InspireMD, Inc.
Form S-1/A
June 21, 2016

As filed with the Securities and Exchange Commission on June 21, 2016

Registration No. 333-210760

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

AMENDMENT NO.4

TO

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**26-2123838**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

321 Columbus Avenue
Boston, Massachusetts 02116
(857) 305-2410

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

James Barry, Ph.D.
President and Chief Executive Officer
InspireMD, Inc.
321 Columbus Avenue
Boston, Massachusetts 02116
(857) 305-2410

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

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

Ralph V. De Martino
Cavas S. Pavri
Schiff Hardin LLP
901 K Street NW Suite 700
Washington, D.C. 20001
Phone (202) 778-6400
Fax: (202) 778-6460

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

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

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

registration statement for the same offering. ¨

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

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

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

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

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price[1]	Amount of Registration Fee[2]	
Series B Convertible Preferred Stock, $0.0001 par value per share	$ 13,500,025.00	$ 1,359.45	
Common stock, $0.0001 par value per share, issuable upon conversion of Series B Convertible Preferred Stock	—		(3)
Common stock, $0.0001 par value per share, issuable as dividends upon conversion of Series B Convertible Preferred Stock[4]	$ 10,125,018.75	$ 1,019.59	
Warrants to purchase shares of Common Stock, $0.0001 par value per share	—		(5)
Common Stock, $0.0001 par value per share, issuable upon exercise of warrants[6]	$ 16,875,031.25	$ 1,699.32	
Placement Agent's Unit Purchase Option			
Units underlying Unit Purchase Option	—	—	
Series B Convertible Preferred Stock, par value $0.0001 per share, included in Unit Purchase Option[7]	$ 590,625.00	$ 59.48	
Common stock, par value $0.0001 per share, issuable upon conversion of Series B Convertible Preferred Stock included in Unit Purchase Option	—		(3)
Common stock, $0.0001 par value per share, issuable as dividends upon conversion of Series B Convertible Preferred Stock included in Unit Purchase Option[4]	$ 354,375.00	$ 35.69	
Warrants to purchase Common Stock included in Unit Purchase Option[7]	—		(5)
Common stock, par value $0.0001 per share, issuable upon exercise of warrants included in Unit Purchase Option[6]	$ 590,625.00	$ 59.48	
Total	$ 42,035,700.00	$ 4,233.01	(8)

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. The fee table assumes offering price of $35 per share of Series B Convertible Preferred Stock, which is based on the closing price of the registrant's common stock on June 20, 2016.

(2) Pursuant to Rule 416 under the Securities Act of 1933, as amended, this registration statement also covers any additional securities that may be offered or issued in connection with any stock split, stock dividend or similar transaction.

(3) No fee is required pursuant to Rule 457(i) under the Securities Act of 1933, as amended.

(4) The holders of Series B Convertible Preferred Stock will be entitled to receive cumulative dividends at the rate per share of 15% per annum of the stated value per share, until the fifth anniversary of the date of issuance of the Series B Convertible Preferred Stock. The dividends become payable, at the registrant's option, in either cash, out of any funds legally available for such purpose, or in shares of common stock, (i) upon any conversion of the Series B Convertible Preferred Stock, (ii) on each such other date as the registrant's board of directors may

determine and (iii) upon liquidation, dissolution or winding up of the registrant; provided, however, that if Series B Convertible Preferred Stock is converted into shares of common stock at any time prior to the fifth anniversary of the date of issuance of the Series B Convertible Preferred Stock, the holder will receive a make-whole payment in an amount equal to all of the dividends that, but for the early conversion, would have otherwise accrued on the applicable shares of Series B Convertible Preferred Stock being converted for the period commencing on the conversion date and ending on the fifth anniversary of the date of issuance, less the amount of all prior dividends paid on such converted Series B Convertible Preferred Stock before the date of conversion. Make-whole payments are payable at the registrant's option in either cash, out of funds legally available for such purpose, or in shares of common stock. The fee table assumes a conversion price of $0.35 and the stated value per share of $35.

(5) No fee is required pursuant to Rule 457(g) under the Securities Act of 1933, as amended.

(6) There will be issued a warrant to purchase 100 shares of common stock for every one share of Series B Convertible Preferred Stock offered. The fee table assumes a warrant exercise price of $0.4375 per share of common stock based on an assumed offering price of $35 per share of Series B Convertible Preferred Stock, which is based on the closing price of the registrant's common stock on June 20, 2016.

(7) Represents shares of Series B Convertible Preferred Stock and warrants to purchase common stock included in a unit purchase option to purchase up to 3.5% of the securities sold in this offering (excluding any shares of common stock to be paid as dividends on the Series B Convertible Preferred Stock) at an exercise price equal to 125% of the public offering price of the Series B Convertible Preferred Stock.

(8) Previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED JUNE 21, 2016

InspireMD, Inc.

385,715 Shares of Series B Convertible Preferred Stock
38,571,500 Shares of Common Stock Underlying the Series B Convertible Preferred Stock

Warrants to Purchase 38,571,500 Shares of Common Stock

38,571,500 Shares of Common Stock Underlying the Warrants

We are offering up to 385,715 shares of our Series B Convertible Preferred Stock (the "Preferred Stock") and warrants to purchase up to 38,571,500 shares of our common stock (and the shares of common stock issuable from time to time upon conversion of the Preferred Stock and payment of dividends accrued on the Preferred Stock in shares of common stock upon conversion of the Preferred Stock and the shares of common stock upon exercise of the warrants). Each share of Preferred Stock we sell in this offering will be accompanied by a warrant to purchase 100 shares of common stock at an exercise price of $ per share of common stock, assuming we sell a share of Preferred Stock and accompanying warrant at a public offering price of $35 per share (100 times $0.35, the last reported sales price of our common stock on June 20, 2016). The shares of Preferred Stock and warrants will be issued separately but can only be purchased together in this offering. Each warrant will be immediately exercisable and will expire on the five year anniversary of the date of issuance.

Our common stock is traded on the NYSE MKT under the symbol "NSPR." Following completion of this offering, we intend to apply to list the warrants on the NYSE MKT. No assurance can be given that such listing will be approved. We do not intend to apply for listing of the Preferred Stock on any securities exchange, and we do not expect that the Preferred Stock will be quoted on the NYSE MKT. On June 20, 2016, the last reported sale price of our common stock as reported on the NYSE MKT was $0.35 per share.

We have retained Dawson James Securities, Inc. to act as placement agent in connection with this offering and to use its "best efforts" to solicit offers to purchase the Preferred Stock and the warrants. We have agreed to pay the placement agent a cash fee equal to 9.0% of the gross proceeds of the offering. There are no minimum purchase requirements. We may not sell the entire amount of the securities being offered pursuant to this prospectus. The placement agent is not purchasing or selling any securities pursuant to this offering, nor are we requiring any minimum purchase or sale of any specific number of securities. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual public offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth below. See "Plan of Distribution" beginning on page 89 of this prospectus for more information regarding these arrangements.

Investing in our Preferred Stock and warrants (and the common stock underlying such securities) involves a high degree of risk. See "Risk Factors" beginning on page 7 of this prospectus before making a decision to purchase our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share[(1)]	Total
Public offering price	$	$
Placement agent fees[(2)]	$	$
Proceeds, before expenses, to us	$	$

(1) Per share price represents the offering price for one share of Preferred Stock and a warrant to purchase 100 shares of common stock.

(2) In addition, we have agreed to reimburse the placement agent for certain offering-related expenses and to issue the placement agent or its designees an option to purchase a number of shares of Preferred Stock and warrants to purchase common stock up to 3.5% of the securities sold in this offering, which option shares, warrants and underlying common stock are also being offered pursuant to this prospectus. See "Plan of Distribution" for more

information.

Because there is no minimum offering amount required as a condition to closing this offering, we may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus. In addition, because there is no escrow account and no minimum offering amount in this offering, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Also, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. See “Risk Factors” for more information. The offering will be terminated by July 10, 2016, and may not be extended.

Certain of our directors have indicated an interest in purchasing an aggregate of up to approximately $1,100,000 in Preferred Stock and accompanying warrants in this offering at the offering price. However, because indications of interest are not binding agreements or commitments to purchase, these directors may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering.

Affiliates and associated persons of Dawson James Securities, Inc. may invest in this offering on the same terms and conditions as the public investors participating in this offering.

The placement agent expects to deliver the shares of Preferred Stock and warrants against payment in New York, New York on or about , 2016.

DAWSON JAMES SECURITIES, INC.

The date of this prospectus is , 2016

TABLE OF CONTENTS

You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. Our management estimates have not been verified by any independent source, and we have not independently verified any third-party information. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ

materially from our assumptions and estimates. See “Cautionary Note Regarding Forward-Looking Statements.”

This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus or incorporated by reference into this prospectus. This summary may not contain all of the information that you should consider before investing in the Preferred Stock and the warrants. You should read this entire prospectus carefully, including the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our historical financial statements and related notes included elsewhere in this prospectus before making an investment decision. In this prospectus, unless the context requires otherwise, all references to "we," "our" and "us" refer to InspireMD, Inc., a publicly traded Delaware corporation, and its direct and indirect subsidiaries, including InspireMD Ltd., unless the context requires otherwise.

Unless otherwise indicated, all information in this prospectus reflects a one-for-ten reverse stock split of our common stock that occurred on October 1, 2015.

Overview

We are a medical device company focusing on the development and commercialization of our proprietary MicroNet™ stent platform technology for the treatment of complex vascular and coronary disease. A stent is an expandable "scaffold-like" device, usually constructed of a metallic material, that is inserted into an artery to expand the inside passage and improve blood flow. Our MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

Our CGuard™ carotid embolic prevention system ("CGuard EPS") combines our MicroNet mesh and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013, and we launched its release on a limited basis in October 2014. In January 2015, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, we announced the full market launch of CGuard EPS in Europe through a distribution agreement with Penumbra, Inc. In September 2015, we also received regulatory approval to commercialize CGuard EPS in Argentina and Colombia. Following the receipt of such regulatory approval, we launched CGuard EPS in Argentina in the first quarter of 2016 and Colombia in the fourth quarter of 2015.

Our MGuard™ Prime™ Embolic Protection System ("MGuard Prime EPS") is marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). MGuard Prime EPS combines the MicroNet with a bare-metal cobalt-chromium based stent and, together with our first generation MGuard stent combining the MicroNet with a bare-metal stainless steel

stent, unless otherwise indicated, we refer to both kinds of bare-metal stents as MGuard coronary products. We market and sell MGuard Prime EPS for the treatment of coronary disease in the European Union. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. However, as a result of a shift in industry preferences away from bare-metal stents in favor of drug-eluting (drug-coated) stents, in 2014 we decided to curtail further development of this product in order to focus on the development of a drug-eluting stent product, MGuard DES™. Due to limited resources, though, our efforts have been limited to testing drug-eluting stents manufactured by potential partners for compatibility and incorporating our MicroNet in-house onto a drug-eluting stent manufactured by a potential partner.

We are also developing a neurovascular flow diverter, which is an endovascular device that directs blood flow away from cerebral aneurysms in order to ultimately seal the aneurysms. Our flow diverter would utilize an open cell, highly flexible metal scaffold to which MicroNet would be attached. We have commenced initial pre-clinical testing of this product in both simulated bench models and standard in vivo pre-clinical models.

We also intend to develop a pipeline of other products and additional applications by leveraging our MicroNet technology to new applications to improve peripheral vascular and neurovascular procedures, such as the treatment of the superficial femoral artery disease, vascular disease below the knee and neurovascular stenting to open diseased vessels in the brain.

Presently, none of our products may be sold or marketed in the United States.

During the first quarter of 2015, we implemented a cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) limiting the focus of clinical and development expenses to only carotid and neurovascular products; (iii) limiting sales and marketing expenses to those related to the CGuard™ EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, rent, etc.). In addition, we decided to alter our commercial strategy by using third party distributors to drive future sales, as opposed to direct sales to hospitals and clinics, which had previously been our focus.

Recent Developments

On March 21, 2016, we sold 1,900,000 shares of our common stock and warrants to purchase 950,000 shares of our common stock in a public offering. Each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the offering. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. This offering resulted in gross proceeds to us of approximately $1.1 million, before deducting the underwriting discount and estimated offering expenses.

On March 21, 2016, we sold 1,033,051 shares of our common stock and warrants to purchase 516,526 shares of our common stock in a private placement. Each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the private placement. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. This private placement resulted in gross proceeds to us of approximately $0.6 million, before deducting placement agent fees and estimated offering expenses.

These sales of securities on March 21, 2016, resulted in aggregate net proceeds to us of approximately $1.4 million, after deducting underwriting discount, placement agent fees and other offering expenses.

Growth Strategy

Our primary business objective is to utilize our proprietary technology to become the industry standard for treatment of complex vascular and coronary disease 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.

- **Grow our presence in existing and new markets for CGuard EPS.** We have fully launched CGuard EPS in most European and Latin American countries, through a combination of distributor sales organizations as well as a partnership with Penumbra, Inc., a global interventional therapies company focused on the neuro and peripheral vascular specialties, to distribute CGuard EPS in Europe in 18 European countries. We are also pursuing additional registrations and contracts in other countries in Europe, Asia and Latin America.

- **Continue to leverage MicroNet 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 continue to broadly develop and protect intellectual property using our mesh technology. Examples of some areas include peripheral vascular disease, neurovascular disease, renal artery disease, and bifurcation disease.

- **Establish relationships with collaborative and development partners to fully develop and market our existing and future products.** We are seeking strategic partners for collaborative research, development, marketing, distribution, or other agreements, which could assist with our development and commercialization efforts for CGuard EPS and our NGuard flow diverter, as well as future efforts with MGuard Prime EPS, MGuard DES, and other potential products that are based on our MicroNet technology.

- **Continue to protect and expand our portfolio of patents.** Our MicroNet technology and the use of patents to protect it are critical to our success. We own numerous patents for our MicroNet technology. Twelve separate patent applications have been filed in the United States some of which have corresponding patent applications and/or issued patents in Canada, China, Europe, Israel, India, and South Africa. We believe these patents and patent applications collectively cover all of our existing products, and may be useful for protecting our future technology developments. We intend to aggressively continue patenting new technology, and to actively pursue any infringement covered by any of our patents. We believe that our patents, and patent applications once allowed, are important for maintaining the competitive differentiation of our products and maximizing our return on research and development investments.

- **Resume development and successfully commercialize the next generation of drug-eluting stent incorporating MicroNet.** While we have limited the focus of product development to carotid and neurovascular products, if we resume development of our coronary products, we plan to evaluate opportunities to further develop a drug-eluting stent that incorporates MicroNet.

Risks Associated with Our Business

Our ability to operate our business and achieve our goals and strategies is subject to numerous risks as discussed more fully in the section titled "Risk Factors," including, without limitation:

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

- adverse economic conditions;
- adverse federal, state and local government regulation, in the United States, Europe, Israel and other foreign jurisdictions;
- price increases for supplies and components;
- inability to carry out research, development and commercialization plans; and
- loss or retirement of key executives and research scientists.

Corporate Information

We were organized in the State of Delaware on February 29, 2008. Our principal executive offices are located at 321 Columbus Avenue, Boston, Massachusetts 02116. Our telephone number is (857) 305-2410. Our website address is *www.inspire-md.com*. Information accessed through our website is not incorporated into this prospectus and is not a part of this prospectus.

The Offering

Issuer	InspireMD, Inc.
Securities offered by us in this offering	Up to 385,715 shares of our Preferred Stock, par value $0.0001 per share (38,571,500 shares of common stock issuable upon conversion of the Preferred Stock and payment of all dividends accrued on the Preferred Stock in an aggregate of 28,928,625 shares of common stock upon conversion of the Preferred Stock at an assumed conversion price of $0.35 and an assumed stated value per share of $35).[(1)] A warrant to purchase 100 shares of common stock will be issued for every one share of Preferred Stock sold in this offering (38,571,500 shares of our common stock issuable upon exercise of the warrants).[(1)]
Preferred Stock offered by us	Up to 385,715 shares of our Preferred Stock will be offered in this offering. This prospectus also relates to the offering of the shares of common stock issuable upon conversion of the Preferred Stock.[(1)]
Conversion	Our Preferred Stock is convertible into shares of our common stock at a conversion price equal to the public offing price per share, or $, subject to adjustment as provided in the certificate of designation, at any time at the option of the holder prior to the fifth anniversary of the date of issuance, at which time all shares of outstanding Preferred Stock shall automatically and without any further action by the holder be converted into shares of our common stock at the then effective conversion price, provided that the holder will be prohibited from converting Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us. The Preferred Stock, to the extent that it has not been converted previously, is subject to full ratchet anti-dilution price protection upon the issuance of equity or equity-linked securities at an effective common stock purchase price of less than the conversion price then in effect, subject to adjustment as provided in the certificate of designation.
Liquidation preference	In the event of our liquidation, dissolution, or winding up, holders of our Preferred Stock will be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Preferred Stock if such shares had been converted to common stock immediately prior to such event (without giving effect for such purposes to any beneficial ownership limitation), subject to the preferential rights of holders of any class or series of our capital stock specifically ranking by its terms senior to the Preferred Stock as to distributions of assets upon such event, whether voluntarily or involuntarily.

Voting Rights	The holders of the Preferred Stock have no voting rights, except as required by law. Any amendment to our certificate of incorporation, bylaws or certificate of designation that adversely affects the powers, preferences and rights of the Preferred Stock requires the approval of the holders of a majority of the shares of Preferred Stock then outstanding.
Dividends	The holders of Preferred Stock will be entitled to receive cumulative dividends at the rate per share of 15% per annum of the stated value per share, until the fifth anniversary of the date of issuance of the Preferred Stock. The dividends become payable, at our option, in either cash, out of any funds legally available for such purpose, or in shares of common stock, (i) upon any conversion of the Preferred Stock, (ii) on each such other date as our board of directors may determine and (iii) upon our liquidation, dissolution or winding up; provided, however, that if Preferred Stock is converted into shares of common stock at any time prior to the fifth anniversary of the date of issuance of the Preferred Stock, the holder will receive a make-whole payment in an amount equal to all of the dividends that, but for the early conversion, would have otherwise accrued on the applicable shares of Preferred Stock being converted for the period commencing on the conversion date and ending on the fifth anniversary of the date of issuance, less the amount of all prior dividends paid on such converted Preferred Stock before the date of conversion. Make-whole payments are payable at our option in either cash, out of funds legally available for such purpose, or in shares of common stock. With respect to any dividend payments and make-whole payments paid in shares of common stock, the number of shares of common stock to be issued to a holder of Preferred Stock will be an amount equal to the quotient of (i) the amount of the dividend payable to such holder divided by (ii) the conversion price then in effect. Our loan and security agreement with Hercules Capital, Inc. (formerly Hercules Technology Growth Capital, Inc.), dated October 23, 2013, as amended, prohibits us from paying cash dividends or distributions on our capital stock.
Warrants offered by us	Warrants to purchase up to 38,571,500 shares of our common stock. Each warrant will be immediately exercisable, have an exercise price of $ per share of common stock and will expire five years from the date of issuance. The exercise price, expiration date and all other warrant terms may be changed without the consent of investors if we, together with warrant holders holding warrants to acquire a majority of the shares of common stock underlying the warrants, consent to such change. See “Description of Securities” for more information. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants.
Common stock outstanding immediately before this offering	10,701,320 shares

Common stock outstanding immediately after this offering	78,201,445 shares (assuming sale of all shares covered by this prospectus, conversion of 385,715 shares of Preferred Stock into 38,571,500 shares of common stock and payment of all dividends accrued on the Preferred Stock in an aggregate of 28,928,625 shares of common stock upon conversion of the Preferred Stock at an assumed conversion price of $0.35 and an assumed stated value per share of $35, and no exercise of any of the warrants offered hereby).(1)
Use of proceeds	We estimate that our net proceeds from this offering will be approximately $12,118,000, after deducting estimated placement agent fees and other estimated offering expenses payable by us (assuming the sale of all shares covered by this prospectus and no exercise of any of the warrants offered hereby).(1) We plan to use the net proceeds of this offering (i) to pay an aggregate amendment fee of $117,333 to holders of our currently outstanding warrants with an exercise price of $72.00 per share, as consideration for entering into an amendment to the securities purchase agreement, dated April 5, 2012, as amended, to remove certain provisions prohibiting issuance of securities containing anti-dilution protective provisions, and (ii) to conduct sales activities related to CGuard EPS and MGuard Prime EPS and develop our pipeline of new products. Any balance of the net proceeds will be used for general corporate purposes. See “Use of Proceeds.”
Dividend policy	We have not declared or paid any cash or other dividends on our capital stock, and we do not expect to declare or pay any cash or other dividends in the foreseeable future other than on the Preferred Stock. See “Dividend Policy.”
Risk factors	You should carefully read and consider the information beginning on page 7 of this prospectus set forth under the heading “Risk Factors” and all other information set forth in this prospectus and the documents incorporated herein and therein by reference before deciding to invest in our Preferred Stock and warrants.
NYSE MKT symbol for common stock	NSPR. Following completion of this offering, we intend to apply to list the warrants on the NYSE MKT. No assurance can be given that such listing will be approved. The Preferred Stock will not be listed on the NYSE MKT or any other exchange or trading market. There is no established trading market for the Preferred Stock or warrants. We do not expect any such trading market to develop for the Preferred Stock. An active trading market for our warrants may not develop following the completion of this offering or, if developed, may not be sustained.

