institute, Inc. an estimated fee of approximately $10 million for conducting the study, subject to adjustment dependent upon changes in the scope and nature of the study, as well as other costs to be determined by the parties.

Critical Accounting Policies

Use of estimates

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

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to revenue recognition including provision for returns, legal contingencies and estimation of the fair value of share-based compensation and convertible debt.

Functional currency

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

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

Fair value measurement

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

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

Concentration of credit risk and allowance for doubtful accounts

Financial instruments that may potentially subject us to a concentration of credit risk consist of cash, cash equivalents and restricted cash, which are deposited in major financial institutions in the U.S., Israel and Germany, and trade accounts receivable. Our trade accounts receivable are derived from revenues earned from customers from various countries. We perform ongoing credit evaluations of our customers' financial condition and, generally, require no collateral from our customers. We also have a credit insurance policy for some of our customers. We maintain an allowance for doubtful accounts receivable based upon the expected ability to collect the accounts receivable. We review our allowance for doubtful accounts quarterly by assessing individual accounts receivable and all other balances based on historical collection experience and an economic risk assessment. If we determine that a specific customer is unable to meet its financial obligations to us, we provide an allowance for credit losses to reduce the receivable to the amount our management reasonably believes will be collected. To mitigate risks, we deposit cash and cash equivalents with high credit quality financial institutions. Provisions for doubtful debts are netted against "Accounts receivable-trade."

Inventory

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

subject to impairment as they approach their expiration dates. We regularly evaluate the carrying value of our inventories and when, in our opinion, factors indicate that impairment has occurred, we establish a reserve against the inventories' carrying value. Our determination that a valuation reserve might be required, in addition to the quantification of such reserve, requires us to utilize significant judgment. Although we make every effort to ensure the accuracy of forecasts of future product demand, any significant unanticipated decreases in demand could have a material impact on the carrying value of our inventories and reported operating results. To date, inventory adjustments have not been material. With respect to inventory on consignment, see "Revenue recognition" below.

Revenue recognition

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

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

As of December 31, 2011, there is no deferred revenue in the balance sheet since, as of this date, the rate of returns can be reliably estimated.

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

We recognize revenue net of value added tax.

Research and development costs

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

Share-based compensation

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

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

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

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

Uncertain tax and value added tax positions

We follow a two-step approach to recognizing and measuring uncertain tax and value added tax positions. The first step is to evaluate the tax and value added tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit. The second step is to measure the tax and value added tax benefit as the largest amount that is more than 50% and 75%, respectively, likely of being realized upon ultimate settlement. Such liabilities are classified as long-term, unless the liability is expected to be resolved within twelve months from the balance sheet date. Our policy is to include interest and penalties related to unrecognized tax benefits within financial expenses.

Results of Operations

Twelve months ended December 31, 2011 compared to twelve months ended December 31, 2010

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

For the twelve months ended December 31, 2011, total gross revenue increased by approximately $2.5 million, or 77.6%, to approximately $5.7 million from approximately $3.2 million during the same period in 2010. This increase in total gross revenue was predominantly volume based, with increased volume accounting for approximately $2.3 million, or approximately 72.5%, and price increases accounting for the remaining approximately $0.2 million, or approximately 5.1%. In general, we focused on opening new markets, such as India, and also increasing sales in existing markets by presenting clinical data at conferences and individual presentations to doctors about the merits of MGuardTM. With respect to individual markets, this increase in gross revenue is mainly attributable to the first time shipment of approximately $1.2 million to our distributor in India during the twelve months ended December 31, 2011, an increase of approximately $0.4 million of gross revenue from our new distributor in Russia, an increase of approximately $0.4 million of gross revenue from our distributor in Israel, an increase of approximately $0.3 million of gross revenue from our distributor in Brazil, an increase of approximately $0.2 million of gross revenue from our distributor in Spain, an increase of approximately $0.2 million of gross revenue from our distributor in Argentina, an increase of approximately $0.1 million of gross revenue from our distributor in South Africa, an increase of approximately $0.1 million of gross revenue from our new distributor for sales in Ukraine, an increase of approximately $0.1 million of gross revenue from our new distributor in the Netherlands and an increase of approximately $0.1 million of gross revenue from our distributor in Mexico. This increase was partially offset by a decrease of approximately $0.2 million in gross revenue from our distributor in Germany, a decrease of approximately $0.2 million in gross revenue from our distributor in Pakistan, a decrease of approximately $0.2 million from our distributor in Poland, a decrease of approximately $0.1 million in gross revenue from our distributor in Italy, and a decrease of approximately $0.1 million in gross revenue to our distributor in France, all due to lower sales volume to these suppliers. We also shipped and recognized gross revenue for approximately $0.2 million more from our remaining distributors during the twelve months ended December 31, 2011, as compared to the same period in 2010.

For the twelve months ended December 31, 2011, net deferred revenue recognized decreased by approximately $1.4 million, or 83.8%, to approximately $0.3 million from approximately $1.7 million during the same period in 2010. The key driver of this decrease was a decrease in the volume of revenue deferred to 2011 compared to the volume of revenue deferred to 2010, accounting for approximately $1.3 million, or approximately 74.5%, with the remaining approximately $0.1 million, or 9.3%, being driven by price decreases in the revenue deferred to 2011 compared to the

revenue deferred to 2010. Revenue recognition out of deferred income had less of an impact in 2011 as compared to 2010 due to the fact that we deferred mainly shipments in 2008 and 2009 that were recognized in 2010. In 2010, only a small set of customers had a large portion of their revenues deferred until 2011.

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

For the twelve months ended December 31, 2010, net deferred revenue recognized of approximately $1.7 million was comprised mainly of shipments from 2008 and 2009 to our distributor in Poland of approximately $1.3 million, to our distributor in Brazil of approximately $0.4 million. For the twelve months ended December 31, 2010, our distributor in Poland, subject to our sole discretion, had the right to return our products. Because we were unable to develop estimates for the level of returns, the $1.3 million worth of shipments made to the distributor in Poland that we recorded as deferred revenues was only recognized during the twelve months ended December 31, 2010 as revenues. As noted above, our distributor in Brazil has a contractual right to return all purchases for up to six months from the delivery date. As also noted above, due to our inability to accurately estimate the rate of return by this distributor, all sales made to it were also deferred until the six month return period elapsed. The deferred revenue of approximately $0.4 million recognized during the twelve months period ended December 31, 2010 accounted for purchases made in December 2009 that were not returned and were not yet recognized as revenues.

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

Research and Development Expense. For the twelve months ended December 31, 2011, research and development expense increased 84.9%, or approximately $1.2 million, to approximately $2.5 million from approximately $1.3 million during the same period in 2010. The increase in cost resulted primarily from higher clinical trial expenses of approximately $1.2 million, attributable mainly to the U.S. Food and Drug Administration clinical trial (approximately $0.9 million) and the MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial)

(approximately $0.3 million), and an increase of approximately $0.3 million in salaries, offset by approximately $0.2 million reduction in miscellaneous expenses and approximately $0.1 million reduction in share based compensation. Research and development expense as a percentage of revenue increased to 41.2% in 2011 from 27.0% in 2010.

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

General and Administrative Expense. For the twelve months ended December 31, 2011, general and administrative expense increased 323.6%, or approximately $9.4 million, to approximately $12.3 million from $2.9 million during the same period in 2010. The increase resulted primarily from an increase in share based compensation of $7.5 million (which predominately pertains to directors' compensation), an increase of approximately $0.5 million in salary expenses (due to an increase in employee infrastructure to accommodate and comply with Securities and Exchange Commission standards and reporting), an increase in investor related activities of approximately $0.5 million (due to us having been a publicly reporting company during the twelve months ended December 31, 2011, but not during the same period in 2010), an increase of approximately $0.5 million in litigation expenses (primarily due to a provision for our potential loss related to a threatened lawsuit from a finder claiming a future success fee and commissions for assistance in finding our distributor in Brazil), approximately $0.3 million in legal fees (also related primarily to compliance with Securities and Exchange Commission standards), and approximately $0.2 million in audit fees to accommodate and comply with Securities and Exchange Commission standards and reporting. This increase was partially offset by a decrease of approximately $0.1 million in miscellaneous expenses. General and administrative expense as a percentage of revenue increased to 204.4% in 2011 from 58.6% in 2010.

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

Tax Expenses. Tax expense remained relatively flat at $2,000 for the twelve months ended December 31, 2011, as compared to $47,000 during the same period in 2010. Our expenses for income taxes reflect primarily the tax liability due to potential tax exposure.

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

Twelve months ended December 31, 2010 compared to twelve months ended December 31, 2009

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

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

For the twelve months ended December 31, 2009, net deferred revenue of approximately $0.1 million was comprised mainly of shipments made in 2009 but deferred and recognized in 2010 to our distributor in Brazil in the amount of approximately $0.4 million, to our distributor in Poland in the amount of $0.2 million and to our distributor in Israel in the amount of $0.2 million, offset by shipments made in 2008 but deferred and recognized in revenue in 2009 from our distributor in Italy in the amount of $0.5 million, and from our distributor in Cyprus in the amount of $0.2 million. See "Twelve months ended December 31, 2011 compared to twelve months ended December 31, 2010" above for the reasons why such revenue was deferred and/or recognized for each of the distributors listed above.

43

Total gross revenue for the twelve months ended December 31, 2010 remained relatively flat in comparison to the twelve months ended December 31, 2009, increasing by approximately $46,000. This increase was predominantly volume based, with increased volume accounting for approximately $263,000, offset by price decreases in the amount of $217,000. The increase in volume was evenly distributed among our distributors. The decrease in prices were due to our penetration of newly opened markets, namely Brazil, Slovakia and Cypress, in 2010, which required reduced prices as compared to 2009.

Gross Profit. For the twelve months ended December 31, 2010, gross profit (revenue less cost of revenues) increased 101.2%, or approximately $1.1 million, to approximately $2.2 million from approximately $1.1 million during the same period in 2010. Our gross margin percentage for the twelve months ended December 31, 2010 increased to 45.5% of revenues, compared to 32.8% during the same period in 2009. In addition to an increase in sales, we were able to improve our gross profit because of reduced production cost per stent driven by reduction in price per unit from our subcontractor and economies of scale. For the twelve months ended December 31, 2010, our average selling price per stent recognized in revenue was $606, and we recognized the sale of 8,171 stents, compared to an average price of $577 per stent and 5,910 stents recognized in revenue for the same period in 2009. Our cost of goods sold per stent decreased from an average of $380 per stent recognized in revenue for the twelve months ended December 31, 2009 to an average of $330 per stent for the same period in 2010. The higher price per stent for the twelve months ended December 31, 2010 was affected by the price of stents sold in 2008 and 2009 to one of our Europeans distributors in Euros when the Euro was much stronger than the U.S. dollar, at an average price of $997 when translated to U.S. dollars.

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

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

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

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

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

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

Liquidity and Capital Resources

Twelve months ended December 31, 2011 compared to twelve months ended December 31, 2010

General. At December 31, 2011, we had cash and cash equivalents of approximately $5.1 million, as compared to $0.6 million at December 31, 2010. The increase is attributable primarily to the private placement conducted in conjunction with the share exchange transactions on March 31, 2011 and other private equity issuances prior to and after the share exchange transactions. We have historically met our cash needs through a combination of issuance of new shares, borrowing activities and sales. Our cash requirements are generally for product development, clinical trials, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

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

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

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

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

Credit Facilities. As of December 31, 2011, we had a long term loan in the amount of approximately $0.1 million bearing interest at the three month U.S. Dollar LIBOR rate plus 4% per annum. The loan is payable in eight quarterly installments during a period of three years that began in April 2010 and ends in January 2012. According to the loan agreement, in case of an “exit transaction,” we will be required to pay to the bank an additional $0.25 million if the sum received in a “liquidity event” or the value of the company in an “IPO” is higher than $100 million.

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

45

Sales of Stock. For the twelve months ended December 31, 2011, we issued an aggregate of 12,315,145 shares of common stock and warrants to purchase 6,709,073 shares of common stock for gross proceeds of approximately $13.7 million and corresponding net proceeds of approximately $12.1 million.

Twelve months ended December 31, 2010 compared to twelve months ended December 31, 2009

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

Cash used in our operating activities was approximately $2.7 million for the twelve months ended December 31, 2010, and approximately $1.5 million for the same period in 2009. The principal reasons for the increase in cash used in operations in 2010 included a net loss of approximately $3.4 million, a decrease of approximately $1.6 million in deferred revenues offset by approximately $1.6 million of non cash share based compensation expense, an increase of approximately $0.4 million in other working capital and $0.3 million of other non cash adjustments.

