

InspireMD, Inc.  
Form 8-K  
April 06, 2011

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

---

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

---

Date of Report (Date of earliest event reported): March 31, 2011

InspireMD, Inc.  
(Exact Name of Registrant as Specified in Charter)

Delaware  
(State or other  
jurisdiction  
of incorporation)

333-162168  
(Commission File  
Number)

26-2123838  
(IRS Employer  
Identification No.)

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

N/A  
(Zip Code)

Registrant's telephone number, including area code: 972-3-6917691

(Former name or former  
address, if changed since  
last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))



Item 2.01 Completion of Acquisition or Disposition of Assets.

Share Exchange

On December 29, 2010, InspireMD, Inc., a Delaware corporation (formerly known as Saguaro Resources, Inc.) (the “Company”) entered into a Share Exchange Agreement (the “Exchange Agreement”) by and among the Company and InspireMD Ltd., a company incorporated under the laws of the State of Israel (“InspireMD”). Subsequent to the date of execution of the Exchange Agreement, shareholders of InspireMD, holding 91.7% of InspireMD’s issued and outstanding ordinary shares, executed a joinder to the Exchange Agreement and became parties thereto (the “InspireMD Shareholders”). Pursuant to the Exchange Agreement, on March 31, 2011, the InspireMD Shareholders transferred all of their ordinary shares in InspireMD to the Company in exchange for 46,471,907 newly issued shares of common stock of the Company. In addition, the remaining holders of InspireMD’s ordinary shares separately transferred all of their ordinary shares of InspireMD to the Company, in exchange for an aggregate of 4,194,756 newly issued shares of common stock of the Company. As a result of these share exchanges, InspireMD became a wholly owned subsidiary of the Company.

Pursuant to the terms and conditions of the Exchange Agreement:

- The InspireMD Shareholders transferred 5,725,962 ordinary shares of InspireMD (which represented 91.7% of InspireMD’s issued and outstanding capital stock immediately prior to the closing of the Share Exchange) to the Company in exchange for 46,471,907 shares of the Company’s common stock. Separately, the holders of 516,792 ordinary shares of InspireMD transferred such shares to the Company in exchange for 4,194,756 shares of the Company’s common stock (collectively, the “Share Exchange”).
- The Company assumed all of InspireMD’s obligations under InspireMD’s outstanding stock options. Immediately prior to the Share Exchange, InspireMD had outstanding stock options to purchase an aggregate of 937,256 shares of its ordinary shares, which outstanding options became options to purchase an aggregate of 7,606,770 shares of common stock of the Company after giving effect to the Share Exchange. Neither the Company nor InspireMD had any other options to purchase shares of capital stock outstanding immediately prior to the closing of the Share Exchange.
- Three-year warrants to purchase up to 125,000 ordinary shares of InspireMD at an exercise price of \$10 per share were assumed by the Company and converted into warrants to purchase 1,014,500 shares of the Company’s common stock at an exercise price of \$1.23 per share.
- Lynn Briggs resigned as the sole officer and director of the Company, and simultaneously with the Share Exchange, a new board of directors and new officers were appointed for the Company. The Company’s new board of directors consists of Ofir Paz and Asher Holzer. In addition, immediately following the Share Exchange, the Company appointed Ofir Paz as its chief executive officer, Asher Holzer as its president and chairman of the board of directors, and Craig Shore as its chief financial officer, secretary and treasurer.

In connection with the closing of the Share Exchange, the Company sold 6,454,002 shares of its common stock at a purchase price of \$1.50 per share and five-year warrants to purchase up to 3,226,999 shares of common stock at an exercise price of \$1.80 per share in a private placement to accredited investors (the "Private Placement"). As part of the Private Placement, certain holders of the 8% convertible debentures, in an aggregate principal amount of \$1,580,000 (the "Bridge Notes"), surrendered \$667,596 of outstanding principal and interest due under such Bridge Notes in exchange for 445,064 shares of common stock and warrants to purchase an aggregate of 225,532 shares of common stock (the "Debt Conversions"). As a result, the Company received aggregate cash proceeds of \$9,013,404 in the Private Placement. The Company, however, permitted one investor in the Private Placement to deliver only \$1,000,000 of its \$2,000,000 subscription amount to the Company, so long as such investor agreed to deliver the additional \$1,000,000 on or prior to April 15, 2011. The unfunded subscription amount for this investor is not included in the amounts listed above. In addition, as a result of the Debt Conversions, there was \$1,000,000 of unpaid principal outstanding under the Bridge Notes, which notes were assumed by the Company with the maturity date being extended to May 15, 2011.

Palladium Capital Advisors, LLC served as the Company's placement agent in the Private Placement and received a fee of \$285,813.50, expenses reimbursement of \$15,000 and was issued a five-year warrant to purchase 373,740 shares of our common stock, at an initial exercise price of \$1.80 per share, with terms identical to the warrants issued to investors in the Private Placement.

Immediately following the closing of the Share Exchange and the Private Placement, under the terms of an Agreement of Conveyance, Transfer and Assignment of Assets and Assumption of Obligations (the "Conveyance Agreement"), the Company transferred all of its pre-Share Exchange assets and liabilities to its wholly owned subsidiary, Saguaro Holdings, Inc., a Delaware corporation ("SplitCo"). Thereafter, pursuant to a stock purchase agreement (the "Stock Purchase Agreement"), the Company transferred all of the outstanding capital stock of SplitCo to Lynn Briggs in exchange for certain indemnifications, waivers and releases, along with the cancellation of an aggregate of 7,500,000 shares of the Company's common stock held by Lynn Briggs (the "Split-Off"), leaving 6,000,000 shares of the Company's common stock outstanding held by persons who were stockholders of the Company prior to the Share Exchange.

In connection with the Share Exchange, the Company also entered into a stock escrow agreement with certain stockholders and Grushko & Mittman, P.C. (the "Stock Escrow Agent"), pursuant to which these stockholders deposited 1,500,000 shares of common stock held by them with the Stock Escrow Agent, which shares shall be released to the Company for cancellation or surrender to an entity designated by the Company should the Company record at least \$10 million in consolidated revenue, as certified by the Company's independent auditors, during the first 12 months following the closing of the Private Placement, yet fail, after a good faith effort, to have the Company's common stock approved for listing on a national securities exchange. On the other hand, should the Company fail to record at least \$10 million in consolidated revenue during the first 12 months following the closing of the Private Placement or have its common stock listed on a national securities exchange within 12 months following the closing on the Private Placement, these escrowed shares shall be released back to the stockholders.

The foregoing description of the Share Exchange and related transactions does not purport to be complete and is qualified in its entirety by reference to the complete text of the (i) Exchange Agreement, which is filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 5, 2011, (ii) the Conveyance Agreement, which is filed as Exhibit 10.3 hereto and (iii) the Stock Purchase Agreement, which is filed as Exhibit 10.4 hereto, each of which is incorporated herein by reference.

The foregoing description of the Private Placement and related transactions does not purport to be complete and is qualified in its entirety by reference to the complete text of the (i) Securities Purchase Agreement, which is filed as Exhibit 10.5 hereto and (ii) the Form of \$1.80 Warrant, which is filed as Exhibit 10.6 hereto, each of which is incorporated herein by reference.

Following (i) the closing of the Share Exchange, (ii) the closing of the Private Placement for \$9,013,404, (iii) the conversion of \$667,596 of the Bridge Notes and (iv) the cancellation of 7,500,000 shares of the Company's common stock in the Split-Off, there were 63,120,665 shares of common stock of the Company issued and outstanding. Approximately 80.3% of such issued and outstanding shares were held by the InspireMD Shareholders, approximately 9.5% were held by the Company's stockholders prior to the Share Exchange and approximately 10.2% were held by the investors in the Private Placement. The foregoing percentages exclude options to purchase up to 9,468,100 shares of common stock reserved for issuance under the Company's equity incentive plan and warrants and other options to purchase up to 7,939,925 shares of common stock (see "Description of Capital Stock").

The shares of the Company's common stock issued to the InspireMD Shareholders in connection with the Share Exchange and the shares of common stock issued to the investors in the Private Placement were not registered under the Securities Act of 1933, as amended (the "Securities Act"), in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act and Regulation D promulgated under that section, which exempts transactions by an issuer not involving any public offering. These securities may not be offered or sold in the U.S. absent registration or an applicable exemption from the registration requirements. Certificates representing these shares contain a legend stating the restrictions applicable to such shares.

Changes to the Business. The Company intends to carry on InspireMD's business as its sole line of business. The Company has relocated its executive offices to 3 Menorat Hamor St. Tel Aviv, Israel and its telephone number is 972-3-6917691.

Changes to the Board of Directors and Executive Officers. Upon the closing of the Share Exchange, the size of the Company's board of directors was increased from one director to two directors, Lynn Briggs resigned as the sole officer and director of the Company and Ofir Paz and Asher Holzer were appointed to the Company's board of directors. Following the Share Exchange, Ofir Paz was appointed as the Company's chief executive officer, Asher Holzer was appointed as the Company's president and chairman of the board of directors, and Craig Shore was appointed as the Company's chief financial officer, treasurer and secretary.

All directors hold office for three-year terms until the election and qualification of their successors. Officers are elected by the board of directors and serve at the discretion of the board.

Accounting Treatment. The Share Exchange is being accounted for as a recapitalization. InspireMD is the acquirer for accounting purposes and, consequently, the assets and liabilities and the historical operations that are reflected in the financial statements herein are those of InspireMD and will be recorded at the historical cost basis of InspireMD.

Tax Treatment. The Share Exchange is intended to constitute a tax-deferred exchange of property governed by Section 351 of the United States Internal Revenue Code of 1986, as amended (the "Code"), or such other tax free reorganization or restructuring provisions as may be available under the Code. Any gain required to be recognized will be subject to regular individual or corporate federal income taxes, as the case may be.

#### Description of Our Company

The Company was incorporated on February 29, 2008 in the State of Delaware to engage in the acquisition, exploration and development of natural resource properties. On March 28, 2011, the Company effectuated a 1-for-3

forward stock split and changed its name from “Saguaro Resources, Inc.” to “InspireMD, Inc.” Immediately following the Share Exchange, the assets and liabilities of the Company that existed prior to the Share Exchange were disposed of pursuant to the Split-Off. In addition, following the Share Exchange, the Company succeeded to the business of InspireMD as its sole line of business.

## Description of Our Business

As used in this Current Report on Form 8-K, all references to “we,” “our” and “us” for periods prior to the closing of the Share Exchange refer to InspireMD Ltd., and for periods subsequent to the closing of the Share Exchange refer to InspireMD, Inc. and its direct and indirect subsidiaries (including InspireMD Ltd).

### Overview

We are an innovative medical device company focusing on the development and commercialization of our proprietary stent platform technology, MGuard™. MGuard™ provides embolic protection in stenting procedures by placing a micron mesh sleeve over a stent (see photograph below of an MGuard™ Stent). Our initial products are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). Of patients with acute myocardial infarction and saphenous vein graft coronary interventions, approximately 15% and 43%, respectively, 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. In clinical trials conducted in Europe and Latin America, MGuard™ has demonstrated a substantial advantage in efficacy and safety over other existing solutions, principally bare-metal stents and drug-eluting stents.

### MGuard™ 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 EU 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 are in the process of replacing 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™ refers to both our initial products and MGuard Prime™ as applicable.

InspireMD is incorporated as a limited company under the laws of the State of Israel and principally based in Tel Aviv, Israel. InspireMD was formed and began operations in 2005. InspireMD became a subsidiary of InspireMD, Inc., a Delaware corporation, on March 31, 2011, as a result of the Share Exchange. In addition, we operate through Inspire MD GmbH, our subsidiary in Germany, where we manufacture our stents by way of a sub-contractor agreement.

#### Our Industry

According to a 2007 World Health Organization report, approximately 7.2 million people worldwide died of coronary heart disease in 2002. 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 CABG 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.

The market for coronary stents is one of the fastest growing markets in the medical devices industry. 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. The percutaneous coronary intervention procedures involving drug-eluting stents are being increasingly used to treat complex coronary artery diseases with an almost 65% penetration rate in 2009.



## Our Products

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

### MGuard™ Deployed in Artery

The protective sleeve provides several clinical benefits:

- given its wide surface coverage of the stent, the mesh diffuses the pressure and the impact on deployment exerted by the stent on the arterial wall and reduces the injury to the vessel and the rate of restenosis;
- it prevents plaque dislodgement and blocks debris from entering the bloodstream during and post procedure (called embolic showers);
- when drug coated, the mesh delivers better coverage and uniform drug distribution on the arterial wall and therefore should reduce the dosage of the active ingredient when compared to approved drug-eluting stents on the market;
- it promotes smooth and stable endothelial cell growth, which is essential for prompt healing and reduces the risk of cell detachment that causes late thrombosis; and
- it maintains the standards of a conventional stent and therefore should require little to no additional training by doctors.

### MGuard™ – Coronary Applications

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

MGuard™ Coronary and MGuard Prime™ with a bio-stable mesh. Our first MGuard™ product, the MGuard™ Coronary with a bio-stable mesh, is comprised of our mesh sleeve wrapped around a 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 MGuard™ Coronary and MGuard Prime™ with a bio-stable mesh reduce the rate of restenosis and provide protection from embolic showers. In comparison to a standard drug-eluting stent, we believe the MGuard™ Coronary and MGuard Prime™ with a bio-stable mesh are more cost effective, as they eliminate the need for anti-platelet drugs such as Plavix, and reduce the risk of late thrombosis.