(1) Based on an assumed offering price of $35 per share of Preferred Stock (which is 100 times $0.35, the last reported sales price of our common stock on June 20, 2016).

The number of shares to be outstanding immediately before and immediately after this offering is based on 10,701,320 shares of our common stock outstanding as of June 20, 2016 and excludes as of that date:

- 91,399 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $72.00 per share;

- 65,912 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $30.00 per share;

- 16,836 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $29.70 per share;

- 313,100 shares of common stock issuable upon the exercise of currently outstanding warrants to purchase one-half of one share of common stock with an exercise price for two warrants of $17.50 per full share;

- 3,436,973 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $5.50 per share;

- 1,466,526 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $0.59 per share;

- 146,653 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $0.7375 per share;

- shares of common stock issuable upon the exercise of currently outstanding warrant issued to Hercules Capital, Inc. on June 13, 2016, equal to $182,399.30, divided by (i) the lowest effective price per share, determined on a common stock-equivalent basis, for which our equity securities are sold and issued by us in an equity financing in which we receive unrestricted aggregate gross cash proceeds of at least $7.5 million, subject to adjustment from time to time in accordance with the terms of the warrant agreement, or (ii) if such equity financing shall not have been consummated on or before July 30, 2016, or if, prior to the consummation of such equity financing, there shall be a transaction involving a change of control or a dissolution, liquidation or winding-up, then the closing price of a share of our common stock on June 13, 2016, subject to adjustment thereafter from time to time;

- 2,700,000 shares of common stock issuable upon conversion of the Preferred Stock and exercise of the warrants to purchase common stock included in the unit purchase option that we have agreed to issue to the placement agent or its designees in this offering, assuming the sale of all shares covered by this prospectus, at a price per share equal to 125% of the public offering price in this offering;

- 1,012,500 shares of common stock issuable as cumulative dividends upon conversion of the Preferred Stock included in the unit purchase option that we have agreed to issue to the placement agent or its designees in this offering, assuming the sale of all shares covered by this prospectus;

- 1,056,852 shares of common stock issuable upon the exercise of currently outstanding options with exercise prices ranging from $0.0001 to $84.00 and having a weighted average exercise price of $8.64 per share;

- 10,122 shares of common stock available for future issuance under our 2011 UMBRELLA Option Plan; and

- 10,212,129 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan.

Unless otherwise stated, all information contained in this prospectus assumes no exercise of the warrants issued in this offering.

Certain of our directors have indicated an interest in purchasing an aggregate of up to approximately $1,100,000 in Preferred Stock and accompanying warrants in this offering at the offering price. However, because indications of interest are not binding agreements or commitments to purchase, these directors may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering.

RISK FACTORS

An investment in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks described below, together with other information in this prospectus, the information and documents incorporated by reference, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business. Please also read carefully the section below entitled "Cautionary Note Regarding Forward-Looking Statements."

Risks Related to Our Business

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

We have yet to establish any history of profitable operations. We reported a net loss of $15.6 million for the fiscal year ended December 31, 2015 and had a net loss of approximately $25 million during the fiscal year ended December 31, 2014. As of March 31, 2016, we had an accumulated deficit of $126 million. We expect to incur additional operating losses for the foreseeable future. There can be no assurance that we will be able to achieve sufficient revenues throughout the year or be profitable in the future.

The report of our independent registered public accounting firm contains an explanatory paragraph as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Because we have had recurring losses and negative cash flows from operating activities, substantial doubt exists regarding our ability to remain as a going concern at the same level at which we are currently performing. Accordingly, the report of Kesselman & Kesselman, our independent registered public accounting firm, with respect to our financial statements at December 31, 2015, includes an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. The doubts regarding our potential ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all.

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 out stockholders' ownership interests.

In order to fully realize all of our business objectives, absent any non-dilutive funding from a strategic partner or some other strategic transactions, we will need to raise additional capital following the completion of this offering, which additional capital may not be available on reasonable terms or at all. For instance, we will need to raise additional funds to accomplish the following:

- development of our current and future products.
- pursuing growth opportunities, including more rapid expansion;
- making capital improvements to improve our infrastructure;
- hiring and retaining qualified management and key employees;
- responding to competitive pressures;
- complying with regulatory requirements such as licensing and registration; and
- maintaining compliance with applicable laws.

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

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

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

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

The voluntary field action of our MGuard Prime EPS we initiated in 2014 could continue to have a significant adverse impact on us.

The manufacturing and marketing of medical devices involves an inherent risk that our products may prove to be defective and cause a health risk even after regulatory clearances have been obtained. Medical devices may also be modified after regulatory clearance is obtained to such an extent that additional regulatory clearance is necessary before the device can be further marketed. In these events, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority.

On April 30, 2014 we initiated a voluntary field corrective action of our MGuard Prime EPS to address the issue of stent retention following reports of MGuard Prime EPS stent dislodgements in patients. Although there have been no reports of death or serious injury as a result of such dislodgements, we decided to suspend shipments of the MGuard Prime EPS and implement a field corrective action to enhance the reliability and performance of the affected product units in the field. We received European regulatory approval to resume manufacturing and distribution of our MGuard Prime EPS stent with a modified stent securement process, and we began shipping products to new customers in our direct markets in Western Europe in late September 2014. We completed the full re-launch of MGuard Prime EPS in 2015, with the exception of Russia.

As a result of our voluntary field action, we are subject to numerous risks and uncertainties, including the following:

- although we resumed manufacturing and distribution of our MGuard Prime EPS stent with a modified stent securement process, our suspension of shipments has and may continue to adversely impact revenue;

- we are more susceptible to claims such as product liability claims, distributor claims and class action lawsuits as a result of the reported product malfunction and voluntary field action, which could significantly increase our costs and may have a material adverse effect on our business, financial condition and results of operations;

- our decision to implement the voluntary field action and discontinue shipments, and any additional action related to such decision, may harm our reputation or the market's perception of our products, which could have a negative impact on our future sales and our ability to generate profits.

In the European Economic Area, we must comply with the EU Medical Device Vigilance System. Under this system, manufacturers are required to take Field Safety Corrective Actions ("FSCAs") to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. A FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

Any adverse event involving our products could result in other future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events, such as the MGuard Prime EPS stent dislodgements, have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business and could harm our reputation and financial results.

In addition to the foregoing, since we initiated our voluntary field action we have received a demand from one distributor that we refund approximately $160,000 in lieu of receiving refitted product and a demand from a second distributor to provide unspecified compensation for pre-paid goods subject to the voluntary field action, related costs and any third claims. We do not believe that these distributors are entitled to any compensation or refunds due to the voluntary field action and we intend to defend ourselves against any such claims, however, regarding the demand from the second distributor, we believe that a loss from any related future proceedings that could range from a minimal amount up to 1,075,000 Euros is reasonably possible. While we are disputing these claims, should an action be filed we could be forced to pay damages which could result in a material adverse effect on our business.

We expect to derive our revenue from sales of our MGuard Prime EPS and CGuard EPS stent products and other products we may develop, such as NGuard. If we fail to generate revenue from these sources, 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 Prime EPS and CGuard EPS stent products and other products we may develop. Future sales of CGuard EPS will be subject to the receipt of regulatory approvals and commercial and market uncertainties that may be outside our control. In addition, sales of MGuard Prime EPS have been hampered by weakened demand for bare metal stents, which may never improve, and we may not be successful in developing a drug-eluting stent product. In addition, there may be insufficient demand for other products we are seeking to develop, such as NGuard. If we fail to generate expected revenues from these products, our results of operations and the value of our business and securities would be materially and adversely affected.

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

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

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the patentability of our pending patent applications. For example, some material references may be in a foreign language and may not be uncovered during examination of our patent applications. Additionally, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the U.S. are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office to determine priority of invention in the 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.

In addition, statutory differences in patentable subject matter depending on the jurisdiction may limit the protection we obtain on certain of the technologies we develop. The laws of some foreign jurisdictions do not offer the same protection to, or may make it more difficult to effect the enforcement of, proprietary rights as in the United States, risk that may be exacerbated if we move our manufacturing to certain countries in Asia. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in any foreign jurisdictions, our business prospects could be substantially harmed.

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

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.

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 Prime EPS and CGuard EPS products at our facility in Tel Aviv, Israel. If there were a disruption to our existing manufacturing facility, we would have no other means of manufacturing our MGuard Prime EPS or CGuard EPS stents 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 Prime EPS or CGuard EPS stents to meet market demand or for use in our current and planned clinical trials, or if our manufacturing process yields substandard stents, our development and commercialization efforts would be delayed.

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

Finally, the production of our stents 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.

Pre-clinical and clinical trials will be lengthy and expensive, and any delay or failure of clinical trials could prevent us from commercializing our MicroNet products, which would materially and adversely affect our results of operations and the value of our business.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the regulatory authorities, including, if we seek in the future to sell our products in the United States, the U.S. Food and Drug Administration. Clinical trials are subject to rigorous regulatory requirements and are expensive and time-consuming to design and implement. They require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. In some trials, a greater number of patients and a longer follow-up period may be required. Patient enrollment in clinical trials and the ability to successfully complete patient follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of our products, or they may be persuaded to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical events unrelated to or related to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays or result in the failure of the clinical trial.

In addition, the length of time required to complete clinical trials for pharmaceutical and medical device products varies substantially according to the degree of regulation and the type, complexity, novelty and intended use of a product, and can continue for several years and cost millions of dollars. The commencement and completion of clinical trials for our existing products and those under development may be delayed by many factors, including governmental or regulatory delays and changes in regulatory requirements, policy and guidelines or our inability or the inability of any potential licensee to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials. In addition, market demand may change for products being tested due to the length of time needed to complete requisite clinical trials. For example, we decided to discontinue our MASTER II trial notwithstanding the resources we had spent on the trial due to the change in market demand for bare metal stents.

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

We believe that physicians will not widely adopt our products unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our products provide a safe and effective alternative to other existing treatments for the conditions we are seeking to address.

If we fail to demonstrate safety and efficacy that is at least comparable to existing and future therapies available on the market, our ability to successfully market our products 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 products will vary. Clinical trials conducted with our products may involve procedures performed by physicians who are technically proficient and are high-volume stent users of such products. Consequently, both short-term and long-term results reported in these clinical trials may be significantly more favorable than typical results of practicing physicians, which could negatively affect rates of adoptions of our products. We also believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our products 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.

Physicians currently consider drug-eluting stents to be the industry standard for treatment of coronary artery disease. None of our current coronary products is a drug-eluting stent, and this may adversely affect our business.

Our ability to attract customers depends to a large extent on our ability to provide goods that meet the customers' and the market's demands and expectations. If we do not have a product that is expected by the market, we may lose customers. The market demand has shifted away from bare metal stents in favor of drug-eluting stents. Our MGuard Prime EPS is a bare-metal stent product, and we have noticed a reduction in the sales level of MGuard Prime EPS compared to the sales level we had in the past. Such sales may never recover and we do not currently have the

resources to develop a drug-eluting stent product. Our failure to provide industry standard devices could adversely affect our business, financial condition and results of operations.

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

Because our products are new and long-term success measures have not been completely validated, regulatory agencies may take a significant amount of time in evaluating product approval applications. Treatments may exhibit a favorable measure using one metric and an unfavorable measure using another metric. Any change in 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 five employees. As a result, we may experience delays in connection with obtaining regulatory approvals for our products.

In addition, the products we and any potential licensees license, develop, manufacture and market are subject to complex regulatory requirements, particularly in the United States, Europe and Asia, which can be costly and time-consuming. There can be no assurance that such approvals will be granted on a timely basis, if at all. Furthermore, there can be no assurance of continued compliance with all regulatory requirements necessary for the manufacture, marketing and sale of the products we will offer in each market where such products are expected to be sold, or that products we have commercialized will continue to comply with applicable regulatory requirements. If a government regulatory agency were to conclude that we were not in compliance with applicable laws or regulations, the agency could institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil and criminal penalties against us, our officers or employees and could recommend criminal prosecution. Furthermore, regulators may proceed to ban, or request the recall, repair, replacement or refund of the cost of, any device manufactured or sold by us. Furthermore, there can be no assurance that all necessary regulatory approvals will be obtained for the manufacture, marketing and sale in any market of any new product developed or that any potential licensee will develop using our licensed technology.

Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any regulatory approvals that we receive for our products will require surveillance to monitor the safety and efficacy of the product and may require us to conduct post-approval clinical studies. In addition, if a regulatory authority approves our products, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements.

Moreover, if we obtain regulatory approval for any of our products, we will only be permitted to market our products for the indication approved by the regulatory authority, and such approval may involve limitations on the indicated uses or promotional claims we may make for our products. In addition, later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or untitled letters;
- holds on clinical trials;
- refusal by the regulatory authority to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions, the imposition of civil penalties or criminal prosecution.

The applicable regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may

have obtained and we may not achieve or sustain profitability.

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.

We are subject to federal, state and foreign healthcare laws and regulations and implementation of or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products. If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to administrative, civil and/or criminal penalties, damages, fines, individual imprisonment, exclusion from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management's attention away from the operation of our business.

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

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

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

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

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

Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our stents based on one or more of these patents. These companies also own patents relating to the use of drugs to treat restenosis, stent architecture, catheters to deliver stents, and stent manufacturing and coating processes and compositions, as well as general delivery mechanism patents like rapid exchange that might be alleged to cover one or more of our products. A number of stent-related patents are owned by very large and well-capitalized companies that are active participants in the stent market. In addition, it is possible that a lawsuit asserting patent infringement, misappropriation of intellectual property, or related claims may have already been filed against us of which we are not aware. As the number of competitors in the stent market grows and as the geographies in which we commercially market grow in number and scope, the possibility of patent infringement by us, and/or a patent infringement or misappropriation claim against us, increases.

These companies have maintained their position in the market by, among other things, establishing intellectual property rights relating to their products and enforcing these rights aggressively against their competitors and new entrants into the market. All of the major companies in the stent and related markets, including Boston Scientific Corporation, C.R. Bard, Inc., W.L. Gore & Associates, Inc. and Medtronic, Inc., have been repeatedly involved in patent litigation relating to stents since at least 1997. The stent and related markets have experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay the introduction of new products and technologies. We may pose a competitive threat to many of the companies in the stent and related markets. Accordingly, many of these companies will have a strong incentive to take steps, through patent litigation or otherwise, to prevent us from commercializing our products. Such litigation or claims would divert attention and resources away from the development and/or commercialization of our product and product development, and could result in an adverse court judgment that would make it impossible or impractical to sell our products in one or more territories.

If we fail to maintain or establish satisfactory agreements or arrangements with suppliers or if we experience an interruption of the supply of materials from suppliers, we may not be able to obtain materials that are necessary to develop our products.

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

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

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

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

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

We face risks associated with litigation and claims.

We may, in the future, be involved in one or more lawsuits, claims or other proceedings. These suits could concern issues including contract disputes, employment actions, employee benefits, taxes, environmental, health and safety, personal injury and product liability matters. In November 2015, we received written communication from a service provider to remit payment amounting to $1,965,000. Given the preliminary stage, our management and legal counsel cannot estimate the outcome of any legal proceedings or settlements related to this communication, however we believe that neither a court loss nor settlement are probable.

On April 26, 2016, Microbanc, LLC and Todd Spenla of Microbanc filed suit in New York State Supreme Court against us seeking approximately $2.2 million and 9% of the amount of stock and warrants sold in 2011 and 2012 in alleged damages relating to certain alleged finders' fees. See "Business — Legal Proceedings" for more information. Due to the uncertainties of litigation, however, we can give no assurance that we will prevail on any claims made against us in any such lawsuit. Also, we can give no assurance that any other lawsuits or claims brought in the future will not have an adverse effect on our financial condition, liquidity or operating results.

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

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

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

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

- foreign currency exchange rate fluctuations;
- greater difficulty in staffing and managing foreign operations;
- greater risk of uncollectible accounts;
- longer collection cycles;
- logistical and communications challenges;
- potential adverse changes in laws and regulatory practices, including export license requirements, trade barriers, tariffs and tax laws;
- changes in labor conditions;
- burdens and costs of compliance with a variety of foreign laws;
- political and economic instability;
- the escalation of hostilities in Israel, which could impair our ability to manufacture our products;
- increases in duties and taxation;
- foreign tax laws and potential increased costs associated with overlapping tax structures;

- greater difficulty in protecting intellectual property;

- the risk of third party disputes over ownership of intellectual property and infringement of third party intellectual property by our products; and

- general economic and political conditions in these foreign markets.

Further, in the past, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business and trade activity with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

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

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

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

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

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

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act were enacted into law in the United States in March 2010. Certain provisions of these acts are not yet fully implemented, it may be a number of years before certain provisions are fully implemented, there remain to be programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impacts will be from the legislation. The legislation levies a 2.3% excise tax, that began on January 1, 2013, on all sales of any U.S. medical device listed with the U.S. Food and Drug Administration under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Part 807, unless the device falls within an exemption from the tax, such as the exemption governing direct retail sale of devices to consumers or for foreign sales of these devices. If we commence sales of our MGuard Prime EPS or CGuard EPS 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. Uncertainties remain regarding what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include

value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the provisions include a reduction in the annual rate of inflation for hospitals which started in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. We cannot predict what healthcare programs and regulations will be implemented or changed at the federal or state level in the United States, or the effect of any future legislation or regulation. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business plan to introduce our products in the United States.

On September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework governing medical devices in the European Union. These proposals are currently being reviewed by the European Parliament and the Council and may undergo significant amendments as part of the legislative process. If adopted by the European Parliament and the Council in their present form, these proposed revisions would, among other things, impose stricter requirements on medical device manufacturers and strengthen the supervising competences of the competent authorities of European Union Member States and the notified bodies. As a result, if and when adopted, the proposed new legislation could prevent or delay the CE marking of our products under development or impact our ability to modify our currently CE marked products on a timely basis. The regulation of advanced therapy medicinal products is also in continued development in the European Union, with the European Medicines Agency publishing new clinical or safety guidelines concerning advanced therapy medicinal products on a regular basis. Any of these regulatory changes and events could limit our ability to form collaborations and our ability to continue to commercialize our products, and if we fail to comply with any such new or modified regulations and requirements it could adversely affect our business, operating results and prospects.

Risks Related to Operating in Israel

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

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

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

Our sole manufacturing facility and certain of our key personnel are located in Israel. Our business is directly affected by the political, economic and military conditions in Israel and its neighbors. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. A state of hostility, varying in degree and intensity, has caused security and economic problems in Israel. Although Israel has entered into peace treaties with Egypt and Jordan, and various agreements with the Palestinian Authority, there has been a marked increase in violence, civil unrest and hostility, including armed clashes, between the State of Israel and the Palestinians since September 2000. The establishment in 2006 of a government in the Gaza Strip by representatives of the Hamas militant group has created heightened unrest and uncertainty in the region. In mid-2006, Israel engaged in an armed conflict with Hezbollah, a Shiite Islamist militia group based in Lebanon, and in June 2007, there was an escalation in violence in the Gaza Strip. From December 2008 through January 2009 and again in November and December 2012, Israel engaged in an armed conflict with Hamas, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In July 2014, Israel launched an additional operation against Hamas operatives in the Gaza strip in response to Palestinian groups launching rockets at Israel. Recent political uprisings and social unrest in Syria are affecting its political stability, which has led to the deterioration of the political relationship between Syria and Israel and have raised new concerns regarding security in the region and the potential for armed conflict. Similar civil unrest and political turbulence is currently ongoing in many countries in the region. The continued political instability and hostilities between Israel and its neighbors and any future armed conflict, terrorist activity or political instability in the region could adversely affect our operations in Israel and adversely affect the market price of our shares of common stock. In addition, several countries restrict doing

business with Israel and Israeli companies have been and are today subjected to economic boycotts. The interruption or curtailment of trade between Israel and its present trading partners could adversely affect our business, financial condition and results of operations.

In addition, some of our officers or key employees may be called to active duty at any time under emergency circumstances for extended periods of time. See "— Our operations could be disrupted as a result of the obligation of certain of our personnel residing in Israel to perform military service."