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

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

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

We believe that funds available at December 31, 2011, together with our anticipated revenues, will fund our operations until at least May or June 2013. Thereafter, or before then to expand the breadth of our present business, we will need to raise further capital, through the sale of additional equity securities or otherwise. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our MGuardTM products, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product offerings. However, we may be unable to raise sufficient additional capital when we need it or raise capital on favorable terms. The terms of any securities issued by us in future financings may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly, possibly postpone or halt our U.S. Food and Drug Administration clinical trial or obtain funds by entering into financing agreements on unattractive terms.

Off Balance Sheet Arrangements

We have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial

condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Recent Accounting Pronouncements

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

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

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

Factors That May Affect Future Operations

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

Tabular Disclosure of Contractual Obligations

The following table summarizes our outstanding contractual obligations as of December 31, 2011:

	Payments due by period (amounts in thousands)				
Contractual Obligations	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Long-term loan (1)	$94	$94	$0	$0	$0
Operating lease obligations (2)	858	304	554	0	0
Accounts Payable	1,670	1,670	0	0	0
Total	$2,622	$2,068	$554	$0	$0

47

(1) Our long-term loan obligations as of December 31, 2011 consisted of a loan with Mizrahi Tefahot Bank. According to our agreement with Mizrahi Tefahot Bank, we received a loan amounting to $750,000, bearing annual interest (quarterly paid) equal to LIBOR + 4%. The loan is payable in eight quarterly installments during a period of 3 years beginning April 2010. As of December 31, 2011, the remaining balance outstanding of this loan was $94,000.

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

Item 7A.Quantitative and Qualitative Disclosures About Market Risk.

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

Interest Rate Exposure

Our exposure to market risk relates primarily to short-term investments, including funds classified as cash equivalents. As of December 31, 2011, all excess funds were invested in time deposits and other highly liquid investments, therefore our interest rate exposure is not considered to be material.

Foreign Currency Exchange Rate Exposure

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

Item 8. Financial Statements and Supplementary Data.

The following financial statements are included as part of this Report (See Item 15):

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

We conducted an evaluation of the effectiveness of our "disclosure controls and procedures" ("Disclosure Controls"), as defined by Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 2011, the end of the period covered by this Annual Report on Form 10-K. The Disclosure Controls evaluation was done under the supervision and with the participation of management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon this evaluation, our CEO and CFO have concluded that our Disclosure Controls were effective at the reasonable assurance level as of December 31, 2011.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements for external reporting purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate over time.

Management, including our CEO and our CFO, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2011. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework. Based on its assessment and those criteria, management has concluded that the Company maintained effective internal control over financial reporting as of December 31, 2011.

Kesselman & Kesselman, Certified Public Accountants, the independent registered public accounting firm that audited the Company's consolidated financial statements included in this Annual Report on Form 10-K, has issued an attestation report on the Company's internal control over financial reporting, which is included herein.

Changes in Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table sets forth information regarding our executive officers and the members of our board of directors.

Name	Age	Position
Ofir Paz	46	Chief Executive Officer and Director
Asher Holzer, Ph.D.	62	President and Director
Craig Shore	50	Chief Financial Officer, Secretary and Treasurer
Eli Bar	47	Senior Vice President of Research and Development and Chief Technical Officer of InspireMD Ltd.
Sara Paz	48	Vice President of Sales of InspireMD Ltd.
Sol J. Barer, Ph.D.	64	Chairman of the Board of Directors
James Barry, Ph.D.	52	Director

Paul Stuka	56	Director
Eyal Weinstein	57	Director

Our directors hold office until the earlier of their death, resignation or removal by stockholders or until their successors have been qualified. Our directors are divided into three classes. Sol J. Barer and Paul Stuka are our class 1 directors, with their terms of office to expire at our 2012 annual meeting of stockholders. Asher Holzer and Eyal Weinstein are our class 2 directors, with their terms of office to expire at our 2013 annual meeting of stockholders. Ofir Paz and James Barry are our class 3 directors, with their terms of office to expire at our 2014 annual meeting of stockholders. At each annual meeting of stockholders, commencing with the 2012 annual meeting, directors elected to succeed those directors whose terms expire shall be elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election, with each director to hold office until his or her successor shall have been duly elected and qualified.

Our officers are elected annually by, and serve at the pleasure of, our board of directors.

Executive Officers and Directors

Ofir Paz has served as our chief executive officer and a director since March 31, 2011. In addition, Mr. Paz has served as the chief executive officer and a director of InspireMD Ltd. since May 2005. From April 2000 through July 2002, Mr. Paz headed the Microsoft TV Platform Group in Israel. In this capacity, Mr. Paz managed the overall activities of Microsoft TV Access Channel Server, a server-based solution for delivering interactive services and Microsoft Windows-based content to digital cable set-top boxes. Mr. Paz joined Microsoft in April 2000 when it acquired Peach Networks, which he founded and served as its chief executive officer. Mr. Paz was responsible for designing Peach Networks' original system architecture, taking it from product design to a viable product, and then managing and leading the company up to and after its acquisition, which was valued at approximately $100 million at the time of such acquisition. Mr. Paz currently serves on the board of directors of A. S. Paz Investment and Management Ltd., S.P. Market Windows Israel Ltd. and Peach Networks Ltd. Mr. Paz received a B.Sc. in Electrical Engineering, graduating cum laude, and a M.Sc. from Tel Aviv University. Mr. Paz's qualifications to serve on the board include his prior experience in successfully establishing and leading technology companies in Israel. In addition, as chief executive officer, Mr. Paz's position on the board ensures a unity of vision between the broader goals our company and our day-to-day operations.

Asher Holzer, PhD, has served as our president since March 31, 2011 and previously also served as our chairman from March 31, 2011 until November 16, 2011. In addition, Dr. Holzer has served as the president and chairman of the board of InspireMD Ltd. since April 2007. Previously, Dr. Holzer founded Adar Medical Ltd., an investment firm specializing in medical device startups, and served as its chief executive officer from 2002 through 2004. Dr. Holzer currently serves on the board of directors of Adar Medical Ltd., O.S.H.-IL The Israeli Society of Occupational Safety and Health Ltd., Ultra-Cure Ltd., GR-Ed Investment and Enterprise Ltd., Vasculogix Ltd., Theracoat Ltd., Cuber Stent Ltd., 2to3D Ltd., and S.P. Market Windows Cyprus. Dr. Holzer earned his PhD in Applied Physics from the Hebrew University. Dr. Holzer is also an inventor and holder of numerous patents. Dr. Holzer brings to the board his more than 25 years of experience in advanced medical devices, as well as expertise covering a wide range of activities, including product development, clinical studies, regulatory affairs, market introduction and the financial aspects of the stent business.

Craig Shore has served as our chief financial officer, secretary and treasurer since March 31, 2011. In addition, since November 10, 2010, Mr. Shore has served as InspireMD Ltd.'s vice president of business development. From February 2008 through June 2009, Mr. Shore served as chief financial officer of World Group Capital Ltd. and Nepco Star Ltd., both publicly traded companies on the Tel Aviv Stock Exchange, based in Tel Aviv, Israel. From March 2006 until February 2008, Mr. Shore served as the chief financial officer of Cellnets Solutions Ltd., a provider of advanced cellular public telephony solutions for low to middle income populations of developing countries based in Azur, Israel. Mr. Shore has over 25 years of experience in financial management in the U.S., Europe and Israel. His experience includes raising capital both in the private and public markets. Mr. Shore graduated with honors and received a B.Sc. in Finance from Pennsylvania State University and an M.B.A. from George Washington University.

Eli Bar has served as InspireMD Ltd.'s senior vice president of research and development and chief technical officer since February 2011. Prior to that, he served as InspireMD Ltd.'s vice president of research and development since October 2006 and engineering manager since June 2005. Mr. Bar has over 15 years experience in medical device product development. Mr. Bar has vast experience building a complete research and development structure, managing teams from the idea stage to an advanced marketable product. He has been involved with many medical device projects over the years and has developed a synthetic vascular graft for femoral and coronary artery replacement, a covered stent and a fully implantable Ventricular Assist Device. Mr. Bar has more than nine filed device and method patents and he has initiated two medical device projects. Mr. Bar is also a director of Blue Surgical Ltd., a medical

device company based in Israel. Mr. Bar graduated from New Haven University in Connecticut with a B.Sc. in Mechanical Engineering.

Sara Paz has served as InspireMD Ltd.'s vice president of sales since September 2010 and was previously, commencing in May 2008, a sales and marketing consultant to InspireMD Ltd. Before joining InspireMD Ltd. in 2008, Ms. Paz had owned and operated an alternative medicine clinic in Israel since 1995.

Sol J. Barer, Ph.D., has served as a director since July 11, 2011 and has served as our chairman since November 16, 2011. Dr. Barer has over 30 years of experience with publicly traded biotechnology companies. In 1980, when Dr. Barer was with Celanese Research Company, he formed the biotechnology group that was subsequently spun out to form Celgene Corporation. Dr. Barer spent 18 years leading Celgene Corporation as president, chief operating officer and chief executive officer, culminating with his tenure as Celgene Corporation's executive chairman and chairman beginning in May 2006 until his retirement in June 2011. Dr. Barer is also a director of Amicus Therapeutics, Inc. and Aegerion Pharmaceuticals, Inc. and serves as a senior advisor to a number of other biotechnology companies. Dr. Barer received a Ph.D. in organic chemistry from Rutgers University. Dr. Barer brings to the board significant scientific and executive leadership experience in the U.S. biotechnology industry and prior service on the board of directors of other publicly-held biopharmaceutical companies, as well as a unique perspective on the best methods of growth for a biotechnology company.

James Barry, Ph.D. has served as a director since January 30, 2012. Dr. Barry has served as executive vice president and chief operating officer at Arsenal Medical Inc., a medical device company focused on local therapy, since September 2011. Dr. Barry also heads his own consulting firm, Convergent Biomedical Group LLC, advising medtech companies on product development, strategy, regulatory challenges and fund raising. Until June 2010, he was senior vice president, corporate technology development at Boston Scientific Corporation, where he was in charge of the corporate research and development and pre-clinical sciences functions. Dr. Barry joined Boston Scientific in 1992 and oversaw its efforts in the identification and development of drug, device and biological systems for applications with implantable and catheter-based delivery systems. He currently serves on a number of advisory boards including the College of Biomedical Engineering at Yale University, the College of Sciences at University of Massachusetts-Lowell, and the Massachusetts Life Science Center. Dr. Barry received his Ph.D. in Biochemistry from the University of Massachusetts-Lowell and holds a B.A. degree in Chemistry from Saint Anselm College. Dr. Barry brings to the board over 20 years of experience in leadership roles in the medical device industry and significant medical technology experience, in particular with respect to interventional cardiology products.

Paul Stuka has served as a director since August 8, 2011. Mr. Stuka has served as the managing member of Osiris Partners, LLC since 2000. Prior to forming Osiris Partners, LLC, Mr. Stuka, with 30 years experience in the investment industry, was a managing director of Longwood Partners, managing small cap institutional accounts. In 1995, Mr. Stuka joined State Street Research and Management as manager of its Market Neutral and Mid Cap Growth Funds. From 1986 to 1994, Mr. Stuka served as the general partner of Stuka Associates, where he managed a U.S.-based investment partnership. Mr. Stuka began his career in 1980 as an analyst at Fidelity Management and Research. As an analyst, Mr. Stuka followed a wide array of industries including healthcare, energy, transportation, and lodging and gaming. Early in his career he became the assistant portfolio manager for three Fidelity Funds, including the Select Healthcare Fund which was recognized as the top performing fund in the U.S. for the five-year period ending December 31, 1985. Mr. Stuka's qualifications to serve on the board include his significant strategic and business insight from his years of experience investing in the healthcare industry.

Eyal Weinstein has served as a director since August 8, 2011. Mr. Weinstein is the chief executive officer of LEOREX Ltd., a company developing and marketing Dermo Cosmetic products. From 2001 to 2007, Mr. Weinstein worked as manager-partner of C.I.G., an economic and accounting consultancy, consulting for leading Israeli banks, including Leumi Bank, Hapoalim Bank, Discount Bank and Bank Hamizrachi. From 2000 to 2001, he was manager-partner of Exseed, a venture capital fund that invested in early-stage companies. Beginning in 1996, Mr. Weinstein was a partner and founder in the establishment of three high-tech companies that were ultimately sold, two to Microsoft Corporation. Mr. Weinstein brings to the board his considerable management and business experience as

an executive of several companies and investment funds in Israel.