MGuard™ Coronary with a drug eluting mesh. We anticipate that the MGuard™ Coronary with a drug-eluting mesh will offer an enhanced clinical profile compared to existing drug-eluting stents. We expect that it will provide enhanced bio-absorbability in comparison to current drug-eluting stents, and more even and uniform drug therapy management. Therefore, once the sleeve is drug infused, the drug would be distributed more uniformly on the vessel wall. Consequently, the total dosage of the medication potentially can be reduced while increasing its efficacy. MGuard™ Coronary with a drug-eluting 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 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.

#### MGuard™ – Carotid Applications

We intend to market our mesh sleeve coupled with a self-expandable stent (a stent that expands without dilation pressure or need of an inflation balloon) for use in carotid applications. According to leading surgeons, embolic protection is critical in all carotid procedures. We believe that our MGuard™ design will provide substantial advantages over existing therapies in treating carotid artery stenosis (blockage or narrowing of the carotid arteries), like conventional carotid stenting and endarterectomy (surgery to remove blockage) given the superior embolic protection characteristics witnessed in coronary arterial disease applications. In addition, we believe that MGuard™ Carotid will provide post-procedure protection against embolic dislodgement, which can occur immediately after a carotid stenting procedure and is often a source of post-procedural strokes. Studies have also shown that approximately half of the incidents of embolic showers associated with carotid stenting occur immediately post-procedure.

#### MGuard™ – Peripheral Applications

We intend to market our mesh sleeve coupled with a self-expandable stent (a stent that expands without dilation pressure or need of an inflation balloon) for use in peripheral applications. Peripheral Artery Disease (“PAD”), also known as peripheral vascular disease, is usually characterized by the accumulation of plaque in arteries in the legs and resulting in strokes, heart attacks, need for amputation of affected joints or even death, when untreated. PAD 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 PAD market consists of three segments: Aortic Aneurysm, Renal, Iliac and Biliary, 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 Biliary 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 MGuard™ design will provide substantial advantages over existing therapies in treating peripheral artery stenosis (blockage or narrowing of the peripheral arteries).

## Product Development and Critical Milestones

Below is a list of the products described above and our projected critical milestones with respect to each. As used below, “Q” stands for our fiscal quarter. While we currently anticipate seeking approval from the U.S. Food and Drug Administration (the “FDA”) for all of our products in the future, we have only outlined a timetable to seek FDA approval for our MGuard™ Coronary plus with bio-stable mesh product in our current business plan.

Product	Indication	Start Development	CE Mark	EU Sales	FDA Approval	U.S. Sales
MGuard™ Coronary Plus Bio-Stable Mesh	Bypass/ Coronary	2005	Oct. 2007	Q1-2008	Q2-2014	Q3-2014
MGuard™ Peripheral Plus Bio-Stable Mesh	Peripheral Arteries	Q1-2011	Q3-2011	Q4-2011	Not applicable	Not applicable
MGuard™ Carotid Plus Bio-Stable Mesh	Carotid Arteries	Q1-2011	Q1-2011	Q2-2011	Not applicable	Not applicable
MGuard™ Coronary Plus Bio-Absorbable Drug-Eluting Mesh	Bypass/ Coronary	Q1-2013	Q3-2016	Q4-2016	Not applicable	Not applicable

## Pre-Clinical Studies

We performed laboratory and animal testing as well as supportive human clinical trials prior to submitting an application for CE Mark approval for our MGuard™ Coronary with bio-stable mesh. We also performed all CE Mark required mechanical testing of the stent. We conducted pre-clinical trials at Harvard and MIT Biomedical Engineering Center BSET lab in 2005 and 2006. In these trials, on average, the MGuard™ Coronary with bio-stable mesh resulted in a 7.5% lower restenosis rate than control bare-metal stents and generally had more effective and safer results. Analysis also indicated that the mesh produced lower levels of inflammation than standard bare metal stents. The table below describes our completed and planned pre-clinical trials.

Product	Stent Platform	Approval Requirement	Start of Study	End of Study
MGuard™ Coronary	Bare-Metal Stent Plus Bio-Stable Mesh	CE Mark (EU+Rest of World)	Q4-2006	Q3-2007
	Drug-Eluting Mesh (Bare-Metal Stent Plus Drug-Eluting Mesh)	CE Mark (EU+ Rest of World ) FDA (U.S.)	Q1-2011 Q4-2012	Q2-2011 Q4-2014
	Cobalt-Chromium Stent Plus Bio-Stable Mesh	FDA	Q1-2011	Q4-2011
MGuard™ Peripheral/Carotid	Self Expanding System Plus Mesh	CE Mark (EU+ Rest of World )	Q1-2011	Q3-2011
MGuard™ Carotid	Self Expanding System Plus Mesh	FDA (U.S.)	Peripheral information on animals can be used	

#### Clinical Trials

The table below describes our completed and planned clinical trials.

Product	Stent Platform	Clinical Trial Sites	Follow-up Requirement	Objective	No. of Patients	Study Status		End of Study
						Start	End Enrollment	
		Germany – two sites	12 months	Study to evaluate safety and performance of MGuard™ system	41	Q4-2006	Q4- 2007	Q2-2008
		Brazil – three sites	12 months		30	Q4-2007	Q1-2008	Q2-2009
		Poland – four sites	6 months		60	Q2-2008	Q3-2008	Q2-2009
		International MGuard™ Observational Study - Europe - 50 sites	12 months		1,000	Q1-2008	Q4-2008	Q4-2010
	Bare-Metal Stent Plus Bio-Stable Mesh	International MGuard™ Observational Study - Israel - 10 sites	6 months		100	Q2-2008	Q4-2009	Q1-2010
		Master randomized control trial -	8-12 months		410	Q1-2011	Q4-2011	Q4-2012

Edgar Filing: InspireMD, Inc. - Form 8-K

	7 countries, 40 centers in Latin America and Europe						
	FDA Study - 40 sites, U.S. and out of U.S.	12 month	Pilot study to evaluate safety and performance of MGuard™ system for FDA and CE Mark approval	580	Q1-2012	Q3-2013	Q4-2013
	South America and Europe – 10 sites	8-12 months	Pilot study to evaluate safety and performance of	500	Q2-2011	Q2-2012	Q1-2013
Drug-Eluting Stent (Bare-Metal Stent + Drug Eluting Mesh)	U.S. – 50 sites	12 months	MGuard™ system for FDA and CE Mark approval	2,000	Q1-2013	Q1-2014	Q4-2014
	Rest of World as a registry study	8-12 months	Evaluation of safety and efficacy for specific indications	400	Q2-2011	Q4-2011	Q4-2012

Product	Stent Platform	Clinical Trial Sites	Follow-up Requirement	Objective	Study Status			
					No. of Patients	Start	End Enrollment	End of Study
MGuard™ Peripheral	Self Expanding System + Mesh	South America and Europe – four sites	12 months	Pilot study to evaluate safety and performance of MGuard™ system for FDA and CE Mark approval	50	Q3-2011	Q3-2012	Q4-2014
		South America and Europe – six sites	6 months		150	Q2-2010	Q4-2010	Q2-2011
		U.S. – 50 sites	6-8 months		500	Q3-2011	Q4-2012	Q2-2013
MGuard™ Carotid	Self Expanding System + Mesh	Rest of World as a registry study	6 months	Evaluation of safety and efficacy for specific indications	200	Q3-2010	Q3-2011	Q1-2012

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

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

Our clinical trials in Brazil and Poland were conducted under leading cardiologists. Our 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 MGuard™ Coronary with bio-stable mesh when used in STEMI patients where percutaneous coronary intervention is the primary line of therapy. Perfect blood flow in the artery was achieved in 90% of patients, perfect blood flow into the heart muscle was achieved in 73% of patients and complete 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 1.7%.



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

Our ongoing observation study in Europe is an open registry launched in the first fiscal quarter of 2009. This registry is expected to enroll up to 1,000 patients and is aimed at establishing the performance of MGuard™ Coronary with bio-stable mesh in a “real world” population. To date, the primary countries to join are Austria, Czech Republic and Hungary. The primary endpoint that this registry will evaluate is the occurrence of major adverse cardiac events at six months following deployment of the stent, and the clinical follow-up will continue for a period of up to one year per patient. As of February 28, 2011, 632 patients of the prospective 1,000 have been enrolled in 18 sites.

Our ongoing observational study in Israel is an open registry launched in the fourth fiscal quarter of 2009. This registry is expected to enroll up to 100 patients. The purpose of this study is to support local Israeli regulatory approval. The primary endpoint that this registry will evaluate is the occurrence of major adverse cardiac events at 30 days following deployment of the stent, and the clinical follow-up will be conducted at six months following deployment of the stent. As of February 28, 2011, 62 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 28, 2011, 3 patients of the prospective 500 have been enrolled.

#### Comparison of Clinical Trial Results to Date with Results Achieved Using Bare Metal Stents Alone

We conducted a meta-analysis of data from the completed trials in Germany, Brazil and Poland and the worldwide registry with respect to saphenous vein graft and STEMI patients in comparison to data contained in published reports on regular bare-metal stent performance in comparable patients. Our meta-analysis included data from the following trials:

- CADILLAC trial; Stone GW, Grines CL, Cox DA, et al., Comparison of angioplasty with stenting, with or without abciximab, in acute myocardial infarction. Published in the New England Journal of Medicine in 2002 (346(13), pages 957-66).
- TYPHOON trial; Spaulding C, Henry P, Teiger E, et al., Sirolimus-eluting versus uncoated stents in acute myocardial infarction. Published in the New England Journal of Medicine in 2006 (355(11), pages 1093-104).
- HORIZONS-AMI trial; Mehran R, Lansky AJ, Witzenbichler B, et al., Bivalirudin in patients undergoing primary angioplasty for acute myocardial infarction (HORIZONS-AMI): 1-year results of a randomised controlled trial. Published in Lancet in 2009 (374(9696), pages 1149-59).
- HORIZONS-AMI trial ; Stone GW, Witzenbichler B, Guagliumi G, et al., Bivalirudin during primary PCI in acute myocardial infarction. Published in the New England Journal of Medicine in 2008 (358(21), pages 2218-30).
- TAPAS trial; Svilaas T, van der Horst IC, Zijlstra F. Thrombus, Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS)--study design. Published in the American Heart Journal in 2006 (151(3), pages 597 e1- e7).

The results of this meta-analysis are described below.



In the STEMI group, perfect blood flow in the artery was reached in 95% of MGuard™ patients, compared to 90% in patients who underwent percutaneous coronary intervention with normal bare-metal stents. More patients experienced restoration of normal electrocardiogram reading (78% versus 50%) and blood flow to the heart muscle (83% versus 39%) with MGuard™ than bare-metal stents. In addition, the occurrence of major adverse cardiac events at six months post-deployment was 3.2% compared with 8.5% in patients treated with bare-metal stents.

In the saphenous vein graft group, with MGuard™, the average incidence of major adverse cardiac events at the 12-month follow-up was 10.0%, compared to 23.5% with bare-metal stents.

#### Future Clinical Trials for MGuard™ Coronary

We anticipate that additional studies will be conducted to meet registration requirements in key countries, particularly the United States and China. Certain countries in Europe also require additional local studies, depending on whether regulatory authorities classify the MGuard™ Coronary with bio-stable mesh as a new device rather than a bare metal stent. Following these studies, we expect that post-marketing trials will be conducted to further establish the safety and efficacy of the MGuard™ Coronary with bio-stable mesh in specific indications. These trials will be designed to facilitate market acceptance and expand the use of the product.

In the first fiscal quarter of 2011, we plan to launch a prospective, randomized study in Europe, Mexico and South America 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 up to 406 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.

We also plan to conduct a large clinical study for FDA approval in the United States. We expect that this study will be a prospective, multicenter, randomized clinical trial. Its primary objective will be to compare 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 and performance goals derived from published data. We expect total enrollment of up to 574 subjects, at up to 40 sites throughout the United States. The 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 secondary endpoint will be 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, nine months and 12 months. This plan is tentative, and is subject to change to conform with FDA regulations and requirements.