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

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

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

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

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

A significant portion of our intellectual property has been developed by our Israeli employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967 (the "Israeli Patent Law"), inventions conceived by an employee during the term and as part of the scope of his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Israeli Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee (the "C&R Committee"), a body constituted under the Israeli Patent Law, shall determine whether the employee is entitled to remuneration for his inventions. The C&R Committee (decisions of which have been upheld by the Israeli Supreme Court) has held that employees may be entitled to remuneration for their service inventions despite having specifically waived any such rights. Further, the C&R Committee has not yet set specific guidelines regarding the method for calculating this remuneration or the criteria or circumstances under which an employee's waiver of his right to remuneration will be disregarded. We generally enter into intellectual property assignment agreements with our employees pursuant to which such employees assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to us service invention rights and have specifically waived their right to receive any special remuneration for such assignment beyond their regular salary and benefits, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current or former employees, or be forced to litigate such claims, which could negatively affect our business.

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

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

The tax benefits that are currently available to us under Israeli law require us to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to pay increased taxes and would likely be denied these benefits in the future.

InspireMD Ltd. has been granted a "Beneficiary Enterprise" status by the Investment Center in the Israeli Ministry of Industry Trade and Labor, and we are therefore eligible for tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959. The main benefit is a two-year exemption from corporate tax, commencing when we begin to generate net income derived from the beneficiary activities in facilities located in Israel, and a reduced corporate tax rate for an additional five years, depending on the level of foreign investment in each year. In addition, under the January 1, 2011 amendment to the Israeli Law for the Encouragement of Capital Investments, 1959, a uniform corporate tax rate of 16% applies to all qualifying income of "Preferred Enterprise," which we may be able to apply as an alternative tax benefit.

The tax benefits available to a Beneficiary Enterprise or a Preferred Enterprise are dependent upon the fulfillment of conditions stipulated under the Israeli Law for the Encouragement of Capital Investments, 1959 and its regulations, as amended, which include, among other things, maintaining our manufacturing facilities in Israel. If we fail to comply with these conditions, in whole or in part, the tax benefits could be cancelled and we could be required to refund any tax benefits that we received in the past. If we are no longer eligible for these tax benefits, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies in 2015 is 26.5% and in 2016 is 25% of taxable income. The termination or reduction of these tax benefits would increase our tax liability, which would reduce our profits.

In addition to losing eligibility for tax benefits currently available to us under Israeli law, if we do not maintain our manufacturing facilities in Israel, we will not be able to realize certain tax credits and deferred tax assets, if any, including any net operating losses to offset against future profits.

The tax benefits available to Beneficiary Enterprises may be reduced or eliminated in the future. This would likely increase our tax liability.

The Israeli government may reduce or eliminate in the future tax benefits available to Beneficiary enterprises and Preferred Enterprises. Our Beneficiary Enterprise status and the resulting tax benefits may not continue in the future at their current levels or at any level. The 2011 amendment regarding Preferred Enterprise may not be applicable to us or may not fully compensate us for the change. The termination or reduction of these tax benefits would likely increase our tax liability. The amount, if any, by which our tax liability would increase will depend upon the rate of any tax increase, the amount of any tax benefit reduction, and the amount of any taxable income that we may earn in the future.

Risks Related to Our Common Stock and this Offering

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

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

- technological innovations or new products and services by us or our competitors;

- additions or departures of key personnel;
- our ability to execute our business plan;
- operating results that fall below expectations;
- loss of any strategic relationship;
- industry developments;
- economic, political and other external factors; and
- period-to-period fluctuations in our financial results.

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

Because there is no minimum required for the offering to close, investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus.

We have not specified a minimum offering amount nor have or will we establish an escrow account in connection with this offering. Because there is no escrow account and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Further, because there is no escrow account in operation and no minimum investment amount, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. Investor funds will not be returned under any circumstances whether during or after the offering.

A continued low trading price could lead the NYSE MKT to take actions toward delisting our common stock, including immediately suspending trading in our common stock.

Pursuant to Section 1003(f)(v) of the NYSE MKT Company Guide (the “Company Guide”), the NYSE MKT could take action to delist our common stock in the event that our common stock trades at levels viewed as abnormally low for a substantial period of time. Our stock has traded at prices less than $1.00 for much of the past several months. In

addition, the NYSE MKT has advised us that its policy is to immediately suspend trading in shares of, and commence delisting procedures with respect to, a listed company if the market price of its shares falls below $0.06 per share at any time during the trading day. The closing price of our common stock on the NYSE MKT on June 20, 2016 was $0.35 per share, and the significant dilutive effect of this offering may result in our stock trading below this threshold and lead NYSE MKT to immediately suspend trading in our common stock.

Even if we complete this offering, our common stock could be delisted from the NYSE MKT if we fail to regain compliance with the NYSE MKT's continued listing standards on the schedule required by the NYSE MKT.

On January 20, 2015, we received a notice indicating that we do not meet certain of the NYSE MKT's continued listing standards as set forth in Part 10 of the Company Guide. Specifically, we were not in compliance with Section 1003(a)(i), Section 1003(a)(ii) and Section 1003(a)(iii) of the Company Guide because we reported stockholders' equity of less than $2 million, $4 million, and $6 million, respectively, as of September 30, 2014 and had net losses in our five most recent fiscal years. In addition, the NYSE MKT indicated that we were not in compliance with Section 1003(a)(iv) of the Company Guide because we have sustained losses that are substantial in relation to our overall operations or our existing financial resources, or our financial condition has become impaired such that it appears questionable, in the opinion of the NYSE MKT, as to whether we will be able to continue operations and/or meet our obligations as they mature. As a result, we have become subject to the procedures and requirements of Section 1009 of the Company Guide.

In order to maintain our listing on the NYSE MKT, we submitted a plan of compliance to the NYSE MKT on February 19, 2015 addressing how we intend to regain compliance with Section 1003(a)(iii) of the Company Guide (which should also make us in compliance with Section 1003(a)(i) and Section(a)(ii) by having stockholders' equity of greater than $2 million and $4 million, respectively) by July 20, 2016 and Section 1003(a)(iv) of the Company Guide by June 1, 2015. On March 9, 2015, we closed a public offering of our common stock and warrants that resulted in net proceeds of approximately $12.5 million after deducting placement agent fees and other estimated offering expenses. In light of this, the NYSE MKT determined that the continued listing deficiency with respect to Section 1003(a)(iv) of the Company Guide has been resolved. In addition, the NYSE MKT has accepted our plan to gain compliance with the Section 1003(a)(iii) of the Company Guide by July 20, 2016.

We believe, based on our current estimate we will be required to complete one or more offerings that will provide us with net proceeds of at least $12 million prior to July 20, 2016 in order to regain compliance with Section 1003(a)(iii) of the Company Guide. The foregoing assumes our net loss for the quarter ending June 30, 2016 is similar to our net loss for March 31, 2016, of which there is no assurance. As this is a best efforts offering, we can provide no assurance that the net proceeds from this offering will provide us with sufficient stockholders' equity to regain compliance with Section 1003(a)(iii) of the Company Guide. We are not required to raise any minimum amount of proceeds from this offering and we may choose to complete this offering at a level that will not satisfy the requirements of Section 1003(a)(iii) of the Company Guide.

If we do not regain compliance with Section 1003(a)(iii) of the Company Guide by July 20, 2016, or if we do not maintain our progress consistent with the plan during the applicable plan period, the NYSE MKT will initiate delisting proceedings. The market price and liquidity of our common stock could be adversely affected by the commencement of such proceedings. If those proceedings resulted in delisting of our common stock and resulting cessation of trading of the stock on the NYSE MKT, we believe that the market price and liquidity of our common stock would be adversely affected.

Our management team may invest or spend the proceeds of this offering in ways with which you may not agree or in ways which may not yield a significant return.

Our management will have broad discretion over the use of proceeds from this offering. We intend to use the net proceeds of this offering to pay an aggregate amendment fee of $117,333 to holders of our currently outstanding warrants with an exercise price of $72.00 per share, as consideration for entering into an amendment to the securities purchase agreement, dated April 5, 2012, as amended, to remove certain provisions prohibiting issuance of securities containing anti-dilution protective provisions and to conduct sales activities related to CGuard EPS and MGuard Prime EPS and for general corporate purposes. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates.

If you purchase the Preferred Stock sold in this offering and assuming its conversion into shares of our common stock, you will experience immediate and substantial dilution in your investment.

Since the price per share of our Preferred Stock being offered in this offering exceeds the net tangible book value per share of our common stock outstanding prior to this offering, you will suffer immediate and substantial dilution with respect to the net tangible book value of the Preferred Stock you purchase in this offering, assuming conversion of the Preferred Stock into shares of our common stock. After giving effect to the sale by us all 385,715 shares of Preferred Stock covered by this prospectus, based on a public offering price of $35 per share of Preferred Stock and accompanying warrant (which is equal to $0.35 per share on an as-converted-to-common stock basis) and deducting estimated placement agent fees and other estimated offering expenses payable by us and assuming conversion of the Preferred Stock into shares of our common stock and payment of all dividends accrued on the Preferred Stock in shares of common stock upon conversion of the Preferred Stock at an assumed conversion price of $0.35 and an assumed stated value per share of $35, you will experience immediate dilution of $0.24 per share of common stock, representing the difference between our as adjusted net tangible book value per share of common stock as of March 31, 2016 and the public offering price. If any outstanding options or warrants are exercised, you could experience further dilution. For the purpose of this calculation, the entire purchase price for the shares of Preferred Stock and accompanying warrants is being allocated to the shares of Preferred Stock, and shares issuable upon exercise of the warrants have not been included. Furthermore, the exercise of outstanding warrants and options may result in further dilution of your investment. See the section entitled “Dilution” on page 29 below for a more detailed illustration of the dilution you will incur if you participate in this offering.

Purchasers in this offering may experience additional dilution in the book value of their investment in the future.

We are not restricted from issuing additional securities in the future, including shares of common stock, securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or substantially similar securities. The issuance of these securities may cause further dilution to our stockholders. In order to raise additional capital, we may in the future offer such additional securities at prices that may not be the same as the price per share in this offering. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, including investors who purchase securities in this offering. The price per share at which we sell additional shares of our common stock or securities convertible into common stock in future transactions may be higher or lower than the price per share in this offering. The exercise of outstanding stock options and the vesting of outstanding restricted stock units may also result in further dilution of your investment.

Because our offering will be conducted on a best efforts basis, there can be no assurance that we can raise the money we need.

The placement agent is offering the securities on a "best efforts" basis with no minimum, and the placement agent is under no obligation to purchase any securities for their own account. The placement agent is not required to sell any specific number or dollar amount of securities in this offering but will use its best efforts to sell the securities offered in this prospectus. As a "best efforts" offering, there can be no assurance that the offering contemplated hereby will ultimately be consummated. If the offering is not consummated or we receive less than the maximum proceeds, our business plans and prospects for the current fiscal year could be adversely affected.

There is no public market for the Preferred Stock or the warrants being offered in this offering.

The Preferred Stock and the warrants are new issues of securities with no established trading market. Following completion of this offering, we intend to apply to list the warrants on the NYSE MKT. No assurance can be given that such listing will be approved. The Preferred Stock will not be listed on any securities exchange and we do not expect the Preferred Stock to be quoted on any quotation system. There is no established trading market for the Preferred Stock or warrants. An active trading market for our warrants may not develop following the completion of this offering or, if developed, may not be sustained. A trading market for the Preferred Stock is not expected to develop, and even if a market develops for the Preferred Stock, it may not provide meaningful liquidity. The absence of a trading market or liquidity for the Preferred Stock or the warrants may adversely affect their value.

The certificate of designation for our Preferred Stock contains anti-dilution provisions that may result in the reduction of the conversion price for the Preferred Stock in the future. This feature may result in an indeterminate number of shares of common stock being issued upon conversion.

The certificate of designation for our Preferred Stock contains anti-dilution provisions, which provisions require the lowering of the conversion price to the purchase price of future offerings. If in the future we issue securities for less than the conversion price of our Preferred Stock, we will be required to further reduce the relevant conversion price, which will result in a greater number of shares of common stock being issuable upon conversion, which in turn will have a greater dilutive effect on our shareholders. In addition, as there is no floor price on the conversion price, we cannot determine the total number of shares issuable upon conversion. As such, it is possible that we will not have sufficient available shares to satisfy the conversion of the Preferred Stock if we enter into a future transaction that lowers the conversion price. If we do not have sufficient available shares for any Preferred Stock conversions, we will be required to increase our authorized shares, which may not be possible and will be time consuming and expensive. The potential for such issuances may depress the price of our common stock regardless of our business performance. We may find it more difficult to raise additional equity capital while our Preferred Stock is outstanding.

The Preferred Stock provides for the payment of dividends in cash or in shares of our common stock, and we may not be permitted to pay such dividends in cash, which will require us to have shares of common stock available to pay the dividends.

Each share of Preferred Stock will be entitled to receive cumulative dividends at the rate per share of 15% per annum of the state value per share, until the fifth anniversary of the date of issuance of the Preferred Stock. The dividends are payable, at our discretion, in cash, out of any funds legally available for such purpose, or in pay-in-kind shares of common stock calculated based on the conversion price, subject to adjustment as provided in the certificate of designation. The conversion price is subject to reduction if in the future we issue securities for less than the conversion price of our Preferred Stock. As there is no floor price on the conversion price, we cannot determine the total number of shares issuable upon conversion or in connection with the dividend. As such, it is possible that we will not have sufficient available shares to pay the dividend in common stock, which would require the payment of the dividend in cash. We will not be permitted to pay the dividend in cash unless we are legally permitted to do so under Delaware law, which requires cash to be available from surplus or net profits neither of which we currently have available. Additionally, we are also subject to certain restrictions pursuant to our loan and security agreement with Hercules Capital, Inc., which prohibits us from paying cash dividends or distributions on our capital stock. As such, we do not expect to have cash available to pay the dividends on our Preferred Stock or to be permitted to make such payments under our loan agreements, and will be relying on having available shares of common stock to pay such dividends, which will result in dilution to our shareholders. If we do not such available shares, we may not be able to satisfy our dividend obligations.

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

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

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

The ongoing internal control provisions of Section 404 of the Sarbanes-Oxley Act of 2002 require us to identify of material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally

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

In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business with us, cause downgrades in our future debt ratings leading to higher borrowing costs and affect how our stock trades. This could in turn negatively affect our ability to access public debt or equity markets for capital.

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

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

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

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

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. Our stockholders and the holders of our options and warrants may sell substantial amounts of our common stock in the

public market. The availability of these shares of our common stock for resale in the public market has the potential to cause the supply of our common stock to exceed investor demand, thereby decreasing the price of our common stock.

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

If securities and/or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely or if our results of operations do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.

Aspects of the treatment of the securities may be uncertain.

The tax treatment of the Preferred Stock and the warrants is uncertain and may vary depending upon whether you are an individual or a legal entity and whether or not you are domiciled in the United States. In the event you are a non-U.S. investor, you should consult your tax advisors as to the consequences, under the tax laws of the country where you are resident for tax purposes, of acquiring, holding and disposing of the Preferred Stock and the warrants.

Risks Related to our Indebtedness

Our obligations under our $10 million principal term loan are secured by all of our assets, so if we default on those obligations, the lender could foreclose on our assets. As a result of these security interests, such assets would only be available to satisfy claims of our general creditors or to holders of our equity securities if we were to become insolvent at a time when the value of such assets exceeded the amount of our indebtedness and other obligations. In addition, the existence of these security interests may adversely affect our financial flexibility.

The lender under our $10 million principal term loan has a security interest in all of our assets and those of InspireMD Ltd., our wholly-owned subsidiary. As a result, if we default under our obligations to the lender, the lender could foreclose on its security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations.

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

The pledge of these assets and other restrictions may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged under the $10 million principal term loan, our ability to incur additional secured indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

Our loan and security agreement contains customary events of default. In addition, an event of default will include the occurrence of a circumstance that would reasonably be expected to have a material adverse effect upon (i) our

business, operations, properties, assets, prospects or condition (financial or otherwise), (ii) our ability to perform our obligations under the agreement and any related loan documents or (iii) the collateral, the lender's liens on the collateral or the priority of such liens.

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

Pursuant to the terms of our loan and security agreement, the lender made a term loan to us and InspireMD Ltd. in aggregate amount of $10 million. We are required to make monthly payments of interest and principal in the amount of approximately $380,000 per month. The current principal amount of the loan as of April 1, 2016 was approximately $3.6 million. On June 13, 2016, the parties to the loan and security agreement entered into an amendment to the loan and security agreement to provide a deferral of payment of principal for a four month period beginning May 1, 2016. However, the deferral is subject to the satisfaction of certain interest only period extension conditions, including us raising net cash proceeds of at least $10 million from the sale of our equity securities with investors acceptable to the lender on or prior to June 30, 2016. The term loan under the loan and security agreement, as amended, matures on (i) April 1, 2017, if we do not complete such sale of our equity securities and the lender does not waive such condition to complete such sale prior to June 30, 2016, or (ii) June 1, 2017, if we complete such sale of our equity securities, or if the lender waives such condition to complete such sale of our equity securities, prior to June 30, 2016.

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

- we may be unable to obtain additional financing to fund working capital, operating losses, capital expenditures or acquisitions on terms acceptable to us, or at all;
- the amount of our interest expense may increase because our term loan has a variable rate of interest at any time that the prime rate, as reported in the Wall Street Journal, is above 5.5%;
- we will need to use a substantial portion of our cash flows to pay principal and interest on our term loan, which will reduce the amount of money we have for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other business activities;

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

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

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

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

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

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

- pay cash dividends to our stockholders;

- redeem or repurchase our common stock or other equity;

- incur additional indebtedness;

- permit liens on assets;

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

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

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

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- loss of a key customer or supplier;

- technical problems with our research and products and potential product liability claims;

- adverse economic conditions;

- adverse federal, state and local government regulation, in the United States, Europe or Israel;

- price increases for supplies and components;

- inability to carry out research, development and commercialization plans; and

- loss or retirement of key executives and research scientists.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. You should review carefully the section entitled “Risk Factors” beginning on page 7 of this prospectus for a discussion of these and other risks that relate to our business and investing in our securities. The forward-looking statements contained or incorporated by reference in this prospectus are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the securities offered under this prospectus, after deducting estimated placement agent fees and other estimated offering expenses payable by us, will be approximately $12,118,000 if we sell the maximum amount of Preferred Stock and warrants offered hereby. However, this is a best efforts offering with no minimum, and we may not sell all or any of the securities; as a result, we may receive significantly less in net proceeds, and the net proceeds received may not be sufficient to continue to operate our business. If a warrant holder elects to exercise the warrants issued in this offering, we may also receive proceeds from the exercise of the warrants. If all of these warrants were to be exercised at an exercise price of $ per share, then we would receive net proceeds of approximately $. We expect to use these proceeds, if any, for operations and general working capital requirements at the time of such exercise. We cannot predict when or if the warrants will be exercised. It is possible that the warrants may expire and may never be exercised.

We intend to use the net proceeds from this offering (i) to pay an aggregate amendment fee of $117,333 to holders of our currently outstanding warrants with an exercise price of $72.00 per share, as consideration for entering into an amendment to the securities purchase agreement, dated April 5, 2012, as amended, to remove certain provisions prohibiting issuance of securities containing anti-dilution protective provisions, and (ii) to conduct sales activities related to CGuard EPS and MGuard Prime EPS and develop our pipeline of new products. Any balance of the net proceeds will be used for general corporate purposes.

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

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

- a change in development plan or strategy;
- the addition of new products or applications;
- technical delays;

- delays or difficulties with our clinical trials;

- negative results from our clinical trials;

- difficulty obtaining regulatory approval;

- failure to achieve sales as anticipated; and

- the availability of other sources of cash including cash flow from operations and new bank debt financing arrangements, if any.

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

A $10 increase or decrease in the anticipated public offering price of $35 per share of Preferred Stock and the accompanying warrant would increase or decrease the net proceeds to us from this offering by approximately $3,510,000, assuming we sell the maximum amount of Preferred Stock and warrants offered hereby and after deducting estimated placement agent fees and other estimated offering expenses payable by us. Similarly, any increase or decrease in the number of shares of Preferred Stock and accompanying warrants that we sell in the offering will increase or decrease our net proceeds in proportion to such increase or decrease, as applicable, multiplied by the offering price per share of Preferred Stock and the accompanying warrant, less estimated placement agent fees and other estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual public offering price, the number of securities sold and other terms of this offering determined at pricing.

PRICE RANGE OF OUR COMMON STOCK

Our common stock has been quoted on the NYSE MKT since April 11, 2013 under the symbol “NSPR.” Prior to that date, it was traded on the OTC Bulletin Board.

