

InspireMD, Inc.
Form S-1/A
June 26, 2018

As filed with the Securities and Exchange Commission on June 26 , 2018

Registration No. 333- 225680

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

AMENDMENT NO.1

TO

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

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

4 Menorat Hamaor St.

**Tel Aviv, Israel 6744832
(888) 776-6804**

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

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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. []

Total: \$ 35,362,500 \$ 4,402.63 (7)

In accordance with Rule 416(a) under the Securities Act of 1933, as amended, the Registrant is also registering (1) hereunder an indeterminate number of additional shares of Common Stock that shall be issuable pursuant to Rule 416 to prevent dilution resulting from stock splits, stock dividends or similar transactions.

The proposed maximum aggregate offering price of the Units proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the aggregate offering price of any Pre-funded Units offered and sold in the offering, and the proposed maximum aggregate offering price of the Pre-funded Units to be sold in the offering (2) will be reduced on a dollar-for-dollar basis based on the aggregate offering price of any Units sold in the offering. Accordingly, the proposed maximum aggregate offering price of the Units and Pre-funded Units (including the shares of Common Stock issuable upon exercise of the Pre-funded Warrants included in the Pre-funded Units), if any, is \$11,500,000.

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

Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate offering price of additional shares of Common Stock and Series D Warrants to purchase Common Stock that the underwriter has the right to purchase. (4)

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

Represents warrants to purchase a number of shares of common stock equal to 6% of the number of shares of common stock sold in this offering (including the number of shares of common stock issuable upon exercise of the pre-funded warrants) at an exercise price equal to 125% of the offering price per unit. (6)

(7) \$1,784.74 of which has been 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 26, 2018

Up to 10,416,666 Units (each Unit contains One Share of Common Stock and One Series D Warrant to purchase One Share of Common Stock)

Up to 10,416,666 Pre-funded Units (each Pre-funded Unit contains One Pre-funded Warrant to Purchase One Share of Common Stock and One Series D Warrant to purchase One Share of Common Stock)

Shares of Common Stock Underlying the Pre-funded Warrants and

Shares of Common Stock Underlying the Series D Warrants

We are offering up to 10,416,666 units (each unit consisting of one share of our common stock and one Series D Warrant to purchase one share of our common stock) pursuant to this prospectus. Each Series D Warrant contained in a unit has an exercise price of \$ _____ per share of common stock. The Series D Warrants contained in the units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the Series D Warrants contained in the units.

We are also offering to each purchaser whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one Series D Warrant to purchase one share

of our common stock) in lieu of units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding common stock (or at the election of the purchaser, 9.99%). Because we will issue a Series D Warrant as part of each unit or pre-funded unit, the number of Series D Warrants sold in this offering will not change as a result of a change in the mix of the units and pre-funded units sold. Each pre-funded warrant contained in a pre-funded unit will be exercisable for one share of our common stock. The purchase price of each pre-funded unit will equal the price per unit being sold to the public in this offering, minus \$0.01, and the exercise price of each pre-funded warrant included in the pre-funded unit will be \$0.01 per share. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants contained in the pre-funded units sold in this offering. Each Series D Warrant contained in a pre-funded unit has an exercise price of \$ per share of common stock. The Series D Warrants contained in the pre-funded units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the Series D Warrants contained in the pre-funded units.

For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. Units and the pre-funded units will not be issued or certificated. The shares of common stock or pre-funded warrants, as the case may be, and the Series D Warrants included in the units or the pre-funded units, can only be purchased together in this offering, but the securities contained in the units or pre-funded units will be issued separately and will be immediately separable upon issuance.

Our common stock is traded on the NYSE American under the symbol “NSPR.” On June 25, 2018, the last reported sale price of our common stock was \$0.81 per share. We have assumed a public offering price of \$0.96 per unit, the last reported sale price for our common stock as reported on the NYSE American on June 21, 2018, and \$0.95 per pre-funded unit. The actual public offering price per unit or pre-funded unit, as the case may be, will be negotiated between us and the underwriter based on the trading of our shares of common stock prior to the offering, among other things, and may be at a discount to the current market price. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final offering price. There is no established public trading market for the pre-funded warrants or Series D Warrants, and we do not expect a market to develop. We do not intend to apply for listing of the pre-funded warrants or Series D Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants or the Series D Warrants will be limited.

Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page 10 of this prospectus and in the documents incorporated by reference into this prospectus for a discussion of risks that should be considered in connection with an investment in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Unit	Per Pre-funded Unit	Total
Public offering price	\$	\$	\$
Underwriting discounts and commissions (7%) (1)	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

(1) We have also agreed to pay the underwriter a management fee equal to 1.0% of the gross proceeds raised in this offering, a non-accountable expense allowance of \$35,000 and reimbursement for legal fees and expenses in the amount of up to \$100,000, and to issue the underwriter or its designees warrants to purchase a number of shares of

common stock equal to 6% of the aggregate number of shares of common stock sold in this offering (including the number of shares of common stock issuable upon exercise of the pre-funded warrants), at an exercise price of \$ per share, which represents 125% of the public offering price per unit. For a description of the additional compensation to be received by the underwriter, see “Underwriting” for more information.

The offering is being underwritten on a firm commitment basis. The underwriter has an option exercisable within 30 days from the date of this prospectus to purchase up to 1,562,500 additional shares of common stock and/or Series D Warrants to purchase up to an additional 1,562,500 shares of common stock from us at the public offering price, less the underwriting discounts and commissions. If the underwriter exercises this option in full, the total underwriting discounts and commissions payable by us will be \$, and the total proceeds to us, before expenses, will be \$, excluding potential proceeds from the exercise of the Series D Warrants included in such option.

Delivery of the securities offered hereby is expected to be made on or about , 2018.

H.C. Wainwright & Co.

The date of this prospectus is , 2018

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You should rely only on the information incorporated by reference or 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 or any document incorporated by reference 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 or incorporated by reference into 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 our securities. You should read this entire prospectus carefully, including the information discussed under “Risk Factors” and the documents incorporated by reference and our financial statements and related notes that are incorporated by reference 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.

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 MicroNet 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. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, and, in 2018, received regulatory approval to commercialize CGuard EPS in India, Vietnam and Ecuador. We consider the addressable market for our CGuard EPS consists of individuals with diagnosed, symptomatic high-grade carotid artery stenosis (HGCS, $\geq 70\%$ occlusion) for whom an intervention is preferable to medical (drug) therapy. This group includes not only carotid artery stenting patients but also individuals undergoing carotid endarterectomy, as the two approaches compete for the same patient population. Assuming full penetration of the intervention caseload by CGuard EPS, we estimate that the addressable market for CGuard EPS was approximately \$1.0 billion in 2017. (source: *Health Research International 2017 Results of Update Report on Global Carotid Stenting Procedures and Markets by Major Geography and Addressable Markets*).

In April 2017, we had a pre-investigational device exemption (“IDE”) submission meeting with the U.S. Food and Drug Administration regarding CGuard EPS where we presented materials that we believed would support a formal IDE submission seeking approval to conduct a human clinical trial in the United States which included our draft synopsis for the clinical trial design. We intend to make a formal submission once sufficient funds are available.

If we receive sufficient proceeds from this offering and future financings, we plan to develop CGuard EPS with a smaller delivery catheter (5 French gauge), which we intend to submit for CE mark approval. We cannot give any assurance that we will receive sufficient (or any) proceeds from this offering or any such future financings or the timing of such financings, if ever. In addition, such additional financings may be costly or difficult to complete. Even if we receive sufficient proceeds from this offering and future financings, there is no assurance that we will be able to timely apply for CE mark approval following our receipt of such proceeds.

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 MicroNet with a bare-metal cobalt-chromium based stent. 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 with MicroNet and seeking to incorporate MicroNet onto a drug-eluting stent manufactured by a potential partner. The FDA has clarified that the primary mode of action for drug-eluting cardiovascular stents, which are regulated as combination products, is that of the device component and has assigned the FDA Center for Devices and Radiological Health (CDRH) primary responsibility for premarket review and regulation, providing some clarity about what to expect regarding the regulatory framework related to the development of MGuard DES™.

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 seal aneurysms in the brain.