#### Planned Trials for future MGuard™ 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 MGuard™ Coronary with bio-stable mesh. We have begun commercialization of MGuard™ 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, China, Belgium, the Netherlands and certain smaller countries in Latin America. By the time we begin marketing this product in the United States, we expect to have introduced the MGuard™ technology to clinics and interventional cardiologists around the world, and to have fostered brand name recognition and widespread adoption of MGuard™ Coronary. We plan to accomplish this by participating in national and international conferences, conducting and sponsoring clinical trials, publishing articles in scientific journals, holding local training sessions and conducting electronic media campaigns.
- Successfully develop the next generation of MGuard™ stents. While we market our MGuard™ Coronary with bio-stable mesh, we intend to develop the MGuard™ Coronary with a drug-eluting mesh. We are also working on our MGuard™ stents for peripheral and carotid. In addition, we released our cobalt-chromium version of MGuard™, MGuard Prime™, in 2010, which we anticipate will replace MGuard™ over the next couple of years.
- Continue to leverage MGuard™ technology to develop additional applications for interventional cardiologists and vascular surgeons. In addition to the applications described above, we believe that we will eventually be able to utilize our proprietary technology to address imminent market needs for new product innovations to significantly improve patients' care. We have 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 MGuard™ portfolio of products. We intend to work closely with leading cardiologists to evaluate and ensure the efficacy and safety of our products. We intend that some of these prominent physicians will serve on our Scientific Advisory Board, which is our advisory committee that advises our board of directors, and run clinical trials with the MGuard™ Coronary stent. We believe these individuals, once convinced of the MGuard™ Coronary stent's superiority, 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 supporting our products, and to promote them at various conferences they attend.
- Continue to protect and expand our portfolio of patents. Our patents and their protection are critical to our success. We have filed ten separate patents for our MGuard™ technology in Canada, China, Europe, Israel, India, South Africa, and the United States, for an aggregate of 35 filed patents. 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.

- 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. We plan to partner with a company in the United States to guide products through FDA approval and to support the sale of MGuard™ stents in the United States.

## Competition

The stent industry is highly competitive. The bare-metal stent and the drug-eluting stent markets in the United States and Europe are dominated by Abbott Laboratories, Boston Scientific Corporation, Johnson & Johnson and Medtronic, Inc. Due to ongoing consolidation in the industry, there are high barriers to entry for small manufacturers in both the European and the United States 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., Civenton AG, OrbusNeich, Biotronik SE & Co. KG, Svelte Medical Systems, Inc. and Stentys SA, among others. To address current issues with drug-eluting stents, The Sorin Group and Civenton 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.

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 91% and 98% of the market share, respectively. The four major players are Abbott Laboratories, Boston Scientific Corporation, Johnson & Johnson and Medtronic, Inc. To date our sales are not significant enough to register in market share.

## Research and Development Expenses

During the 2010 fiscal year and the 2009 fiscal year, we spent approximately \$1.3 million and \$1.3 million in research and development, respectively.

## Sales and Marketing

### Sales and Marketing

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

Until FDA approval of our MGuard™ 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, Benelux, Denmark, Hungary, Poland, Slovenia, Czech Republic and Slovakia.

In addition to utilizing local and regional distributor networks, we are using international trade shows and industry conferences to gain market exposure and brand recognition. We plan to capitalize on our association with world-renowned 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 MGuard™ Coronary has initially penetrated the market by entering market segments with indications that present high risks of embolic dislodgement, notably acute myocardial infarction and saphenous vein graft coronary interventions, which comprise approximately 50% of an \$8 billion global coronary products market. We believe, however, that the benefits of utilizing the MGuard™ product for many other stenting procedures will lead to rapid market acceptance and adoption.

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 thrombosis, 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 are marketing our platform technology, MGuard™, as a superior and cost effective solution to these currently unmet needs of interventional cardiologists. We believe our MGuard™ technology is clinically superior to bare-metal stents because it reduces vessel injury and thereby reduces restenosis, providing embolic protection during and post-procedure. We believe our MGuard™ technology is clinically superior to drug-eluting stents, due to its lower thrombosis rate, protection from embolic showers during and post-procedure, and potential elimination of the need for anti-platelet drugs. Additionally, the MGuard™ Coronary is more cost effective than typical drug-eluting stents, even before taking into account the added cost of mandated drug therapies.

In addition to the significant benefits of the MGuard™ technology, it 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 MGuard™ products sold to date have been designed and labeled in such a way as to facilitate the utilization of existing reimbursement codes, and we intend to continue to design and label our products in a manner consistent with this goal.

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

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

## Intellectual Property

### Patents

We have filed ten separate patents for our MGuard™ technology, in Canada, China, Europe, Israel, India, South Africa, and the United States, 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. None of these patents have been granted as of the date of this Current Report on Form 8-K. 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 MGuard™ 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 FDA and other corresponding foreign agencies.

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. These laws and regulations range from simple product registration requirements in some countries to complex clearance and production controls in others. As a result, the processes and time periods required to obtain foreign marketing approval may be longer or shorter than those necessary to obtain FDA market authorization. These differences may affect the efficiency and timeliness of international market introduction of our products. For countries in the European Union (“EU”), 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 and pass an initial and annual facilities audit inspections to ISO 13485 standards by an EU inspection agency. We have obtained ISO 13485 quality system certification and the products we currently distribute into the EU display the required CE mark. In order to maintain certification, we are required to pass annual facilities audit inspections conducted by EU inspectors.

In the United States, the medical devices that will be manufactured and sold by us will be subject to laws and regulations administered by the FDA, including regulations concerning the prerequisites to commercial marketing, the conduct of clinical investigations, compliance with the Quality System Regulation, or QSR, and labeling.

A manufacturer may seek market authorization for a new medical device through the rigorous Premarket Approval, or PMA, application process, which requires the FDA to determine that the device is safe and effective for the purposes intended.

We will also be required to register with the FDA as a medical device manufacturer. As such, our manufacturing facilities will be subject to FDA inspections for compliance with QSR. 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 FDA 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. FDA regulations also govern product labeling and prohibit a manufacturer from marketing a medical device for unapproved applications. If the FDA 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.

In addition, international sales of medical devices manufactured in the United States that have not been approved or cleared by the FDA for marketing in the United States are subject to FDA export requirements. These require that we obtain documentation from the medical device regulatory authority of the destination country stating that sale of the medical device is not in violation of that country’s medical device laws, and, under some circumstances, may require us to apply to the FDA for permission to export a device to that country.

## Customers

Our customer base is varied. We began selling our product to customers in Europe in January 2009 and have since expanded our global distribution network to Canada, Southeast Asia, India and Latin America. Sixty six percent (66%) of our 2010 revenues were generated in Europe. Our major customer in 2010 was Hand-Prod Sp. Z o.o, a Polish distributor, that accounted for 29% of our revenues. In addition, other current significant customers are in Germany, Italy, Spain, Brazil and India.





## Manufacturing and Suppliers

We manufacture our stainless steel MGuard™ stent through a combination of outsourcing and assembly at our own facility. Third parties in Germany manufacture the base stent and catheter materials, and we add our proprietary mesh sleeve to the stent. Our current exclusive product supplier is QualiMed GmbH (“QualiMed”). QualiMed is a specialized German stent manufacturer that electro polishes and crimps the stent onto a balloon catheter that creates the base for our MGuard™ stents. QualiMed 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 is responsible for integrating the mesh covered stent with the delivery system, sterilization, packaging and labeling. Our proprietary mesh sleeve is supplied by Biogeneral, Inc., a San Diego, California-based specialty polymer manufacturer for medical and engineering applications.

Our MGuard Prime™ cobalt-chromium stent was designed by Svelte Medical Systems Inc., and is being manufactured and supplied by MeKo Laserstrahl-Materialbearbeitung. 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.

## 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 and Slovakia, France, Slovenia, Greece, Cyprus, Portugal, Spain, Sweden, Poland, Hungary, Estonia, Lithuania, Ukraine, United Kingdom, Kazakhstan, Turkey, Latvia, Brazil, Chile, Costa Rica, Mexico, Argentina, Venezuela, Colombia, Peru, India, Sri Lanka, Korea, Malaysia, Pakistan, Thailand, Taiwan and Israel. We are currently in discussions with multiple distribution companies in Europe, Asia, and Latin America and expect to have distribution representatives in at least 30 countries by the end of 2011. We are also pursuing regional distribution agreements, which we expect will increase our market coverage and penetration.

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 will automatically renew for an additional three years unless modified by either party.

## Employees

As of December 31, 2010, we had 45 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.

## Properties

Our headquarters are located in Tel Aviv, Israel where we currently have an 825 square meter facility that employs 25 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.



## 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, 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 1,476,027 Israeli new shekel (“NIS”), additional compensation for holding back wages, and options to purchase 250,000 of InspireMD’s ordinary shares at an exercise price of 0.01 NIS per share. We intend to assert a vigorous defense to the litigation.

On November 3, 2010, Eftan Consulting and Investments Ltd. (“Eftan”), a company wholly owned by a former legal counsel of InspireMD, filed suit in the District Court in Tel Aviv, claiming that according to an agreement between Eftan and InspireMD dated April 1, 2005, pursuant to which Eftan was retained to provide legal services to InspireMD, Eftan is entitled options to purchase to 61,120 ordinary shares of InspireMD at an exercise price of 0.01 NIS per share. We intend to assert a vigorous defense to the litigation.

There are no proceedings in which any of our directors, officers or affiliates or any registered or beneficial shareholders is an adverse party or has a material interest adverse to our interest.

## Forward-Looking Statements

Statements in this Current Report on Form 8-K and other written reports made from time to time by us that are not historical facts constitute so-called “forward-looking statements,” all of which are subject to risks and uncertainties. Forward-looking statements can be identified by the use of words such as “expects,” “plans,” “will,” “forecasts,” “project,” “intends,” “estimates,” and other words of similar meaning. Forward-looking statements are likely to address our growth strategy, financial results and product and development programs, among other things. One must carefully consider any such statement and should understand that many factors could cause actual results to differ from our forward-looking statements. Such risks and uncertainties include but are not limited to those outlined in the section entitled “Risk Factors” and other risks detailed from time to time in our filings with the Securities and Exchange Commission or otherwise. These factors may include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

Information regarding market and industry statistics contained in this Report is included based on information available to us that we believe is accurate. It is generally based on industry and other publications that are not produced for purposes of securities offerings or economic analysis. We have not reviewed or included data from all sources, and cannot assure investors of the accuracy or completeness of the data included in this Report. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services. We do not assume any obligation to update any forward-looking statement. As a result, investors should not place undue reliance on these forward-looking statements.



## Management's Discussion and Analysis of Financial Condition and Results of Operations

This discussion should be read in conjunction with the other sections of this Report, including "Risk Factors," "Description of Business" and the Financial Statements attached hereto pursuant to Item 9.01 and the related exhibits. The various sections of this discussion contain a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risk factors described throughout this Report. See "Forward-Looking Statements." Our actual results may differ materially.

### Recent Events

On December 29, 2010, InspireMD entered into a Share Exchange Agreement with the Company and on March 31, 2011 the Share Exchange was consummated (see "Item 2.01 Completion of Acquisition or Disposition of Assets—Share Exchange" for a description of the Share Exchange). In connection with this Share Exchange, we succeeded to the business of InspireMD as our sole line of business. The Share Exchange is being accounted for as a recapitalization, with InspireMD deemed to be the accounting acquirer and the Company the acquired company. Accordingly, InspireMD's historical financial statements for periods prior to the consummation of the Share Exchange have become those of the registrant. Operations reported for periods prior to the Share Exchange are those of InspireMD.

### Overview

We are an innovative medical device company focusing on the development and commercialization of our proprietary stent platform technology, MGuard™, used in interventional cardiology and other vascular procedures.

In connection with the closing of the Share Exchange, we elected to report our financial results in accordance with generally accepted accounting principles in the United States ("U.S. GAAP") and as such, to report our financial results in United States dollars.

### Critical Accounting Policies

#### Use of estimates

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

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

#### Functional currency

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

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

#### Fair value measurement

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

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

#### Concentration of credit risk and allowance for doubtful accounts

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

#### 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. In respect to inventory on consignment, see "Revenue recognition" below.

#### Revenue recognition

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



When returns cannot be reliably estimated, both revenues and related direct costs are eliminated, as the products are deemed unsold. Accordingly, both related revenues and costs are deferred, and presented under “Deferred revenues” and “Inventory on consignment”, respectively.

We recognize revenue net of value added tax (VAT).

Research and development costs

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

Share-based compensation

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

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

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

Uncertain tax and vat positions

We follow a two-step approach to recognizing and measuring uncertain tax and VAT positions. The first step is to evaluate the tax and VAT 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 VAT 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

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

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



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

**Research and Development Expense.** For the year ended December 31, 2010, research and development expense increased 0.6% to \$1.338 million from \$1.330 million in 2009. Research and development expense as a percentage of revenue decreased to 27.0% in 2010 from 39.0% in 2009.

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

**General and Administrative Expense.** For the year ended December 31, 2010, general and administrative expense increased 97.5% to approximately \$2.9 million from \$1.5 million in 2009. The increase in cost resulted primarily from a large increase in the amount of our share options being issued and the corresponding accounting charges and overall accounting and legal expenses. General and administrative expense as a percentage of revenue increased to 58.6% in 2010 from 43.0% in 2009.

**Financial Expenses (Income).** For the year ended December 31, 2010, financial expense increased to approximately \$0.2 million from \$(0.04) million in 2009. The increase in expense resulted primarily from a one time financial income recording of \$0.3 million in 2009 pertaining to the cancellation of the conversion feature of a convertible loan that was repaid in the same year. Financial expense as a percentage of revenue increased to 3.1% in 2010, compared to financial income as a percent of revenue of -1.2% in 2009.

**Tax Expenses.** Tax expense remained flat at \$47,000 in 2010 and 2009. Our expenses for income taxes reflect primarily the tax liability due to potential tax exposure.

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

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

#### Liquidity and Capital Resources

**General.** At December 31, 2010, we had cash and cash equivalents of approximately \$636,000, as compared to \$376,000 in 2009. We have historically met our cash needs through a combination of issuance of new shares, borrowing activities and sales. Our cash requirements are generally for product development, clinical trials, marketing and sales activities, finance and administrative cost, capital expenditures and overall working capital.