Family Relationships

Ofir Paz and Sara Paz are husband and wife.

Agreements with Executive Officers

Ofir Paz

On April 1, 2005, InspireMD Ltd. entered into an employment agreement with Ofir Paz to serve as InspireMD Ltd.'s chief executive officer. Such employment agreement was subsequently amended on October 1, 2008 and March 28, 2011. Pursuant to this employment agreement, as amended, Mr. Paz was entitled to a monthly gross salary of $15,367. Mr. Paz was also entitled to certain social and fringe benefits as set forth in the employment agreement, which totaled 25% of his gross salary, as well as a company car. Mr. Paz was also entitled to a minimum bonus equivalent to three monthly gross salary payments based on achievement of objectives and board of directors approval. Mr. Paz was eligible to receive stock options pursuant to this agreement following its six month anniversary, subject to board approval. If Mr. Paz's employment was terminated with or without cause, he was entitled to at least six months' prior notice and would have been paid his salary and all social and fringe benefits in full during such notice period.

On April 1, 2011, in order to obtain more favorable tax treatment in Israel, the employment agreement with Mr. Paz was terminated and InspireMD Ltd. entered into a consultancy agreement with A.S. Paz Management and Investment Ltd., an entity wholly-owned by Mr. Paz, through which Mr. Paz was retained to serve as InspireMD Ltd.'s chief executive officer. Pursuant to this consultancy agreement, Mr. Paz was entitled to a monthly consultancy fee of $21,563. Mr. Paz was also entitled to a minimum bonus equivalent to three monthly gross salary payments based on achievement of objectives and board of directors approval. If Mr. Paz's employment was terminated without cause, he was entitled to at least six months' prior notice and would have been paid his consultancy fee during such notice period.

At the request of the compensation committee, Mr. Paz agreed, effective as of December 1, 2011, to terminate his consultancy agreement, be compensated as an employee and enter into a new employment agreement on substantially the same terms as the consultancy agreement. Since December 1, 2011, Mr. Paz has been an employees of ours and has received the same level of compensation (i.e., base salary and benefits) as under his consultancy agreement. We are in the process of finalizing his employment agreement, but we expect that its terms will be substantially the same as those of the consultancy agreement.

For a description of certain severance and pension payments to which Mr. Paz was and will be entitled under his agreements, see "Item 11. Executive Compensation—Potential Payments Upon Termination or Change of Control."

Asher Holzer

On April 1, 2005, InspireMD Ltd. entered into an employment agreement with Dr. Asher Holzer to serve as InspireMD Ltd.'s president. Such employment agreement was subsequently amended on March 28, 2011. Pursuant to this employment agreement, as amended, Dr. Holzer was entitled to a monthly gross salary of $15,367. Dr. Holzer was also entitled to certain social and fringe benefits as set forth in the employment agreement, which totaled 25% of his gross salary, as well as a company car. Dr. Holzer was also entitled to a minimum bonus equivalent to three monthly gross salary payments based on achievement of objectives and board of directors approval. Dr. Holzer was eligible to receive stock options pursuant to this agreement following its six month anniversary, subject to board approval. If Dr. Holzer's employment was terminated with or without cause, he was entitled to at least six months' prior notice and would have been paid his salary and all social and fringe benefits in full during such notice period.

On April 29, 2011, effective April 1, 2011, in order to obtain more favorable tax treatment in Israel, the employment agreement with Dr. Holzer was terminated and InspireMD Ltd. entered into a consultancy agreement with The Israeli Society Ltd., an entity wholly-owned by Dr. Holzer, through which Dr. Holzer was retained to serve as InspireMD Ltd.'s president. Pursuant to this consultancy agreement, Dr. Holzer was entitled to a monthly consultancy fee of

$21,563. Dr. Holzer was also entitled to a minimum bonus equivalent to three monthly gross salary payments based on achievement of objectives and board of directors approval. If Dr. Holzer's employment was terminated without cause, he was entitled to at least six months' prior notice and would have been paid his consultancy fee during such notice period.

At the request of the compensation committee, Dr. Holzer agreed, effective as of December 1, 2011, to terminate his consultancy agreement, be compensated as an employee and enter into a new employment agreement on substantially the same terms as the consultancy agreement. Since December 1, 2011, Dr. Holzer has been an employees of ours and has received the same level of compensation (i.e., base salary and benefits) as under his consultancy agreement. We are in the process of finalizing his employment agreement, but we expect that its terms will be substantially the same as those of the consultancy agreement.

For a description of certain severance and pension payments to which Dr. Holzer was and will be entitled under his agreements, see "Item 11. Executive Compensation—Potential Payments Upon Termination or Change of Control."

Craig Shore

On November 28, 2010, InspireMD Ltd. entered into an employment agreement with Craig Shore to serve as InspireMD Ltd.'s vice president of business development. Pursuant to the employment agreement, Mr. Shore was entitled to a monthly gross salary of $8,750, which amount increased to $10,200 upon consummation of our share exchange transactions on March 31, 2011 and which further increased to $10,620 as of July 1, 2011. Mr. Shore is also entitled to certain social and fringe benefits as set forth in the employment agreement. Mr. Shore is also entitled to, and received, a grant of options to purchase 45,000 restricted ordinary shares of InspireMD Ltd. which were converted into options to purchase 365,223 shares of our common stock following the consummation of our share exchange transactions on March 31, 2011; such options shall fully vest if Mr. Shore's employment is terminated in connection with a change of control. If Mr. Shore's employment is terminated without cause, Mr. Shore shall be entitled to at least 30 days' prior notice and shall be paid his salary in full and all social and fringe benefits during such notice period. If a major change of control of InspireMD Ltd. occurs, Mr. Shore will be entitled to at least 180 days' prior written notice and shall be paid his salary in full and all social and fringe benefits during such notice period. If Mr. Shore is terminated for cause, he is not entitled to any notice.

For a description of certain severance and pension payments to which Mr. Shore is entitled under his employment agreement, see "Item 11. Executive Compensation—Potential Payments Upon Termination or Change of Control."

Eli Bar

On June 26, 2005, InspireMD Ltd. entered into an employment agreement with Eli Bar to serve as InspireMD Ltd.'s engineering manager. Pursuant to this employment agreement, Mr. Bar is entitled to a monthly gross salary of $8,750, which amount increased to $10,620 as of July 1, 2011. Mr. Bar is also entitled to certain social and fringe benefits as set forth in the employment agreement including a company car. If Mr. Bar's employment is terminated without cause, he is entitled to at least 60 days' prior notice and shall be paid his salary in full and all social and fringe benefits during such notice period.

For a description of certain severance and pension payments to which Mr. Bar is entitled under his employment agreement, see "Item 11. Executive Compensation—Potential Payments Upon Termination or Change of Control."

Sara Paz

On May 6, 2008, InspireMD Ltd. entered into a consultancy agreement for marketing services with Sara Paz, the wife of Ofir Paz, our chief executive officer. Pursuant to this consultancy agreement, Ms. Paz was paid by InspireMD Ltd. a fixed hourly fee of $45 (154 New Israeli Shekels) in Israel and a fixed daily fee of $400 abroad with respect to her services. Under this consultancy agreement, either party was able to terminate the agreement, in whole or in part, without cause by submitting written notice of such termination to the other party at least 14 days prior to such termination.

On September 1, 2011, effective April 1, 2011, our consultancy agreement was terminated and InspireMD Ltd. and Sara Paz Management and Marketing Ltd., an entity wholly-owned by Ms. Paz, entered into a new consultancy agreement pursuant to which Ms. Paz was retained to serve as InspireMD Ltd.'s vice president of sales. Pursuant to this consultancy agreement, Ms. Paz was entitled to a monthly consultancy fee of $12,500 (42,684 New Israeli Shekels) from April 1, 2011 through June 30, 2011 and is entitled to a monthly consultancy fee of $15,500 (52,927 New Israeli Shekels) thereafter. This new consultancy agreement has no termination date, but may be terminated without cause by InspireMD Ltd. upon 30 days notice to Sara Paz Management and Marketing Ltd. and may be terminated with cause by the InspireMD Ltd. immediately, upon the occurrence of certain events, such as a breach by Ms. Paz of fiduciary duties owed to InspireMD Ltd.

For a description of certain severance and pension payments to which Ms. Paz is entitled under her consultancy agreement, see “Item 11. Executive Compensation—Potential Payments Upon Termination or Change of Control.”

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and officers, and persons who own more than ten percent of our common stock, to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of our common stock. Directors, officers and persons who own more than ten percent of our common stock are required by Securities and Exchange Commission regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us, during the year ended December 31, 2011, each of our directors, officers and greater than ten percent stockholders complied with all Section 16(a) filing requirements applicable to our directors, officers and greater than ten percent stockholders, except that each of Mr. Paz and Dr. Holzer reported one transaction on a late Form 4, Mr. Shore did not report his ownership of options and warrants on his initial Form 3 filing, although such Form was amended to include such ownership, Mr. Weinstein filed one late Form 3 reporting no beneficial ownership of our securities and reported one transaction on a late Form 4 and Mr. Stuka filed one late Form 3 reporting beneficial ownership of shares of our common stock and warrants and reported one transaction on a late Form 4.

Board Committees

Our board of directors has established an audit committee, a nominating and corporate governance committee and a compensation committee, each of which has the composition and responsibilities described below.

Audit Committee. Our audit committee is currently comprised of Messrs. Stuka and Weinstein and Dr. Barer, each of whom our board has determined to be financially literate and qualify as an independent director under Section 5605(a)(2) of the rules of the Nasdaq Stock Market. Mr. Stuka is the chairman of our audit committee and qualifies as a financial expert, as defined in Item 407(d)(5)(ii) of Regulation S-K. The audit committee’s duties are to recommend to our board of directors the engagement of independent auditors to audit our financial statements and to review our accounting and auditing principles. The audit committee will review the scope, timing and fees for the annual audit and the results of audit examinations performed by the internal auditors and independent public accountants, including their recommendations to improve the system of accounting and internal controls.

Nominating and Corporate Governance Committee. Our compensation committee is currently comprised of Messrs. Stuka and Weinstein and Dr. Barer, each of whom qualify as an independent director under Section 5605(a)(2) of the rules of the Nasdaq Stock Market. Mr. Stuka is the chairman of our nominating and corporate governance committee. The nominating and corporate governance committee identifies and recommends to our board of directors individuals qualified to be director nominees. In addition, the nominating and corporate governance committee recommends to our board of directors the members and chairman of each board committee who will periodically review and assess our code of business conduct and ethics and our corporate governance guidelines. The nominating and corporate governance committee also makes recommendations for changes to our code of business conduct and ethics and our corporate governance guidelines to our board of directors, reviews any other matters related to our corporate governance and oversees the evaluation of our board of directors and our management.

The nominating and corporate governance committee will consider all proposed nominees for the board of directors, including those put forward by stockholders. Stockholder nominations should be in writing, addressed to the nominating and corporate governance committee in care of the secretary at InspireMD, Inc., 3 Menorat Hamaor St., Tel Aviv, Israel, 67448, in accordance with the provisions of our Amended and Restated Bylaws.

56

Compensation Committee. Our compensation committee is currently comprised of Messrs. Stuka and Weinstein and Dr. Barer. Mr. Weinstein is the chairman of our compensation committee. The compensation committee reviews and approves our salary and benefits policies, including compensation of executive officers. The compensation committee also administers our stock option plans and recommends and approves grants of stock options under such plans.

Code of Ethics

We intend to adopt a code of ethics that applies to our officers, directors and employees, including our principal executive officer and principal accounting officer, but have not done so to date due to our relatively small size. We intend to adopt a written code of ethics in the near future. Once adopted, the full text of our code of ethics will be published on our website at www.inspire-md.com. We intend to disclose future amendments to certain provisions of the code of ethics, or waivers of such provisions granted to executive officers and directors, on this website within five business days following the date of such amendment or waiver.

Item 11. Executive Compensation.

Compensation Discussion and Analysis

The Compensation Discussion and Analysis discusses the principles underlying our executive compensation policies and decisions for our named executive officers. It provides qualitative information regarding the manner in which compensation is earned by our named executive officers and places in context the data presented in the tables that follow. In addition, we address the compensation paid or awarded during 2011 to our named executive officers: Ofir Paz, our chief executive officer (principal executive officer), Craig Shore, our chief financial officer, secretary and treasurer (principal financial and accounting officer), Asher Holzer, Ph.D., our president, Eli Bar, the senior vice president of research and development and chief technical officer of InspireMD Ltd., and Sara Paz, the vice president of sales of InspireMD Ltd.