The following table sets forth the intra-day high and low sales price per share for our common stock, as reported on the NYSE MKT, for the periods indicated. The sales prices for our common stock prior to October 1, 2015, are adjusted for the one-for-ten reverse stock split of our common stock that occurred on such date:

	Common Stock	
	High	Low
Fiscal Year Ending December 31, 2016		
Second quarter (through June 20, 2016)	$ 0.62	$ 0.32
First quarter	$ 0.95	$ 0.39
Fiscal Year Ended December 31, 2015		
Fourth quarter	$ 2.12	$ 0.63
Third quarter	$ 3.20	$ 1.50
Second quarter	$ 4.20	$ 1.90
First quarter	$ 10.10	$ 2.30
Fiscal Year Ended December 31, 2014		
Fourth quarter	$ 22.30	$ 7.00
Third quarter	$ 30.20	$ 18.10
Second quarter	$ 32.50	$ 17.90
First quarter	$ 38.00	$ 24.80

The closing price of our common stock on the NYSE MKT on June 20, 2016 was $0.35 per share. Immediately prior to this offering, we had 10,701,320 issued and outstanding shares of common stock, which were held by approximately 214 holders of record.

DIVIDEND POLICY

In the past, we have not declared or paid cash dividends on our capital stock. Our loan and security agreement with Hercules Capital, Inc. (formerly Hercules Technology Growth Capital, Inc.), dated October 23, 2013, as amended, prohibits us from paying cash dividends or distributions on our capital stock. Even if we are permitted to pay cash dividends in the future, we do not intend to do so. Rather, we intend to retain future earnings, if any, to fund the operation and expansion of our business and for general corporate purposes.

27

CAPITALIZATION

The following table summarizes our cash and cash equivalents, certain other items from our historical consolidated balance sheet, and capitalization as of March 31, 2016:

- on an actual basis; and
- on an unaudited as adjusted basis, giving effect to (1) the filing of the amendment to our amended and restated certificate of incorporation to increase the number of authorized shares of common stock from 50,000,000 to 150,000,000, which was filed on May 25, 2016, and (2) our receipt of the net proceeds from the sale by us in this offering of Preferred Stock and warrants at an anticipated public offering price of $35 per share of Preferred Stock, assuming the conversion of all of the Preferred Stock into shares of common stock and payment of all dividends accrued on the Preferred Stock in shares of common stock upon conversion of the Preferred Stock and after deducting estimated placement agent fees and other estimated offering expenses payable by us.

For the purposes of the Capitalization discussion, we determined the assumed number of shares by dividing (x) $13,500,000 that we anticipate raising in this offering by (y) an assumed offering price of $35 per share of Preferred Stock, which is 100 times $0.35, the last reported sales price of our common stock on June 20, 2016. The actual number of shares sold in this offering will be determined by dividing (x) $13,500,000 by (y) the public offering price as mutually determined by the placement agent and us. The as adjusted information below is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual public offering price, the number of securities sold and other terms of this offering determined at pricing. You should read this table together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited financial statements and the related notes appearing elsewhere in this prospectus.

	March 31, 2016 (in thousands) (unaudited)	
	Actual	As Adjusted
Cash and cash equivalents	1,999	14,116
Equity:		
Common stock, par value $0.0001 per share – 50,000,000 shares authorized and 10,722,974 shares issued and outstanding actual; 150,000,000 shares authorized and 78,223,099 shares issued and outstanding as adjusted[(1)]	1	8
Preferred stock, par value $0.0001 per share; 5,000,000 shares authorized:		
Series A Preferred Stock, par value $0.0001 per share; none issued and outstanding at March 31, 2015 and as adjusted	—	—
Series B Convertible Preferred Stock, par value $0.0001 per share; none issued and outstanding at March 31, 2015; 385,715 shares issued as adjusted	—	—
Additional paid-in capital	122,209	134,319

Accumulated deficit	(125,605)	(125,605)
Total equity	(3,395)	8,722

(1) 78,223,099 shares issued and outstanding as adjusted includes 38,571,500 shares of common stock underlying Preferred Stock being sold in this offering and 28,928,625 shares of common stock as payment of all dividends accrued on the Preferred Stock upon conversion of the Preferred Stock at an assumed conversion price of $0.35 and an assumed stated value per share of $35 and does not include 38,571,500 shares of common stock issuable upon the full exercise of the warrants being sold in this offering, 2,700,000 shares of common stock issuable upon conversion of the Preferred Stock and exercise of the warrants to purchase common stock included in the placement agent’s unit purchase option, and 1,012,500 shares of common stock issuable as cumulative dividend upon conversion of the Preferred Stock included in the placement agent’s unit purchase option.

DILUTION

The discussion assumes the price of $0.35 per share of common stock, which is the last reported sales price of our common stock on June 20, 2016, and an offering price of $35 per share of Preferred Stock and the accompanying warrant to purchase common stock, which is 100 times the last reported sales price of our common stock on June 20, 2016.

If you invest in our Preferred Stock, your interest will be diluted to the extent of the difference between the price per share of Preferred Stock you pay in this offering and the as adjusted net tangible book value per share of our common stock immediately after this offering (assuming the conversion of all of the Preferred Stock into shares of common stock). For the purpose of such calculation, the entire purchase price for the shares of Preferred Stock and accompanying warrants is being allocated to the shares of Preferred Stock, and the shares issuable upon exercise of the accompanying warrants have not been included.

Our net tangible book value of our common stock as of March 31, 2016 was approximately $(3,470), or approximately $(0.32) per share of common stock based on 10,722,974 shares outstanding (including 10,671,187 vested restricted shares and 51,787 unvested restricted shares) at that time. “Net tangible book value” is total assets minus the sum of liabilities and intangible assets. “Net tangible book value per share” is net tangible book value divided by the total number of shares outstanding.

After giving effect to the sale of 385,715 shares of Preferred Stock and accompanying warrants to purchase 38,571,500 shares of our common stock in the aggregate amount of $13,500,000 in this offering and deducting estimated placement agent fees and other estimated offering expenses payable by us, our net tangible book value as of March 31, 2016 would have been approximately $8,647,000, or approximately $0.11 per share of common stock based on 78,223,099 shares of common stock outstanding on a pro forma basis at that time (assuming conversion of 385,715 shares of Preferred Stock into 38,571,500 shares of common stock, payment of all dividends accrued on the Preferred Stock in an aggregate of 28,928,625 shares of common stock upon conversion of the Preferred Stock at an assumed conversion price of $0.35 and an assumed stated value per share of $35 and no exercise of any of the warrants offered hereby). This represents an immediate increase in net tangible book value of $0.43 per share to our existing stockholders and an immediate dilution of approximately $0.24 per share to new investors participating in this offering (assuming conversion of all of the Preferred Stock into shares of common stock), as illustrated by the following table:

Public offering price per share of common stock	$0.35
Net tangible book value per share of common stock as of March 31, 2016	$(0.32)

Increase in net tangible book value per share of common stock attributable to the offering	$0.43
Pro forma net tangible book value per share of common stock as of March 31, 2016 after giving effect to the offering	$0.11
Dilution in net tangible book value per share of common stock to new investors in the offering	$0.24

The discussion of dilution, and the table quantifying it, attribute no value to the warrants being issued in this offering and assume no exercise of any of the warrants offered hereby or thereby or any outstanding options or warrants or other potentially dilutive securities. The exercise of potentially dilutive securities having an exercise price less than the offering price would increase the dilutive effect to new investors.

In particular, the table above excludes the following potentially dilutive securities as of March 31, 2016:

- 91,399 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $72.00 per share;
- 65,912 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $30.00 per share;
- 16,836 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $29.70 per share;
- 313,100 shares of common stock issuable upon the exercise of currently outstanding warrants to purchase one-half of one share of common stock with an exercise price for two warrants of $17.50 per full share;

- 3,436,973 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $5.50 per share;

- 1,466,526 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $0.59 per share;

- 146,653 shares of common stock issuable upon the exercise of currently outstanding warrants with an exercise price of $0.7375 per share;

- shares of common stock issuable upon the exercise of currently outstanding warrant issued to Hercules Capital, Inc. on June 13, 2016, equal to $182,399.30, divided by (i) the lowest effective price per share, determined on a common stock-equivalent basis, for which our equity securities are sold and issued by us in an equity financing in which we receive unrestricted aggregate gross cash proceeds of at least $7.5 million, subject to adjustment from time to time in accordance with the terms of the warrant agreement, or (ii) if such equity financing shall not have been consummated on or before July 30, 2016, or if, prior to the consummation of such equity financing, there shall be a transaction involving a change of control or a dissolution, liquidation or winding-up, then the closing price of a share of our common stock on June 13, 2016, subject to adjustment thereafter from time to time;

- 2,700,000 shares of common stock issuable upon conversion of the Preferred Stock and exercise of the warrants to purchase common stock included in the unit purchase option that we have agreed to issue to the placement agent or its designees in this offering, assuming the sale of all shares covered by this prospectus, at a price per share equal to 125% of the public offering price in this offering;

- 1,012,500 shares of common stock issuable as cumulative dividends upon conversion of the Preferred Stock included in the unit purchase option that we have agreed to issue to the placement agent or its designees in this offering, assuming the sale of all shares covered by this prospectus;

- 1,056,852 shares of common stock issuable upon the exercise of currently outstanding options with exercise prices ranging from $0.0001 to $84.00 and having a weighted average exercise price of $8.64 per share;

- 10,122 shares of common stock available for future issuance under our 2011 UMBRELLA Option Plan; and

- 10,212,129 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan.

To the extent that any of these options are exercised, new options are issued under our equity incentive plans and subsequently exercised or we issue additional shares of common stock in the future, there will be further dilution to new investors participating in this offering.

We may sell less than 385,715 shares of Preferred Stock. An increase of 10,000 shares in the number of shares of Preferred Stock sold by us would increase our as adjusted net tangible book value after this offering by approximately $0.3 million, or $0.002 per share, and the dilution per share to new investors would be approximately $0.24 per share, assuming conversion of all of the Preferred Stock into shares of common stock and that the public offering price remains the same and after deducting estimated placement agent fees and other estimated offering expenses payable by us.

Similarly, a decrease of 10,000 shares of Preferred Stock in the number of shares sold by us would decrease our as adjusted net tangible book value after this offering by approximately $0.3 million, or $0.002 per share, and the dilution per share to new investors would be approximately $0.24 per share, assuming conversion of all of the Preferred Stock into shares of common stock and that that the public offering price remains the same and after deducting estimated placement agent fees and other estimated offering expenses payable by us.

Assuming the issuance of all Preferred Stock and accompanying warrants offered by us in this offering and assuming the conversion of all of the Preferred Stock into shares of common stock, each $10 increase (decrease) in the anticipated public offering price of $35 per share of Preferred Stock and the accompanying warrant would increase (decrease) our pro forma as adjusted net tangible book value by approximately $3.5 million, the pro forma as adjusted net tangible book value per share by approximately $0.04 per share and the dilution to investors in this offering by approximately $0.06 per share, assuming the number of shares of Preferred Stock and warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated placement agent fees and other estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual public offering price, the number of securities sold and other terms of this offering determined at pricing.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

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

Overview

We are a medical device company focusing on the development and commercialization of our proprietary MicroNet stent platform technology for the treatment of complex coronary and vascular disease. A stent is an expandable "scaffold-like" device, usually constructed of a metallic material, that is inserted into an artery to expand the inside passage and improve blood flow. Our MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures. Our MGuard Prime EPS, which incorporate our MicroNet platform technology, is marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

Our second product, CGuard EPS combines our MicroNet mesh and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013, and we launched its release on a limited basis in October 2014. In January 2015, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, we announced the full market launch of CGuard EPS in Europe through a distribution agreement with Penumbra, Inc. In September 2015, we also received regulatory approval to commercialize CGuard EPS in Argentina and Colombia. Following the receipt of such regulatory approval, we launched CGuard EPS in Argentina in the first quarter of 2016 and Colombia in the fourth quarter of 2015.

We are also developing a neurovascular flow diverter, which is an endovascular device that directs blood flow away from cerebral aneurysms in order to ultimately seal the aneurysms. Our flow diverter would utilize an open cell, highly flexible metal scaffold to which MicroNet would be attached. We have commenced initial pre-clinical testing of this product in both simulated bench models and standard in vivo pre-clinical models.

We also intend to develop a pipeline of other products and additional applications by leveraging our MicroNet technology to new applications to improve peripheral vascular and neurovascular procedures, such as the treatment of the superficial femoral artery disease, vascular disease below the knee and neurovascular stenting to open diseased vessels in the brain.

Presently, none of our products may be sold or marketed in the United States.

Recent Events

During the first quarter of 2015, we implemented a cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) limiting the focus of clinical and development expenses to only carotid and neurovascular products; (iii) limiting sales and marketing expenses to those related to the CGuard EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, rent, etc.). In addition, we decided to alter our commercial strategy by using third party distributors to drive future sales, as opposed to direct sales to hospitals and clinics, which had previously been our focus.

On March 21, 2016, we sold 1,900,000 shares of our common stock and warrants to purchase 950,000 shares of our common stock in a public offering. Each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the offering. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. This offering resulted in gross proceeds to us of approximately $1.1 million, before deducting the underwriting discount and estimated offering expenses.

On March 21, 2016, we sold 1,033,051 shares of our common stock and warrants to purchase 516,526 shares of our common stock in a private placement. Each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the private placement. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. This private placement resulted in gross proceeds to us of approximately $0.6 million, before deducting placement agent fees and estimated offering expenses.

These sales of securities on March 21, 2016 resulted in aggregate net proceeds to us of approximately $1.4 million, after deducting underwriting discount, placement agent fees and other offering expenses.

Critical Accounting Policies

We prepared our consolidated financial statements for inclusion in this report in accordance with U.S. Generally Accepted Accounting Principles ("U.S. GAAP"). U.S. GAAP represents a comprehensive set of accounting and disclosure rules and requirements, and applying these rules and requirements requires management judgments and estimates including, in certain circumstances, choices between acceptable U.S. GAAP alternatives. The following is a discussion of our most critical accounting policies, judgments and uncertainties that are inherent in our application of U.S. GAAP.

Use of estimates

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

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to inventory valuations, royalty buyout and legal contingencies.

Functional currency

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

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 and cash equivalents, which are deposited in major financially sound institutions in the United States, Israel and Germany, and trade accounts receivable. Our trade accounts receivable are derived from revenues earned from customers from various countries. We perform ongoing credit evaluations of our customers' financial condition and, generally, require no collateral from customers. We also have a credit insurance policy for some 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 management reasonably believes will be collected, which is netted against "Accounts receivable — Trade".

Inventory

Inventories are stated at the lower of cost (cost is determined on a "first-in, first-out" basis) or market value. Our inventories generally have a limited shelf life and are subject to impairment as they approach their expiration dates. We regularly evaluate the carrying value of our inventories and when, based on such evaluation, factors indicate that impairment has occurred, we impair the inventories' carrying value.

Revenue recognition

Revenue is recognized when delivery has occurred, evidence of an arrangement exists, title and risks and rewards for the products are transferred to the customer, collection is reasonably assured and product returns can be reliably estimated.

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 and expensed over the requisite service period, net of estimated forfeitures. We estimate forfeitures based on historical experience and anticipated future conditions.

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

In addition, certain share-based awards are performance based and dependent upon achieving certain goals. With respect to these awards, we estimate the expected pre-vesting award probability that the performance conditions will be achieved. We only recognize expense for those shares that are expected to vest.

Uncertain tax and value added tax positions

We follow a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit. If under the first step a tax provision is assessed to be more likely than not of being sustained on audit, the second step is performed, under which the tax benefit is measured as the largest amount that is more than 50% likely to be 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 related to unrecognized tax benefits within "Financial expenses (income) — net."

Fair value measurement

We measure fair value and disclose fair value measurements for financial assets and liabilities. Fair value is based on 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.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and consider counterparty credit risk in our assessment of fair value.

Allocation of issuance proceeds

When debt or equity is issued with other components that are subsequently measured at fair value, the proceeds are allocated first to such components (such as warrants and embedded derivatives in the debt that require bifurcation at their fair values), then the residual amount of the proceeds is allocated to the debt or equity. When other components

are classified in equity, the proceeds are allocated based on relative fair values.

33

Results of Operations

Three months ended March 31, 2016 compared to the three months ended March 31, 2015

Revenues. For the three months ended March 31, 2016, revenue increased by $0.1 million, or 18.2%, to $0.6 million, from $0.5 million during the same period in 2015. This increase was predominantly driven by a 437.4% increase in sales of CGuard EPS from $60,000 in the three months ended March 31, 2015 to $0.3 million in the same period in 2016. This increase in CGuard EPS sales were partially offset by a 41.7% decrease in sales of MGuard Prime EPS from $0.4 million in the three months ended March 31, 2015 to $0.3 million in the same period in 2016, predominantly driven by a decrease in sales due to the trend of doctors increasingly using drug-eluting stents rather than bare metal stents in ST-segment elevation myocardial infarction, the most severe form of a heart attack, referred to as STEMI, patients.

With respect to regions, the increase in revenue was primarily attributable to an increase of $0.1 million in revenue from our distributors in Europe.

Gross Profit (Loss). For the three months ended March 31, 2016, we had a gross profit (revenue less cost of revenues) of $66,000, as compared to a gross loss (revenue less cost of revenues) of $37,000, during the same period in 2015, representing an increase of $0.1 million. This increase in gross profit was attributable to an increase in revenues of $0.1 million (see above for explanation) and a decrease of write-offs of inventory of $0.2 million, which were primarily related to a decrease of write-offs of MGuard Prime EPS units during the three months ended March 31, 2016, as compared to the same period in 2015, partially offset by an increase of $0.1 million in material and labor costs due to the increased sales and an increase of $0.1 million related to the underutilization of our manufacturing resources. Gross margin (gross profits as a percentage of revenue) increased to 11.7% in the three months ended March 31, 2016 from (7.8)% in the same period in 2015.

Research and Development Expenses. For the three months ended March 31, 2016, research and development expenses decreased by 64.6%, or $0.9 million, to $0.5 million, from $1.4 million during the same period in 2015. This decrease in research and development expenses resulted primarily from a decrease of $0.3 million in clinical trial and development costs associated with CGuard EPS, a decrease of $0.3 million in compensation expenses, a decrease of $0.1 million in clinical trial expenses associated with our MASTER II trial, a decrease of $0.1 million of expenses related to the development of a drug eluting coronary stent and a decrease of $0.1 million in miscellaneous clinical and development expenditures related to MGuard Prime EPS. Such decreases are the results of the implementation of our cost reduction/focused spending plan beginning in the first quarter of 2015.

Selling and Marketing Expenses. For the three months ended March 31, 2016, selling and marketing expenses decreased by 62.0%, or $0.6 million, to $0.4 million, from $1.0 million during the same period in 2015. This decrease in selling and marketing expenses resulted primarily from a decrease of $0.4 million in compensation expenses due to our transition away from direct sales in favor of using third party distributors, a decrease of $0.1 million in travel expenses associated with the decreased size of our sales force and a decrease of $0.1 million in miscellaneous expenses. The decrease in spending was a result of our cost reduction/focused spending plan.

General and Administrative Expenses. For the three months ended March 31, 2016, general and administrative expenses decreased by 19.3%, or $0.4 million, to $1.6 million, from $2.0 million during the same period in 2015. The decrease in general and administrative expenses resulted primarily from a decrease of $0.2 million in miscellaneous expenses such as investor relations, audit, rent, consultants and travel, as part of our cost reduction/focused spending plan, a decrease of $0.1 million of share based compensation expenses pertaining to the change in our forfeiture rate assumptions of restricted stock of our chief executive officer and a decrease of $0.1 million in litigation expenses following a one-time charge in Argentina of $0.1 million in the three months ended March 31, 2015.

Restructuring and Impairment Expenses. For the three months ended March 31, 2015 we incurred $0.5 million of restructuring and impairment expenses made up of $0.3 million of expenses related to the impairment of an MGuard royalties buyout option due to anticipated lower sales in the future, $0.1 million of cash payouts and $0.1 million of restricted shares given to terminated employees in connection with our restructuring. No such expense occurred during the same period in 2016.

Financial Expenses. For the three months ended March 31, 2016, financial expenses decreased by 27.8% or $0.1 million, to $0.2 million, from $0.3 million during the same period in 2015. The decrease in financial expenses resulted from a decrease of $0.1 million of interest expenses due to the reduction in principal of our outstanding indebtedness.

Tax Expenses (Income). For the three months ended March 31, 2016 there was no material change in tax expenses (income) compared to the same period in 2015.

Net Loss. Our net loss decreased by $2.6 million, or 49.9%, to $2.6 million for the three months ended March 31, 2016 from $5.2 million during the same period in 2015. The decrease in net loss resulted primarily from a decrease of $2.4 million in operating expenses primarily associated with lower research and development, sales and marketing and restructuring expenses, due to our cost reduction/focused spending plan, a decrease of $0.1 million in financial expenses and an increase of $0.1 million in gross profit.