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

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



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

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

**Credit Facilities.** As of December 31, 2010, we had a long term loan in the amount of approximately \$0.4 million bearing interest at the three month US\$ libor rate plus 4% per annum. The loan is payable in eight quarterly installments during a period of three years beginning April 2010 and ending on 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 at an "IPO" is higher than \$100 million.

**Convertible Loan.** As of December 31, 2010, we had a convertible loan with an aggregate principal amount outstanding of approximately \$1,580,000. The convertible loan bears 8% interest and is repayable or convertible upon the maturity date or, if the Share Exchange is consummated prior to the maturity date, then the convertible loan is convertible at the option of the holder into shares of our common stock following the Share Exchange at a price of \$1.50 per share. The convertible loan is also convertible into shares of InspireMD if the Share Exchange does not occur and upon certain other circumstances. This summary description of the convertible loan is qualified in its entirety by reference to the Convertible Debenture attached hereto as Exhibit 10.8 and the Securities Purchase Agreement entered into in connection therewith and attached hereto as Exhibit 10.10.

**Loans from Shareholder.** In August 2007, two shareholders loaned us \$40,000, with no interest rate and with no specific terms of repayment. These loans were repaid partially during March 2009 and the remaining amount during February 2011.

**Sales of Stock.** During the fourth quarter of 2010 and January 2011, we issued an aggregate of 145,000 ordinary shares for consideration of approximately \$1.4 million.

#### 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, both against the United States dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products.

#### Off Balance Sheet Transactions and Related Matters

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 FASB 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 our consolidated financial statements.

In January 2010, the FASB updated the “Fair Value Measurements Disclosures.” 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 require 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 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. We do not expect that the adoption of this new guidance will have a material impact on our consolidated financial statements.

## Risk Factors

Our business and an investment in our securities are subject to a variety of risks. The following risk factors describe the most significant events, facts or circumstances that we believe could have a material adverse effect upon our business, financial condition, results of operations, ability to implement our business plan, and the market price for our securities. Many of these events are outside of our control. The risks described below are not the only ones facing our Company. Additional risks not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of these risks actually occur, our business, financial condition or results of operation may be materially adversely affected. In such case investors in our securities could lose all or part of their investment.

### Risks Related to Our Business

Our failure to successfully market, sell, manufacture or distribute our stent products would have a material adverse effect on our business and the value of our business.

We have limited experience marketing, selling, manufacturing or distributing the products we intend to sell, if and when we receive the regulatory approvals required to do so. Furthermore, we will need to substantially increase our manufacturing, marketing, sales and distribution capabilities in order to do so successfully. If unsuccessful in any of these activities, our business and the value of our securities could be materially and adversely affected.

We expect to derive our revenue from sales of our MGuard™ stent products. 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 commercial and market uncertainties that are 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.

Market acceptance of our products, and the products of any future licensees, is uncertain.

Even if our products are developed successfully and achieve all necessary regulatory approvals, they may not enjoy commercial acceptance or success, which would adversely affect our potential market share, and our business, financial condition and results of operations. Several factors could limit the successful commercialization of our products, including:

- limited market acceptance or familiarity among patients, physicians, medical centers and third-party purchasers;
  - inadequate reimbursement for our products by third party payors;
  - our inability to develop a sales force or distributors capable of effectively marketing our products;
  - our inability to manufacture and supply a sufficient amount of products to meet market demands; and
  - the number, relative effectiveness, and cost of competing products that may enter the market.

The foregoing factors could also limit the successful commercialization by any future licensee of products incorporating our technology, which would ultimately affect our results of operations.

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 no experience scaling our manufacturing capability, and if we are unable to increase our production to meet demand, our business and results of operations would suffer.

To be successful, we must manufacture products of sufficient quality in sufficient quantities to meet demand, in compliance with regulatory requirements, and at an acceptable cost. We have no experience in large-scale manufacturing, and may not be able to develop commercially viable manufacturing capabilities or increase our capacity to meet increased demand for our interventional cardiology products. We will need to expand our production facilities for our products if we receive sizeable orders. An important element in the manufacture of our products will be our ability to scale our unit volume to meet sales projections, while maintaining high product quality. To date, the application of the mesh sleeve to the stent has been a manual process. We are dependent upon SewFine LLC for the development of a process to automate the production of our MGuard™ stent products. We and any potential licensee may also encounter manufacturing problems in relation to the following:

- production yields;
- quality control and assurance;





- availability of third-party components or products;
- shortages of qualified personnel;
- compliance with local and international regulations;
- production and distribution costs; and
- development of advanced manufacturing techniques and process controls.

To the extent we use third-party manufacturers or enter into manufacturing joint ventures with third parties, we cannot be certain that we will be able to contract with such companies on acceptable terms, if at all, or that such third parties will satisfy our quality standards or meet supply requirements on a timely basis, if at all.

Clinical trials necessary to support a pre-market approval application will be expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit.

Clinical trials necessary to support a pre-market approval (“PMA”) application 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 the PMA applications for the Cypher stent and the Taxus Express2 stent, which are approved by the FDA and currently marketed, involved patient populations of approximately 1,000 and 1,300, respectively, and a 12-month follow up period. The FDA may require us to submit data on a greater number of patients or for a longer follow-up period. 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.

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, or CABG, 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- 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.

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 obtain necessary regulatory approvals, if such approvals are received at all.

Because our products are new and long-term success measures have not been completely validated, regulatory agencies, including the FDA, 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 FDA 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 30 employees. As a result, we may experience a long regulatory process in connection with obtaining regulatory approvals for our products.

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, 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 FDA and other regulatory bodies. In particular, we and our suppliers will be required to comply with QSR for the manufacture of our MGuard™ stent, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing approval in the United States. The FDA enforces the QSR through unannounced inspections. We and our third-party manufacturers and suppliers have not yet been inspected by the FDA 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 FDA 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 FDA or other regulatory bodies;
- product recall or seizure;

Edgar Filing: InspireMD, Inc. - Form 8-K

- 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 would harm our reputation and 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, the approval may be subject to limitations on the indicated uses for which the product may be marketed. If the FDA 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 FDA 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 FDA. If the FDA 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 QSR, 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. For example, Boston Scientific Corporation has initiated significant recalls of its stent products due to manufacturing and other quality issues associated with the products.

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 the United States and many other foreign jurisdictions, we must obtain separate regulatory approvals. 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 FDA approval. Foreign regulatory approval processes may include all of the risks associated with obtaining CE Mark or FDA 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.



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.

The products we and any potential licensees license, develop, manufacture and market are subject to complex regulatory requirements in the United States, Europe and Asia. The process of obtaining regulatory approvals to market a medical device, particularly in the United States, Europe and Japan, 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 continuing 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.

Clinical trials for our stent products involve a lengthy and expensive process, and there is a substantial risk of delay or failure. Any such delay or failure would prevent us from commercializing our stent products, which would materially and adversely affect our results of operations and the value of our business.

Our lead product in development, the MGuard™ Coronary with bio-stable mesh, is currently undergoing human clinical trials. None of our other potential products have yet to begin human clinical trials. Clinical trials can be lengthy, time-consuming and expensive. 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;
- 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;
  - delays in patient enrollment and variability in the number and types of patients available for clinical trials;
  - difficulty in maintaining contact with patients after treatment, resulting in incomplete follow-up data; and
    - varying interpretation of data by regulatory agencies.

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

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

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. If we cannot obtain necessary materials or components, we may be unable to manufacture products of sufficient quality in sufficient quantities to meet customer needs. We may also be unable to develop new products and applications and conduct clinical trials. This would compromise our ability to obtain necessary regulatory approvals, thereby impairing our ability to expand into new markets or develop new products.

Our stents may be subject to certain pricing restrictions that could reduce our product revenue.

The successful commercialization of our stents will depend, in part, on the extent to which third-party reimbursement is available from government health administration authorities, private health care insurers and other health-care funding organizations. Some element of price control over medical devices exists in most major markets and third party reimbursement is highly variable and complex. 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. There can be no assurance that health administration or third party coverage will allow any potential licensee or us to achieve pricing that provides an appropriate return on such licensees' or our investment. If any potential licensee fails to achieve such pricing, it may de-emphasize or cease to commercialize our products, which could have a material adverse effect on our business and results of operations.

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.

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

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

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

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

- foreign currency exchange rate fluctuations;
- greater difficulty in staffing and managing foreign operations;
- greater risk of uncollectible accounts;
- 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.

We intend to design the protocol of our planned pivotal U.S. clinical trial for our MGuard Prime™ stent based in part on prior clinical trials that used different stents. The results of these prior clinical trials may not be indicative of the clinical results we would obtain for our U.S. pivotal clinical trial.

We intend to commercialize our technology in the United States in the form of our MGuard Prime™ stent, which is a cobalt-chromium stent covered with a polymer mesh. We have only limited clinical data on our MGuard™ Coronary with bio-stable mesh stent, which we derived from the MGuard™ Coronary with bio-stable mesh study. We intend to design the protocol for our planned United States pivotal clinical trial based on the results of prior clinical trials. This trial is being designed in large part based on the results of our MGuard™ Coronary with bio-stable mesh study.

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, 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 additional 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.

In addition, while we have validated our manufacturing process for consistency, we have experienced drug release kinetic variability within and between manufacturing lots, and we may experience similar issues in the future. Manufacturing lot variability may result in unfavorable clinical trial results.

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.

Our manufacturing facilities and the manufacturing facilities of our suppliers must comply with applicable regulatory requirements. If we fail to achieve regulatory approval for these manufacturing facilities, our business and results of operations would be harmed.

Completion of our clinical trials and commercialization of our product candidates requires access to, or the development of, manufacturing facilities that meet applicable regulatory standards to manufacture a sufficient supply of our products. The FDA and other regulatory bodies must approve facilities that manufacture our products for commercial purposes, as well as the manufacturing processes and specifications for the product. Suppliers of components of, and products used to manufacture our products, must also comply with FDA and foreign regulatory requirements, which often require significant time, money and record-keeping and quality assurance efforts and subject our and our suppliers to potential regulatory inspections and stoppages. Our suppliers may not satisfy these requirements. If we or our suppliers do not achieve the required regulatory approval for our manufacturing operations, our commercialization efforts could be delayed, which would harm our business and results of operations.

Quality issues in our manufacturing processes could delay clinical development and commercialization efforts.

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.

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

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

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third party payors may adversely affect the demand for our products currently under development and limit our ability to sell our product candidates on a profitable basis. In addition, third party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired and future revenues, if any, would be adversely affected.

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

The Patient Protection and Affordable Care Act and Health Care and Educational Reconciliation Act (the “Health Care Acts”) were enacted into law in March 2010. Certain provisions of the Health Care 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 United States, this new tax may materially and adversely affect our business and results of operations. The legislation also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the provisions include a reduction in the annual rate of inflation for hospitals starting in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level in the United States, or the effect of any future legislation or regulation. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business and results of operations.

Many of our competitors are much larger than us, with significant resources and incentives to initiate litigation against us.

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, Johnson & Johnson and Medtronic, 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 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 United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the United States Patent and Trademark Office, or USPTO, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO to determine priority of invention in the United States. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the United States. The laws of some foreign jurisdictions do not protect intellectual property rights to the same degree as in the United States, and many companies have encountered significant difficulties in protecting 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.

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 depend on single-source suppliers for some of the components in our MGuard™ stent. The loss of such suppliers could delay our clinical trials or prevent or delay commercialization of our MGuard™ stent.

Some of the components of our products are currently provided by only one vendor, or a single-source supplier. We depend on QualiMed, which manufactures the body of the stent, as well as MeKo, BMT and SewFine for various important elements of our products. We may have difficulty obtaining similar components from other suppliers that are acceptable to the FDA 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 manufacture and delivery of our MGuard™ stent would be interrupted 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 FDA 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.

If we are unable to manage our expected growth, we may not be able to commercialize our products, including our MGuard™ stent.

We intend to continue to rapidly expand operations and grow our research and development, product development and administrative operations and invest substantially in our manufacturing facilities. This expansion has and is expected to continue to place a significant strain on our management and operational and financial resources. In particular, the commencement of our planned pivotal clinical trial in the United States will consume a significant portion of management's time and our financial resources. To manage expected growth and to commercialize our MGuard™ stent, we will be required to improve existing, and implement new, operational and financial systems, procedures and controls and expand, train and manage our growing employee base. 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.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the regulatory and healthcare systems in ways that could impact our ability to sell our products profitably, if at all. In the United States in recent years, new legislation has been proposed at the federal and state levels that would effect major changes in the healthcare system. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted. The potential for adoption of these proposals affects or will affect our ability to raise capital, obtain additional collaborators and market our products. We expect to experience pricing pressures in connection with the future sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. Our results of operations could be adversely affected by future healthcare reforms.

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 1968 (the "ISL"). Section 15 to the ISL requires the filing of a prospectus with the Israel Security Authority (the "ISA") 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. We filed an application for "No action" with the ISA in connection with the foregoing. To date, the ISA has not provided any response to such application. A failure to receive "No action" relief could expose us to fines and other remedies that could be detrimental to us.