We formed a compensation committee on September 21, 2011. Prior to that date, all compensation decisions for Mr. Paz and Dr. Holzer were made by our board of directors. Mr. Paz was responsible for the executive compensation packages of Messrs. Shore and Bar and Ms. Paz. Because of the potential conflict of interest, Dr. Holzer and Mr. Shore also reviewed and approved Mr. Paz's decision with respect to Ms. Paz's compensation before it was implemented. The current compensation packages of Mr. Paz and Dr. Holzer were determined before our share exchange transactions on March 31, 2011, when InspireMD Ltd. was a private Israeli company. In accordance with Israeli law, their compensation was submitted to and approved by the stockholders of InspireMD Ltd. on February 28, 2011. Our board of directors also reviewed and approved Mr. Shore's compensation package after the share exchange transactions.

Going forward, the compensation committee of our board of directors will review at least annually and determine the executive compensation packages for Mr. Paz and Dr. Holzer, including approving any grants of stock options. Mr. Paz will remain responsible for making recommendations to our compensation committee with respect to the executive compensation packages for Messrs. Shore and Bar and Ms. Paz, including any grants of stock options.

In considering compensation for our named executive officers, the board of directors has historically relied upon the officer's performance and contribution to our development and achievements. We did not engage in any formal benchmarking or conduct or obtain any formal surveys of executive compensation at peer companies. We also considered general compensation trends.

The compensation committee is currently conducting its review of named executive officer compensation for 2012. The compensation committee has retained the services of a compensation consultant to assist with this review,

and anticipates that it may engage in formal benchmarking of our named executive officers' compensation against that at companies that it considers to be comparable to us. Based on this data, the compensation committee may target our overall compensation packages, or elements of our compensation packages, to fall within a certain percentile of the comparator group. The compensation committee has not made such a decision at this time.

We have entered into agreements with all of our named executive officers. These agreements are summarized under "Executive Officers and Directors – Agreements with Executive Officers." Mr. Paz and Dr. Holzer were compensated pursuant to consultancy agreements beginning on April 1, 2011. However, at the request of the compensation committee, Mr. Paz and Dr. Holzer agreed, effective as of December 1, 2011, to terminate their consultancy agreements, be compensated as employees and enter into new employment agreements on substantially the same terms as the consultancy agreements. Since December 1, 2011, Mr. Paz and Dr. Holzer have been employees of ours and have received the same level of compensation (i.e., base salary and benefits) as under their consultancy agreements. We are in the process of finalizing their employment agreements, but we expect that their terms will be substantially the same as those of the consultancy agreements.

Philosophy of Compensation

The goals of our compensation policy are to ensure that executive compensation rewards management for helping us achieve our financial goals (increased sales, profitability, etc.) and meet our clinical trial milestones and aligns management's overall goals and objectives with those of our stockholders. To achieve these goals, our board of directors and, going forward, our compensation committee, aims to:

- provide a competitive compensation package that enables us to attract and retain superior management personnel;
- relate compensation to our overall performance, the individual officer's performance and our assessment of the officer's future potential;
- reward our officers fairly for their role in our achievements; and
- align executives' objectives with the objectives of stockholders by granting equity awards to encourage executive stock ownership.

We have determined that in order to best meet these objectives, our executive compensation program should balance fixed and bonus compensation, as well as cash and equity compensation, as discussed below. Historically, there has been no pre-established policy or target for the allocation between either cash and non-cash or short-term and long-term incentive compensation for our executive officers.

Components of Compensation

The principal components of compensation for our named executive officers are base salary/consulting fees, equity based grants, personal benefits and perquisites and, potentially in the future, cash bonuses.

Base Salary/Consulting Fees. The primary component of compensation for our named executive officers is base salary (or consulting fees for our named executive officers who are employed pursuant to consultancy agreements). Base salary levels for our named executive officers have historically been determined based upon an evaluation of a number of factors, including the individual officer's level of responsibility, length and depth of experience and our assessment of the officer's future potential with our company, performance and, to the extent available, general compensation levels of similarly situated executives and general compensation trends. Although our employment and consultancy agreements with our named executive officers set forth a fixed base salary, salaries have been reviewed periodically and changed, when deemed appropriate, by oral or written amendment to the applicable officer's agreement. For 2011, we generally increased the base salaries of our executive officers, in part as a reflection of our becoming a publicly traded company in the U.S. and the accompanying increased responsibilities for our executive officers. Prior to April 1, 2011, Ms. Paz was compensated on an hourly basis, based on a fixed hourly consulting fee.

For 2012 and in the future, the compensation committee intends to review each named executive officer's base salary/consulting fee on an annual basis. In addition to the factors described above, in setting base salary, the compensation committee intends to consider the recommendations of our compensation consultant and more formal data regarding the compensation levels of similarly situated executives.

Equity Based Grants. An additional principal component of our compensation policy for named executive officers consists of grants under the InspireMD, Inc. 2011 UMBRELLA Option Plan. Under this plan, among other awards, executive officers may be granted stock options. Since its formation, the compensation committee of the board of directors has administered the grants of awards under the InspireMD, Inc. 2011 UMBRELLA Option Plan, and prior to its formation, the board of directors administered such awards. To date, all equity incentive awards have been made either (i) in accordance with negotiated terms set forth in our employment or consultancy agreements, at levels deemed necessary to attract or retain the executive at the time of such negotiations and determined taking into account the recipient's overall compensation package and the goal of aligning such executive's interest with that of our stockholders, or (ii) at the discretion of the compensation committee without reference to any formal targets or objectives, when deemed appropriate in connection with extraordinary efforts or results or necessary in order to retain the executive in light of the executive's overall compensation package.

We believe that equity ownership of our company by our named executive officers will further align the interests of our executive officers with those of our stockholders.

For 2012 and in the future, our compensation committee intends to consider during our annual compensation review whether to grant equity incentive awards to our named executive officers, and the terms of any such awards, including whether to set any performance targets or other objective or subjective criteria related to the final grant or vesting of such awards. The compensation committee will also retain the flexibility to make additional grants throughout the year if deemed necessary or appropriate in order to retain our named executive officers or reward extraordinary efforts or achievements.

Personal Benefits and Perquisites. Certain of our named executive officers are entitled to additional personal benefits in accordance with what we believe to be customary practice and law in Israel, including contributions towards pension and vocational studies funds, annual recreational allowances, a company car, a daily food allowance and a company phone. We believe these benefits are commonly provided to executives in Israel, and we therefore believe that it is necessary for us to provide these benefits in order to attract and retain superior management personnel.

Cash Bonus. Historically, we have never paid cash bonuses to our executives; however, our consultancy agreements with Mr. Paz and Dr. Holzer provided for cash bonuses to be paid at the discretion of our board of directors in an amount not less than three months' salary, and we believe that their new employment agreements will also provide for the payment of a discretionary cash bonus. We believe that cash bonus payments are an appropriate means to reward significant achievement and contribution to us by an executive officer, especially for officers that already hold significant equity positions in our company. Therefore, for 2012 and going forward, cash bonuses may become a more significant component of our compensation policy for executive officers. We intend to consider the amount of cash bonus that each of our named executive officers should be entitled to receive at the end of the year in connection with our annual compensation review, taking into account each executive's total compensation package, the recommendations of our compensation consultant, and any more formal data we obtain regarding the compensation levels of similarly situated executives We will also consider in connection with such review whether to designate certain financial or operational metrics or other objective or subjective criteria in determining the final amounts of such awards.

Compensation of Named Executive Officers

Compensation of Chief Executive Officer. In 2011, Mr. Paz's total compensation was $247,039, as compared to $219,160 in total compensation in 2010. Mr. Paz's total compensation was comprised of (i) salary payments under his employment agreement with us, (ii) consulting fees paid pursuant to the consultancy agreement InspireMD Ltd. entered into with A.S. Paz Management and Investment Ltd., an entity wholly-owned by Mr. Paz, through which Mr.

Paz was retained to serve as InspireMD Ltd.'s chief executive officer from April 1, 2011 through November 30, 2011, (iii) salary payments made during December 2011, and (iv) benefits and perquisites, as more fully discussed below. In 2011, Mr. Paz's salary compensation was $42,425 under his employment agreement, $122,970 under the consultancy agreement with A.S. Paz Management and Investment Ltd and $15,371 as an employee in December 2011, for a total of $180,766, as compared to $89,197 under his employment agreement and $78,491 under a consultancy agreement that was in effect prior to his employment agreement, for a total of $167,688, in 2010. In determining the compensation for Mr. Paz in 2011, our board of directors evaluated the corporate and organizational accomplishments of our company in 2010, as well as Mr. Paz's individual accomplishments. Mr. Paz's 2011 compensation was also increased in anticipation of our company becoming a publicly traded company in the U.S. and the additional obligations that would entail for our chief executive officer. Mr. Paz's compensation package for 2011 was determined before our share exchange transactions on March 31, 2011, when InspireMD Ltd. was a private Israeli company. In accordance with Israeli law, his compensation was submitted to and approved by the stockholders of InspireMD Ltd. on February 28, 2011.

Mr. Paz also received various benefits as both our salaried employee and our consultant, many of which either are required by Israeli law or we believe are customarily provided to Israeli executives. These benefits included contributions to his pension and vocational studies funds, an annual recreation payment, a company car, a cell-phone and a daily food allowance. In 2011, Mr. Paz's benefits compensation through payments made to him as an employee and through payments made to A.S. Paz Management and Investment Ltd was $66,273, as compared to $51,472 in 2010. Our board of directors determined that equity based compensation would be inappropriate for Mr. Paz, in light of his current equity holdings in our company.

Compensation of Chief Financial Officer, Secretary and Treasurer. Mr. Shore was initially hired as our Vice President of Business Development and was promoted to his current position on March 31, 2011. In 2011, Mr. Shore's total compensation was $419,433, as compared to $13,162 in total compensation in 2010, which represented compensation paid from the commencement of Mr. Shore's employment on November 24, 2010. Mr. Shore's total compensation was comprised of salary payments under his employment agreement with us, an option grant under the InspireMD, Inc. 2011 UMBRELLA Option Plan, as more fully discussed below, and benefits and perquisites, as more fully discussed below. In 2011, Mr. Shore's annual salary was $118,333, as compared to $9,912 in 2010. Pursuant to his employment agreement with us, Mr. Shore's monthly salary was automatically increased during 2011, upon the consummation of our share exchange transactions. Upon Mr. Paz's recommendation, Mr. Shore's salary was further increased as of July 1, 2011 by an additional $838 per month on July 1, 2011. In determining to make such additional increase, Mr. Paz considered the corporate and organizational accomplishments of our company since Mr. Shore joined us, his role in such accomplishments, his general performance, his increased responsibilities as chief financial officer, the desire to ensure that his compensation is high enough to retain his services and the desire to make his compensation consistent with what we pay to our other senior executives.

Mr. Shore also received various benefits, many of which either are required by Israeli law or we believe are customarily provided to Israeli executives, including contributions to his pension and vocational studies funds, an annual recreation payment, a company car, a company cell phone, and a daily food allowance. In 2011, Mr. Shore's benefits compensation was $35,280, as compared to $3,250 in 2010.

In addition, in February 2011, Mr. Shore was granted options that currently represent the right to acquire up to 365,223 shares of our common stock at an exercise price of $1.23 per share. This award was part of the initial package negotiated with Mr. Shore in connection with his hiring in November 2010. The number of shares for which such award was exercisable and the exercise price were originally set forth in Mr. Shore's employment agreement and related to shares of InspireMD Ltd. The per share price was determined based on the price at which InspireMD Ltd. had most recently raised capital. The option was converted into the current number of shares at the current exercise price through the share exchange transactions. The options vest on an annual basis over three years. The options had a fair market value of $260,554 as of February 27, 2011. In determining to grant Mr. Shore a significant portion of his compensation in the form of options, our board of directors believed that it was important to give Mr. Shore an equity interest in us. Providing Mr. Shore with an equity stake was viewed by our board as important, as Mr. Shore previously did not hold any such stake in us, as opposed to Mr. Paz and Dr. Holzer. In determining the number of shares to award to Mr. Shore, Mr. Paz and our board of directors considered the need to provide Mr. Shore with a compensation package that was sufficient to attract him to accept employment with us, given that his base salary was believed to be relatively low for his position, and the desire to provide Mr. Shore with an equity position in our company that was significant enough to align his objectives with those of our stockholders and allow Mr. Shore to share in our future financial growth and the benefits of the share exchange and our becoming a U.S. public company.