Twelve months ended December 31, 2015 compared to the twelve months ended December 31, 2014

Revenues. For the twelve months ended December 31, 2015, revenue decreased by $0.5 million, or 18.1%, to $2.3 million, from $2.8 million during the same period in 2014. This decrease was predominantly driven by a decrease in sales of our MGuard coronary products of $1.2 million, or 42.6%, from $2.8 million in the twelve months ended December 31, 2014 to $1.6 million in the same period in 2015. This decrease in sales of MGuard Prime EPS was predominantly driven by a decrease in sales volume of $0.8 million, or 28.9% due to the trend of doctors increasingly using drug-eluting stents rather than bare metal stents in STEMI patients, which impacted current sales. Price decreases to our distributors drove the remaining decrease of $0.4 million, or 13.7%, of MGuard Prime EPS, due to lower average sales prices necessary to remain competitive amongst sharp price decreases in the coronary stent market, as well as the effects of the weakening of the Euro against the U.S dollar. These decreases, however, were partially offset by an increase of $0.7 million of sales of our new product CGuard EPS, which was launched in October 2014.

With respect to regions, the decrease in revenue was primarily attributable to a decrease of $0.7 million in revenue from our distributors in the Middle East and a decrease of $0.1 million in revenue from our distributors in Asia, partially offset by an increase of $0.3 million in revenue from our distributors in Europe.

Gross Profit (Loss). For the twelve months ended December 31, 2015, we had a gross loss (revenue less cost of revenues) of $0.3 million, as compared to a gross profit of $0.8 million during the same period in 2014, representing a decrease of 137.8%, or $1.1 million. This decrease in gross profit was attributable to a decrease in revenues of $0.5 million (see above for explanation), an increase of write-offs of inventory of $0.4 million, which were primarily related to write-offs of MGuard Prime EPS units due to expected lower sales in the future resulting from industry preferences for drug eluting stents, and our transition to a third party distributor commercial strategy, an increase in labor and material costs of $0.3 million attributable to higher material and labor costs for CGuard EPS, as well as an increase of $0.3 million related to underutilization of our manufacturing resources. These increases, however, were partially offset by a decrease of $0.4 million in costs associated with the voluntary field action. Gross margin (gross profits as a percentage of revenue) decreased from 27.8% in the twelve months ended December 31, 2014 to (12.8)%

in the same period in 2015. The decrease in gross margin of 40.6% was driven mainly by write-offs of inventory, the change in product mix, including a higher percentage of CGuard EPS, which has higher material and labor costs than our MGuard coronary products, and a lower average sales price of MGuard Prime EPS.

Research and Development Expenses. For the twelve months ended December 31, 2015, research and development expenses decreased by 58.3%, or $5.1 million, to $3.6 million, from $8.7 million during the same period in 2014. This decrease in research and development expenses resulted primarily from a decrease of $3.4 million in clinical trial expenses associated with our MASTER II trial, a decrease of $0.5 million in clinical trial and development costs associated with CGuard EPS, which were predominantly related to our CARENET (**CAR**otid **E**mbolic protection using micro**NET**) trial, a decrease of $0.3 million in compensation expenses, a decrease of $0.3 million of expenses related to our stent retention program, which we concluded in 2014, a decrease of $0.2 million in travel expenses and a decrease of $0.4 million in miscellaneous clinical and development expenditures related to MGuard Prime EPS. The decreases in compensation, travel and miscellaneous clinical and development expenditures related to MGuard Prime EPS are the results of the implementation of our cost reduction/focused spending plan in the first quarter of 2015. Research and development expenses as a percentage of revenue decreased to 157.7% for the twelve months ended December 31, 2015, from 310.3% in the same period in 2014.

Selling and Marketing Expenses. For the twelve months ended December 31, 2015, selling and marketing expenses decreased by 51.9%, or $3.4 million, to $3.2 million, from $6.6 million during the same period in 2014. This decrease in selling and marketing expenses resulted primarily from a decrease of $2.2 million in compensation expenses due to our transition away from direct sales in favor of using third party distributors, a decrease of $0.5 million in travel expenses associated with the decreased size of our sales force, a decrease of $0.5 million in trade show participation related expenditures and a decrease of $0.2 million in miscellaneous expenses. The decrease in spending of the above was a result of our cost reduction/focused spending plan. Selling and marketing expenses as a percentage of revenue decreased to 137.6% in the twelve months ended December 31, 2015, from 234.7% in the same period in 2014.

General and Administrative Expenses. For the twelve months ended December 31, 2015, general and administrative expenses decreased by 30.0%, or $2.7 million, to $6.4 million, from $9.1 million during the same period in 2014. The decrease in general and administrative expenses resulted primarily from a decrease of $2.1 million in compensation due to a decrease in share-based compensation driven by lower valued ESOP grants made to our management and directors, as well as a decrease in salary expenses due to a reduced headcount as part of our cost reduction/focused spending plan. In line with our cost reduction/focused spending plan, we also had a decrease of $0.2 million in legal expenses, a decrease of $0.1 million in travel expenditures and a decrease of $0.4 million in miscellaneous expenses. General and administrative expenses as a percentage of revenue decreased to 276.5% in the twelve months ended December 31, 2015 from 323.8% in the same period in 2014.

Restructuring and Impairment Expenses. For the twelve months ended December 31, 2015, we incurred $1.0 million of restructuring and impairment expenses made up of $0.6 million of expenses related to the impairment of an MGuard Prime EPS royalty buyout option due to anticipated lower sales in the future due to the shift in industry preferences away from bare metal stents in favor of drug eluting stents, $0.2 million of cash payouts and $0.1 million of restricted shares given to employees terminated in connection with our cost reduction/focused spending plan and $0.1 million in fees associated with our early exit from a portion of our lease in our Boston office. Restructuring and impairment expenses as a percentage of revenue was 42.5% for the twelve months ended December 31, 2015.

Financial Expenses. For the twelve months ended December 31, 2015, financial expenses decreased by 20.9%, or $0.3 million, to $1.1 million, from $1.4 million during the same period in 2014. The decrease in financial expenses resulted from a decrease of $0.4 of interest expenses due to the reduction in principal of our outstanding indebtedness, partially offset by an increase in miscellaneous expenses of $0.1 million. Financial expenses as a percentage of revenue decreased to 47.4% in the twelve months ended December 31, 2015, from 49.1% in the same period in 2014.

Tax Expenses (Income). For the twelve months ended December 31, 2015 there was no material change in tax expenses (income) compared to the same period in 2014.

Net Loss. Our net loss decreased by $9.5 million, or 37.9%, to $15.6 million for the twelve months ended December 31, 2015 from $25.1 million during the same period in 2014. The decrease in net loss resulted primarily from a decrease of $10.2 million in operating expenses primarily associated with lower research and development expenses, due to our cost reduction/focused spending plan, and a decrease of $0.3 million in financial expenses, partially offset by a decrease of $1.0 million in gross profit (see above for explanation).

Liquidity and Capital Resources

We had an accumulated deficit as of March 31, 2016, as well as net losses and negative operating cash flows in recent years. We expect to continue incurring losses and negative cash flows from operations until our products (primarily CGuard EPS) reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we do not have sufficient resources to fund operations beyond June 2016. Therefore, there is substantial doubt about our ability to continue as a going concern.

Our plans include the continued commercialization of our products and raising capital through sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances however, that we will be successful in obtaining the level of financing needed for our operations. If we are unsuccessful in commercializing our products and raising capital, we may need to reduce activities, curtail or cease operations.

On October 23, 2013, we entered into a loan and security agreement with Hercules Capital, Inc., which was subsequently amended on November 19, 2013, July 23, 2014, and June 13, 2016, pursuant to which we received a loan of $10 million, before deduction of issuance costs. Interest on the loan is determined on a daily basis at a variable rate equal to the greater of either (i) 10.5%, or (ii) the sum of (A) 10.5% plus (B) the prime rate minus 5.5%. On June 13, 2016, we amended the loan and security agreement to provide that, among other things, the principal payment otherwise due and payable will be suspended for a four month period beginning May 1, 2016, provided, that we receive unrestricted and unencumbered net cash proceeds in an amount of at least $10 million from the sale of our equity securities with investors acceptable to the lender on or prior to June 30, 2016. The term loan under the loan and security agreement, as amended, matures on (i) April 1, 2017, if we do not complete such sale of our equity securities and the lender does not waive such condition to complete such sale prior to June 30, 2016, or (ii) June 1, 2017, if we complete such sale of our equity securities, or if the lender waives such condition to complete such sale of our equity securities, prior to June 30, 2016. Our obligations under the loan and security agreement are secured by a grant of a security interest in all of our assets. In addition, in connection with the loan and security agreement, on October 23, 2013, we issued the lender a five year warrant to purchase 168,351 shares of our common stock at a per share exercise price of $2.97. On June 13, 2016, in connection with the amendment to the loan and security agreement, we issued the lender a five year warrant to purchase up to the number of shares of common stock equal to $182,399.30, divided by (i) the lowest effective price per share, determined on a common stock-equivalent basis, for which our equity securities are sold and issued by the Company in an equity financing in which we receive unrestricted aggregate gross cash proceeds of at least $7.5 million, subject to adjustment from time to time in accordance with the terms of the warrant agreement, or (ii) if such equity financing shall not have been consummated on or before July 30, 2016, or if, prior to the consummation of such equity financing, there shall be a transaction involving a change of control or a dissolution, liquidation or winding-up, then the closing price of a share of our common stock on June 13, 2016, subject to adjustment thereafter from time to time in accordance with the terms of the warrant agreement.

On October 23, 2013, we entered into an at-the-market issuance sales agreement with MLV & Co. LLC ("MLV"), pursuant to which we may issue and sell shares of our common stock in an aggregate amount up to $40 million from time to time in an "at-the-market" offering as defined in Rule 415 under the Securities Act of 1933, as amended, through MLV as our sales agent. On August 15, 2014, we sold 94,800 shares of our common stock, at $24.00 per share, pursuant to the at-the-market issuance sales agreement with MLV. These sales resulted in net proceeds to us of approximately $2.2 million. We paid MLV compensation at a commission rate of 3% of the gross sales. Prior to these sales, we have not made any sales under this "at-the-market" equity offering program, and, as of December 31, 2015, shares of our common stock having an aggregate value of approximately $37.7 million remained available for sale under this offering program. Such sales were made pursuant to our effective $75 million shelf registration statement filed with the Securities and Exchange Commission in October 2013 (File No. 333-191875). Our securities purchase agreement with purchasers of shares of our common stock and warrants to purchase our common stock, dated March 4, 2015, entered into in connection with the public offering described below, prohibits us from issuing and selling additional shares of our common stock under this "at-the-market" equity offering program until March 9, 2017.

On November 7, 2014, we sold 626,189 shares of our common stock and warrants to purchase 313,100 shares of our common stock in a registered direct offering. The shares of common stock were sold at a negotiated purchase price of $13.00 per share, and each purchaser received a warrant to purchase one-half of a share of common stock for each share of common stock that it purchased in the offering. The warrants are non-exercisable for six months after the date of issuance and have a term of exercise of 42 months after the date of issuance and an exercise price of $17.50. This offering resulted in net proceeds to us of approximately $7.4 million after deducting placement agent fees and other estimated offering expenses. Such sales were made pursuant to the $75 million shelf registration statement.

On March 9, 2015, we sold 3,436,968 shares of our common stock and warrants to purchase 3,436,968 shares of our common stock in a public offering. Each purchaser received a warrant to purchase one share of common stock for each share of common stock that it purchased in the offering. The warrants have a term of exercise of 5 years from the date of issuance and an exercise price of $5.50. This offering resulted in net proceeds to us of approximately $12.4 million after deducting placement agent fees and other estimated offering expenses. Such sales were made pursuant to the $75 million shelf registration statement.

On March 21, 2016, we sold 1,900,000 shares of our common stock and warrants to purchase 950,000 shares of our common stock in a public offering. Each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the offering. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. This offering resulted in gross proceeds to us of approximately $1.1 million.

On March 21, 2016, we sold 1,033,051 shares of our common stock and warrants to purchase 516,526 shares of our common stock in a private placement. Each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the offering. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. This offering resulted in

gross proceeds to us of approximately $0.6 million.

These offerings on March 21, 2016, resulted in net proceeds to us of approximately $1.4 million after deducting placement agent fees and other estimated offering expenses. The sale of 1,900,000 shares of our common stock and warrants to purchase 950,000 shares of our common stock was made pursuant to the $75 million shelf registration statement.

As of June 21, 2016, shares of our common stock having an aggregate value of approximately $49.7 million remained available for sale under the shelf registration statement, including approximately $37.7 million remaining available for sale under "at-the-market" equity offering program; however, because our current aggregate value of public float is below $75 million, we may not sell more than the equivalent of one-third of our public float during any 12 consecutive months, and as of June 21, 2016, we have no "shelf capacity" under the $75 million shelf registration statement and cannot make further sales pursuant to such shelf registration statement.

Three months ended March 31, 2016 compared to the three months ended March 31, 2015

General. At March 31, 2016, we had cash and cash equivalents of $2.0 million, as compared to $3.3 million as of December 31, 2015. We have historically met our cash needs through a combination of issuing new shares, borrowing activities and product sales. Our cash requirements are generally for research and development, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was $1.9 million for the three months ended March 31, 2016 and $4.6 million for the same period in 2015. The principal reason for the usage of cash in our operating activities for the three months ended March 31, 2016 was a net loss of $2.6 million, offset primarily by $0.7 million in non-cash share based compensation that was largely paid to our directors and chief executive officer. The principal reason for the usage of cash in our operating activities for the three months ended March 31, 2015 was a net loss of $5.2 million, as well as an increase in working capital of $0.9 million, offset by $1.0 million in non-cash share-based compensation that was largely paid to our directors and chief executive officer, $0.3 million of non-cash expenses related to the impairment of our royalties buyout option (discussed above), $0.1 million of non-cash financial expense and $0.1 million of depreciation and amortization expenses.

Cash provided by our investing activities was $90,000 during the three months ended March 31, 2016, resulting from the receipt of cash previously funded to employee retirement funds, compared to $11,000 of cash used by our investing activities during the same period in 2015.

Cash provided by financing activities for the three months ended March 31, 2016 was $0.5 million, compared to $11.6 million during the same period in 2015. The principal source of the cash provided by financing activities during the three months ended March 31, 2016 was the issuance of shares and warrants in a concurrent public offering and private placement for approximately $1.5 million of proceeds, offset by loan repayments of $1.0 million The principal source of the cash provided by financing activities during the three months ended March 31, 2015 relates to funds received from the issuance of shares and warrants of approximately $12.5 million in a public offering, offset by the repayment of a loan of $0.9 million and $0.1 million of payments made by us in satisfaction of tax withholding obligations associated with the vesting of restricted stock held by some of our employees.

As of March 31, 2016, our current liabilities exceeded our current assets by a multiple of 2.1. Current assets decreased by $1.3 million during the period and current liabilities increased by $0.2 million during the period. As a result, our working capital deficit increased by $1.5 million to $3.7 million at March 31, 2016.

Twelve months ended December 31, 2015 compared to the twelve months ended December 31, 2014

General. At December 31, 2015, we had cash and cash equivalents of $3.3 million, as compared to $6.3 million as of December 31, 2014. We have historically met our cash needs through a combination of issuing new shares, borrowing activities and product sales. Our cash requirements are generally for research and development, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was $11.6 million for the twelve months ended December 31, 2015 and $19.4 million for the same period in 2014. The principal reasons for the usage of cash in our operating activities for the twelve months ended December 31, 2015 were a net loss of $15.6 million, as well as an increase in working capital of $0.2 million, offset by $3.1 million in non-cash share based compensation that was largely paid to our directors, chief executive officer and chief operating officer $0.6 million of non-cash expenses related to the impairment of our royalty buyout option (discussed above), $0.3 million of non-cash financial expenses and $0.2 million of depreciation and amortization expenses. The principal reasons for the usage of cash in our operating activities for the twelve months ended December 31, 2014, were a net loss of $25.1 million, offset by $4.1 million in non-cash share-based compensation that was largely paid to our directors and chief executive officer, a decrease in working capital of $0.9 million, $0.4 million of non-cash financial expense and $0.3 million of depreciation and amortization expenses.

Cash used in our investing activities was $23,000 during the twelve months ended December 31, 2015, compared to $86,000 during the same period in 2014. The decrease in cash used in our investing activities resulted primarily from a decrease in purchases of property, plant and equipment.

Cash provided by financing activities for the twelve months ended December 31, 2015, was $8.6 million, compared to $8.3 million during the same period in 2014. The principal source of the cash provided by financing activities during the twelve months ended December 31, 2015 was the issuance of shares and warrants in a public offering for approximately $12.4 million after deducting placement agent fees and other estimated offering expenses, offset by loan repayments of $3.7 million and $0.1 million of payments made by us in satisfaction of tax withholding obligations associated with the vesting of restricted stock held by some of our employees. The principal source of the cash provided by financing activities during the twelve months ended December 31, 2014, relates to funds received from the issuance of shares in a registered direct offering of $7.4 million and funds received from the issuance of at-the-market shares of $2.2 million, offset by the repayment of a loan of $1.2 million.

As of December 31, 2015, our current liabilities exceeded our current assets by a multiple of 1.5. Current assets decreased by $4.7 million during the period and current liabilities decreased by $1.6 million during the period. As a result, our working capital surplus decreased by $3.1 million to a working capital deficit of $2.3 million at December 31, 2015.

Off Balance Sheet Arrangements

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

Recent Accounting Pronouncements

In April, 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2015-03, “Simplifying the Presentation of Debt Issuance Costs.” The new guidance requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. The new guidance does not affect the recognition and measurement of debt issuance costs. The new guidance became effective during the first quarter of 2016 and was applied on a retrospective basis. As of March 31, 2016 and December 31, 2015, $68,000 and $85,000, respectively were deducted from the carrying value of the “Current maturity of loan” in the condensed consolidated balance sheets.

In May 2014, the FASB issued Accounting Standards Codification 606, Revenue from contracts with customers. The objective of the new revenue standard is to provide a single, comprehensive revenue recognition model for all contracts with customers to improve comparability within industries, across industries, and across capital markets. The revenue standard contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services, based on a five step model that includes the identification of the contract with the customer and the performance obligations in the contract, determination of the transaction price, allocation of the transaction price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies a performance obligation. The revenue standard is effective for annual periods beginning on or after December 15, 2016. We are currently evaluating the impact, if any, the adoption of this guidance will have on its consolidated financial statements.

On July 9, 2015, the FASB approved a one-year deferral of the effective date of Accounting Standards Update No. 2014-09, “Revenue from Contracts with Customers,” such that it is effective beginning on or after December 15, 2017 for public entities. Reporting entities may choose to adopt the standard as of the original effective date.

On July 22, 2015, the FASB issued Accounting Standards Update No. 2015-11, “Simplifying the Measurement of Inventory,” which requires that inventory within the scope of the guidance be measured at the lower of cost and net realizable value. Inventory measured using last-in, first-out and the retail inventory method are not impacted by the new guidance. The new guidance will be effective for public business entities in fiscal years beginning after December 15, 2016, including interim periods within those years. Prospective application is required. Early adoption is permitted as of the beginning of an interim or annual reporting period. We are currently evaluating the impact of the standard on its consolidated financial statements.

In March 2016, FASB issued Accounting Standards Update which simplifies certain aspects of the accounting for share-based payments, including accounting for income taxes, classification of awards as either equity or liabilities, classification on the statement of cash flows as well as allowing an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. This Accounting Standards Update is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted in any annual or interim period for which financial statements have not yet been issued, and all amendments in the Accounting Standards Update that apply must be adopted in the same period. We are currently evaluating the new guidance to determine the impact it may have on our consolidated financial statements. In addition, the impact on our consolidated financial statements upon adoption is dependent on our share price at option expiration dates and restricted stock vesting dates.

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

BUSINESS

Overview

We are a medical device company focusing on the development and commercialization of our proprietary MicroNet stent platform technology for the treatment of complex vascular and coronary disease. A stent is an expandable "scaffold-like" device, usually constructed of a metallic material, that is inserted into an artery to expand the inside passage and improve blood flow. Our MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

Our CGuard EPS combines our MicroNet mesh and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013, and we launched its release on a limited basis in October 2014. In January 2015, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, we announced the full market launch of CGuard EPS in Europe through a distribution agreement with Penumbra, Inc. In September 2015, we also received regulatory approval to commercialize CGuard EPS in Argentina and Colombia. Following the receipt of such regulatory approval, we launched CGuard EPS in Argentina in the first quarter of 2016 and Colombia in the fourth quarter of 2015.