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 raised approximately \$9,681,000 million in the Private Placement, and we 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;
- 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.

#### Risks Related to Our Organization and Our Common Stock

As a result of the Share Exchange, we became a company that is subject to the reporting requirements of federal securities laws, which can be expensive and may divert resources from other projects, thus impairing our ability to grow.

As a result of the Share Exchange, we became a public reporting company and, accordingly, subject to the information and reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and other federal securities laws, including compliance with the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”). The costs of preparing and filing annual and quarterly reports, proxy statements and other information with the Securities and Exchange Commission (including reporting of the Share Exchange) and furnishing audited reports to stockholders will cause our expenses to be higher than they would have been if we remained privately held and did not consummate the Share Exchange.

If we fail to establish and maintain an effective system of internal control, we may not be able to report our financial results accurately or to prevent fraud. Any inability to report and file our financial results accurately and timely could harm our reputation and adversely impact the trading price of our common stock.

It may be time consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by the Sarbanes-Oxley Act. We may need to hire additional financial reporting, internal controls and other finance personnel in order to develop and implement appropriate internal controls and reporting procedures. 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. In addition, if we are unable to comply with the internal controls requirements of the Sarbanes-Oxley Act, then we may not be able to obtain the independent accountant certifications required by such act, which may preclude us from keeping our filings with the Securities and Exchange Commission current and may adversely affect any market for, and the liquidity of, our common stock.



Public company compliance may make it more difficult for us to attract and retain officers and directors.

The Sarbanes-Oxley Act and new rules subsequently implemented by the Securities and Exchange Commission have required changes in corporate governance practices of public companies. As a public company, we expect these new rules and regulations to increase our compliance costs and to make certain activities more time consuming and costly. As a public company, we also expect that these new rules and regulations may make it more difficult and expensive for us to obtain director and officer liability insurance in the future and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers.

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”. Securities analysts of major brokerage firms may not provide coverage of us since there is no incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will, in the future, want to conduct any secondary offerings on our behalf.

Our stock price may be volatile.

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

- changes in our industry;
- competitive pricing pressures;
- our ability to obtain working capital financing;
- additions or departures of key personnel;
- limited “public float” in the hands of a small number of persons whose sales or lack of sales could result in positive or negative pricing pressure on the market price for our common stock;
- sales of our common stock;
- our ability to execute our business plan;
- operating results that fall below expectations;
- loss of any strategic relationship;
- regulatory 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 materially and adversely affect the market price of our common stock.

Our securities are restricted securities with limited transferability.

Our securities should be considered a long-term, illiquid investment. Our common stock has not been registered under the Securities Act, and cannot be sold without registration under the Securities Act or any exemption from registration. In addition, our common stock is not registered under any state securities laws that would permit its transfer. Because of these restrictions, a stockholder will likely find it difficult to liquidate an investment in our

common stock.

-40-

---

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 which 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.

Our shares of common stock are very thinly traded, and the price may not reflect our value and there can be no assurance that there will be an active market for our shares of common stock in the future.

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. Investors may not be able to liquidate their investment or liquidate it at a price that reflects the value of the business. If a more active market should develop, the price may be highly volatile. Because there may be a low price for our shares of common stock, many brokerage firms may not be willing to effect transactions in the securities. Even if an investor finds a broker willing to effect a transaction in the shares of our common stock, the combination of brokerage commissions, transfer fees, taxes, if any, and any other selling costs may exceed the selling price. Further, many lending institutions will not permit the use of such shares of common stock as collateral for a loans.

We may apply the proceeds of the Private Placement to uses that ultimately do not improve our operating results or increase the price of our common stock.

We intend to use \$1,000,000 of the net proceeds from the Private Placement to complete the Dr. Gregg Stone-Dr. Alexandre Abizaid trials, \$7,600,000 for the FDA trials with Harvard Clinical Research Institute and the remainder for general corporate purposes. However, our management has broad discretion in how we actually use these proceeds. These proceeds could be applied in ways that do not ultimately improve our operating results or otherwise increase the value of our common stock.

We may need additional financing which may not be available on acceptable terms, which may in turn dilute your investment in us.

Our future capital requirements will depend on many factors including but not limited to: continued market acceptance of our services; competitive pressure on the price of our products; the extent to which we invest in new locations, develop new relationships with producers of polymers and chemicals as well as consumers of polymers and chemicals; and the response of competitors to our products. We believe that the existing cash balances, including the net proceeds from the Private Placement, and funds generated from operations will provide us with sufficient funds to finance our operations for the foreseeable future. To the extent that our current funds, together with existing resources, are insufficient to fund our activities over the long-term, we may need to raise additional funds through equity or debt financing or from other sources. The sale of additional equity or convertible debt may result in additional dilution to our stockholders and such securities may have rights, preferences or privileges senior to those of the common stock. To the extent that we rely upon debt financing, we will incur the obligation to repay the funds borrowed with interest and may become subject to covenants and restrictions that restrict operating flexibility. No assurance can be given that additional equity or debt financing will be available or that, if available, it can be obtained on terms favorable to us or our stockholders. Failure to obtain necessary financing could have a material adverse effect on our business, financial condition and results of operations.

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.

#### Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information as of March 31, 2011 regarding the beneficial ownership of our common stock, taking into account the consummation of the Share Exchange and the closing of the Private Placement, by (i) each person or entity who, to our knowledge, beneficially owns more than 5% of our common stock; (ii) each executive officer; (iii) each director; and (iv) all of our officers and directors as a group. Unless otherwise indicated in the footnotes to the following table, each of the stockholders named in the table has sole voting and investment power with respect to the shares of our common stock beneficially owned. Except as otherwise indicated, the address of each of the stockholders listed below is: c/o InspireMD Ltd., 3 Menorat Hamor Street, Tel Aviv, Israel.

Name of Beneficial Owner	Number of Shares Beneficially Owned(1)	Percentage Beneficially Owned (2)
Ofir Paz	10,263,752	16.3%
Asher Holzer	10,300,437	16.3%
Craig Shore	0	0
Bary Oren	365,223	0.6%
Eli Bar	838,658	1.3%
All officers and directors as a group (5 persons)	21,768,070	34.5%

- (1) Unless otherwise indicated, includes shares owned by a spouse, minor children, and relatives sharing the same home, as well as entities owned or controlled by the named beneficial owner. Shares of common stock beneficially owned and the respective percentages of beneficial ownership of common stock assumes the exercise of all options, warrants and other securities convertible into common stock beneficially owned by such person or entity currently exercisable or exercisable within 60 days of March 31, 2011. Shares issuable pursuant to the exercise of stock options and warrants exercisable within 60 days are deemed outstanding and held by the holder of such options or warrants for computing the percentage of outstanding common stock beneficially owned by such person, but are not deemed outstanding for computing the percentage of outstanding common stock beneficially owned by any other person.
- (2) Based on 63,120,665 shares of our common stock outstanding immediately following the Share Exchange and Private Placement.

## Executive Officers and Directors

The following persons became our executive officers and directors on March 31, 2011, upon the effectiveness of the Share Exchange, and hold the positions set forth opposite their respective names.

Name	Age	Position
Ofir Paz	45	Chief Executive Officer and Director
Asher Holzer, PhD	61	President and Chairman of the Board of Directors
Craig Shore	49	Chief Financial Officer, Secretary and Treasurer
Eli Bar	46	Senior Vice President of Research and Development and Chief Technical Officer of InspireMD
Bary Oren	37	Chief Financial Officer of Operations of InspireMD

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. Ofir Paz is our class 1 director, with his term of office to expire at our 2012 annual meeting of stockholders. Asher Hozer is our class 2 director, with his term of office to expire at our 2013 annual meeting of stockholders. We currently do not have a class 3 director. 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 the consummation of the Share Exchange on March 31, 2011. In addition, Mr. Paz has served as the chief executive officer and a director of InspireMD 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 in 1993 and 1997, respectively.

Asher Holzer, PhD, has served as our president and chairman of the board since the consummation of the Share Exchange on March 31, 2011. In addition, Dr. Holzer has served as the president and chairman of the board of InspireMD since April 2007. Dr. Holzer has more than 25 years of experience in advanced medical devices. His expertise covers a wide range of activities, including product development, clinical studies, regulatory affairs, market introduction, and the financial aspects of the stent business. Previously, Dr. Holzer founded Adar Medical, 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 in 1980. Dr. Holzer is also an inventor and holder of numerous patents.

Craig Shore has served as our chief financial officer, secretary and treasurer since the consummation of the Share Exchange on March 31, 2011. In addition, since November 10, 2010, Mr. Shore has served as InspireMD'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 United States, 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 in 1983 and 1988, respectively.

Eli Bar has served as InspireMD's senior vice president of research and development and chief technical officer since February 2011. Prior to that, he served as InspireMD'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 in 1996 with a B.Sc. in Mechanical Engineering.

Bary Oren has served as InspireMD's chief financial officer since September 2009. During June 2006 through July 2009, he served as the chief financial officer of Peninsula Financial Limited, a commercial finance institution which provides factoring services and creative cash-flow solutions for businesses. Mr. Oren led the company's efforts to raise funds from investors as well as from the public on the Tel-Aviv Stock Exchange. From March 2004 through June 2006, Mr. Oren served as chief financial officer and vice president of business development of Bankrate Limited, a consulting firm which provides financial management services. Prior to 2004, Mr. Oren served as an auditor and financial advisor in several accounting firms, including PricewaterhouseCoopers Israel. Mr. Oren is a CPA and graduated from Tel Aviv University with degrees in Accounting and Economics and an MBA in 1999 and 2003, respectively.



## Agreements with Executive Officers

### Ofir Paz

On April 1, 2005, InspireMD entered into an employment agreement with Ofir Paz to serve as InspireMD'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 is entitled to a monthly gross salary of NIS 55,000. Mr. Paz is also entitled to certain social and fringe benefits as set forth in the employment agreement, which total 25% of his gross salary, as well as a company car. Mr. Paz is also entitled to a minimum bonus equivalent to three monthly gross salaries based on achievement of objectives and board of directors approval. Mr. Paz is eligible to receive stock options pursuant to this agreement following its six month anniversary, subject to board approval. If Mr. Paz's employment is terminated with or without cause, he is entitled to at least six months' prior notice and shall be paid his salary and all social and fringe benefits in full during such notice period. If Mr. Paz's employment is terminated without cause, Mr. Paz shall also be entitled to certain severance payments equal to the total amount that was contributed to and accumulated in his severance payment fund. 8.33% of Mr. Paz's gross monthly salary is transferred to his severance payment fund each month. The total amount accumulated in his severance payment fund as of Dec. 31, 2010 was approximately \$79,000.

This summary description of the Mr. Paz's employment agreement is qualified in its entirety by reference to such employment agreement, as amended, attached hereto as Exhibits 10.14, 10.15 and 10.16.

### Asher Holzer

On April 1, 2005, InspireMD entered into an employment agreement with Dr. Asher Holzer to serve as InspireMD's president. Such employment agreement was subsequently amended on March 28, 2011. Pursuant to this employment agreement, as amended, Dr. Holzer is entitled to a monthly gross salary of NIS 55,000. Dr. Hozer is also entitled to certain social and fringe benefits as set forth in the employment agreement, which total 25% of his gross salary, as well as a company car. Dr. Holzer is also entitled to a minimum bonus equivalent to three monthly gross salaries based on achievement of objectives and board of directors approval. Dr. Holzer is eligible to receive stock options pursuant to this agreement following its six month anniversary, subject to board approval. If Dr. Holzer's employment is terminated with or without cause, he is entitled to at least six months' prior notice and shall be paid his salary and all social and fringe benefits in full during such notice period. If Dr. Holzer's employment is terminated without cause, Dr. Holzer shall also be entitled to certain severance payments equal to the total amount that was contributed to and accumulated in his severance payment fund. 8.33% of Dr. Holzer's gross monthly salary is transferred to his severance payment fund each month. The total amount accumulated in his severance payment fund as of Dec. 31, 2010 was approximately \$77,000.

This summary description of the Dr. Holzer's employment agreement is qualified in its entirety by reference to such employment agreement attached hereto as Exhibits 10.17 and 10.18.

### Eli Bar

On June 26, 2005, InspireMD entered into an employment agreement with Eli Bar to serve as InspireMD's engineering manager. Pursuant to this employment agreement, Mr. Bar is entitled to a monthly gross salary of NIS 30,000. 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. If Mr. Bar's employment is terminated without cause, Mr. Bar shall also be entitled to certain severance payments equal to the product obtained by multiplying the number of months Mr. Bar was employed by us by 8.33% of his current monthly salary.

This summary description of the Mr. Bar's employment agreement is qualified in its entirety by reference to such employment agreement attached hereto as Exhibit 10.19.

#### Bary Oren

On August 25, 2009, InspireMD entered into an employment agreement with Bary Oren to serve as InspireMD's director of finance. Pursuant to this employment agreement, Mr. Oren is entitled to a monthly gross salary of NIS 33,600. Mr. Oren is also entitled to certain social and fringe benefits as set forth in the employment agreement. InspireMD can terminate Mr. Oren for cause with at least 60 days' prior written notice. If Mr. Oren's employment is terminated, he shall be paid his salary in full and all social and fringe benefits during such notice period. If Mr. Oren's employment is terminated without cause, Mr. Oren shall also be entitled to certain severance payments equal to the product obtained by multiplying the number of months Mr. Oren was employed by InspireMD by 8.33% of his gross monthly salary.