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

In 2017, we decided to shift our commercial strategy to focus on sales of our products through local distribution partners and our own internal sales initiatives to gain greater reach into all the relevant clinical specialties and to expand our geographic coverage. Pursuant to our new strategy, we completed our transition away from a single distributor covering 18 European countries to a direct distribution model intended to broaden our sales efforts to key clinical specialties. All territories previously covered by our former European distributor were transferred to local distributors by June 2017. We also have begun to participate in international trade shows and industry conferences in an attempt to gain market exposure and brand recognition.

Growth Strategy

Our primary business objective is to utilize our proprietary MicroNet technology and products 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 to achieve this objective.

Widen the adoption of CGuard EPS. We are seeking to transition current users of conventional carotid stents to use CGuard EPS and vascular surgeons to use CGuard EPS in filter protected carotid artery stenting instead of vascular surgery if possible. We publish and present our clinical data and support investigator-initiated clinical registries, which we plan to continue and expand. We have partnered and will continue to seek out partnerships with appropriate societies focused on the treatment of stroke. We will also continue to engage advisory boards and to develop a network of key opinion leaders to assist us in widening the adoption of CGuard EPS.

Grow our presence in existing and new markets for CGuard EPS. We have launched CGuard EPS in most European and Latin American countries through a comprehensive distributor sales organizations network. We will continue to focus on larger growing markets through this network. We are also pursuing additional product registrations and distribution contracts with local distributors in other countries in Europe, the Middle East, Asia and Latin America. Once sufficient funds are available, we intend to make an IDE submission seeking approval to conduct a human clinical trial in the United States.

Continue to leverage our 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 MicroNet 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, 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. Seventeen patent applications have been filed (seven of which are now pending) 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 technological 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 MGuard DES. While we have limited the focus of product development to our carotid products, if we resume development of our coronary products, we plan to evaluate opportunities to further develop MGuard DES.

Recent Developments

Recent Financings and Recapitalization

On March 14, 2017, we closed a “best efforts” public offering of 1,069,822 shares of Series C Convertible Preferred Stock (the “Series C Preferred Stock”), Series B warrants to purchase 122,269 shares of common stock and Series C warrants to purchase 122,269 shares of common stock. The Series C Warrants expired on September 14, 2017. The Series B warrants have a term of five years and an exercise price of \$70.00 per share of common stock, subject to adjustment as provided in the Series B warrants. We received gross proceeds of approximately \$6.8 million from the offering, before deducting placement agent fees and offering expenses.

On December 1, 2017, as part of a planned recapitalization, we sold 750 shares of Series D Convertible Preferred Stock (the “Series D Preferred Stock”) to an institutional accredited investor (the “Series D Investor”) in a private placement (the “Series D Private Placement”) pursuant to a securities purchase agreement (the “Series D Purchase Agreement”), dated November 28, 2017, for aggregate gross proceeds of \$750,000. The stated value of each share of Series D Preferred Stock is \$1,000, and the Series D Preferred Stock was initially convertible, at the option of the holder, into shares of our common stock (subject to the beneficial ownership limitation set forth in the certificate of designation for the Series D Preferred Stock (“Series D Certificate of Designation”)), at a conversion price of \$7.00 per share, subject to adjustment as provided in the Series D Certificate of Designation. Pursuant to the Series D Purchase Agreement and the Series D Certificate of Designation, the purchasers of Series D Preferred Stock have the option, subject to certain limitations, to exchange their Series D Preferred Stock into the securities issued in a subsequent offering (the “Series D Exchange Right”) or into the securities we sell in an offering of our common stock or common stock equivalents for gross proceeds of at least \$8 million (a “Qualified Offering”) on a \$1.00 per stated value for \$1.00 new subscription amount basis. In addition, in accordance with the Series D Purchase Agreement, the certificate of designation for the Series B Preferred Stock was amended to provide that each share of outstanding Series B Convertible Preferred Stock (the “Series B Preferred Stock”) will be automatically exchanged into the securities we sell in a Qualified Offering on a \$1.00 per stated value for \$1.00 new subscription amount basis. As a result of the issuance and sale of the Series D Preferred Stock, the conversion price of our outstanding shares of Series B Preferred Stock was reduced to \$7.00 pursuant to the anti-dilution adjustment provisions of the Series B Preferred Stock. There was no change to the conversion price of our outstanding Series C Preferred Stock as a result of an amendment made to the terms of the Series C Preferred Stock exempting the issuance of the Series D Preferred Stock from the anti-dilution adjustment provisions of the Series C Preferred Stock. The conversion price for each of our Series B Preferred Stock, our Series C Preferred Stock and our Series D Preferred was subsequently reduced to \$3.00 per share and then to \$1.75 as described below.