Also, in May 2011, Mr. Shore was awarded a warrant to purchase 3,000 shares of our common stock at an exercise price of $1.80 per share as a bonus payment for his work performed in connection with our share exchange transactions. The warrant had a fair market value of $5,266 and vested immediately. The award was given in recognition of Mr. Shore's extraordinary efforts related to our private placement transaction on March 31, 2011.

Compensation of President. In 2011, Dr. Holzer's total compensation was $245,406, as compared to $209,592 in total compensation in 2010. Dr. Holzer's total compensation was comprised of (i) salary payments under his employment agreement with us, (ii) consulting fees paid pursuant to the consultancy agreement InspireMD Ltd. entered into with OSHIL, The Israeli Society Ltd., an entity wholly-owned by Dr. Holzer, through which Dr. Holzer was retained to serve as InspireMD Ltd.'s president from April 1, 2011 through November 30, 2011, (iii) salary payments made during December 2011, and (iv) benefits and perquisites, as more fully discussed below. In 2011, Dr. Holzer's salary compensation was $42,425 under his employment agreement, $122,970 under the consultancy agreement with OSHIL, The Israeli Society Ltd., and $15,371 as an employee in December 2011, for a total of $180,766, as compared to $89,197 under his employment agreement and $74,791 under a consultancy agreement that was in effect prior to his employment agreement, for a total of $163,988, in 2010. In determining the compensation for Dr. Holzer in 2011, our board of directors evaluated the corporate and organizational accomplishments of our company in 2010, as well as Dr. Holzer's individual accomplishments and contributions to our accomplishments. Our board of directors determined that an increase in compensation for Dr. Holzer was appropriate in 2011, in part, in anticipation of our company becoming a U.S. publicly traded company in 2011 and the increased responsibilities that would result for our president. Dr. Holzer's compensation package for 2011 was determined before the share exchange transactions, when InspireMD Ltd. was a private Israeli company. In accordance with Israeli law, his compensation was submitted to and approved by the stockholders of InspireMD Ltd. on February 28, 2011.

Dr. Holzer also received various benefits as both our salaried employee and our consultant, many of which either are required by Israeli law or we believe are customarily provided to Israeli executives. These benefits included contributions to his pension and vocational studies funds, an annual recreation payment, a company car and cell phone, and a daily food allowance. In 2011, Dr. Holzer's benefits compensation through payments made to him as an employee and through payments made to OSHIL, The Israeli Society Ltd. was $64,640, as compared to $45,604 in 2010. Our board of directors determined that equity based compensation would be inappropriate for Dr. Holzer, in light of his current equity holdings in our company.

Compensation of Senior Vice President of Research and Development and Chief Technical Officer of InspireMD Ltd. In 2011, Mr. Bar's total compensation was $350,394, as compared to $942,689 in total compensation in 2010. Mr. Bar's total compensation was comprised of salary payments under his employment agreement with us, option grants under the InspireMD, Inc. 2011 UMBRELLA Option Plan, as more fully discussed below, and benefits and perquisites, as more fully discussed below. In 2011, Mr. Bar's annual salary was $122,760, as compared to $91,684 in 2010. In determining the compensation for Mr. Bar in 2011, Mr. Paz evaluated the corporate and organizational accomplishments of our company in 2010, particularly with respect to the development of our products, as well as Mr. Bar's individual achievements and contributions to such accomplishments. Mr. Bar's increase in salary during 2011 reflected his significant contributions to our success in 2010, and our desire to retain him going forward. His 2011 salary was increased to the level it had been in August 2008, prior to salary reductions throughout the company.

Mr. Bar also received various benefits, many of which either are required by Israeli law or we believe are customarily provided to Israeli executives, including contributions to his pension and vocational studies funds, an annual recreation payment, a company car, a company cell phone, and a daily food allowance. In 2011, Mr. Bar's benefits compensation was $42,459, as compared to $32,496, in 2010.

In addition, in June 2011, Mr. Bar was awarded options to acquire up to 200,000 shares of common stock at an exercise price of $2.75 per share as a bonus payment for his significant contributions to our company. In determining to make such award, Mr. Paz considered Mr. Bar's continued exemplary performance and contributions to the clinical development of our product and the desire to continue to retain his services and keep his compensation consistent with what we pay to our other senior executives. We determined that granting Mr. Bar more of an equity interest would further increase his opportunity to share in our future financial success and align his objectives with those of our stockholders. The options vest on an annual basis over a three year period. The options had a fair market value of $268,381 as of June 1, 2011. The exercise price was the fair market value of our common stock on the date of grant. In August 2011, we cancelled these options and reissued an option to purchase 200,000 shares of common stock at an exercise price of $1.93 because our board of directors determined that the $2.75 exercise price was too far out of the money to achieve the compensatory and incentive purposes of the options. The exercise price of the new option was the fair market value of our common stock on the date of grant. The fair value of the 200,000 options as of August 31, 2011 was $185,175.

Mr. Bar also received two option awards in July 2010. The first award currently represents the right to acquire up to 608,707 shares of our common stock at an exercise price of $0.001 per share. The number of shares for which such award was exercisable and the exercise price originally related to shares of InspireMD Ltd. The per share price was set at $0.01 per share. The option was converted into the current number of shares at the current exercise price through the share exchange transactions. The second award currently represents the right to acquire up to 81,161 shares of our common stock at an exercise price of $1.23 per share. The number of shares for which such award was exercisable and the exercise price also originally related to shares of InspireMD Ltd. The per share price was determined based on the price at which InspireMD Ltd. had most recently raised capital. The option was converted into the current number of shares at the current exercise price through the share exchange transactions. Both awards were made in recognition of Mr. Bar's contributions to our corporate and organizational achievements. The first award was related to Mr. Bar's performance over the long-term of his tenure with us and to our desire to grant Mr. Bar an equity stake that would not be at risk. In particular, in determining to make this award, the board of directors took into account the fact that, from September 2008 to April 2009, Mr. Bar accepted several salary reductions, which resulted in his monthly salary being reduced from approximately $10,133 to approximately $7,387. Mr. Bar's salary remained approximately $7,387 per month until August 2010, at which time his monthly salary was increased to $8,000. Furthermore, our board of directors decided that recognizing Mr. Bar's efforts and sacrifices through an equity award was the most appropriate form of compensation, as it would also serve to give Mr. Bar an additional equity interest in us. Providing Mr. Bar with an increased equity stake was viewed by our board as important, as Mr. Bar's existing options were deemed a very small stake in comparison to that held by Mr. Paz and Dr. Holzer. The second award was intended as a more traditional annual incentive award and related primarily to Mr. Bar's performance in 2010 and our desire to grant Mr. Bar traditional options whose value would fluctuate depending on the performance of our common stock. Both option awards vest one-twelfth quarterly commencing with the quarter in which they were granted. The first award had a fair market value of $750,000 as of July 25, 2010. The second award had a fair market value of $68,509 as of July 31, 2010.

Compensation of Vice President of Sales of InspireMD Ltd. In 2011, Ms. Paz's total compensation was $782,016, as compared to $77,603 in total compensation in 2010. Ms. Paz's total compensation was comprised of (i) payments for consulting fees under a consultancy agreement InspireMD Ltd. entered into with Ms. Paz which terminated on March 31, 2011 and provided for the payment of a fixed hourly consulting fee of $45 for services provided in Israel and a fixed daily consulting fee of $400 for services provided outside of Israel, and (ii) payments for consulting fees under a consultancy agreement InspireMD Ltd. entered into with Sara Paz Management and Marketing Ltd, an entity wholly-owned by Ms. Paz, through which Ms. Paz was retained to serve as InspireMD Ltd.'s vice president of sales as of April 1, 2011, (iii) an option grant under the InspireMD, Inc. 2011 UMBRELLA Option Plan, as more fully discussed below, and (iv) benefits and perquisites, as more fully discussed below. Ms. Paz's payments under her consultancy agreements were $112,136 in 2011 as compared to $77,603 in 2010. In determining the compensation for Ms. Paz in 2011, Mr. Paz evaluated the corporate and organizational achievements of our company in 2010, with a particular emphasis on our sales growth, to which Ms. Paz's work contributed, her contributions and perceived future potential on a full-time basis and the compensation paid to similarly situated executives within our company. Dr. Holzer and Mr. Shore approved Mr. Paz's determination with respect to Ms. Paz's compensation.

In conjunction with InspireMD Ltd. entering into the consultancy agreement with Sara Paz Management and Marketing Ltd, we commenced paying Ms. Paz the benefits required by Israeli law and comparable benefits to our other executives. As such, pursuant to the consultancy agreement, in 2011, Ms. Paz received various benefits, including contributions to her pension and vocational studies funds, an annual recreation payment, a company car, a company cell phone, and a daily food allowance. In 2011, Ms. Paz's benefits compensation was $30,473.

In addition, in recognition of Ms. Paz's contributions to our corporate and organizational achievements in 2010, particularly with respect to the increased sales of our products, in June 2011, our board of directors awarded Ms. Paz options to acquire up to 365,225 shares of common stock at an exercise price of $1.50 per share. The options vest on

a monthly basis over a three year period. The options had a fair market value of $639,407 as of June 1, 2011. The amount was determined with reference to the award made to Mr. Shore during 2011, for an approximately equal number of shares. The exercise price was the fair market value of our common stock on the date of grant. We did not consider the Black-Scholes valuation of the grant prior to making it. We did take into account the desire to provide Ms. Paz with an equity position in our company, separate from that of her husband, that would further align her objectives with those of our stockholders and allow her to share in our future financial growth.

Impact of Tax Laws

Deductibility of Executive Compensation. Generally, under U.S. law, a company may not deduct compensation of more than $1,000,000 that is paid to an individual employed by the company who, on the last day of the taxable year, either is the company's principal executive officer or an individual who is among the three highest compensated officers for the taxable year (other than the principal executive officer or the principal financial officer). The $1,000,000 limitation on deductions does not apply to certain types of compensation, including qualified performance-based compensation, and only applies to compensation paid by a publicly-traded corporation (and not compensation paid by non-corporate entities). Because the compensation deducted in the U.S. for each individual to whom this rule applies has historically been less than $1,000,000 per year, we do not believe that the $1,000,000 limitation will affect us in the near future. If the deductibility of executive compensation becomes a significant issue, our compensation plans and policies may be modified to maximize deductibility if our board of directors and we determine that such action is in our best interests.

Impact of Israeli Tax Law. The awards granted to employees pursuant to Section 102 of the Tax Ordinance under the InspireMD, Inc. 2011 UMBRELLA Option Plan may be designated by us as approved options under the capital gains alternative, or as approved options under the ordinary income tax alternative.

To qualify for the capital gains alternative, certain requirements must be met, including registration of the options in the name of a trustee. Each option, and any shares of common stock acquired upon the exercise of the option, must be held by the trustee for a period commencing on the date of grant and deposit into trust with the trustee and ending 24 months thereafter.

Under the terms of the capital gains alternative, we may not deduct expenses pertaining to the options for tax purposes.

Under the InspireMD, Inc. 2011 UMBRELLA Option Plan, we may also grant to employees options pursuant to Section 102(b)(3) of the Israeli Tax Ordinance that are not required to be held in trust by a trustee. This alternative, while facilitating immediate exercise of vested options and sale of the underlying shares, will subject the optionee to the marginal income tax rate of up to 45% as well as payments to the National Insurance Institute and health tax on the date of the sale of the shares or options. Under the InspireMD, Inc. 2011 UMBRELLA Option Plan, we may also grant to non-employees options pursuant to Section 3(I) of the Israeli Tax Ordinance. Under that section, the income tax on the benefit arising to the optionee upon the exercise of options and the issuance of common stock is generally due at the time of exercise of the options.

Allotment of these options may be subject to terms of the tax ruling that has been obtained by InspireMD Ltd. from the Israeli tax authorities according to Section 103 of the Israeli tax ordinance, with regard to the share exchange. According to the tax pre-ruling, the exchange of shares and options of InspireMD Ltd. for shares and options of our company pursuant to the share exchange will not result in an immediate tax event for InspireMD Ltd.'s former shareholders, but a deferred tax event, subject to certain conditions as stipulated in the tax pre-ruling. The main condition of the tax pre-ruling is a restriction on the exchanged shares for two years from December 31, 2010 for shareholders holding over of 5%.