This summary description of the Mr. Oren's employment agreement is qualified in its entirety by reference to such employment agreement attached hereto as Exhibit 10.20.

#### Craig Shore

On November 28, 2010, InspireMD entered into an employment agreement with Craig Shore to serve as InspireMD's vice president of business development. Pursuant to this employment agreement, Mr. Shore is entitled to a monthly gross salary of NIS 30,000. Upon completion of the Share Exchange, Mr. Shore became entitled to a monthly gross salary of NIS 35,000. Mr. Shore is also entitled to certain social and fringe benefits as set forth in the employment agreement. Mr. Shore is also entitled to a grant of options to purchase 45,000 restricted ordinary shares of InspireMD; provided that such restricted 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 during the first six months of Mr. Shore's employment, he is entitled to at least 14 days' prior notice and shall be paid his salary in full and all social and fringe benefits during such notice period. If Mr. Shore's employment is terminated without cause after the first six months of Mr. Shore's employment, he is 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 occurs (not including the Share Exchange), 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 with cause, he is not entitled to any notice.

In addition, if Mr. Shore's employment is terminated without cause, Mr. Shore shall also be entitled to certain severance payments equal to the product obtained by multiplying the number of months Mr. Shore was employed by InspireMD by 8.33% of his gross monthly salary.

This summary description of the Mr. Shore's employment agreement is qualified in its entirety by reference to such employment agreement attached hereto as Exhibit 10.21.

### Executive Compensation

#### Summary Compensation Table

The table below sets forth, for our last two fiscal years, the compensation earned by (i) Ofir Paz, our chief executive officer, (ii) Asher Holzer, our president and chairman of the board, (iii) Eli Bar, InspireMD's vice president of research and development, and (iv) Bary Oren, InspireMD's director of finance.

Edgar Filing: InspireMD, Inc. - Form 8-K

Name and Principal Position	Year	Salary (\$)(1)	Bonus (\$)(1)	Option Awards(2)	All Other Compensation (\$)(1)	Total (\$)(1)
<b>Ofir Paz(3)</b>						
Chief Executive Officer	2010	118,700	-	-	78,515	197,214
	2009	104,301	-	-	57,755	162,057
<b>Asher Holzer(3)</b>						
President and Chairman	2010	122,412	-	-	74,813	197,225
	2009	106,879	-	-	55,177	162,056
<b>Eli Bar</b>						
Vice President, Research and Development	2010	111,667	-	818,509	-	930,176
	2009	106,001	-	-	-	106,001
<b>Bary Oren</b>						
Director of Finance	2010	114,780	-	495,962	-	610,742
	2009	25,592	-	100,000	-	125,592
<b>Behar Shmuel</b>						
Former Chief Financial Officer	2010	-	-	-	-	-
	2009	107,858	-	-	-	107,858

(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 2010 was 3.7319 NIS per dollar and the average exchange rate for 2009 was 3.9228 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 and 2010, in accordance with SFAS 123(R). For a description of SFAS 123(R) and the assumptions used in determining the value of the options, see the notes to the financial statements attached hereto pursuant to Item 9.01 of this Current Report on Form 8-K

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

Outstanding Equity Awards at Fiscal Year-End

The following table shows information concerning unexercised options outstanding as of December 31, 2010 for each of 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	-	-	-	-
Asher Holzer	-	-	-	-

Edgar Filing: InspireMD, Inc. - Form 8-K

Eli Bar	243,480	-	0.001	10/28/2016
	365,220	-	0.001	12/29/2016
	152,175	456,525	0.001	7/22/2020
	20,290	60,870	1.23	7/28/2020
Bary Oren	50,725	30,435	0.001	8/23/2019
	253,625	152,175	1.23(1)	1/1/2020

(1) If we issue an option to buy our securities at a lower per share exercise price, then the per share exercise price applicable to these options shall be adjusted to the lowest per share exercise price of any subsequently issued options.

## 2010 Director Compensation

Name	Fees Earned or Paid in Cash \$	Option Awards(1)(2) \$	All Other Compensation \$	Total \$
David Ivry(3)	6,083	133,398	-	139,481
Robert Fischell(3)	3,783	-(4)	-	3,783
Fellice Pelled (3)	5,885	133,398	-	139,283

(1) Based on the fair market value of the stock awards on the date of grant.

(2) The following directors own the following number of fully vested options to purchase common stock: David Ivry (162,320) and Fellice Pelled (162,320).

(3) Each of David Ivry, Robert Fischell and Fellice Pelled resigned as directors of InspireMD on March 31, 2011.

(4) We are currently obligated to issue to Robert Fischell options to purchase 162,320 shares of common stock.

Other than Mr. Paz and Dr. Holzer, we paid each director \$330 per meeting for each board meeting attended and \$1,230 for each quarter served on the board of directors. We also granted annually to each director options to purchase 81,160 shares of our common stock at an exercise price per share equal to the fair market value price per share of our common stock on the grant date. The options vest over four quarters from the grant date. During the fiscal year ended December 31, 2010, our directors received the compensation from us for their services as set forth in the table above.

## 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.

## 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.

## Board Committees

We expect our board of directors, in the future, to appoint an audit committee, nominating committee and compensation committee, and to adopt charters relative to each such committee. We intend to appoint such persons to committees of the board of directors as are expected to be required to meet the corporate governance requirements imposed by a national securities exchange, although we are not required to comply with such requirements until we elect to seek a listing on a national securities exchange. In addition, we intend that a majority of our directors will be independent directors, of which at least one director will qualify as an “audit committee financial expert,” within the meaning of Item 407(d)(5) of Regulation S-K, as promulgated by the Securities and Exchange Commission. We do not currently have an “audit committee financial expert” since we currently do not have an audit committee in place.

## Description of Capital Stock

### Authorized Capital Stock

We have authorized 130,000,000 shares of capital stock, par value \$0.0001 per share, of which 125,000,000 are shares of common stock and 5,000,000 are shares of “blank check” preferred stock.

### Capital Stock Issued and Outstanding

After giving effect to the Share Exchange, the issuance of 6,454,002 shares of common stock in the Private Placement and the cancellation of 7,500,000 shares of common stock in the Split-Off, we have issued and outstanding securities on a fully diluted basis as follows:

63,120,665 shares of common stock;

no shares of preferred stock;

outstanding options to purchase up to an aggregate of 7,606,770 shares of common stock with a weighted average exercise price of approximately \$0.54 per share; and

Warrants to purchase up to an aggregate of 7,128,739 shares of common stock, of which (i) warrants to purchase 3,226,999 shares of common stock were issued to investors in the Private Placement at an exercise price of \$1.80 per share, (ii) a warrant to purchase 373,740 shares of common stock was issued to the Placement Agent in connection with the Private Placement at an exercise price of \$1.80 per share, (iii) a warrant to purchase 6,833 shares of common stock was issued to an employee in connection with the Private Placement at an exercise price of \$1.80 per share, (iv) a warrant to purchase 6,667 shares of common stock was issued to a consultant in connection with the Private Placement at an exercise price of \$1.80 per share, (v) warrants to purchase 1,014,500 shares of common stock exchanged for outstanding warrants held by the investors in the Bridge Financing at an exercise price of \$1.23 per share, and (vi) warrants to purchase 2,500,000 shares of common stock were issued to certain consultants in consideration for consulting services at an exercise price of \$1.50 per share.

### Common Stock

The holders of our common stock are entitled to one vote per share. Our certificate of incorporation does not provide for cumulative voting. The holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds; however, the current policy of our board of directors is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the

holders of our common stock are entitled to share ratably in all assets that are legally available for distribution. The holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock, which may be designated solely by action of our board of directors and issued in the future.



## Preferred Stock

Our board of directors is authorized, subject to any limitations prescribed by law, without further vote or action by our stockholders, to issue from time to time shares of preferred stock in one or more series. Each series of preferred stock will have such number of shares, designations, preferences, voting powers, qualifications and special or relative rights or privileges as shall be determined by our board of directors, which may include, among others, dividend rights, voting rights, liquidation preferences, conversion rights and preemptive rights.

## Warrants

### \$1.80 Warrants

In connection with the Private Placement, on March 31, 2011, we issued investors five-year warrants to purchase up to an aggregate of 3,226,999 shares of common stock at an exercise price of \$1.80 per share. We are prohibited from effecting the exercise of any such warrant to the extent that as a result of such exercise the holder of the exercised warrant beneficially owns more than 4.99% in the aggregate of the issued and outstanding shares of our common stock calculated immediately after giving effect to the issuance of shares of our common stock upon the exercise of the warrant. The warrants contain provisions that protect their holders against dilution by adjustment of the purchase price in certain events such as stock dividends, stock splits and other similar events. If at any time after the one year anniversary of the original issuance date of such warrants there is no effective registration statement registering, or no current prospectus available for, the resale of the shares of common stock underlying the warrant, then the holders of such warrants have the right to exercise the warrants by means of a cashless exercise. In addition, if (i) the volume-weighted average price of our common stock for 15 consecutive trading days is at least 250% of the exercise price of the warrants; (ii) the 20-day average daily trading volume of our common stock has been at least 175,000 shares; (iii) a registration statement providing for the resale of the common stock issuable upon exercise of the warrants is effective and (iv) the common stock is listed for trading on a national securities exchange, then we may require each investor to exercise all or a portion of its warrant pursuant to the terms described above within seven business days following the delivery of a notice of acceleration. Any warrant that is not exercised as aforesaid shall expire automatically at the end of such 7-day period.

### Placement Agent Warrant

In connection with the Private Placement, we issued Palladium Capital Advisors, LLC a five-year warrant to purchase up to 373,740 shares of common stock at an exercise price of \$1.80 per share. The terms of this warrant are identical to the \$1.80 Warrants described above.

### Employee Private Placement Warrant

In connection with the Private Placement, we issued Craig Shore, our chief financial officer, secretary and treasurer, a five-year warrant to purchase up to 6,833 shares of common stock at an exercise price of \$1.80 per share. The terms of this warrant are identical to the \$1.80 Warrants described above.

### Consultant Private Placement Warrant

In connection with the Private Placement, we issued to a consultant, a five-year warrant to purchase up to 6,667 shares of common stock at an exercise price of \$1.80 per share. The terms of this warrant are identical to the \$1.80 Warrants described above.

### \$1.23 Warrants

In connection with the Share Exchange, on March 31, 2011, we issued certain investors warrants to purchase up to an aggregate of 1,014,500 shares of our common stock at an exercise price of \$1.23 per share. These warrants may be exercised any time on or before July 20, 2013 and were issued in exchange for warrants to purchase up to 125,000 ordinary shares of InspireMD at an exercise price of \$10 per share. We are prohibited from effecting the exercise of any such warrant to the extent that as a result of such exercise the holder of the exercised warrant beneficially owns more than 9.99% in the aggregate of the issued and outstanding shares of our common stock calculated immediately after giving effect to the issuance of shares of our common stock upon the exercise of the warrant. The warrants contain provisions that protect their holders against dilution by adjustment of the purchase price in certain events such as stock dividends, stock splits and other similar events. In addition, if at any time following the one year anniversary of the original issuance date of the warrants, (i) our common stock is listed for trading on a national securities exchange, (ii) the closing sales price of our common stock for 15 consecutive trading days is at least 165% of the exercise price of the warrants; (iii) the 15 day average daily trading volume of our common stock has been at least 150,000 shares and (iv) a registration statement providing for the resale of the common stock issuable upon exercise of the warrants is effective, then we may require each investor to exercise all or a portion of its warrant pursuant to the terms described above at any time upon at least 15 trading days prior written notice. Any warrant that is not exercised as aforesaid shall expire automatically at the end of the 15-day notice period.

This summary description of the warrants is qualified in its entirety by reference to the Form of \$1.80 Warrant attached hereto as Exhibit 10.6 and the Form of \$1.23 Warrant attached hereto as Exhibit 10.7.

### \$1.50 Consultant Warrants

In connection with the Share Exchange, on March 31, 2011, we issued Endicott Management Partners, LLC, The Corbran LLC and David Stefansky three-year warrants to purchase up to an aggregate of 2,500,000 shares of common stock at an exercise price of \$1.50 per share. The terms of these warrants are identical to the \$1.80 Warrants described above, except that the exercise price for the \$1.50 Consultant Warrants is \$1.50 per share.

### Stock Options

#### 2006 Employee Stock Option Plan

InspireMD previously adopted the Inspire M.D. Ltd. 2006 Employee Stock Option Plan (the "2006 Plan") which provides for the granting of stock options to employees, officers, consultants, and directors. Under the 2006 Plan, 9,739,200 shares of common stock have been reserved for issuance under awards, and options to purchase 6,795,584 shares of common stock have been granted to date under the 2006 Plan. As further described below, upon the closing of the Share Exchange, we became the sponsor of the 2006 Plan, and the 2006 Plan became a sub-plan to the 2011 UMBRELLA Option Plan.