Our MGuard Prime EPS is marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). MGuard Prime EPS combines the MicroNet with a bare-metal cobalt-chromium based stent and, together with our first generation MGuard stent combining the MicroNet with a bare-metal stainless steel stent, unless otherwise indicated, we refer to both kinds of bare-metal stents as MGuard coronary products. We market and sell MGuard Prime EPS for the treatment of coronary disease in the European Union. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. However, as a result of a shift in industry preferences away from bare-metal stents in favor of drug-eluting (drug-coated) stents, in 2014 we decided to curtail further development of this product in order to focus on the development of a drug-eluting stent product, MGuard DES. Due to limited resources, though, our efforts have been limited to testing drug-eluting stents manufactured by potential partners for compatibility and incorporating our MicroNet in-house onto a drug-eluting stent manufactured by a potential partner. We are also developing a neurovascular flow diverter, which is an endovascular device that directs blood flow away from cerebral aneurysms in order to ultimately seal the aneurysms. Our flow diverter would utilize an open cell, highly flexible metal scaffold to which MicroNet would be attached. We have commenced initial pre-clinical testing of this product in both simulated bench models and standard in vivo pre-clinical models.

We also intend to develop a pipeline of other products and additional applications by leveraging our MicroNet technology to new applications to improve peripheral vascular and neurovascular procedures, such as the treatment of the superficial femoral artery disease, vascular disease below the knee and neurovascular stenting to open diseased vessels in the brain.

Presently, none of our products may be sold or marketed in the United States.

During the first quarter of 2015, we implemented a cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) limiting the focus of clinical and development expenses to only carotid and neurovascular products; (iii) limiting sales and marketing expenses to those related to CGuard EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, rent, etc.). In addition, we decided to alter our commercial strategy by using third party distributors to drive future sales, as opposed to direct sales to hospitals and clinics, which had previously been our focus.

Recent Developments

On March 21, 2016, we sold 1,900,000 shares of our common stock and warrants to purchase 950,000 shares of our common stock in a public offering. Each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the offering. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. This offering resulted in gross proceeds to us of approximately $1.1 million, before deducting the underwriting discount and estimated offering expenses.

On March 21, 2016, we sold 1,033,051 shares of our common stock and warrants to purchase 516,526 shares of our common stock in a private placement. Each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the private placement. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. This private placement resulted in gross proceeds to us of approximately $0.6 million, before deducting placement agent fees and estimated offering expenses.

These sales of securities on March 21, 2016 resulted in aggregate net proceeds to us of approximately $1.4 million, after deducting underwriting discount, placement agent fees and other offering expenses.

Growth Strategy

Our primary business objective is to utilize our proprietary technology to become the industry standard for treatment of complex vascular and coronary disease 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.

- **Grow our presence in existing and new markets for CGuard EPS.** We have fully launched CGuard EPS in most European and Latin American countries, through a combination of distributor sales organizations as well as a partnership with Penumbra, Inc., a global interventional therapies company focused on the neuro and peripheral vascular specialties, to distribute CGuard EPS in 18 European countries. We are also pursuing additional registrations and contracts in other countries in Europe, Asia and Latin America.

- **Continue to leverage MicroNet 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 continue to broadly develop and protect intellectual property using our mesh technology. Examples of some areas include peripheral vascular disease, neurovascular disease, renal artery disease, and bifurcation disease.

- **Establish relationships with collaborative and development partners to fully develop and market our existing and future products.** We are seeking strategic partners for collaborative research, development, marketing, distribution, or other agreements, which could assist with our development and commercialization efforts for CGuard EPS and our NGuard flow diverter, as well as future efforts with MGuard Prime EPS, MGuard DES, and other potential products that are based on our MicroNet technology.

- **Continue to protect and expand our portfolio of patents.** Our MicroNet technology and the use of patents to protect it are critical to our success. We own numerous patents for our MicroNet technology. Twelve separate patent applications have been filed in the United States some of which have corresponding patent applications and/or issued patents in Canada, China, Europe, Israel, India, and South Africa. We believe these patents and patent applications collectively cover all of our existing products, and may be useful for protecting our future technology developments. We intend to aggressively continue patenting new technology, and to actively pursue any infringement covered by any of our patents. We believe that our patents, and patent applications once allowed, are important for maintaining the competitive differentiation of our products and maximizing our return on research and development investments.

- **Resume development and successfully commercialize the next generation of drug-eluting stent incorporating MicroNet.** While we have limited the focus of product development to carotid and neurovascular products, if we resume development of our coronary products, we plan to evaluate opportunities to further develop a drug-eluting stent that incorporates MicroNet.

Business Segment and Geographic Areas

Prior to October 2014, all revenue was derived from sales of MGuard Prime EPS, our bare-metal coronary stent. For the twelve months ended December 31, 2015, 70% of our revenue was derived from sales of this product. For financial information about our one operating and reportable segment and geographic areas, refer to “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Note 13 to our financial statements for the year ended December 31, 2015.

Our Industry

Carotid

Carotid arteries are located on each side of the neck and provide the primary blood supply to the brain. Carotid artery disease, also called carotid artery stenosis, is a type of atherosclerosis (hardening of the arteries) that is one of the major risk factors for ischemic stroke. In carotid artery disease, plaque accumulates in the artery walls, narrowing the artery and disrupting the blood supply to the brain. This disruption in blood supply, together with plaque debris breaking off the artery walls and traveling to the brain, are the primary causes of stroke. According to the World Heart Federation (*http://www.world-heart-federation.org/cardiovascular-health/stroke/*, last visited on Mar. 11, 2016), every year, 15 million people worldwide suffer a stroke, and nearly six million die and another five million are left permanently disabled. According to the same source, stroke is the second leading cause of disability, after dementia.

The potential global market value of carotid stents is approximately $500 million, approximately $300 million of which consists of the U.S. market and approximately $200 million of which consists of the rest of the world (*source: JMP Securities 2014 and Cowen 2014)*. Carotid artery stenting is a minimally invasive treatment option for carotid artery disease and an alternative to carotid endarterectomy, where a surgeon accesses the blocked carotid artery though an incision in the neck, and then surgically removes the plaque. Endovascular techniques using stents and carotid embolic prevention system protect against plaque and debris traveling downstream, blocking off the vessel and disrupting blood flow. We believe that the use of a stent with an embolic protection system should increase the number of patients being treated since it would avoid the need for complex surgery.

Coronary

Physicians and patients may select from among a variety of treatments to address coronary artery disease, including pharmaceutical therapy, balloon angioplasty, stenting with bare metal or drug-eluting stents, and coronary artery bypass graft procedures, with the selection often depending upon the stage of the disease.

The global market value of coronary products is estimated at $5.9 billion, of which $4.2 billion is for stable angina and $1.7 billion is for acute myocardial infarctions according to Health Research International (June 2011). According to the 2014 MEDTECH OUTLOOK produced in December 2013 by BMO Capital Markets (“MEDTECH OUTLOOK”), revenues from the global coronary stent market are predicted to slightly decline, although in volume of stents the market is predicted to continue to grow. We believe the growth in volume is due to the appeal for less invasive percutaneous coronary intervention (“PCI”) procedures and advances in technology coupled with the increase in the elderly population, obesity rates and advances in technology.

Neurovascular

The neurovascular market focuses on catheter-delivered products used to treat strokes that already happened or unruptured brain aneurysms that could lead to strokes. In the latter case, coils are wound into blood vessel bulges to block blood flow entering the aneurysms to prevent the aneurysms from rupturing. Endovascular treatment of arterial aneurysm has evolved substantially over the past two decades, transitioning from an investigational therapy into routine clinical practice and ultimately emerging as the treatment of choice for many lesions *(source: Medtech Ventures 2009, Aneurysm Flow Modulating Device Market).* We believe that the market for aneurysm flow modulating devices is still in the embryonic stage with windows of opportunities for early entrance.

The current global market for the aneurysm flow modulating devices is estimated at $550 million, and the current market value of the flow diversion market segment is estimated to be $125 million. The neurovascular market includes over-the-wire, flow-guided microcatheters, guiding catheters, coil and liquid embolics, neurovascular stents and flow diversion stents. According to iData Research, the market is expected to be driven by the conversion from surgical procedures to endovascular techniques in the treatment of aneurysms and arteriovenous malformations.

Peripheral

Peripheral vascular diseases ("PVD") are caused by the formation of atherosclerotic plaques in arteries, which carry blood to organs, limbs and head. It is also known as peripheral artery occlusive disease or peripheral artery disease. It comprises diseases pertaining to both peripheral veins and peripheral arteries, affecting the peripheral and cardiac circulation in the body. PVD includes diseases outside of the heart and brain, but most times refers to the leg and foot.

The global market value of PVDs is estimated at $1.7 billion (*source: Global Data 2011*). The overall peripheral vascular devices market consists of nine different product segments: peripheral vascular stents, chronic total occlusion devices, peripheral transluminal angioplasty balloon catheters, atherectomy devices, percutaneous transluminal angioplasty guidewires, aortic stents, embolic protection devices, synthetic surgical grafts and inferior vena cava filters *(source: Grand View Research 2014).*Treatment modalities and methods have considerably improved during the last several years, and this trend is expected to continue (*source: Global Data 2011*). Stents and balloons hold the majority of the share in the peripheral vascular devices market. Peripheral stents are more often used in combination with balloon angioplasty to open the veins, so that blood can flow through the blocked veins in the body.

The growing prevalence of PVD is expected to cause increased demand for treatment options. The expansion of the elderly population is contributing to increasing incidence rates of PVD. The percentage of the global population above the age of 50 is expected to reach 17% by 2030. As the risk of developing PVD increases with age, a growing elderly population translates into a growing incidence of PVD (*source: Global Data 2011*). The growing global geriatric population base also triggers increasing demand for minimally invasive endovascular procedures on account

of their shorter recovery time, lesser scaring and lesser chances of post surgery infections. In addition, a growing prevalence of disease causing lifestyle factors and eating habits such as high consumption of alcohols and tobacco products is expected to boost peripheral vascular devices market demand by triggering the incidence rates of cardiac arrest, blood clotting and other vascular diseases *(source: Grand View Research 2014).*

Our Products

Below is a summary of our current products and products under development, and their intended applications.

MicroNet

MicroNet is our proprietary circular knitted mesh which wraps around a stent to protect patients from plaque debris flowing downstream upon deployment. MicroNet is made of a single fiber from a biocompatible polymer widely used in medical implantations. The size, or aperture, of the current MicroNet 'pore' is only 150-180 microns in order to maximize protection against the potentially dangerous plaque and thrombus.

CGuard — Carotid Applications

Our CGuard EPS combines our MicroNet mesh and a self-expandable nitinol stent (a stent that expands without balloon dilation pressure or need of an inflation balloon) in a single device for use in carotid artery applications. MicroNet is placed over and attached to an open cell nitinol metal stent platform which is designed to trap debris and emboli that can dislodge from the diseased carotid artery and potentially travel to the brain and cause a stroke. This danger is one of the greatest limitations of carotid artery stenting with conventional carotid stents and stenting methods. The CGuard EPS technology is a highly flexible stent system that conforms to the carotid anatomy.

Our CGuard EPS with over-the-wire delivery system received CE mark approval in the European Union in March 2013. In October 2014, we initiated a limited market release of CGuard EPS with over-the-wire delivery system for use in carotid artery applications in Germany, Poland and Italy.

In September 2014, we reported the results of the CGuard CARENET trial at the Transcatheter Cardiovascular Therapeutics ("TCT") conference in Washington D.C. In the CARENET trial, the CGuard EPS system demonstrated better results over historical data using conventional commercially available carotid stents. In the third quarter of 2015 the results of the CGuard CARENET trial were published in the Journal of the American College of Cardiology. In November 2015, positive twelve month follow-up data from the CGuard CARENET trial was presented at the 42nd Annual Symposium on Vascular and Endovascular Issues, documenting the benefits of the CGuard MicroNet technology as well as the patency benefits (maintaining the artery open) of the internal and external carotid arteries at twelve months.

We believe that our CGuard EPS design provides advantages over existing therapies in treating carotid artery stenosis, such as conventional carotid stenting and surgical endarterectomy, given the superior embolic protection characteristics provided by the MicroNet. We believe the MicroNet will provide acute embolic protection at the time of the procedure, but more importantly, we believe that CGuard EPS will provide post-procedure protection against embolic dislodgement, which can occur up to 48 hours post-procedure. It is in this post-procedure time frame that embolization is the source of post-procedural strokes in the brain. Schofer, et al. ("Late cerebral embolization after

emboli-protected carotid artery stenting assessed by sequential diffusion-weighted magnetic resonance imaging," *Journal of American College of Cardiology Cardiovascular Interventions*, Volume 1, 2008) have shown that the majority of the incidents of embolic showers associated with carotid stenting occur post-procedure.

In the first quarter of 2015, we introduced CGuard RX, the new rapid exchange delivery system for CGuard EPS. The rapid exchange delivery system has a guidewire that passes through the delivery system, running through the guiding catheter. It has one port, and thus, can be operated by one operator, while an over-the-wire-delivery system has two lumens and ports and requires two operators to perform the procedure. Our rapid exchange delivery system received CE mark approval in January 2015. We launched our CGuard EPS in Europe with the rapid exchange delivery system in multiple medical specialties that perform carotid artery stenting. These customers include interventional cardiologists, vascular surgeons, interventional neuroradiologists and interventional radiologists.

In September 2015, we announced full market launch of CGuard EPS by our distribution partner, Penumbra, Inc., in 18 CE marked countries in Europe. In October 2015, we received regulatory approval to commercialize CGuard EPS in Argentina and Colombia. Following the receipt of such regulatory approval, we launched CGuard EPS in Argentina in the first quarter of 2016 and Colombia in the fourth quarter of 2015. We are currently preparing materials required to conduct a clinical trial in the United States and have a draft clinical protocol synopsis that we believe could support a clinical trial for submission for approval by the U.S. Food and Drug Administration. Once complete, we plan to request a pre-submission guidance meeting with the U.S. Food and Drug Administration.

MGuard Products — Coronary Applications

Bare-Metal Stent MGuard Product. Our MGuard Prime EPS coronary product is comprised of MicroNet wrapped around a cobalt-chromium based bare-metal stent. In comparison to a conventional bare-metal stent, we believe our MGuard Prime EPS coronary product with MicroNet mesh provides protection from dangerous embolic showers in patients experiencing ST-segment elevation myocardial infarction, the most severe form of a heart attack, referred to as STEMI. Standard stents were not engineered for heart attack patients. Rather, they were designed for treating stable angina patients whose occlusion is different from that of an occlusion in a heart attack patient. In acute heart attack patients, the plaque or thrombus is unstable and often breaks up as the stent is implanted causing downstream blockages in a significant portion of heart attack patients. Our MGuard Prime EPS is integrated with a precisely engineered micro net mesh that is designed to prevent the unstable arterial plaque and thrombus that caused the heart attack blockage from breaking off.

During the fourth quarter of 2014, due to a shift in industry preferences away from bare-metal stents in favor of drug-eluting (drug-coated) stents, we decided to curtail developing and promoting our bare-metal stent platform and instead focus on the development of a drug-eluting stent product. Although we have curtailed development and promotion of MGuard Prime EPS, our distributors and sales staff generally cover all of our current products in the market including MGuard Prime EPS.

Drug-Eluting Stent MicroNet Product Candidate. During 2015, we completed the second phase of development work for our MGuard DES, pursuant to which we incorporated our MicroNet with a drug-eluting stent manufactured by a prospective partner. We believe that a drug-eluting stent with MicroNet has the potential to improve certain performance metrics over the MGuard Prime EPS and attract a broader portion of the cardiologists in the worldwide stent market who are more accustomed to using drug-eluting stents. However, due to our limited resources we have tabled further development of MGuard DES at this time.

NGuard — Neurovascular Applications

We are developing a neurovascular flow diverter, which is an endovascular device that directs blood flow away from cerebral aneurysms to ultimately seal the aneurysms. Flow diversion is a growing market segment within the neurovascular medical device field. Current commercial flow diverters are highly flexible dense metal mesh tubes that go across most types of cerebral aneurysms and divert the blood flow away from the aneurysm with the desired end result of sealing the aneurysm. The challenges with the current flow diverters are that they (i) are difficult to place given the high metal content in the device, which makes it more difficult to move the device through the delivery system due to resistance from the metal, and to subsequently accurately place it, (ii) need to be accurately placed to avoid crossing and blocking other cerebral vessels, which could cause additional damage by cutting off blood flow to sections of the brain, (iii) require chronic use of anti-thrombotic medications due to the amount of metal in the

cerebral vasculature, which could cause thrombotic complications, and (iv) do not allow a physician to reaccess the aneurysm if the aneurysm does not seal, in which event the aneurysm may need to be treated with another therapy such as aneurysm coils, due to the tight metal mesh that will not allow other devices to pass through the flow diverter.

Our flow diverter prototype will include our MicroNet that has been employed in CGuard EPS and MGuard Prime EPS. MicroNet has already demonstrated the ability to effectively seal aneurysms in both human coronary arteries using the MGuard Prime EPS and aneurysms in the carotid arteries using CGuard EPS in human clinical situations without the need for additional devices or procedures (coils or a second stent) (*source: Journal of Medical Case Reports http://www.jmedicalcasereports.com/content/4/1/238*). For our flow diverter, we plan to utilize an open cell, highly flexible metal scaffold to which MicroNet would be attached. We believe our flow diverter could be more accurately delivered due to a lower metal content scaffold than current commercial flow diverters; lower metal content in our flow diverter may reduce the need for long-term anticoagulation; the open cell metal scaffold combined with the MicroNet may allow passage of other devices through the MicroNet mesh without compromising the MicroNet, thus allowing a physician to reaccess the aneurysm, if needed; and our flow diverter should be capable of being delivered through a state-of-the-art microcatheter for accurate placement without constant repositioning. We have tested early flow diverter prototypes in both simulated aneurysm bench models using various MicroNet configurations with varying aperture sizes, as well as in standard in vivo pre-clinical models, in which we observed aneurysm sealing and also wide open side branch vessels across which the device was placed.

We expect to complete the development work on our flow diverter and submit for CE mark approval in 2017.

PVGuard — Peripheral Vascular Applications

We intend to develop our MicroNet mesh sleeve and a self-expandable stent for use in peripheral vascular applications, to which we refer to as PVGuard. PVDs are usually characterized by the accumulation of plaque in arteries in the legs. This accumulation can lead to the need for amputation or even death, when untreated. PVD is treated either by trying to clear the artery of the blockage, or by implanting a stent in the affected area to push the blockage out of the way of normal blood flow.

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

We estimate that we may complete the development work on our PVGuard and submit for CE mark approval in 2018.

Completed Clinical Trials for CGuard EPS — CARENET

The CARENET trial was the first multi-center study of CGuard EPS following the receipt of CE mark of this device in March 2013. The CARENET trial was designed to evaluate feasibility and safety of CGuard EPS in treatment of carotid lesions in consecutive patients suitable for coronary artery stenting ("CAS") in a multi-operator, real-life setting. The acute, 30 day, magnetic resonance imaging ("MRI"), ultrasound and six month clinical event results were presented at the LINC conference in Leipzig, Germany in February, 2015. In the third quarter of 2015, the results of the CGuard CARENET trial were published in the Journal of the American College of Cardiology. In November 2015, positive twelve month follow-up data from the CGuard CARENET trial was presented at the 42nd Annual Symposium on Vascular and Endovascular Issues, documenting the benefits of the CGuard MicroNet technology as well as the patency benefits (maintaining the artery open) of the internal and external carotid arteries at twelve months.

MACCE (myocardial infarction ("MI"), stroke or death) was 0.0% at 30 days. At six months, there was one case of death, which was not stent or procedure-related, and MACCE was increased to 3.6%. At twelve months there were three cases of death, which were not stent or procedure-related, and MACCE was 11.1%.

	30 days (n=30)	6 months (n=28)	12 months (n=27)
MACCE (MI, stroke, death)	(0)0.0 %	(1)3.6 %	(3)11.1 %
MI	(0)0.0 %	(0)0.0 %	(0)0.0 %
Stroke	(0)0.0 %	(0)0.0 %	(0)0.0 %
Death	(0)0.0 %	(1)3.6 %	(3)11.1 %

In addition, 30 day and 6 month follow-up data from the CARENET study determined the following MACCE events as compared to MACCE events from studies using conventional carotid stents:

	30 days (14 trials, 5255 patients)[(1)]	**6 months (3 trials, 1053 patients)[(2)]**
MACCE (MI, stroke, death)	5.72 %	8.09 %

(1) Trials included in analysis: ARCHeR pooled, ARMOUR, BEACH, CABERNET, CREATE, EMPIRE, EPIC, MAVErIC 1+2, MAVErIC International, PRIAMUS, SAPPHIRE, SECURITY, PROFI, ICSS

(2) Values extrapolated from event curves (*source: The CARENET all-comer trial using the CGuard micronet-covered carotid embolic prevention stent, presented by Dr. Piotr Musialek at the LINC 2015 conference*)

CAS carries the risk of cerebral embolization during and following the procedure, leading to life-threatening complications, mainly cerebral ischemic events. Diffusion-weighted magnetic resonance imaging (DW-MRI) is a sensitive tool used to identify cerebral emboli during CAS by measuring "lesions" within the brain which are areas that are ischemic and do not receive oxygenated blood due to cerebral emboli. In the CARENET trial, 37.0% of patients treated with CGuard EPS had new ischemic lesions at 48 hours after the procedure, with an average volume of 0.039 cm^3. Of these lesions, there was only one that remained at 30 days following the procedure and all others had resolved. Complete details appear in the following table. Where there is a second number shown below after a ±,it indicates the rate of error.