Termination Payments

Our agreements with Messrs. Paz, Bar and Shore, Dr. Holzer and Ms. Paz and Israeli law provide for payments and other compensation in the event of termination under certain circumstances, as more fully described under "Executive Compensation – Potential Payments Upon Termination or Change of Control." These provisions are comprised of (i) notice periods of varying length prior to a termination without cause (180 days for Mr. Paz and Dr. Holzer, 30 days in general and 180 days following certain change in control events for Mr. Shore, 60 days for Mr. Bar and 30 days for Ms. Paz), (ii) severance payments as required by Israeli law, (iii) vesting of Mr. Shore's, options upon his termination in connection with a change of control and (iv) vesting of Mr. Shore's, Mr. Bar's and Ms. Paz's options automatically upon a change of control if such stock options are not assumed or substituted by the surviving company. We believe that having these provisions in our agreements with our officers enables our officers to focus solely on the performance of their jobs by providing them with security in the event of certain terminations of employment. With respect to the notice provisions, we believe that these provide us with a mechanism to ensure a successful transition if we have to replace one of our named executive officers. In addition, we have provided these benefits to our officers because we believe it is necessary for retention purposes, to attract well qualified and talented executives and, in the case of severance payments, to comply with Israeli law. In exchange for these protections, our officers have agreed to be bound by certain restrictive covenants, including confidentiality, non-competition and non-solicitation provisions.

Risk Considerations in our Compensation Programs

Our compensation committee believes that risks arising from our policies and practices for compensating employees are not reasonably likely to have a material adverse effect on us and do not encourage risk taking that is reasonably likely to have a material adverse effect on us. Our compensation committee believes that the structure of our executive compensation program mitigates risks by avoiding any named executive officer placing undue emphasis on any particular performance metric at the expense of other aspects of our business.

2011, 2010 and 2009 Summary Compensation Table

The table below sets forth, for our last three fiscal years, the compensation earned by Ofir Paz, our chief executive officer, Craig Shore, our chief financial officer, secretary and treasurer, Asher Holzer, our president and former chairman of the board, Eli Bar, InspireMD Ltd.'s senior vice president of research and development and chief technical officer, Sara Paz, InspireMD Ltd.'s vice president of sales, and Lynn Briggs, our former president, chief executive officer, chief financial officer, secretary and treasurer.

Name and Principal Position	Year	Salary ($)(1)	Bonus ($)(1)	Option Awards($)(2)	All Other Compensation ($)(1)	Total ($)(1)
Ofir Paz(3)						
Chief Executive Officer	2011	57,796	-	-	189,243(4)	247,039
	2010	89,197	-	-	129,963(4)	219,160
	2009	76,524	-	-	129,909(4)	206,433
Craig Shore						
Chief Financial Officer,						
Secretary and Treasurer	2011	118,333	-	260,554	40,546(5)	419,433
	2010	9,912	-	-	3,250(5)	13,162(6)
Asher Holzer(3)	2011	57,796	-	-	187,610(7)	245,406

President and Former Chairman						
	2010	89,197	-	-	120,395(7)	209,592
	2009	73,526	-	-	109,054(7)	182,580
Eli Bar						
Senior Vice President, Research and Development and Chief Technical Officer of InspireMD Ltd.	2011	122,760	-	185,175(8)	42,459(9)	350,394
	2010	91,684	-	818,509	32,496(9)	942,689
	2009	86,971	-	-	38,585(9)	125,556
Sara Paz						
Vice President of Sales of InspireMD Ltd.	2011	-	-	639,407	142,609(10)	782,016
	2010	-	-	-	77,603(10)	77,603
	2009	-	-	-	59,197(10)	59,197
Lynn Briggs(11)						
Former President, CEO, CFO, Secretary and Treasurer	2011	-	-	-	-	-
	2010	-	-	-	-	-
	2009	-	-	-	-	-

(1) Compensation amounts received in non-U.S. currency have been converted into U.S. dollars using the average exchange rate for the applicable year. The average exchange rate for 2011 was 3.5781 NIS per dollar, the average exchange rate for 2010 was 3.7330 NIS per dollar and the average exchange rate for 2009 was 3.9326 NIS per dollar.

(2) The amounts in this column reflect the dollar amounts recognized for financial statement reporting purposes with respect to the years ended December 31, 2009, 2010 and 2011, in accordance with FASB ASC Topic 718. Fair value is based on the Black-Scholes option pricing model using the fair value of the underlying shares at the measurement date. For additional discussion of the valuation assumptions used in determining stock-based compensation and the grant date fair value for stock options, see "Management's Discussion and Analysis of Financial Condition and Results of Operation — Critical Accounting Policies—Share-Based Compensation" and Note 2—"Significant Accounting Policies" and Note 11—"Share-Based Compensation" of the Notes to the Consolidated Financial Statements for Two Years Ended December 31, 2010 and Note 7—Fair Value Measurement" of the Notes to the Condensed Consolidated Financial Statements for the Nine months ended September 30, 2011 included herein.

(3) Both Mr. Paz and Dr. Holzer are directors but do not receive any additional compensation for their services as directors.

(4) Mr. Paz's other compensation consisted of $57,612 in consulting salary and $72,297 in benefits in 2009, $78,491 in consulting salary and $51,472 in benefits in 2010 and $122,970 in consulting salary and $66,273 in benefits in 2011. In each of 2009, 2010 and 2011, Mr. Paz's benefits included our contributions to his severance, pension, vocational studies and disability funds, an annual recreation payment, a company car and cell phone, and a daily food allowance. In 2011, the car-related benefits for Mr. Paz were valued at $26,473, which was comprised of aggregate payments of $19,992 towards a car and related expenses for approximately nine months of the year, and the use of a company car for approximately three months of the year, which was valued at $6,481, as computed by the Israeli taxation authorities.

(5) Mr. Shore's other compensation consisted solely of benefits in 2010 and consisted of a warrant award valued at $5,266 and $35,280 in benefits in 2011. In each of 2010 and 2011, Mr. Shore's benefits included our contributions to his severance, pension, vocational studies and disability funds, an annual recreation payment, a company car and cell phone, and a daily food allowance.

(6) Mr. Shore's total compensation in 2010 represented amounts paid beginning on November 24, 2010, the date of the commencement of Mr. Shore's employment with us.

(7) Dr. Holzer's other compensation consisted of $55,040 in consulting salary and $54,014 in benefits in 2009, $74,791 in consulting salary and $45,604 in benefits in 2010 and $122,970 in consulting salary and $64,640 in benefits in 2011. In each of 2009, 2010 and 2011, Dr. Holzer's benefits included our contributions to his severance, pension, vocational studies and disability funds, an annual recreation payment, a company car and cell phone, and a daily food allowance.

(8) On June 1, 2011, Mr. Bar was awarded options to acquire up to 200,000 shares of common stock at an exercise price of $2.75 per share as a bonus payment for his contributions to our company in 2010. The options had a fair market value of $268,381. In August 2011, we cancelled the option to purchase 200,000 shares of common stock that were awarded to Mr. Bar in June 2011 and reissued an option to purchase 200,000 shares of common stock at an exercise price of $1.93 because our board of directors determined that the $2.75 exercise price was too far out of the money to achieve the compensatory and incentive purposes of the options. The new options had a fair market value of $185,175.

(9) Mr. Bar's other compensation in 2009, 2010 and 2011 consisted solely of benefits, including our contributions to his severance, pension, vocational studies and disability funds, an annual recreation payment, a company car and cell phone, and a daily food allowance.

(10) Ms. Paz's other compensation consisted of $59,197 in consulting salary in 2009, $77,603 in consulting salary in 2010 and $112,136 in consulting salary and $30,473 in benefits, including our contributions to her severance, pension, vocational studies and disability funds, an annual recreation payment, a company car and cell phone, and a daily food allowance, in 2011.

(11) Ms. Briggs resigned as our sole officer and director in connection with our share exchange transactions on March 31, 2011. She received no compensation for services, but was reimbursed for any out-of-pocket expenses that she incurred on our behalf.

2011 Grants of Plan-Based Awards

The following table sets forth information regarding grants of plan-based awards to our named executive officers in 2011:

Name	Grant Date	Option Awards: Number of Securities Underlying (#)	Exercise or Base Price of Option Awards Options ($/Sh)	Grant Date Fair Value of Option Awards ($)
Ofir Paz Chief Executive Officer	-	-	-	-
Craig Shore	2/27/2011	365,223	1.23	260,544
Chief Financial Officer, Secretary and Treasurer	5/20/2011	3,000(1)	1.80	5,266
Asher Holzer President and Former Chairman	-	-	-	-
Eli Bar (2)				
Senior Vice President, Research and				
Development and Chief Technical Officer of	6/1/2011	200,000	2.75	268,381
InspireMD Ltd.	8/31/2011	200,000	1.93	185,175
Sara Paz Vice President of Sales of InspireMD Ltd.	6/1/2011	365,225	1.50	639,407
Lynn Briggs(3)				
Former President, CEO, CFO, Secretary and				
Treasurer	-	-	-	-

66

(1) On May 20, 2011, Mr. Shore was awarded a warrant to purchase 3,000 shares of our common stock at an exercise price of $1.80 per share as a bonus payment for his work performed in connection with our share exchange transactions. The warrant had a fair market value of $5,266 and vested immediately. The award was given in recognition of Mr. Shore's extraordinary efforts related to our private placement transaction on March 31, 2011.

(2) On June 1, 2011, Mr. Bar was awarded options to acquire up to 200,000 shares of common stock at an exercise price of $2.75 per share as a bonus payment for his contributions to our company in 2010. The options had a fair market value of $268,381. In August 2011, we cancelled the option to purchase 200,000 shares of common stock that were awarded to Mr. Bar in June 2011 and reissued an option to purchase 200,000 shares of common stock at an exercise price of $1.93 because our board of directors determined that the $2.75 exercise price was too far out of the money to achieve the compensatory and incentive purposes of the options. This resulted in a change in fair market value to $185,175.

(3) Ms. Briggs resigned as our sole officer and director in connection with our share exchange transactions on March 31, 2011.

Outstanding Equity Awards at Fiscal Year-End 2011

The following table shows information concerning unexercised options outstanding as of December 31, 2011 for each of our named executive officers. There are no outstanding stock awards with our named executive officers:

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date
Ofir Paz	-	-	-	-
Craig Shore	121,741	243,482 (1)	1.23	2/27/2021
Asher Holzer	-	-	-	-
Eli Bar	243,481	-	0.001	10/28/2016
	365,224	-	0.001	12/29/2016
	304,353	304,354(2)	0.001	7/22/2020
	40,581	40,580(2)	1.23	7/28/2020
	-	200,000(3)	1.93	5/23/2016
Sara Paz	-	365,225(4)	1.50	6/1/2016

(1) These options were granted in February 2011 and vest annually commencing on November 23, 2011 and vesting on the next two anniversaries of that date.

(2) These options were granted in July 2010 and vest one-twelfth quarterly commencing with the quarter in which they were granted.

(3) These options were granted in August 2011 and vest annually commencing on May 23, 2012 and vesting on the next two anniversaries of that date.

(4) These options were granted in June 2011 and vest annually commencing on April 8, 2012 and vesting on the next two anniversaries of that date.

Option Exercises and Stock Vested

There were no stock options exercised by our named executive officers during 2011.

2011 UMBRELLA Option Plan

On March 28, 2011, our board of directors and stockholders adopted and approved the InspireMD, Inc. 2011 UMBRELLA Option Plan, which was subsequently amended on October 31, 2011. Under the InspireMD, Inc. 2011 UMBRELLA Option Plan, we have reserved 15,000,000 shares of our common stock as awards to the employees, consultants, and service providers to InspireMD, Inc. and its subsidiaries and affiliates worldwide.

The InspireMD, Inc. 2011 UMBRELLA Option Plan currently consists of three components, the primary plan document that governs all awards granted under the InspireMD, Inc. 2011 UMBRELLA Option Plan, and two appendices: (i) Appendix A, designated for the purpose of grants of stock options and restricted stock to Israeli employees, consultants, officers and other service providers and other non-U.S. employees, consultants, and service providers, and (ii) Appendix B, which is the 2011 U.S. Equity Incentive Plan, designated for the purpose of grants of stock options and restricted stock awards to U.S. employees, consultants, and service providers who are subject to the U.S. income tax.