## 2011 UMBRELLA Option Plan

On March 28, 2011, our board of directors and stockholders adopted and approved the InspireMD, Inc. 2011 UMBRELLA Option Plan (the “2011 Umbrella Plan”). Under the 2011 Umbrella Plan, we reserved 9,468,100 shares of our common stock as awards to the employees, consultants, and service providers to InspireMD, Inc. and its subsidiaries and affiliates worldwide (the “Group”). The 2011 Umbrella Option Plan is filed as Exhibit 10.1 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011.

The 2011 Umbrella Plan currently consists of three components, the primary plan document that governs all awards granted under the Plan, and two appendices: (i) Appendix A, designated for the purpose of grants of stock options to Israeli employees and officers of the Group and any other service providers who are subject to Israeli income tax, 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.

Upon the closing of the Share Exchange, we became the sponsor of the 2006 Plan and the 2006 Plan became a sub-plan under Appendix A to the 2011 Umbrella Plan. All outstanding option awards previously granted under the 2006 Plan will be treated as granted under the 2011 Umbrella Plan. Thus, all outstanding options to purchase ordinary shares of InspireMD (which are converted to options to purchase shares of common stock of Saguardo pursuant to the Exchange Agreement) will be converted to options to purchase shares of common stock of InspireMD, Inc.

The purpose of the 2011 Umbrella 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 2011 Umbrella Plan will be administered by our board of directors until such time as such authority has been delegated to a committee of the board of directors (the “Administrator”). Unless terminated earlier by the board of directors, the 2011 Umbrella Plan will expire on March 27, 2012.

The Administrator will determine the recipients of the awards and the number of shares of common stock subject to such awards. Subject to the terms of the 2011 Umbrella Plan, the terms and conditions of each award of options or restricted stock (for U.S. grants), including vesting conditions and the effect of a termination of service, will be determined by the Administrator. Awards granted pursuant to the 2011 Umbrella Plan will be evidenced by a written award agreement. The Administrator will interpret the 2011 Umbrella Plan and any awards granted under the plan and any such determination by the Administrator will be final and conclusive, unless otherwise determined by the board of directors.

To date, no awards have been granted pursuant to the 2011 Umbrella Plan, other than the awards to be assumed which were previously granted pursuant to the 2006 Plan, as described above.

## Stock Options Issued Outside of the 2006 Plan and 2011 Umbrella Plan

In addition to the foregoing, we have granted options to purchase 811,186 shares of common stock outside of the 2006 Plan and the 2011 Umbrella Plan.

## Commitments to Grant Stock Options

We currently have a commitment to issue options to purchase a maximum aggregate of 564,874 shares of common stock to five of our customers, contingent on such customers’ achieving specified sales targets for 2011. We anticipate

issuing these options pursuant to the 2011 Umbrella Plan.

-52-

---

We currently have a commitment to issue options to purchase a maximum aggregate of 271,886 shares of common stock to finders, employees and other consultants, subject to board approval. We anticipate issuing these options pursuant to the 2011 Umbrella Plan.

We currently have a commitment to issue options to purchase a maximum aggregate of 124,865 shares of common stock to certain recipients, subject to execution of the appropriate documentation by each recipient. We anticipate issuing these options pursuant to the 2011 Umbrella Plan.

#### Dividend Policy

We currently intend to use all available funds to develop our business and do not anticipate that we will pay dividends in the future. We can give no assurances that we will ever have excess funds available to pay dividends.

#### Indemnification of Directors and Officers

The Delaware General Corporation Law (“DGCL”) provides, in general, that a corporation incorporated under the laws of the State of Delaware, such as us, may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than a derivative action by or in the right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another enterprise, against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person’s conduct was unlawful. In the case of a derivative action, a Delaware corporation may indemnify any such person against expenses (including attorneys’ fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification will be made in respect of any claim, issue or matter as to which such person will have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery of the State of Delaware or any other court in which such action was brought determines such person is fairly and reasonably entitled to indemnity for such expenses.

Our certificate of incorporation and bylaws provide that we will indemnify our directors, officers, employees and agents to the extent and in the manner permitted by the provisions of the DGCL, as amended from time to time, subject to any permissible expansion or limitation of such indemnification, as may be set forth in any stockholders’ or directors’ resolution or by contract.

We also have director and officer indemnification agreements with each of our executive officers and directors that provide, among other things, for the indemnification to the fullest extent permitted or required by Delaware law, provided that such indemnitee shall not be entitled to indemnification in connection with any “claim” (as such term is defined in the agreement) initiated by the indemnitee against us or our directors or officers unless we join or consent to the initiation of such claim, or the purchase and sale of securities by the indemnitee in violation of Section 16(b) of the Exchange Act.

Any repeal or modification of these provisions approved by our stockholders shall be prospective only, and shall not adversely affect any limitation on the liability of a director or officer of ours existing as of the time of such repeal or modification.



We are also permitted to apply for insurance on behalf of any director, officer, employee or other agent for liability arising out of his actions, whether or not the DGCL would permit indemnification. 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 (see "Executive Compensation—Directors' and Officers' Liability Insurance").

#### Anti-Takeover Effect of Delaware Law, Certain By-Law Provisions

Our certificate of incorporation and bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control of our company. These provisions are as follows:

- they provide that special meetings of stockholders may be called only by our chairman, our president or by a resolution adopted by a majority of our board of directors;
- they do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in our board of directors; and
- they allow us to issue, without stockholder approval, up to 5,000,000 shares of preferred stock that could adversely affect the rights and powers of the holders of our common stock.

In addition, we are subject to the provisions of Section 203 of the DGCL, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior, did own, 15% or more of the voting stock.

#### Trading Information

Our common stock is currently approved for quotation on the OTC Bulletin Board maintained by the Financial Industry Regulatory Authority, Inc. under the symbol SAGU and there is no active trading market for our stock. We have notified the OTC Bulletin Board of our name change and will obtain a new symbol. As soon as practicable, and assuming we satisfy all necessary initial listing requirements, we intend to apply to have our common stock listed for trading on the NYSE Amex Equities or The Nasdaq Stock Market, although we cannot be certain that any of these applications will be approved.

#### Transfer Agent

The transfer agent for our common stock is Columbia Stock Transfer Company. We will serve as warrant agent for the \$1.80 Warrants, the \$1.23 Warrants, the Warrant issued to the Placement Agent in connection with the Private Placement and the \$1.50 Consultant Warrants.



## 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.

## Board Committees

We expect our board of directors, in the future, to appoint an audit committee, nominating committee and compensation committee, and to adopt charters relative to each such committee. We intend to appoint such persons to committees of the board of directors as are expected to be required to meet the corporate governance requirements imposed by a national securities exchange, although we are not required to comply with such requirements until we elect to seek a listing on a national securities exchange.

## Item 3.02 Unregistered Sales of Equity Securities.

### Sales by InspireMD, Inc. (formerly known as Saguaro Resources, Inc.)

On June 16, 2008, Saguaro Resources, Inc. completed an offering of 2,500,000 shares of its common stock at a price of \$0.005 per share to Lynn Briggs, its president, chief executive officer, chief financial officer and secretary-treasurer. The total amount received from that offering was \$12,500. These shares were issued pursuant to Section 4(2) of the Securities Act and corresponding provisions of state securities laws, which exempt transactions by an issuer not involving a public offering.

On March 31, 2011, pursuant to the Share Exchange, we issued 46,471,907 shares of common stock to the InspireMD Shareholders in exchange for 91.7% of the issued and outstanding capital stock of InspireMD. Subsequent to March 31, 2011, we issued 4,194,756 shares of common stock to the InspireMD Shareholders in exchange for the remaining 8.3% of the issued and outstanding capital stock of InspireMD. In addition, in connection with the Share Exchange, we (i) assumed three year warrants to purchase up to 125,000 ordinary shares of InspireMD at an exercise price of \$10 per share that were converted into newly issued warrants to purchase up to 1,014,500 shares of our common stock at an exercise price of \$1.23 per share and (ii) options to purchase up to 937,256 ordinary shares of InspireMD with a weighted average exercise price of \$4.35 that were converted into options to purchase up to 7,606,770 shares of our common stock with a weighted average exercise price of \$0.54 per share. The securities issued in the Share Exchange were not registered under the Securities Act, or the securities laws of any state, and were offered and sold pursuant to the exemption from registration under the Securities Act provided by either Regulation S under the Securities Act or Section 4(2) and Regulation D (Rule 506) under the Securities Act.

On March 31, 2011, we entered into a Securities Purchase Agreement with 30 accredited investors, pursuant to which we issued 6,454,002 shares of common stock at a purchase price of \$1.50 per share and five-year warrants to purchase up to 3,226,999 shares of common stock at an exercise price of \$1.80 per share, resulting in aggregate cash proceeds of \$9,013,404 and the cancellation of \$667,596 of indebtedness under the Bridge Notes. The securities sold in this offering were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration under the Securities Act provided by either Regulation S under the Securities Act or Section 4(2) and Regulation D (Rule 506) under the Securities Act.

On March 31, 2011, upon the consummation of the Private Placement, we issued a five-year warrant to purchase up to 373,740 shares of common stock at an exercise price of \$1.80 per share, to Palladium Capital Advisors, LLC, our placement agent in the Private Placement. The warrant was not registered under the Securities Act, or the securities laws of any state, and was offered and sold in reliance on the exemption from registration afforded by Section 4(2)

and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws, which exempt transactions by an issuer not involving a public offering.

-55-

---

On March 31, 2011, upon the consummation of the Private Placement, we issued a five-year warrant to purchase up to 6,833 shares of common stock at an exercise price of \$1.80 per share, to Craig Shore, our chief financial officer, secretary and treasurer. The warrant was not registered under the Securities Act, or the securities laws of any state, and was offered and sold in reliance on the exemption from registration afforded by Section 4(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws, which exempt transactions by an issuer not involving a public offering.

On March 31, 2011, upon the consummation of the Private Placement, we issued a five-year warrant to purchase up to 6,667 shares of common stock at an exercise price of \$1.80 per share, to a consultant. The warrant was not registered under the Securities Act, or the securities laws of any state, and was offered and sold in reliance on the exemption from registration afforded by Section 4(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws, which exempt transactions by an issuer not involving a public offering.

On March 31, 2011, we issued three-year warrants to purchase up to an aggregate of 2,500,000 shares of common stock at an exercise price of \$1.50 per share, to Endicott Management Partners, LLC, The Corbran LLC and David Stefansky, in consideration for consulting services. The warrants were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration afforded by Section 4(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws, which exempt transactions by an issuer not involving a public offering.

On March 31, 2011, upon consummation of the Private Placement, the principal and all accrued but unpaid interest under the Bridge Notes converted into 445,064 shares of common stock at a conversion price of \$1.50 per share. The securities issued in connection with the conversion of the Bridge Notes were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration afforded by Section 4(2) and Regulation D (Rule 506) under the Securities Act and corresponding provisions of state securities laws, which exempt transactions by an issuer not involving a public offering. Each of the holders of the Bridge Notes was an accredited investor.

#### Sales by InspireMD

On July 22, 2010, InspireMD entered into a Securities Purchase Agreement with three accredited investors pursuant to which InspireMD issued 8% convertible debentures in the aggregate principal amount of \$1,580,000 and three year warrants to purchase up to 125,000 ordinary shares (1,014,500 shares of common stock following the Share Exchange) at an exercise price of \$10 per share (the "Bridge Financing"). The securities sold in the Bridge Financing were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration afforded by Regulation S under the Securities Act or under Section 4(2) of the Securities Act regarding transactions not involving a public offering.

On January 29, 2009, InspireMD entered into a loan agreement with Bank Mizrahi pursuant to which InspireMD issued 28,932 ordinary shares (234,812 shares of common stock following the Share Exchange) as partial consideration for Bank Mizrahi providing us a credit facility. The securities sold were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration afforded by Regulation S under the Securities Act or under Section 4(2) of the Securities Act regarding transactions not involving a public offering. The loan agreement is attached hereto as Exhibit 10.23.

Between January 1, 2008 and February 28, 2011, InspireMD issued an aggregate of 569,011 ordinary shares (4,618,094 shares of common stock following the Share Exchange) to 61 investors in a series of closings, at a purchase price of \$10 (\$1.23 following the Share Exchange) per share. The securities sold were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration afforded by Regulation S under the Securities Act or under Section 4(2) of the Securities Act regarding transactions not involving a public offering.

Between January 1, 2008 and February 28, 2011, InspireMD issued an aggregate of 68,270 ordinary shares (554,079 shares of common stock following the Share Exchange) due to the exercise of options to purchase ordinary shares, at a purchase price of \$0.01 per share. The securities sold were not registered under the Securities Act, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration afforded by Regulation S under the Securities Act or under Section 4(2) of the Securities Act regarding transactions not involving a public offering.

Item 4.01 Changes in Registrant's Certifying Accountant.

On March 31, 2011, in connection with the Share Exchange, we dismissed Stan J.H. Lee, CPA as our independent registered public accounting firm. Stan J.H. Lee, CPA had previously been engaged as the principal accountant to audit our financial statements (when we were known as Saguaro Resources, Inc.). The reason for the dismissal of Stan J.H. Lee, CPA is that, following the consummation of the Share Exchange on March 31, 2011, our primary business became the business conducted by InspireMD. The independent registered public accountant of InspireMD is the firm of Kesselman & Kesselman, Certified Public Accountants, a member of PricewaterhouseCoopers International Limited ("PWC"). We believe that it is in our best interest to have PWC continue to work with our business, and we therefore retained PWC as our new principal independent registered accounting firm, effective as of March 31, 2011. PWC is located at Trade Tower, 25 Hamered Street, Tel Aviv, 68125, Israel. The decision to change accountants was approved by our board of directors on March 31, 2011.

