

InspireMD, Inc.
Form S-1/A
June 17, 2016

As filed with the Securities and Exchange Commission on June 17, 2016

Registration No. 333-210760

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

AMENDMENT NO.3

TO

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

3841

(Primary Standard Industrial Classification Code Number)

26-2123838

(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
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(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:

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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 "

Smaller reporting company x

(Do not check if a smaller reporting company)

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⁾	\$ 843,763.00	\$ 84.97	
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⁾	\$ 506,257.50	\$ 50.99	
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⁾	\$ 843,762.50	\$ 84.97	
Total	\$ 42,693,875.50	\$ 4,299.28	(8)

Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities

(1) 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 16, 2016.

Pursuant to Rule 416 under the Securities Act of 1933, as amended, this registration statement also covers any (2) 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. 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 16, 2016.
- (6) Represents shares of Series B Convertible Preferred Stock and warrants to purchase common stock included in a unit purchase option to purchase up to 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.
- (7)
- (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 17, 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 16, 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 16, 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 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

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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 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 offering 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

Each holder of Preferred Stock is entitled to the number of votes equal to the number of whole shares of common stock into which the shares of Preferred Stock held by such holder is then convertible (subject to the limitation on conversion set forth in the section “Conversion” above) with respect to any and all matters presented to the stockholders for their action or consideration. Holders of Preferred Stock vote together with the holders of common stock as a single class, except as provided by law.

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	<p>We estimate that our net proceeds from this offering will be approximately \$12,055,000, 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⁾</p> <p>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.”</p>
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 16, 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 16, 2016 and excludes as of that date:

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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;

- 3,857,200 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;

- 1,446,450 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 16, 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 tense identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and will probably not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or our management’s good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, 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 \$12,055,000 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 \$2,792,000, 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 16, 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 16, 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.

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 16, 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	14,054
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	134,257

Accumulated deficit	(125,605)	(125,605)
Total equity	(3,395)	8,660

(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, 3,857,200 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 1,446,450 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 16, 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 16, 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 \$8,585,000, 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)

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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;

3,857,200 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;

1,446,450 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.

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 E