On February 21, 2018, the Series D Purchase Agreement was amended to require us (i) to use 15% of the proceeds from any subsequent offering of our securities that is not a Qualified Offering to redeem the outstanding shares of the Series C Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the

Series C Preferred Stock, and (ii) upon closing of any subsequent offering that is a Qualified Offering, to exchange all remaining outstanding shares of Series C Preferred Stock held by the Series D Investor for any securities issued in such Qualified Offering on a \$1.00 per stated value for \$1.00 new subscription amount basis (subject to the beneficial ownership limitation set forth in the certificate of designation for the Series C Preferred Stock). In the event that we fail, or are unable, to issue securities issued in the Qualified Offering to the Series D Investor in exchange for such investor's remaining Series C Preferred Stock due to limitations mandated by the NYSE American, the Securities and Exchange Commission, or for any other reason, we are required to offer to purchase from such investor those shares of Series C Preferred Stock not exchanged for the securities sold in the Qualified Offering at a per share purchase price equal to the stated value of Series C Preferred Stock.

On February 26, 2018, we and the Series D Investor entered into a waiver agreement which provided that (i) the Series D Exchange Right would not be applicable to an offering of up to \$7,000,000 which occurred no later than March 9, 2018, (ii) we shall reduce the conversion price of the Series D Preferred Stock to the public offering price of our common stock in such offering, (iii) instead of using 15% of the proceeds from such offering to redeem shares of Series C Preferred Stock held by the Series D Investor, we shall use 15% of the proceeds from such offering to redeem a portion of the outstanding shares of Series D Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series D Preferred Stock, and (iv) we shall file a registration statement with the Securities and Exchange Commission under the Securities Act of 1933, as amended, in order to register the resale of the shares of common stock issuable upon the conversion of the Series D Preferred Stock as soon as practicable following the closing of such offering, but in no event later than seven days following such closing and to cause such registration statement to become effective as soon as practical after its filing.

On March 1, 2018, we closed an underwritten public offering of 1,000,000 shares of our common stock at a price to the public of \$3.00 per share, thus triggering the rights under the above described February 26, 2018 agreement. Upon closing of the offering, we used 15% of the proceeds from the offering to redeem 450 shares of Series D Preferred Stock. As a result of such offering, the conversion price for each of our Series B Preferred Stock, our Series C Preferred Stock and our Series D Preferred Stock was reduced to \$3.00 per share.

On March 28, 2018, we and the Series D Investor entered into the second waiver agreement which provided that (i) the Series D Exchange Right would not be applicable to a subsequent financing consisting solely of shares of common stock, which shall be publicly registered on Form S-3 for gross proceeds to us of up to \$5,000,000, to be consummated by not later than April 3, 2018 (the “Planned April 2018 Offering”), (ii) our obligation to use 15% of the proceeds from any subsequent offering of our securities that is not a Qualified Offering to redeem the outstanding shares of the Series C Preferred Stock held by the Series D Investor would not be applicable to the Planned April 2018 Offering, (iii) we shall reduce the conversion price of the Series D Preferred Stock to the public offering price of our common stock sold in the Planned April 2018 Offering, and (iv) we shall use \$300,000 of the proceeds from the Planned April 2018 Offering to redeem outstanding shares of Series C Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series C Preferred Stock.

On April 2, 2018, we closed an underwritten public offering of 2,857,143 shares of our common stock at a price to the public of \$1.75 per share, thus triggering the rights under the above described March 28, 2018 second waiver agreement. Upon closing of the offering, we used \$300,000 of the proceeds from the offering to redeem 46,875 shares of our Series C Preferred Stock held by the Series D Investor. As a result of such offering, the conversion price for each of our Series B Preferred Stock, our Series C Preferred Stock and our Series D Preferred Stock was reduced to \$1.75 per share.