The report of Stan J.H. Lee, CPA on our financial statements for the fiscal years ended June 30, 2009 and June 30, 2010 did not contain an adverse opinion or disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope or accounting principles, except that the report raised substantial doubt as to our ability to continue as a going concern.

From our inception through March 31, 2011, there were no disagreements with Stan J.H. Lee, CPA on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure which, if not resolved to the satisfaction of Stan J.H. Lee, CPA, would have caused it to make reference to the matter in connection with its reports.

From our inception through March 31, 2011, we did not consult PWC regarding either: (i) the application of accounting principles to a specific completed or contemplated transaction, or the type of audit opinion that might be rendered on our financial statements; or (ii) any matter that was the subject of a disagreement as defined in Item 304(a)(1)(iv) of Regulation S-K.

On February 7, 2007, InspireMD appointed Ernst & Young, LLP (“Ernst & Young”) as its independent accountant and on August 15, 2010, InspireMD dismissed Ernst & Young as its independent accountant. Ernst & Young issued reports on InspireMD’s financial statements for the year ended December 31, 2006. Ernst & Young also issued financial statements for tax purposes for the years ended December 31, 2007 and 2008. On October 6, 2010, InspireMD’s board of directors unanimously approved the appointment of PWC as its independent accountant commencing with work to be performed in relation to its nine month period ended September 30, 2010, and the years ended December 31, 2007, 2008 and 2009. InspireMD had no occasion in 2008 and 2009 and any subsequent interim period prior to October 6, 2010 upon which it consulted with PWC on any matters.

During the fiscal years ended December 31, 2008 and 2009, and the subsequent interim period through August 15, 2010, there were (i) no disagreements with Ernst & Young on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreement(s), if not resolved to Ernst & Young’s satisfaction, would have caused Ernst & Young to make reference to the subject matter of the disagreement(s) in connection with its reports for such years, and (ii) no reportable events within the meaning set forth in Item 304(a)(1)(v) of Regulation S-K.

We have made the contents of this Current Report on Form 8-K available to Stan J.H. Lee, CPA and requested that Stan J.H. Lee, CPA furnish us a letter addressed to the Securities and Exchange Commission as to whether Stan J.H. Lee, CPA agrees or disagrees with, or wishes to clarify our expression of, our views, or containing any additional information. A copy of Stan J.H. Lee, CPA’s letter to the Securities and Exchange Commission is included as Exhibit 16.1 to this Current Report on Form 8-K.

We have made the contents of this Current Report on Form 8-K available to Ernst & Young and requested that Ernst & Young furnish us a letter addressed to the Securities and Exchange Commission as to whether Ernst & Young agrees or disagrees with, or wishes to clarify our expression of, our views, or containing any additional information. We will file such letter as an amendment to this Current Report on Form 8-K upon receipt.

Item 5.01 Changes in Control of Registrant.

Reference is made to the disclosure set forth under Item 2.01 of this Current Report on Form 8-K, which disclosure is incorporated herein by reference.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Our sole officer and director immediately prior to the Share Exchange resigned from all positions with us as of March 31, 2011, effective upon the closing of the Share Exchange. In connection with the Share Exchange, Ofir Paz and Asher Holzer were appointed to our board of directors consists and Ofir Paz was appointed as our chief executive officer, Asher Holzer was appointed as our president and chairman and Craig Shore was appointed as our chief financial officer, secretary and treasurer. Reference is made to the disclosure set forth under Item 2.01 of this Current Report on Form 8-K, which disclosure is incorporated herein by reference.

Item 5.06 Change in Shell Company Status.

Following the consummation of the Share Exchange described in Item 2.01 of this Current Report on Form 8-K, we believe that we are not a shell corporation as that term is defined in Rule 405 of the Securities Act and Rule 12b-2 of the Exchange Act.



Item 7.01 Regulation FD Disclosure.

In connection with the Private Placement, we provided the investors with an investor presentation regarding the operations of and plans for the company (the “Investor Presentation”) and financial projections for the company (the “Financial Projections”). A copy of the Investor Presentation is furnished as Exhibit 99.1 to this report and a copy of the Financial Projections is furnished as Exhibit 99.2 to this report.

The forward-looking statements in the Investor Presentation and the Financial Projections are based on management’s present expectations and beliefs about future events. As with any projection or forecast, these statements are inherently susceptible to uncertainty and changes in circumstances. We are under no obligation to, and expressly disclaim any obligation to, update or alter its forward-looking statements whether as a result of such changes, new information, subsequent events or otherwise. See “Item 2.01 Completion of Acquisition or Disposition of Assets—Forward-Looking Statements” and “Item 2.01 Completion of Acquisition or Disposition of Assets—Risk Factors.”

The information furnished pursuant to this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of InspireMD under the Securities Act or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(a) Financial Statements of Businesses Acquired. In accordance with 9.01(a), InspireMD’s audited financial statements for the fiscal years ended December 31, 2010 and 2009 are filed in this Current Report on Form 8-K as Exhibit 99.3.

(b) Pro Forma Financial Information. In accordance with Item 9.01(b), our pro forma financial statements are filed in this Current Report on Form 8-K as Exhibit 99.4.

(c) Shell Company Transactions. Reference is made to Items 9.01(a) and 9.01(b) above and the exhibits referenced to therein, which are incorporated herein by reference.

(d) Exhibits.

Exhibit Number	Description
2.1	Share Exchange Agreement, dated as of December 29, 2010, by and among InspireMD Ltd., Saguaro Resources, Inc., and the Shareholders of InspireMD Ltd. that are signatory thereto (incorporated by reference to Exhibit 10.1 to Saguaro Resources, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on January 5, 2011)
2.2	Amendment to Share Exchange Agreement, dated February 24, 2011
2.3	Second Amendment to Share Exchange Agreement, dated March 25, 2011
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to InspireMD, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
3.2	

Edgar Filing: InspireMD, Inc. - Form 8-K

Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to InspireMD, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)

10.1 2011 Umbrella Option Plan (incorporated by reference to Exhibit 10.1 to InspireMD, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)

-59-

---



Edgar Filing: InspireMD, Inc. - Form 8-K

Exhibit Number	Description
10.2	Form of Stock Option Award Agreement
10.3	Agreement of Conveyance, Transfer and Assignment of Assets and Assumption of Obligations, dated as of March 31, 2011
10.4	Stock Purchase Agreement, by and between InspireMD, Inc. and Lynn Briggs, dated as of March 31, 2011
10.5	Securities Purchase Agreement, dated as of March 31, 2011, by and among InspireMD, Inc. and certain purchasers set forth therein
10.6	Form of \$1.80 Warrant
10.7	Form of \$1.23 Warrant
10.8	\$1,250,000 Convertible Debenture, dated July 20, 2010, by and between InspireMD Ltd. and Genesis Asset Opportunity Fund, L.P.
10.9	Unprotected Leasing Agreement, dated February 22, 2007, by and between Block 7093 Parcel 162 Company Ltd. Private Company 510583156 and InspireMD Ltd.
10.10	Securities Purchase Agreement, dated as of July 22, 2010, by and among InspireMD Ltd. and certain purchasers set forth therein
10.11	Manufacturing Agreement, by and between InspireMD Ltd. and QualiMed Innovative Medizinprodukte GmbH, dated as of September 11, 2007
10.12	Development Agreement, by and between InspireMD Ltd. and QualiMed Innovative Medizinprodukte GmbH, dated as of January 15, 2007
10.13	License Agreement, by and between Svelte Medical Systems, Inc. and InspireMD Ltd., dated as of March 19, 2010
10.14	Agreement, by and between InspireMD Ltd. and Ofir Paz, dated as of April 1, 2005
10.15	Amendment to the Employment Agreement, by and between InspireMD Ltd. and Ofir Paz, dated as of October 1, 2008
10.16	Second Amendment to the Employment Agreement, by and between InspireMD Ltd. and Ofir Paz, dated as of March 28, 2011
10.17	Personal Employment Agreement, by and between InspireMD Ltd. and Asher Holzer, dated as of April 1, 2005
10.18	Amendment to the Employment Agreement, by and between InspireMD Ltd. and Asher Holzer, dated as of March 28, 2011
10.19	Personal Employment Agreement, by and between InspireMD Ltd. and Eli Bar, dated as of June 26, 2005
10.20	Employment Agreement, by and between InspireMD Ltd. and Bary Oren, dated as of August 25, 2009
10.21	Employment Agreement, by and between InspireMD Ltd. and Craig Shore, dated as of November 28, 2010
10.22	Form of Indemnification Agreement between InspireMD, Inc. and each of the directors and executive officers thereof
10.23	Agreement with Bank Mizrahi Tefahot LTD. for a loan to InspireMD Ltd. in the original principal amount of \$750,000
16.1	Letter from Stan J.H. Lee, CPA, dated March 31, 2011
21.1	List of subsidiaries
99.1	Investor Presentation
99.2	Financial Projections
99.3	InspireMD Ltd. financial statements for the fiscal years ended December 31, 2010 and 2009

99.4 Pro forma unaudited consolidated financial statements as of December 31,  
2010

-60-

---

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INSPIREMD, INC.

Dated: April 6, 2011

By: /s/ Asher Holzer  
Name: Asher Holzer  
Title: President

-61-

---

EXHIBIT INDEX

Exhibit Number	Description
2.1	Share Exchange Agreement, dated as of December 29, 2010, by and among InspireMD Ltd., Saguaro Resources, Inc., and the Shareholders of InspireMD Ltd. that are signatory thereto (incorporated by reference to Exhibit 10.1 to Saguaro Resources, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on January 5, 2011)
2.2	Amendment to Share Exchange Agreement, dated February 24, 2011
2.3	Second Amendment to Share Exchange Agreement, dated March 25, 2011
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to InspireMD, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to InspireMD, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
10.1	2011 Umbrella Option Plan (incorporated by reference to Exhibit 10.1 to InspireMD, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
10.2	Form of Stock Option Award Agreement
10.3	Agreement of Conveyance, Transfer and Assignment of Assets and Assumption of Obligations, dated as of March 31, 2011
10.4	Stock Purchase Agreement, by and between InspireMD, Inc. and Lynn Briggs, dated as of March 31, 2011
10.5	Securities Purchase Agreement, dated as of March 31, 2011, by and among InspireMD, Inc. and certain purchasers set forth therein
10.6	Form of \$1.80 Warrant
10.7	Form of \$1.23 Warrant
10.8	\$1,250,000 Convertible Debenture, dated July 20, 2010, by and between InspireMD Ltd. and Genesis Asset Opportunity Fund, L.P.
10.9	Unprotected Leasing Agreement, dated February 22, 2007, by and between Block 7093 Parcel 162 Company Ltd. Private Company 510583156 and InspireMD Ltd.
10.10	Securities Purchase Agreement, dated as of July 22, 2010, by and among InspireMD Ltd. and certain purchasers set forth therein
10.11	Manufacturing Agreement, by and between InspireMD Ltd. and QualiMed Innovative Medizinprodukte GmbH, dated as of September 11, 2007
10.12	Development Agreement, by and between InspireMD Ltd. and QualiMed Innovative Medizinprodukte GmbH, dated as of January 15, 2007
10.13	License Agreement, by and between Svelte Medical Systems, Inc. and InspireMD Ltd., dated as of March 19, 2010
10.14	Agreement, by and between InspireMD Ltd. and Ofir Paz, dated as of April 1, 2005
10.15	Amendment to the Employment Agreement, by and between InspireMD Ltd. and Ofir Paz, dated as of October 1, 2008
10.16	Second Amendment to the Employment Agreement, by and between InspireMD Ltd. and Ofir Paz, dated as of March 28, 2011
10.17	Personal Employment Agreement, by and between InspireMD Ltd. and Asher Holzer, dated as of April 1, 2005

10.18 Amendment to the Employment Agreement, by and between InspireMD Ltd.  
and Asher Holzer, dated as of March 28, 2011

-62-

---

- 10.19 Personal Employment Agreement, by and between InspireMD Ltd. and Eli Bar, dated as of June 26, 2005
- 10.20 Employment Agreement, by and between InspireMD Ltd. and Bary Oren, dated as of August 25, 2009
- 10.21 Employment Agreement, by and between InspireMD Ltd. and Craig Shore, dated as of November 28, 2010
- 10.22 Form of Indemnification Agreement between InspireMD, Inc. and each of the directors and executive officers thereof
- 10.23 Agreement with Bank Mizrahi Tefahot LTD. for a loan to InspireMD Ltd. in the original principal amount of \$750,000
- 16.1 Letter from Stan J.H. Lee, CPA, dated March 31, 2011
- 21.1 List of subsidiaries
- 99.1 Investor Presentation
- 99.2 Financial Projections
- 99.3 InspireMD Ltd. financial statements for the fiscal years ended December 31, 2010 and 2009
- 99.4 Pro forma unaudited consolidated financial statements as of December 31, 2010