The purpose of the InspireMD, Inc. 2011 UMBRELLA Option Plan is to provide an incentive to attract and retain employees, officers, consultants, directors, and service providers whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in our development and financial success. The InspireMD, Inc. 2011 UMBRELLA Option Plan is administered by our compensation committee. Unless terminated earlier by the board of directors, the InspireMD, Inc. 2011 UMBRELLA Option Plan will expire on March 27, 2021.

Potential Payments Upon Termination or Change of Control

Our agreements with Messrs. Paz, Bar and Shore, Dr. Holzer and Ms. Paz as well as Israeli law provide for payments and other compensation in the event of their termination or a change of control of us under certain circumstances, as described below.

Chief Executive Officer. Pursuant to Mr. Paz's consultancy agreement and, we anticipate, our new employment agreement with Mr. Paz, we possess the right to terminate his employment without "cause" (as such term is defined in the agreement) upon at least 180 days prior notice to Mr. Paz. During such notice period, we will continue to compensate Mr. Paz according to his agreement and Mr. Paz will be obligated to continue to discharge and perform all of his duties and obligations under the agreement, and to cooperate with us and use his best efforts to assist with the integration of any persons that we have delegated to assume Mr. Paz's responsibilities. We believe that this arrangement will assist us in achieving a successful transition upon Mr. Paz's departure. Mr. Paz is entitled to terminate his employment with us in the event that we do not fulfill our undertakings under our agreement, upon at least 30 days prior notice to us, during which time we may cure the breach. During such notice period, we will continue to compensate Mr. Paz according to his agreement and Mr. Paz will be obligated to continue to discharge and perform all of his duties and obligations under the agreement.

If Mr. Paz's employment is terminated for any reason other than for cause, as a senior executive under Israeli law, he will also be entitled to severance payments equal to the total amount that has been contributed to and accumulated in his severance payment fund. The total amount accumulated in his severance payment fund as of December 31, 2011 was $1,199, as adjusted for conversion from New Israeli Shekels to U.S. Dollars.

We are entitled to terminate Mr. Paz's employment immediately at any time for "cause" (as such term is defined in the agreement and the Israeli Severance Payment Act 1963), upon which, after meeting certain requirements under the applicable law and recent Israeli Labor court requirements, we believe we will have no further obligation to compensate Mr. Paz and Mr. Paz will not be entitled to the amount that has been contributed to and accumulated in his severance payment fund.

Also, upon termination of Mr. Paz's employment for any reason, we will compensate him for all unused vacation days accrued.

Chief Financial Officer, Secretary and Treasurer. Subject to certain conditions, either party to our employment agreement with Mr. Shore may terminate the employment agreement without "cause" (as such term is defined in Mr.

Shore's employment agreement with us) upon at least 30 days prior notice to the other party or, in the event of a major change of control in terms of the ownership of shares of our common stock or our intellectual property, upon at least 180 days prior notice. During such notice period, we will continue to compensate Mr. Shore according to his employment agreement and Mr. Shore will be obligated to continue to discharge and perform all of his duties and obligations under his employment agreement, and to cooperate with us and use his best efforts to assist with the integration of any persons that we have delegated to assume Mr. Shore's responsibilities. We believe that this arrangement with Mr. Shore will assist us in achieving a successful transition upon Mr. Shore's departure. In addition, upon termination without "cause," we have the right to pay Mr. Shore a lump payment representing his compensation for the notice period and terminate Mr. Shore's employment immediately.

If we terminate Mr. Shore's employment without cause, Mr. Shore will be entitled, under Israeli law, to severance payments equal to his last month's salary multiplied by the number of years Mr. Shore has been employed with us. In order to finance this obligation, we make monthly contributions equal to 8.33% of Mr. Shore's salary to a severance payment fund. The total amount accumulated in Mr. Shore's severance payment fund as of December 31, 2011 was $8,474, as adjusted for conversion from New Israeli Shekels to U.S. Dollars. However, if Mr. Shore's employment is terminated without cause, on account of a disability or upon his death, as of December 31, 2011, Mr. Shore would have been entitled to receive $10,967 in severance under Israeli law, thereby requiring us to pay Mr. Shore $2,493, in addition to releasing the $8,474 in Mr. Shore's severance payment fund. On the other hand, pursuant to his employment agreement, Mr. Shore is entitled to the total amount contributed to and accumulated in his severance payment fund in the event of the termination of his employment as a result of his voluntary resignation. In addition, Mr. Shore would be entitled to receive his full severance payment under Israeli law, including the total amount contributed to and accumulated in his severance payment fund, if he retires from our company at or after age 67.

We are entitled to terminate Mr. Shore's employment immediately at any time for "cause" (as such term is defined in the agreement and the Israeli Severance Payment Act 1963), upon which, after meeting certain requirements under the applicable law and recent Israeli Labor court requirements, we believe we will have no further obligation to compensate Mr. Shore.

In addition, pursuant to Mr. Shore's employment agreement, in the event of a change of control of our company, the majority of shares of our common stock or our intellectual property that results in the termination of Mr. Shore's employment within one year of such change of control, the stock options granted to Mr. Shore in accordance with the terms of his employment agreement that were unvested will vest immediately upon such termination. Furthermore, pursuant to terms contained in Mr. Shore's stock option award agreement, in the event of a change of control of our company, the stock options granted to Mr. Shore that were unvested will vest immediately upon such change of control if such stock options are not assumed or substituted by the surviving company.

Also, upon termination of Mr. Shore's employment for any reason, we will compensate him for all unused vacation days accrued.

President. Pursuant to Dr. Holzer's consultancy agreement and, we anticipate, our new employment agreement with Dr. Holzer, we possess the right to terminate his employment without "cause" (as such term is defined in the agreement) upon at least 180 days prior notice to Dr. Holzer. During such notice period, we will continue to compensate Dr. Holzer according to his agreement and Dr. Holzer will be obligated to continue to discharge and perform all of his duties and obligations under the agreement, and to cooperate with us and use his best efforts to assist with the integration of any persons that we have delegated to assume Dr. Holzer's responsibilities. We believe that this arrangement will assist us in achieving a successful transition upon Dr. Holzer's departure. Dr. Holzer is entitled to terminate his employment with us in the event that we do not fulfill our undertakings under our agreement, upon at least 30 days prior notice to us, during which time we may cure the breach. During such notice period, we will continue to compensate Dr. Holzer according to his agreement and Dr. Holzer will be obligated to continue to discharge and perform all of his duties and obligations under the agreement.

If Dr. Holzer's employment is terminated for any reason other than for cause, as a senior executive under Israeli law, he will also be entitled to severance payments equal to the total amount that has been contributed to and accumulated in his severance payment fund. The total amount accumulated in his severance payment fund as of December 31, 2011 was $1,199, as adjusted for conversion from New Israeli Shekels to U.S. Dollars.

We are entitled to terminate Dr. Holzer's employment immediately at any time for "cause" (as such term is defined in the agreement and the Israeli Severance Payment Act 1963), upon which, after meeting certain requirements under the applicable law and recent Israeli Labor court requirements, we believe we will have no further obligation to

compensate Dr. Holzer and Dr. Holzer will not be entitled to the amount that has been contributed to and accumulated in his severance payment fund.

Also, upon termination of Dr. Holzer's employment for any reason, we will compensate him for all unused vacation days accrued.

Senior Vice President of Research and Development and Chief Technical Officer of InspireMD Ltd. Subject to certain conditions, either party to our employment agreement with Mr. Bar may terminate the employment agreement without "cause" (as such term is defined in Mr. Bar's employment agreement with us) upon at least 60 days prior written notice to the other party. During such notice period, we will continue to compensate Mr. Bar according to his employment agreement and Mr. Bar will be obligated to continue to discharge and perform all of his duties and obligations under his employment agreement, and to cooperate with us and use his best efforts to assist with the integration of any persons that we have delegated to assume Mr. Bar's responsibilities. We believe that our severance arrangement with Mr. Bar will assist us in achieving a successful transition upon Mr. Bar's departure. In addition, upon termination without "cause," we have the right to pay Mr. Bar a lump payment representing his compensation for the notice period and terminate Mr. Bar's employment immediately.

If Mr. Bar's employment is terminated without cause, Mr. Bar will also be entitled under Israeli law to severance payments equal to his last month's salary multiplied by the number of years Mr. Bar has been employed with us. In order to finance this obligation, we make monthly contributions equal to 8.33% of Mr. Bar's salary each month to a severance payment fund. The total amount accumulated in his severance payment fund as of December 31, 2011 was $57,870, as adjusted for conversion from New Israeli Shekels to U.S. Dollars. However, if Mr. Bar's employment was terminated without cause, on account of a disability or upon his death, as of December 31, 2011, Mr. Bar would be entitled to receive $65,278 in severance under Israeli law, thereby requiring us to pay Mr. Bar $7,408, in addition to releasing the $57,870 in his severance payment fund. In addition, Mr. Bar would be entitled to receive his full severance payment under Israeli law, including the total amount contributed to and accumulated in his severance payment fund, if he retires from our company at or after age 67.

We are entitled to terminate Mr. Bar's employment immediately at any time for "cause" (as such term is defined in the agreement and the Israeli Severance Payment Act 1963), upon which, after meeting certain requirements under the applicable law and recent Israeli Labor court requirements, we believe we will have no further obligation to compensate Mr. Bar.

In addition, pursuant to terms contained in Mr. Bar's stock option award agreement, in the event of a change of control of our company, the stock options granted to Mr. Bar that were unvested will vest immediately upon such change of control if such stock options are not assumed or substituted by the surviving company. Also, upon termination of Mr. Bar's employment for any reason, we will compensate him for all unused vacation days accrued.

Vice President of Sales of InspireMD Ltd. Subject to certain conditions, either party to our consultancy agreement with Ms. Paz may terminate the agreement without "cause" (as such term is defined in her consultancy agreement) upon at least 30 days prior written notice to the other party. During such notice period, we will continue to compensate Ms. Paz according to her consultancy agreement and Ms. Paz will be obligated to continue to discharge and perform all of her duties and obligations under her consultancy agreement, and to cooperate with us and use her best efforts to assist with the integration of any persons that we have delegated to assume Ms. Paz's responsibilities. We believe that our severance arrangement with Ms. Paz will assist us in achieving a successful transition upon Ms. Paz's departure. Ms. Paz is entitled to terminate her employment with us in the event that we do not fulfill our undertakings under our agreement, upon at least 30 days prior notice to us, during which time we may cure the breach. During such notice period, we will continue to compensate Ms. Paz according to her agreement and Ms. Paz will be obligated to continue to discharge and perform all of his duties and obligations under the agreement.

In addition, pursuant to terms contained in Ms. Paz's stock option award agreement, in the event of a change of control of our company, the stock options granted to Ms. Paz that were unvested will vest immediately upon such change of control if such stock options are not assumed or substituted by the surviving company.

We are entitled to terminate Ms. Paz's employment immediately at any time for any reason, upon which we believe we will have no further obligation to compensate Ms. Paz under her consultancy agreement or Israeli law, except as provided above.

The following tables show, as of December 31, 2011, potential payments to our named executive officers for various scenarios involving a resignation, termination, change of control, retirement, death or disability, using, where applicable, the closing price of our common stock of $2.18 (as reported on the OTC Bulletin Board as of December 30, 2011). Compensation amounts to be paid in non-U.S. currency have been converted into U.S. dollars using 3.821 NIS per dollar, which was the exchange rate as of December 31, 2011.