NYSE American Notification

On August 17, 2017, we received a notice from NYSE American indicating that we do not meet the continued listing standards of the NYSE American as set forth in Part 10 of the NYSE American Company Guide (the “Company Guide”). Specifically, we were not in compliance with Section 1003(a)(iii) of the Company Guide because we reported stockholders’ equity of less than \$6 million as of June 30, 2017, and net losses in our five most recent fiscal years ended December 31, 2016. As a result, we became subject to the procedures and requirements of Section 1009 of the Company Guide. On October 19, 2017, NYSE American accepted our plan to regain compliance with Section 1003(a)(iii) of the Company Guide by February 17, 2019. We are subject to periodic review by the NYSE American staff during the period covered by the compliance plan. Failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the plan period could result in our common stock being delisted from the NYSE American.

On November 22, 2017, we received an additional letter from the NYSE American indicating that we are not in compliance with the stockholders' equity and net income continued listing standards set forth in Section 1003(a)(ii) of the Company Guide because we reported stockholders' equity of less than \$4 million as of September 30, 2017. We have until February 17, 2019, to regain compliance with the continued listing requirements.

On January 16, 2018, we received notification from the NYSE American that we are not in compliance with certain NYSE American continued listing standards. The deficiency letter states that our shares of common stock have been selling for a low price per share for a substantial period of time. Pursuant to Section 1003(f)(v) of the Company Guide, the NYSE American staff determined that our continued listing is predicated on us effecting a reverse stock split of our common stock or otherwise demonstrating sustained price improvement within a reasonable period of time, which the staff determined to be until July 16, 2018.

Reverse Stock Split

Effective as of 5:00 p.m. Eastern Time on February 7, 2018, we amended our amended and restated certificate of incorporation in order to effectuate a 1-for-35 reverse stock split of our outstanding shares of common stock. Although we expect that the reverse stock split will result in an increase in the market price of our common stock, the reverse stock split may not result in a permanent increase in the market price of our common stock, which is dependent on many factors, including general economic, market and industry conditions and other factors. We have adjusted all outstanding restricted stock units, stock options, preferred stock and warrants entitling the holders to purchase shares of our common stock as a result of the reverse stock split, as required by the terms of these securities. In particular, we have reduced the conversion ratio for each security, and increased the exercise price in accordance with the terms of each security based on the reverse stock split ratio (i.e., the number of shares issuable under such securities has been divided by thirty-five, and the exercise price per share has been multiplied by thirty-five). Also, we reduced the number of shares reserved for issuance under the InspireMD, Inc. 2013 Long-Term Incentive Plan and the 2011 UMBRELLA Option Plan, proportionately based on the reverse stock split ratio. The reverse stock split did not otherwise affect any of the rights currently accruing to holders of our common stock, or options or warrants exercisable for our common stock. All share and related option and warrant information presented in this prospectus have been retroactively adjusted to reflect the reduced number of shares outstanding and the increase in share price which resulted from this action.

Offering Securities Issuances Upon the Consummation of this Offering

We expect this offering to constitute a Qualified Offering under the terms of the Series D Purchase Agreement, as amended, and the certificate of designation for the Series B Stock. If this offering constitutes a Qualified Offering, as discussed under “Recent Developments—*Recent Financings and Recapitalization*,” upon consummation of this offering:

- each outstanding share of Series B Preferred Stock will be automatically exchanged into the securities we sell in this offering on a \$1.00 per stated value for \$1.00 new subscription amount basis (or, in the event that such
- (i) exchange would otherwise cause the holder to exceed the beneficial ownership limitation set forth in the certificate of designation for the Series B Preferred Stock, a like security to ensure that the holder does not exceed the beneficial ownership limitation as result of the exchange);
- (ii) each outstanding share of Series C Preferred Stock held by the Series D Investor will be automatically exchanged into the securities we sell in this offering on a \$1.00 per stated value for \$1.00 new subscription amount basis (subject to the beneficial ownership limitation set forth in the certificate of designation for the Series C Preferred Stock), or, to the extent that we fail, or are unable, to issue securities issued in this offering to the Series D Investor in exchange for such investor’s Series C Preferred Stock due to limitations mandated by the NYSE American, the Securities and Exchange Commission, or for any other reason, those shares of Series C Preferred Stock not exchanged for the securities sold in this offering will be redeemed at a per share purchase price equal to

the stated value of Series C Preferred Stock; and

- (iii) the Series D Investor, at its option, subject to certain limitations, may exchange its Series D Preferred Stock into the securities issued in this offering on a \$1.00 per stated value for \$1.00 new subscription amount basis.