	48 hours n=27	30 days n=26
Subjects with new Acute Ischemic Lesions ("AIL")	10	1
Incidence of new lesions	37.0%	4.0%
Total number new AIL	83	1
Avg. number new AIL per patient	3.19 ± 10.33	0.04 ± 0.20
Average lesion volume (cm^3)	0.039 ± 0.08	0.08 ± 0.00
Maximum lesion volume (cm^3)	0.445	0.116
Permanent AIL at 30 days	—	1

The healing process of the tissue and in-stent restenosis can be measured by a non-invasive form of ultrasound called duplex ultrasound. This type of ultrasound measures the velocity of the blood that flows within the carotid arteries, which increases exponentially as the lumen of the internal carotid artery narrows and the percent stenosis increases. One of the measurements is called PSV (peak systolic volume) and is known to be highly correlated to the degree of in-stent restenosis; PSV values higher than 300 cm/sec are indicative of >70% stenosis, while PSV values lower than 104 cm/sec are indicative of <30% restenosis and healthy healing. In the CARENET trial, duplex ultrasound measurements done at 30 days, 6 months and 12 months following the stenting procedure all attest to healthy normal healing without restenosis concerns, as the PSV values were 60.96 cm/sec ± 22.31, 85.24 cm/sec ± 39.56, and 90.22 cm/sec ± 37.72 respectively. The internal carotid artery was patent in all patients (100%).

The conclusions of the CARENET trial were:

- CARENET trial demonstrated safety of CGuard EPS stent, with 30 day MACCE of 0%.

- Incidence of new ipsilateral lesions (percent of patients with new lesions on the ipsilateral side (same side where the stent was employed)) at 48 hours was reduced by almost half compared to published data, and volume was reduced almost tenfold.

- All but one lesion had resolved completely by 30 days.

- Twelve month data showed no change in peak systolic velocity between 6 months and 12 months, suggesting no restenosis concerns.

- CGuard EPS offers unique clinical benefits for patients undergoing CAS with unprecedented safety.

Ongoing Physician-Sponsored Clinical Trials for CGuard — PARADIGM Study

PARADIGM (**P**rospective evaluation of **A**ll-comer pe**R**cutaneous c**A**roti**D** revascularization **I**n symptomatic and increased-risk asymptomatic carotid artery stenosis, using C**G**uard™ **M**esh-covered embolic prevention stent system) is an investigator-led, single center study with the objective of evaluating feasibility and outcome of routine anti-embolic stent system in unselected, consecutive carotid patients (all-comers) referred for carotid revascularization, initiated in 2015.

The PARADIGM included evaluation of 71 CGuard EPS procedures in 68 unselected all-comer patients and continues to show favorable angiographic and clinical outcomes in using CGuard EPS in patients with carotid artery disease as follows:

- CGuard EPS success and procedure success rate were 100%.
- Periprocedural complications were 0% and remained at 0% at 30 days following the procedure.
- No major adverse cardiac or neurological events occurred periprocedurally or at 30 days following the procedure, pursuant to operator-independent neurologist and non-invasive cardiologist evaluation.

In May 2016, CGuard EPS reported positive results in PARADIGM-101, an investigator-led clinical evaluation of the CGuard EPS system for routine use in 101 consecutive, increased risk patients undergoing carotid artery stenting. In the PARADIGM-101 study, the investigator conducted clinical evaluation of the safety and periprocedural and 30 day clinical efficacy of routine use of the CGuard EPS system in unselected carotid stenosis patients, building upon the earlier PARADIGM study, and also assessed the CGuard EPS's ability to minimize vessel narrowing after carotid stenting. The results of the PARADIGM-101 study were presented at the EuroPCR 2016 Late-Breaking Clinical Trial Session in Paris, France.

The conclusions of the PARADIGM-101 study were:

- CGuard EPS delivery success was 99.1%. The clinical evaluation also found no device foreshortening or elongation.
- At 48 hours, MACCE was at 0%.

- At 30 days, MACCE was at 0% as determined by independent neurological and angiographic evaluation.

The results of the PARADIGM-101 study support that CGuard EPS can safely be used on a high risk, all-comer population of patients with carotid artery stenosis and indicate that routine use of CGuard EPS may prevent cerebral events, such as strokes, by holding plaque against the vessel wall, preventing emboli from being released into the blood stream.

Ongoing Physician-Initiated Study for CGuard — IRON-Guard Registry

The IRON-Guard (**I**talian **R**egistry of car**O**tid ste**N**ting with the C-**GUARD** mesh-stent) is a physician-initiated, Italian, prospective, multicenter, single-arm study with a total of 200 patients from 29 clinicians from 23 different centers planned to be enrolled. The objective of the registry is to evaluate the clinical outcome of treatment by means of stenting with the CGuard patients requiring CAS due to significant extra-cranial carotid artery stenosis. The primary endpoint of this study is the 30-day rate of major adverse events, defined as the cumulative incidence of any periprocedural (≤ 30 days post-procedure) death, stroke or MI. The secondary endpoints are rate of late ipsilateral stroke (31 through 365 days), system technical success, device malfunctions, major adverse events, serious device-related and procedure-related adverse events, target lesion revascularization, and in-stent restenosis rates. The anticipated duration of this study is approximately 24 months, namely 12 months per patient follow-up, with a recruitment period of 12 months. (*source: Setacci, et. al., J Cardiovasc Surg. 2015 May 2*)

Completed Clinical Trials for MGuard Bare-Metal Coronary Products

We have completed eight clinical trials with respect to our first generation stainless steel-based MGuard stent and our cobalt-chromium based MGuard Prime EPS stent. Our first generation MGuard stent combining the MicroNet with a stainless steel stent received CE mark approval for the treatment of coronary artery disease in the European Union in October 2007. We subsequently replaced the stainless steel stent with a more advanced cobalt-chromium based stent for MGuard Prime EPS.

The First in Men (FIM) study conducted in Germany from the fourth quarter of 2006 through the second quarter of 2008 focused on patients with occlusion in their stent graft. This group is considered to be in “high risk” for complications during and shortly after the procedure due to the substantial risk of occurrence of a thromboembolic event. The study demonstrated MGuard stent’s safety in this high risk group. This study was followed by the GUARD study in Brazil in 2007 with a similar patient population which reinforced the safety profile of MGuard stents in patients prone to procedural complications. The MAGICAL study was a pilot study in STEMI patients conducted in Poland from 2008 through 2012 which demonstrated safety, measured by MACE rates at 30 days following the stent procedure, as well as efficacy results, measured by the ability of MGuard to reestablish blood flow into the infarcted area of the muscle. Furthermore, we conducted three registries (iMOS, IMR and iMOS Prime) that confirmed the feasibility of MGuard and MGuard Prime EPS for the treatment of STEMI patients and the safety of MGuard and MGuard Prime EPS in the STEMI patient group. Safety was repeatedly demonstrated in these trials and registries by the low mortality rate in the first month after the procedure.

In the second calendar quarter of 2011, we began the MGuard for Acute ST Elevation Reperfusion Trial (which we refer to as our "MASTER I trial"), a prospective, randomized study, which demonstrated that among patients with acute STEMI undergoing emergency PCI, patients treated with MGuard had superior rates of epicardial coronary flow (blood flow within the vessels that run along the outer surface of the heart) and complete ST-segment resolution, or restoration of blood flow to the heart muscle after a heart attack, compared to those treated with commercially-approved bare metal or drug-eluting stents. The results of this trial are summarized in greater detail below.

Finally, the MASTER II trial, which we initially initiated as part of our efforts to seek approval of our MGuard Prime EPS by the U.S. Food and Drug Administration, was discontinued at our election in its current form in light of market conditions moving toward the use of drug-eluting stents over bare-metal stents. Analysis of the patients already enrolled in the MASTER II trial prior to its suspension, however, reconfirmed the MASTER I safety results due to a continued low mortality rate.

MASTER I Trial

In the second calendar quarter of 2011, we began the MASTER I trial, a prospective, randomized study in Europe, South America and Israel to compare the MGuard with commercially-approved bare metal and drug-eluting stents in achieving superior myocardial reperfusion (the restoration of blood flow) in primary angioplasty for the treatment of acute STEMI. The MASTER I trial enrolled 433 subjects, 50% of whom were treated with an MGuard stent and 50% of whom were treated with a commercially-approved bare metal or drug-eluting stent. The detailed acute and 30 days results from the trial were presented at the TCT conference on October 24, 2012 and published (Prospective, Randomized, Multicenter Evaluation of a Polyethylene Terephthalate Micronet Mesh–Covered Stent (MGuard) in ST-Segment Elevation Myocardial Infarction, Stone et. Al, *JACC*, 60; 2012). The results were as follows:

- The primary endpoint of post-procedure complete ST-segment resolution was statistically significantly improved in patients randomized to the MGuard stent compared to patients receiving a commercially-approved bare metal or drug-eluting stent (57.8% vs. 44.7%).

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

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

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

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

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

The twelve month results from the MASTER I trial were presented at the TCT conference on October 29, 2013 and published (Mesh-Covered Embolic Protection Stent Implantation in ST-Segment–Elevation Myocardial Infarction Final 1-Year Clinical and Angiographic Results From the MGUARD for Acute ST Elevation Reperfusion Trial, Dudek e. el, *Coronary Interventions*, 2014. The results were as follows:

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

thrombosis, were comparable between the MGuard stent and commercially-approved bare metal or drug-eluting stents.

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

A detailed table with the results from the MASTER I trial is set forth below. The "p-Value" refers to the probability of obtaining a given test result. Any p value less than 0.05 is considered statistically significant.

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

Future Clinical Trials for CGuard EPS and MGuard Prime EPS

Post-marketing clinical trials (outside the United States) could be conducted to further evaluate the safety and efficacy of CGuard EPS in specific indications. These trials would be designed to facilitate market acceptance and expand the use of the product. We should be able to rely upon CE mark approval of the product and other supporting clinical data to obtain local approvals.

We are currently preparing materials required to conduct a clinical trial in the United States and have a draft clinical protocol synopsis that we believe could support a clinical trial for submission for approval by the U.S. Food and Drug Administration. Once complete, we plan to request a pre-submission guidance meeting with the U.S. Food and Drug Administration.

We do not anticipate conducting additional post-marketing clinical trials for our bare-metal MGuard coronary products.

Competition

The markets in which we compete are highly competitive, subject to change and impacted by new product introductions and other activities of industry participants.

Carotid

The carotid stent markets in the United States and Europe are dominated by Abbott Laboratories, Boston Scientific Corporation, Covidien Ltd. (currently part of Medtronic, Inc.), and Cordis Corporation. Gore Medical and Terumo Medical Corporation produce mesh-covered carotid stents. All of these larger companies have substantially greater capital resources, larger customer bases, broader product lines, larger sales forces, greater marketing and management resources, larger research and development staffs and larger facilities than ours and have established reputations and relationships with our target customers, as well as worldwide distribution channels that are more effective than ours. However, we believe that the European market is somewhat fragmented, and, in our opinion, smaller competitors may be able to gain market share with greater flexibility.

Coronary

The bare-metal stent and the drug-eluting stent markets in the United States and Europe are dominated by Abbott Laboratories, Boston Scientific Corporation, and Medtronic, Inc. In the future, we believe that physicians will look to next-generation stent technology to compete with existing therapies. These new technologies will likely include bio-absorbable stents, stents that focus on treating bifurcated lesions, and stents with superior polymer and drug coatings, and many industry participants are working to improve stenting procedures in the future as the portfolio of available stent technologies rapidly increases.

According to the MEDTECH OUTLOOK, the three major players (Abbott Laboratories, Boston Scientific Corporation and Medtronic, Inc.) in the worldwide coronary stent market have a combined total market share of approximately 92%. To date, our sales are not significant enough to register in market share. As such, one of the challenges we face to further our product growth is the competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. Most of our current and potential competitors, including but not limited to those listed above, have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. 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.

Neurovascular

Stryker Corporation dominated the global interventional neurology market in 2014. The other key players in this market include Medtronic plc, Johnson & Johnson, Terumo Corporation, Penumbra, Inc., Abbott Laboratories, Merit Medical Systems, Inc., W. L. Gore & Associates, Inc., Microport Scientific Corporation, and Medikit Co., Ltd., among others. (*source: Markets and Markets 2015).*

Research and Development Expenses

During the twelve months ended December 31, 2015 and 2014, we spent $3.6 million and $8.7 million, respectively, on research and development.

Sales and Marketing

Sales and Marketing

Currently, we are actively selling our MGuard coronary products with a bio-stable MicroNet through local distributors in Europe, Latin America, the Middle East and Asia.

Based on the positive CGuard EPS clinical data, we commercially launched CGuard EPS in CE marked countries in early 2015. We initially sold CGuard products through a distributor network as we did with MGuard coronary products. On August 5, 2015, InspireMD, Ltd., our wholly owned subsidiary, entered into a distribution agreement with Penumbra, Inc., and, in September 2015, we announced full market launch of CGuard EPS by Penumbra, Inc. in 18 CE marked countries in Europe.

We plan to focus our marketing efforts primarily on Europe, Asia and Latin America. In addition to utilizing local and regional distributor networks, we are using international trade shows and industry conferences to gain market exposure and brand recognition. We plan to work with leading physicians to enhance our marketing efforts.

Product Positioning

The MGuard coronary products have initially penetrated the market by entering segments with indications that present high risks of embolic dislodgement, notably acute MI and saphenous vein graft coronary interventions. Even though MGuard technology has demonstrated its advantages with clinical data, it is based on a bare-metal platform while the market demand has shifted away from bare-metal stents in favor of drug-eluting stents.

When treating carotid artery disease, we believe that there is an opportunity to enter the market with bare-metal stent platform and to become a competitive player without a drug-eluting stent platform. Therefore, we believe that CGuard EPS is poised for commercial growth in 2016 as more and more positive clinical data is presented. Finally, we do not expect that it would be crucial to use a drug-eluting stent platform to compete in certain new markets such as the neurovascular market, and hence, we plan to continue to explore this area of opportunity.

Insurance Reimbursement

In most countries, a significant portion of a patient's medical expenses is covered by third-party payers. Third-party payers can include both government funded insurance programs and private insurance programs. While each payer develops and maintains its own coverage and reimbursement policies, the vast majority of payers have similarly established policies. All of the MGuard coronary products and CGuard 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 present and future 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 coronary products and CGuard products or in order to obtain a higher reimbursement price. In these situations, we intend to complete the required clinical studies to obtain reimbursement approval in countries where it makes economic sense to do so.

Intellectual Property

Patents

We have filed sixteen patent applications, twelve of which are pending in the United States covering aspects of our MGuard and CGuard technology. We have filed corresponding patent applications to some of these in Canada, China, Europe, Israel, India and South Africa, for an aggregate total of 46 patents and pending applications including four issued U.S. patents. These patent rights are directed to cover percutaneous therapy, knitted stent jackets, stent and filter assemblies, *in vivo* filter assembly, optimized stent jackets, stent apparatuses for treatment via body lumens and methods of use, stent apparatuses for treatment via body lumens and methods of manufacture and use, among others. In lay terms, these patent applications generally cover three aspects of our products: the mesh sleeve with and without a drug, the product and the delivery mechanism of the stent. On October 27, 2010, our South African patent application pertaining to "Stent Apparatus for Treatment via Body Lumens and Method of Use" was issued as South African Patent No. 2007/10751. On October 25, 2011, our patent application pertaining to "In Vivo Filter Assembly," U.S. Patent Application 11/582,354, was issued as U.S. Patent 8,043,323. On June 13, 2012, our patent application pertaining to "Filter Assemblies," Chinese Patent Application No. 200780046659.9, was issued as Chinese Patent No. ZL200780046659.9. On September 26, 2012, our patent application pertaining to "Bifurcated Stent Assemblies," Chinese Patent Application No. 200780046676.2, was issued as Chinese Patent No. ZL200780046676.2. On October 10, 2012, our patent application pertaining to "Knitted Stent Jackets," Chinese Patent Application No. 200780046697.4, was issued as Chinese Patent No. ZL200780046697.4. On January 2, 2013, our patent application pertaining to "Optimized Stent Jacket," Chinese Patent Application No. 200780043259.2, was issued as Chinese Patent No. ZL200780043259.2. We have also had Israeli Patent No. 198189 entitled "Filter Assemblies" issued March 27, 2014, and Patent No. 198190, entitled "Knitted Stent Jackets" issued Feb. 1, 2014, and Canadian Patent No. 2609687 entitled "Stent Apparatuses For Treatment Via Body Lumens" issued April 22, 2014. Israeli Patent No. 198,188 entitled "Bifurcated Stent Assemblies" issued May 1, 2014 and Israeli Patent No. 198,665 entitled "Optimized Stent Jacket" issued May 28, 2014. U.S. Patent Application No. 11/797,168, filed May 1, 2007, was issued as U.S. Patent No. 8,961,586 on February 24, 2015. Canadian Patent No. 2,666,712 entitled "Filter Assemblies" issued March 31, 2015. Canadian Patent No. 2,666,728 entitled "Knitted Stent Jackets" issued June 23, 2015. U.S. Patent No. 9,132,261 entitled "*In Vivo* Filter Assembly" and U.S. Patent No. 9,132,003, entitled "Optimized Drug-Eluting Stent Assembly" each issued September 15, 2015. Canadian Patent No. 2,843,097 entitled "Stent Apparatuses for Treatment Via Body Lumens and Methods of Use" issued October 27, 2015. Chinese Patent No. 201210320950.3 entitled "Knitted Stent Jackets" issued December 2, 2015. Chinese Patent No. ZL201210454357.8, entitled "Optimized Stent Jacket" issued December 9, 2015. We also believe that one or more additional pending patent applications, upon issuance, will cover our existing products. We also believe that the patent applications we have filed, in particular those covering the use of a knitted micron-level mesh sleeve over a stent for various indications, if issued as patents with claims substantially in their present form, would likely create a significant barrier for another company seeking to use similar technology.

Trademarks

We use the InspireMD®, MGuard® and MGuard Prime® trademarks in connection with our products. We have registered these trademarks in the European Union. The trademarks are renewable indefinitely, so long as we make the appropriate filings when required. We also have registrations for Carenet®, CGuard® and the MNP Micronet Protection Logo in the European Union and a supplemental registration for Micronet® in the United States. We have also applied to register the names Carenet™, CGuard™ InspireMD™, SmartFit™, PV Guard™, AGuard™, and MGuard Prime™ as trademarks in the United States We also use and may have common law rights to various trademarks, trade names, and service marks.

Government Regulation

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

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

As noted below, we have regulatory approval and have made sales in MGuard Prime EPS, CGuard EPS or both products either through distributors pursuant to distribution agreements or directly, in the following countries: Argentina, Australia, Austria, Belarus, Belgium, Brazil, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Malta, Mexico, Netherlands, Norway, Poland, Portugal, Romania, Russia, Saudi Arabia, Serbia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, and the United Kingdom. In addition, we have distribution agreements for our products in Uzbekistan, Canada, Venezuela, and Armenia, although we have not yet obtained regulatory approval to sell our products in those countries, and we are awaiting regulatory approval to sell our products in Russia (for CGuard EPS) and Malaysia. While each of the European Union member countries accepts the CE mark as its sole requirement for marketing approval, some of these countries still require us to take additional steps in order to gain reimbursement rights for our products. Furthermore, while we believe that certain of the above-listed countries that are not members of the European Union accept the CE mark as a primary requirement for marketing approval, each such country requires additional regulatory requirements for final marketing approval of our products. Furthermore, we are currently targeting additional countries in Europe, Asia, and Latin America, however, even if all governmental regulatory requirements are satisfied in each such country, we anticipate that obtaining marketing approval in each country could take as few as three months or as many as twelve months or more, due to the nature of the approval process in each individual country, including typical wait times for application processing and review, as discussed in greater detail below.

In October 2007, our first generation MGuard stent combining the MicroNet with a stainless steel stent received CE mark approval for the treatment of coronary artery disease in the European Union. We subsequently replaced the first generation MGuard product with MGuard Prime EPS, which uses a more advanced cobalt-chromium based stent. Our MGuard Prime EPS received CE mark approval in the European Union in October 2010 and marketing approval in those countries listed in the table below. We are currently seeking marketing approval for the MGuard Prime EPS in Malaysia. We are focused on seeking marketing approval in these countries because we believe that these countries represent the strongest opportunities for us to grow with respect to our sales.