Type of Event	Voluntary Resignation Upon Breach By Us	Voluntary Resignation	Termination for Cause	Termination Not for Cause	Death	Disability	Termination Not for Cause in Connection with a Change of Control	Change of Control (No Termination)
Ofir Paz								
Employment agreement payments	$20,625(1)	$123,750(2)	—	$123,750(2)	—	—	$123,750 (2)	—
Severance payments(3)	$1,199	$1,199	—	$1,199	$1,199	$1,199	$1,199	—
Accrued vacation payments(4)	$56,336	$56,336	$56,336	$56,336	$56,336	$56,336	$56,336	—
Value of accelerated options	—	—	—	—	—	—	—	—
Craig Shore								
Employment agreement payments	$12,719(5)	$12,719 (5)	—	$12,719 (5)	—	—	$76,312 (2)	—

Severance payments	$8,474 (6)	$8,474 (6)	—	$10,967 (7)	$10,967 (7)	$10,967 (7)	$10,967 (7)	—
Accrued vacation payments(4)	$7,495	$7,495	$7,495	$7,495	$7,495	$7,495	$7,495	—
Value of accelerated options	—		—	—	—	—	$231,307.90 (8)	$231,307.90 (9
Asher Holzer								
Employment agreement payments	$20,895 (1)	$125,370 (2)	—	$125,370 (2)	—	—	$125,370 (2)	—
Severance payments(3)	$1,199	$1,199	—	$1,199	$1,199	$1,199	$1,199	—
Accrued vacation payments(4)	$51,022	$51,022	$51,022	$51,022	$51,022	$51,022	$51,022	—
Value of accelerated options	—	—	—	—	—	—	—	—
Eli Bar								
Employment agreement payments	$25,674 (10)	$25,674 (10)	—	$25,674 (10))	—	—	$25,674 (10)	—
Severance payments	—	—	—	$65,278 (7)	$65,278 (7)	$65,278 (7)	$65,278 (7)	—
Accrued vacation payments(4)	$36,720	$36,720	$36,720	$36,720	$36,720	$36,720	$36,720	—
Value of accelerated options	—		—	—	—	—	$751,736 (11)	$751,736 (
Sara Paz								
Consultancy agreement payments	$13,852 (5)	$13,852 (5)	—	$13,852 (5)	—	—	$13,852 (5)	—
Severance payments	—	—	—	—	—	—	—	—
Accrued vacation payments	—	—	—	—	—	—	—	—
Value of accelerated options	—	—	—	—	—	—	$248,353 (14)	$248,353 (

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(1) Represents total compensation for 30 days, during which we are permitted to cure our breach of the agreement. During such notice period, we will continue to compensate the officer according to his agreement and the officer will be obligated to continue to discharge and perform all of his duties and obligations under the agreement. The officer would also have the option to terminate his employment voluntarily and remain with us for 180 days, during which time we will continue to compensate the officer according to his agreement and the officer will be obligated to continue to discharge and perform all of his duties and obligations under the agreement.

(2) Represents total compensation for 180 days, during which time we will continue to compensate the officer according to his agreement and the officer will be obligated to continue to discharge and perform all of his duties and obligations under the agreement.

(3) Represents the total amount that has been contributed to and accumulated in his severance payment fund.

(4) Pursuant to Israeli law, the value of a vacation day is equal to gross salary divided by 22 working days per month.

(5) Represents total compensation for 30 days, during which time we will continue to compensate the officer according to his or her agreement and the officer will be obligated to continue to discharge and perform all of his or her duties and obligations under the agreement.

(6) Represents the total amount that has been contributed to and accumulated in his severance payment fund, to be paid pursuant to his employment agreement.

(7) Represents the total amount to be paid under Israeli law in the event of termination not for cause, calculated based upon the officer's monthly salary as of December 30, 2011, multiplied by his years of employment with us.

(8) Represents the vesting of options to purchase 243,482 shares of our common stock, multiplied by the difference between the exercise price of $1.23 and the closing price of our common stock of $2.18 (as reported on the OTC Bulletin Board as of December 30, 2011), which shall occur upon termination of Mr. Shore's employment within one year of a change of control.

(9) Assumes that such stock options are not assumed or substituted by the surviving company and represents the vesting of options to purchase 243,482 shares of our common stock, multiplied by the difference between the exercise price of $1.23 and the closing price of our common stock of $2.18 (as reported on the OTC Bulletin Board as of December 30, 2011).

(10) Represents total compensation for 60 days, during which time we will continue to compensate the officer according to his agreement and the officer will be obligated to continue to discharge and perform all of his duties and obligations under the agreement.

(11) Assumes that such stock options are not assumed or substituted by the surviving company and represents the sum of the vesting of options to purchase 304,353 shares of our common stock, multiplied by the difference between the exercise price of $0.001 and the closing price of our common stock of $2.18 (as reported on the OTC Bulletin Board as of December 30, 2011), the vesting of options to purchase 40,580 shares of our common stock, multiplied by the difference between the exercise price of $1.23 and the closing price of our common stock of $2.18 and the vesting of options to purchase 200,000 shares of our common stock, multiplied by the difference between the exercise price of $1.93 and the closing price of our common stock of $2.18.

(12) Assumes that such stock options are not assumed or substituted by the surviving company and represents the vesting of options to purchase 365,225 shares of our common stock, multiplied by the difference between the exercise

price of $1.50 and the closing price of our common stock of $2.18 (as reported on the OTC Bulletin Board as of December 30, 2011).

Director Compensation

The following table shows information concerning the directors of InspireMD Ltd., other than Ofir Paz and Asher Holzer, through March 31, 2011.

Name	Fees Earned or Paid in Cash ($)	Option Awards(1) ($)	All Other Compensation ($)	Total ($)
David Ivry(2)	4,269	-	-	4,269
Robert Fischell(2)	5,292	-	-	5,292
Fellice Pelled (2)	4,716	-	-	4,716

(1) The amounts in this column reflect the dollar amounts recognized for financial statement reporting purposes with respect to the year ended December 31, 2010, in accordance with FASB ASC Topic 718. Fair value is based on the Black-Scholes option pricing model using the fair value of the underlying shares at the measurement date. For additional discussion of the valuation assumptions used in determining stock-based compensation and the grant date fair value for stock options, see “Management’s Discussion and Analysis of Financial Condition and Results of Operation — Critical Accounting Policies—Share-Based Compensation” and Note 2—“Significant Accounting Policies” and Note 11—“Share-Based Compensation” of the Notes to the Consolidated Financial Statements for Two Years Ended December 31, 2010 and Note 7—Fair Value Measurement” of the Notes to the Condensed Consolidated Financial Statements for the Nine months ended September 30, 2011 included herein.

(2) Each of David Ivry, Robert Fischell and Fellice Pelled resigned as directors of InspireMD, Ltd. on March 31, 2011. Pursuant to the terms of the directors’ vested options, the vested options expired thirty days after the directors’ resignations. However, in connection with their resignation, we granted Mr. Ivry and Mr. Pelled replacement options. As of December 31, 2011, the following directors owned the following number of outstanding options to purchase common stock: David Ivry (162,322) and Fellice Pelled (162,322).

Through March 31, 2011, other than Mr. Paz and Dr. Holzer, we previously paid each director $330 per meeting for each board meeting attended and $1,230 for each quarter served on the board of directors.

The following table shows information concerning our directors other than Mr. Paz and Dr. Holzer, during the fiscal year ended December 31, 2011.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards(1) ($)	All Other Compensation ($)	Total ($)
Sol J. Barer, Ph.D.	-	5,655,000(2)	4,783,659	-	10,438,659
Paul Stuka	-	-	111,344	-	111,344
Eyal Weinstein	-	-	27,836	-	27,836

(1) The amounts in this column reflect the dollar amounts recognized for financial statement reporting purposes with respect to the year ended December 31, 2010, in accordance with FASB ASC Topic 718. Fair value is based on the Black-Scholes option pricing model using the fair value of the underlying shares at the measurement date. For additional discussion of the valuation assumptions used in determining stock-based compensation and the grant date fair value for stock options, see “Management’s Discussion and Analysis of Financial Condition and Results of Operation — Critical Accounting Policies—Share-Based Compensation” and Note 2—“Significant Accounting Policies” and Note 11—“Share-Based Compensation” of the Notes to the Consolidated Financial Statements for Two Years Ended December 31, 2010 and Note 7—Fair Value Measurement” of the Notes to the Condensed Consolidated Financial Statements for the Nine months ended September 30, 2011 included herein.

(2) On November 16, 2011, in connection with his appointment as chairman of our board of directors, we issued Dr. Barer 2,900,000 shares of our common stock, all of which were immediately vested. The fair market value was $1.95 per share.

We do not currently provide cash compensation to our directors for acting as such, although we may do so in the future. We reimburse our directors for reasonable expenses incurred in connection with their service as directors. In addition, in 2011, we made the following option grants to the following directors. Each grant was made under the InspireMD, Inc. 2011 UMBRELLA Option Plan, unless otherwise noted.

Name	Shares Subject to Options	Exercise Price	Vesting Schedule	Expiration	Fair Market Value on Grant Date
Sol J. Barer, Ph.D.	1,000,000(1)(2)	$1.50	Fully vested upon grant.	September 30, 2011(3)	$1,000,255
	500,000(2)	$2.50	One-half annually in 2012 and 2013 on the anniversary of the date of grant, provided that if Dr. Barer is	July 11, 2021	$709,997

		(i) not reelected as a director at our 2012 annual meeting of stockholders, or (ii) not nominated for reelection as a director at our 2012 annual meeting of stockholders, the option vests and becomes exercisable on the date of such failure to be reelected or nominated.

1,450,000(1)(4)	$1.95	In substantially equal monthly installments (with any fractional shares vesting on the last vesting date) on the last business day of each calendar month over a two year period from the date of grant, with the first installment vesting on November 30, 2011, provided that Dr. Barer is still providing services to us in some capacity as of each such vesting date.	November 16, 2021	$1,536,703
725,000(1)	$1.95	Upon the date we become listed on a registered national securities exchange (such as the New York Stock Exchange, NASDAQ Stock Market, or the NYSE Amex), provided that such listing occurs on or before December 31, 2012, and provided further that Dr. Barer is still providing services to us in some capacity as of such vesting date.	November 16, 2021	$768,352
725,000(1)(4)	$1.95	Upon the date that we receive research coverage	November 16, 2021	$768,352

	from at least two investment banks that ranked in the top 20 investment banks in terms of underwritings as of their most recently completed fiscal year, and/or leading analysts, as ranked by either the Wall Street Journal, the Financial Times, Zacks Investment Research or Institutional Investor, provided that we receive such coverage on or before December 31, 2012, and, provided further that Dr. Barer is still providing services to us in some capacity as of such vesting date.

Paul Stuka	100,000(2)	$1.95	One-third annually in 2012, 2013 and 2014 on the anniversary of the date of grant, provided that if Mr. Stuka is (i) not reelected as a director at our 2012 annual meeting of stockholders, or (ii) not nominated for reelection as a director at our 2012 annual meeting of stockholders, the option vests and becomes exercisable on the date of such failure to be reelected or nominated.	August 8, 2021	$111,344
Eyal Weinstein	25,000(2)	$1.95	One-third annually in 2012, 2013 and 2014 on the anniversary of the date of grant, provided that if Mr. Weinstein is required to resign from the board due to medical reasons, the option vests and becomes exercisable on the date of Mr. Weinstein's resignation for medical reasons.	August 8, 2021	$27,836

(1) This option was issued outside the InspireMD, Inc. 2011 UMBRELLA Option Plan.

(2) This option was granted in connection with the appointment of this person to our board of directors.

(3) This option was exercised in full by Dr. Barer on September 28, 2011.

(4) This option was granted to Dr. Barer in connection with his appointment as chairman of our board of directors on November 16, 2011.

In addition to the foregoing, on November 16, 2011, in connection with his appointment as chairman of our board of directors, we issued Dr. Barer 2,900,000 shares of our common stock, all of which were immediately vested.

In addition to the foregoing, on January 30, 2012, in connection his appointment to our board of directors, we issued James Barry, Ph.D. an option to purchase 100,000 shares of our common stock, which will vest one-third annually in 2013, 2014 and 2015 on the anniversary of the date of grant, provided that if Dr. Barry is (i) not reelected as a director at our 2014 annual meeting of stockholders, or (ii) not nominated for reelection as a director at our 2014 annual meeting of stockholders, the option vests and becomes exercisable on the date of such failure to be reelected or nominated.

Directors' and Officers' Liability Insurance

We currently have directors' and officers' liability insurance insuring our directors and officers against liability for acts or omissions in their capacities as directors or officers, subject to certain exclusions. Such insurance also insures us against losses which we may incur in indemnifying our officers and directors. In addition, we have entered into indemnification agreements with key officers and directors and such persons shall also have indemnification rights under applicable laws, and our certificate of incorporation and bylaws.

Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2011, Messrs. Stuka and Weinstein and Dr. Barer served on our compensation committee. We established our compensation committee during the fiscal year ended December 31, 2011. Prior to that, we did not have a compensation committee and during such period, Ofir Paz, our chief executive officer, and Asher Holzer, our president and former chairman, participated in deliberations of the board of directors concerning executive officer compensation. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Compensation Committee Report

The compensation committee has reviewed and discussed the Compensation Discussion and Analysis with the members of our management and, based on such review and discussions, the compensation committee recommended to the board of directors that the Compensation Discussion and Analysis be included in this Annual Report on Form 10-K.

COMPENSATION COMMITTEE
Eyal Weinstein, Chairman
Paul Stuka
Sol J. Barer