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 our stockholders’ ownership interests;

our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products;

delisting of our common stock from NYSE American;

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;

market acceptance and adoption of our 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;

insufficient or inadequate reimbursement by governmental and other third party payers for our products;

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 4 Menorat Hamaor St., Tel Aviv, Israel 6744832. Our telephone number is (888) 776-6804. 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

Units offered by us 10,416,666 units, each consisting of one share of our common stock and one Series D Warrant to purchase one share of our common stock

Pre-funded units offered by us in this offering We are also offering to each purchaser whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding shares of common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of common stock and one Series D Warrant to purchase one share of common stock) in lieu of units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding shares of common stock (or, at the election of the purchaser, 9.99%). The purchase price of each pre-funded unit will equal the public offering price at which the units are being sold to the public in this offering, minus \$0.01, and the exercise price of each pre-funded warrant included in each pre-funded unit will be \$0.01 per share. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. Because we will issue a Series D Warrant as part of each unit or pre-funded unit, the number of Series D Warrants sold in this offering will not change as a result of a change in the mix of the units and pre-funded units sold.

Series D Warrants offered by us in the offering Series D Warrants to purchase an aggregate of 10,416,666 shares of common stock. Each unit and each pre-funded unit includes one Series D Warrant to purchase one share of our common stock. Each Series D Warrant entitles the holder to purchase one share of common stock at an exercise price of \$ per share, will be immediately exercisable and will expire on the 5th anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the Series D Warrants.

Option to purchase additional securities The underwriter has an option to purchase up to 1,562,500 additional shares of common stock and/or Series D Warrants to purchase up to an additional 1,562,500 shares of common stock from us at the public offering price, less underwriting discounts and commissions. The underwriter may exercise this option at any time and from time to time within 30 days from the date of this prospectus.

Common stock outstanding prior to this offering: 6,453,428 shares of common stock

Common stock outstanding after this offering: 16,870,094 shares of common stock, assuming no sale of pre-funded units (or 18,432,594 shares of common stock if the underwriter exercises in full its option to purchase additional securities, assuming no sale of pre-funded units).

Use of
Proceeds

We plan to use the net proceeds of this offering for research and development, including the development of and manufacturing enhancements for CGuard EPS and to further our efforts to obtain an IDE approval for CGuard EPS, and for capital expenditures, working capital and other general corporate purposes, as well as potential acquisition. In addition, we may be required to use the net proceeds of this offering to redeem outstanding shares of our Series C Preferred Stock from the Series D Investor, pursuant to the Series D Purchase Agreement, as amended. See “Use of Proceeds” on page 35 of this prospectus.

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Dividend Policy	We have not declared or paid any cash or other dividends on our common stock, and we do not expect to declare or pay any cash or other dividends in the foreseeable future. See “Dividend Policy.”
Risk Factors	Investing in our common stock or pre-funded warrants involves a high degree of risk. See “Risk Factors” beginning on page 10 of this prospectus and the other information included or incorporated by reference in this prospectus.
NYSE American symbol for common stock:	“NSPR.” We do not plan to list the pre-funded warrants or the Series D Warrants on the NYSE American or any other securities exchange or trading market. There is no established trading market for the Series D Warrants or the pre-funded warrants, and we do not expect a trading market to develop. Without a trading market, the liquidity of the pre-funded warrants and the Series D Warrants will be extremely limited.

The number of shares of common stock to be outstanding immediately after this offering is based on 6,453,428 shares of our common stock outstanding as of June 22 , 2018 (unless otherwise indicated), and excludes:

412,878 shares of common stock issuable upon the exercise of warrants outstanding as of June 22 , 2018, with an exercise price ranging from \$2.1875 to \$25,987.50 per share;

594,791 shares of common stock or 594,791 shares of common stock underlying pre-funded warrants and 594,791 shares of common stock underlying Series D Warrants issuable upon the exchange of the 17,303 shares of Series B Preferred Stock (stated value per share of \$33.00) outstanding as of June 22 , 2018, upon consummation of this offering on a \$1.00 per stated value for \$1.00 new subscription amount basis , based on an assumed public offering price of \$0.96 per unit, which is the last reported sale price for our common stock as reported on the NYSE American on June 21, 2018;