The CGuard EPS received CE mark approval in the European Union on March 14, 2013 and marketing approval in those countries listed in the table below. We are currently seeking marketing approval for CGuard EPS in Brazil and Russia.

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

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

CGuard EPS Sales

Countries	MGuard Prime EPS Approval	MGuard Prime EPS Sales	CGuard EPS Approval		
Argentina	Y	Y	Y	Y	
Armenia	N	N	N	N	
Australia	Y	Y	N	N	
Austria	Y	Y	Y	N	
Belarus	Y	Y	Y	Y	
Belgium	Y	Y	Y	N	
Brazil	Y	Y	N	N	
Chile	N	Y	(1) N	Y	(1)
Colombia	Y	Y	Y	Y	
Croatia	Y	Y	Y	N	
Cyprus	Y	Y	Y	Y	
Czech Republic	Y	Y	Y	N	
Denmark	Y	N	Y	N	
Estonia	Y	Y	Y	N	

Countries	MGuard Prime EPS Approval	MGuard Prime EPS Sales	CGuard EPS Approval	CGuard EPS Sales
Finland	Y	Y	Y	N
France	Y	Y	Y	N
Germany	Y	Y	Y	Y
Greece	Y	N	Y	N
Holland (Netherlands)	Y	Y	Y	Y
Hungary	Y	Y	Y	N
Iceland	Y	N	Y	N
India	Y	N	N	N
Ireland	Y	Y	Y	N
Israel	Y	Y	Y	Y
Italy	Y	Y	Y	Y
Kazakhstan	N	N	N	N
Latvia	Y	Y	Y	Y
Lithuania	Y	Y	Y	Y
Liechtenstein	Y	N	Y	N
Luxemburg	Y	N	Y	N
Malaysia	N	Y	(2) N	N
Malta	Y	Y	Y	N
Mexico	Y	Y	N	N
Norway	Y	Y	Y	N
Poland	Y	Y	Y	Y
Portugal	Y	N	Y	N
Romania	Y	Y	Y	Y
Russia	Y	Y	N	N
Saudi Arabia	Y	Y	N	N
Serbia	Y	N	N	N
Slovakia	Y	Y	Y	Y
Slovenia	Y	Y	Y	Y
South Africa	Y	(3) Y	N	N
Spain	Y	Y	Y	Y
Sweden	Y	Y	Y	N
Switzerland	Y	Y	Y	N
Taiwan	Y	N	N	N
United Kingdom	Y	Y	Y	N
Uzbekistan	N	N	N	N
Venezuela	N	N	N	N

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

(2) Due to the changes made to the relevant regulations in Malaysia that became effective in November 2015, we are required to register our product. Sales of MGuard Prime EPS were made to our distributor in Malaysia prior to the date such change became effective. On November 29, 2015 we initiated registration process required pursuant to the amended regulation.

(3) We believe that we have regulatory approval for MGuard Prime EPS in South Africa based upon information from our former distributor in such country, who was responsible for obtaining the regulatory approval for MGuard Prime EPS. However, the certificate evidencing regulatory approval was held by our former distributor and we cannot guarantee that it is in full force and effect. Our distribution agreement with the distributor in South Africa expired pursuant to the terms of such distribution agreement on February 1, 2015.

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

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

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

Customers

Our customer base is varied. We began shipping our product to customers in Europe in January 2008 and have since expanded our global distribution network to Southeast Asia, India, Latin America and Israel. We currently have distribution agreements for our CE mark-approved MGuard Prime EPS and/or CGuard EPS with medical product distributors based in Europe, the Middle East, Asia Pacific, Australia and Latin America. We are currently in discussions with additional distribution companies in Europe, Asia, and Latin America.

For the twelve months ended December 31, 2015, 79% of our revenue was generated in Europe, and 17% of our revenue was generated in Latin America, with the remaining 4% of our revenue generated in the rest of the world. Our major customers in the twelve months ended December 31, 2015 were Avidal Group GmbH, a distributor in Germany that accounted for 11% of our revenues, and Cardio Medical Sales L.P, a distributor in Belarus that accounted for 10% of our revenues.

Our agreement with Avidal Group GmbH grants Avidal Group GmbH the right to be a distributor of MGuard Prime EPS and CGuard EPS in Germany until March 2017, subject to the achievement of certain order minimums. The term of the agreement may be renewed for an additional 12 month term by written consent of both parties no later than October 31 of the last year of the term. Either party may terminate the agreement for any reason with 60 days' prior written notice. Under our agreement with Avidal Group GmbH, as amended, Avidal Group GmbH was required to purchase 850 MGuard Prime EPS and 225 CGuard EPS from us in 2015. Although Avidal Group GmbH did not adhere to their order minimum for 2015, we did not terminate their right to be our distributor of MGuard Prime EPS and CGuard EPS in Germany.

Our agreement with Cardio Medical Sales L.P, as amended, grants Cardio Medical Sales L.P the right to be the non-exclusive distributor of MGuard Prime EPS and CGuard EPS in Belarus until December 2016, subject to the achievement of certain order minimums. Under our agreement with Cardio Medical Sales L.P, Cardio Medical Sales L.P was required to purchase 450 MGuard Prime EPS from us in 2015, 70 MGuard Prime EPS in 2016 and 30 CGuard EPS in 2016. Although Cardio Medical Sales L.P did not adhere to their order minimum for 2015, we did not terminate their right to be our exclusive distributor of MGuard Prime EPS and CGuard EPS in Belarus.

Penumbra Distribution Agreement

On August 5, 2015, InspireMD, Ltd., our wholly owned subsidiary, entered into a distribution agreement with Penumbra, Inc., pursuant to which Penumbra, Inc. will act as the exclusive distributor of CGuard EPS in Austria, France, Sweden, Denmark, Norway, Finland, Estonia, Lithuania, Portugal, Switzerland and the United Kingdom and Ireland. The territory covered by the distribution agreement also includes non-exclusive rights to distribute CGuard EPS in Latvia, Belgium, the Netherlands, Luxembourg, Germany and Poland.

Under the terms of the distribution agreement, we will use all commercially reasonable efforts to obtain all required permits, licenses and other approvals necessary to import, market or sell CGuard EPS in the territory covered by the distribution agreement. Within 60 days after receipt of all such required approvals in a given territory, Penumbra, Inc. will place its initial stocking order for CGuard EPS, for which Penumbra, Inc. will pay one-half of the purchase price upon placing such order and the remainder of the purchase price 30 days after receipt of CGuard products and our invoice for such CGuard EPS products. If, in our reasonable discretion, Penumbra, Inc. fails to order a sufficient quantity of CGuard EPS to successfully commercialize CGuard EPS in the applicable territory, then we may reduce the territory covered by the distribution agreement upon providing 60 days' notice to Penumbra, Inc.

The distribution agreement requires Penumbra, Inc. to use commercially reasonable efforts to purchase CGuard EPS in certain minimum target amounts agreed to by the parties for the 2015 and 2016 calendar years. For all subsequent calendar years during the term of the distribution agreement, the parties will agree to the minimum annual purchase targets at least 30 days prior to the commencement of such calendar year, which shall be determined in good faith by mutual agreement, taking into account various relevant factors, including but not limited to the sales attained during the preceding calendar year and prevailing market conditions. The parties fixed the initial prices to be paid by Penumbra, Inc. for CGuard EPS through December 31, 2015, which were subject to certain reductions for inventory shelf life and other adjustments negotiated by the parties.

The initial term of the distribution agreement ends on December 31, 2018, unless sooner terminated pursuant to the termination rights set forth in the distribution agreement. Either party may terminate the distribution agreement (i) without cause upon providing 60 days' notice to the other party, (ii) upon the other party's material breach of the distribution agreement, which is not cured 30 days after written notice of such breach from the non-breaching party to the breaching party and (iii) immediately without notice upon the bankruptcy, insolvency, dissolution, assignment for the benefit of creditors or similar event with respect to the other party. We may also terminate the distribution agreement if we reasonably believe that Penumbra, Inc., or any party acting on its behalf, has violated the United States Foreign Corrupt Practices Act of 1977. In addition, if at any time during the term of the distribution agreement, Penumbra, Inc. distributes or offers for sale products that, in our reasonable judgment, compete with CGuard EPS, then we may terminate the distribution agreement or change the exclusive rights granted to non-exclusive rights upon providing 30 days' notice to Penumbra, Inc.

Pursuant to the distribution agreement, we are subject to customary covenants and other continuing regulatory, record-keeping and reporting obligations.

The distribution agreement also contains a limited three year warranty for CGuard EPS and other mutual confidentiality and indemnification obligations for us and Penumbra, Inc.

Most of our current agreements with our distributors stipulate that, and we expect our future agreements with our distributors to stipulate that, while we shall assist in training by providing training materials, marketing guidance, marketing materials, and technical guidance, each distributor will be responsible for carrying out local registration, sales and marketing activities. In addition, in most cases, all sales costs, including sales representatives, incentive programs, and marketing trials, will be borne by the distributor. Under current agreements, distributors purchase stents from us at a fixed price. Our current agreements with distributors are generally for a term of two to three years.

Manufacturing and Suppliers

The polymer fiber for MicroNet is supplied by Biogeneral, Inc., a San Diego, California-based specialty polymer manufacturer for medical and engineering applications.

Natec Medical Ltd. supplies us with catheters that help create the base for our CGuard EPS stents. Our agreement with Natec Medical Ltd., as amended, which may be terminated by us upon eight months' notice, calls for a minimum order of 2,000 catheters and commitment to purchase the remaining stock of components for production of the catheters in the event we fail to meet the minimum order for up to approximately $87,000 in 2016.

Natec Medical Ltd. supplies us with catheters that help create the base for our MGuard Prime EPS. Our agreement with Natec Medical Ltd., which may be terminated by either party upon six months' notice, calls for non-binding minimum orders.

The cobalt-chromium stent for our MGuard Prime EPS was designed by Svelte Medical Systems Inc. We have an agreement with Svelte Medical Systems Inc., as amended, that grants us a non-exclusive, worldwide license for production and use of the MGuard Prime cobalt-chromium stent for the life of the stent's patent, subject to the earlier termination of the agreement upon the bankruptcy of either party or the uncured default by either party under any material provision of the agreement. Our royalty payments to Svelte Medical Systems Inc. are determined by the sales volume of MGuard Prime EPS. Currently, the royalty rate is 2.9% of all net sales. We have mutual indemnification obligations with Svelte Medical Systems Inc. for any damages suffered as a result of third party actions based upon breaches of representations and warranties or the failure to perform certain covenants in the license agreement, and Svelte Medical Systems Inc. will also indemnify us for any damages suffered as a result of third party actions based upon intellectual property or design claims against the cobalt-chromium stent for the MGuard Prime EPS.

We manufacture our CGuard EPS and MGuard Prime EPS at our own facility. The bare-metal cobalt-chromium stents for our MGuard Prime EPS and the self-expanding bare-metal stents for our CGuard EPS are being manufactured and supplied by MeKo Laserstrahl-Materialbearbeitung. Our agreement with MeKo Laserstrahl-Materialbearbeitung for the production of electro polished L605 bare-metal stents for MGuard Prime EPS and CGuard EPS is priced on a per-stent basis, subject to the quantity of stents ordered. The complete assembly process for MGuard Prime EPS and CGuard EPS, 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 EPS and CGuard EPS have been assembled, they are sent for sterilization in Germany and then back to Israel for final packaging.

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

A CGuard EPS consists of a CGuard stent and the delivery system. Each CGuard stent is manufactured from two main components, a self-expending stent and the mesh polymer. The stent is made out of nitinol. This material is readily available and we acquire it in the open market. The mesh is made from polyethylene terephthalate. We have pending patent rights that cover the proposed CGuard stent with mesh. This material is readily available in the market as well, because it is used for many medical applications. In the event that our supplier can no longer supply this material in fiber form, we would need to qualify another supplier, which could take several months. The delivery system for CGuard is made out of polymer tubes we acquire from an original equipment manufacturer. In the event that our supplier can no longer supply this material, we would need to qualify another supplier, which could take several months. In addition, in order to retain the approval of the CE mark, we are required to perform periodic audits of the quality control systems of our key suppliers in order to insure that their products meet our predetermined specifications.

Employees

As of June 21, 2016, we had 33 full-time employees. Except for one of our employees in Europe, our employees are not party to any collective bargaining agreements. We do not expect the collective bargaining agreements to which our employees are party to have a material effect on our business or results of operations. We consider our relations with our employees to be good. We believe that our future success will depend, in part, on our continued ability to attract, hire and retain qualified personnel.

Properties

Our headquarters are located in Boston, Massachusetts, where we lease approximately 1,580 square feet of executive office space. In addition, in Tel Aviv, Israel, we currently have a 1,000 square meter office and manufacturing facility that has the capacity to manufacture and assemble 4,800 stents per month, based upon the production schedule of one shift per day. We believe that our current facility is sufficient to meet anticipated future demand by adding additional shifts to our current production schedule.

Legal Proceedings

From time to time, we may be involved in litigation that arises through the normal course of business.

On April 26, 2016, Microbanc, LLC and Todd Spenla of Microbanc, LLC filed suit in the New York State Supreme Court (New York County) against us asserting claims for breach of agreement, quantum meruit, unjust enrichment and fraud and seeking approximately $2.2 million and 9% of the amount of stock and warrants sold in 2011 and 2012 in alleged damages relating to certain alleged finders' fees that they claim are owed. Due to the uncertainties of litigation, however, we can give no assurance that we will prevail on any claims made against us in any such lawsuit. Also, we can give no assurance that any other lawsuits or claims brought in the future will not have an adverse effect on our financial condition, liquidity or operating results.

As of the date of this filing, we are not aware of any other material legal proceedings to which we or any of our subsidiaries is a party or to which any of our property is subject, nor are we aware of any such threatened or pending litigation other than the foregoing suit filed by Microbanc, LLC and Todd Spenla.

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

Corporate Information

We were organized in the State of Delaware on February 29, 2008. Our principal executive offices are located at 321 Columbus Avenue, Boston, Massachusetts 02116. Our telephone number is (857) 305-2410. Our website address is *www.inspire-md.com*. Information accessed through our website is not incorporated into this prospectus and is not a part of this prospectus.

MANAGEMENT

Executive Officers and Directors

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

Name	Age	Position
James Barry, Ph.D.	56	President, Chief Executive Officer and Director
Craig Shore	55	Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer
Sol J. Barer, Ph.D.[(1)(2)(3)]	68	Chairman of the Board of Directors
Isaac Blech	66	Vice Chairman of the Board of Directors
Michael Berman[(1)(2)]	58	Director
Campbell Rogers, M.D.	54	Director
Paul Stuka[(1)(2)(3)]	61	Director

(1) Member of our audit committee

(2) Member of our nominating and corporate governance committee

(3) Member of our compensation committee

Our directors hold office until the earlier of their death, resignation or removal by stockholders or until their successors have been qualified. Our directors are divided into three classes. Sol J. Barer, Ph.D. and Paul Stuka are our Class 1 directors, with their terms of office to expire at our 2018 annual meeting of stockholders. Michael Berman and Campbell Rogers, M.D. are our Class 2 directors, with their terms of office to expire at our 2019 annual meeting of stockholders. Isaac Blech and James Barry, Ph.D. are our Class 3 directors, with their terms of office to expire at our 2017 annual meeting of stockholders. At each annual meeting of stockholders, 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 hold office until the earlier of their death, resignation or removal by our board of directors or until their successors have been selected. They serve at the pleasure of our board of directors.

James Barry, Ph.D. has served as our president and chief executive officer since June 6, 2016, and as a director since January 30, 2012. Prior to becoming our president and chief executive officer, Dr. Barry has served as our executive vice president and chief operating officer since July 14, 2014. Dr. Barry has served as executive vice president and chief operating officer at Arsenal Medical Inc., a medical device company focused on local therapy, since September 2011. Dr. Barry also heads his own consulting firm, Convergent Biomedical Group LLC, advising medtech companies on product development, strategy, regulatory challenges and fund raising. Until June 2010, he was senior vice president, corporate technology development at Boston Scientific Corporation, where he was in charge of the corporate research and development and pre-clinical sciences functions. Dr. Barry joined Boston Scientific in 1992 and oversaw its efforts in the identification and development of drug, device and biological systems for applications with implantable and catheter-based delivery systems. He currently serves on a number of advisory boards including the College of Biomedical Engineering at Yale University, the College of Sciences at University of Massachusetts-Lowell and the Massachusetts Life Science Center and as a director of pSivida Corp (NASDAQ: PSDV). Dr. Barry received his Ph.D. in Biochemistry from the University of Massachusetts-Lowell and holds a B.A. degree in Chemistry from Saint Anselm College. Dr. Barry brings to the board over 20 years of experience in leadership roles in the medical device industry and significant medical technology experience, in particular with respect to interventional cardiology products, and as chief executive officer, Dr. Barry's position on the board ensures a unity of vision between the broader goals of our company and our day-to-day operations.

Craig Shore has served as our chief financial officer, secretary and treasurer since March 31, 2011 and as our chief administrative officer since May 3, 2013. In addition, from November 10, 2010 through March 31, 2011, Mr. Shore served as InspireMD Ltd.'s vice president of business development. From February 2008 through June 2009, Mr. Shore served as chief financial officer of World Group Capital Ltd. and Nepco Star Ltd., both publicly traded companies on the Tel Aviv Stock Exchange, based in Tel Aviv, Israel. From March 2006 until February 2008, Mr. Shore served as the chief financial officer of Cellnets Solutions Ltd., a provider of advanced cellular public telephony solutions for low to middle income populations of developing countries based in Azur, Israel. Mr. Shore has over 25 years of experience in financial management in the 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.

Sol J. Barer, Ph.D. has served as a director since July 11, 2011 and has served as our chairman since November 16, 2011. Dr. Barer has over 25 years of experience with publicly traded biotechnology companies. In 1980, when Dr. Barer was with Celanese Research Company, he formed the biotechnology group that was subsequently spun out to form Celgene Corporation. Dr. Barer spent 18 years leading Celgene Corporation as president, chief operating officer and chief executive officer, culminating with his tenure as Celgene Corporation's executive chairman from June 2010 until January 2011 and chairman from May 2006 until June 2010 and from January 2011 until his retirement in June 2011. Dr. Barer is also a director of Cerecor, Inc., Edge Therapeutics, Inc., Medgenics, Inc., Centrexion Corporation, RestorGenex Corporation, ContraFect Corporation, Amicus Therapeutics, Inc. and Aegerion Pharmaceuticals, Inc. and serves as a senior advisor to a number of other biotechnology companies. Dr. Barer received a Ph.D. in organic chemistry from Rutgers University. Dr. Barer brings to the board significant scientific and executive leadership experience in the U.S. biotechnology industry and prior service on the board of directors of other publicly-held biopharmaceutical companies, as well as a unique perspective on the best methods of growth for a biotechnology company.

Isaac Blech has served as a director and our vice chairmen since January 22, 2016. Mr. Blech is a renowned biotechnology entrepreneur and investor, who, over the past 32 years, has founded and served on the board of companies which have produced major advances in a broad array of diseases, including the diagnosis of chlamydia, herpes, syphilis and HIV, and the treatment of cystic fibrosis, sexual dysfunction, multiple myeloma and brain cancer. The companies he established include Celgene Corporation (NASDAQ: CELG), ICOS Corporation, Nova Pharmaceutical Corporation, Pathogenesis Corporation and Genetics Systems Corporation. Mr. Blech's current roles include director and founder of Cerecor, Inc. (NASDAQ: CERC), a public company developing new treatments for central nervous system disorders, director of ContraFect Corporation (NASDAQ: CFRX), a public infectious disease company, director of Medgenics, Inc. (NYSE: MDGN), a public company creating new treatments for rare diseases, and vice chairman of Edge Therapeutics, Inc. (NASDAQ: EDGE), a public company that treats life-threatening neurological conditions. He is vice chairman of Centrexion Corporation, a private company which is developing new modalities of pain control, vice chairman of Regenovation, Inc., a private company developing new ways to regenerate human tissue, vice chairman of X4 Pharmaceuticals, a private cancer immunology company, vice chairman of Sapience Therapeutics, a private oncology company and vice chairman of Aridis Pharmaceuticals, a private company with a product to treat pneumonia. He also serves as vice chairman of WaveGuide Corporation, a private company developing the world's smallest NMR machine, vice chairman of root9B Technologies, Inc. (OTC: RTNB), a public cyber security company, and vice chairman of The SpendSmart Payments Company (OTC: SSPC), a public electronic rewards company.

Our board of directors believes that Mr. Blech's broad experiences as a founder, director and major investor in numerous biotechnology companies provide him with the qualifications and skills to serve as a director.