1,290,040 shares of common stock or 1,290,040 shares of common stock underlying pre-funded warrants and 1,290,040 shares of common stock underlying Series D Warrants issuable upon the exchange of the 306,917 shares of Series C Preferred Stock (stated value per share of \$6.40) outstanding as of June 22 , 2018, held by the Series D Investor upon consummation of this offering on a \$1.00 per stated value for \$1.00 new subscription amount basis (to the extent that stockholder approval for such exchange of Series C Preferred Stock is not required under the Company Guide), constituting 19.99% of the number of shares of common stock issued and outstanding as of June 22, 2018, based on an assumed public offering price of \$0.96 per unit, which is the last reported sale price for our common stock as reported on the NYSE American on June 21, 2018;

263,033 shares of common stock issuable upon conversion of 71,923 shares of Series C Preferred Stock outstanding as of June 22 , 2018, held by holders other than the Series D Investor (excluding additional shares of common stock, if any, that we will be required to issue to the holders of our Series C Preferred Stock other than the Series D Investor as a result of the full ratchet anti-dilution price protection in the certificate of designation for the Series C Preferred Stock because the effective assumed public offering price of common stock in this offering is lower than \$1.75 per share) at the conversion price of \$1.75 per share and the stated value per share of \$6.40;

216,454 additional shares of common stock that we will be required to issue to the holders of our Series C Preferred Stock other than the Series D Investor upon conversion of shares of our Series C Preferred Stock as a result of the full ratchet anti-dilution price protection in the certificate of designation for the Series C Preferred Stock, based on shares of Series C Preferred Stock that would remain outstanding as of June 22, 2018, after giving effect to any automatic exchange of shares of Series C Preferred Stock held by the Series D Investor into the securities we sell in this offering and any redemption of outstanding shares of our Series C Preferred Stock held by the Series D Investor not exchanged for the securities sold in this offering, if applicable, based on an assumed public offering price of \$0.96 per unit, which is the last reported sale price for our common stock as reported on the NYSE American on June 21, 2018 (see “Risk Factors — Risks Related to Our Common Stock, Preferred Stock, Warrants and this Offering—*If the effective price per share of common stock included in the units or issuable upon exercise of the pre-funded warrants included in the pre-funded units being offered in this offering is less than the current conversion price of our Series C Preferred Stock, we will be required to issue additional shares of common stock, as applicable, to the holders of the Series C Preferred Stock that have not been converted into the securities we sell in this offering, which will be dilutive to all of our other stockholders, including new investors in this offering.*”);

171,429 shares of common stock issuable upon the conversion of the shares of Series D Preferred Stock outstanding as of June 22, 2018, at the conversion price of \$1.75 per share and the stated value per share of \$1,000.00 or, at the election of the Series D Investor, 312,500 shares of common stock or 312,500 shares of common stock underlying pre-funded warrants and 312,500 shares of common stock underlying Series D Warrants issuable upon the exchange of the 300 shares of Series D Preferred Stock (stated value per share of \$1,000.00) outstanding as of June 22, 2018, held by the Series D Investor upon consummation of this offering on a \$1.00 per stated value for \$1.00 new subscription amount basis, based on an assumed public offering price of \$0.96 per unit, which is the last reported sale price for our common stock as reported on the NYSE American on June 21, 2018;

67,925 shares of common stock and 67,925 shares of common stock underlying Series D Warrants issuable upon the exchange of the Series B Preferred Stock and 225 shares of common stock issuable upon exercise of the Series A Warrants, which Series B Preferred Stock and Series A Warrants are included in the units issuable upon exercise of the unexercised portion of the unit purchase option that we issued to Dawson James Securities, Inc. (“Dawson James”), the placement agent in the public offering that closed on July 7, 2016, based on an assumed public offering price of \$0.96 per unit, which is the last reported sale price for our common stock as reported on the NYSE American on June 21, 2018;

8,073 shares of common stock issuable upon the exercise of options outstanding as of June 22, 2018, with exercise prices ranging from \$0.0001 to \$73,500 and having a weighted average exercise price of \$1,197.58 per share;

281 shares of common stock available for future issuance under our 2011 UMBRELLA Option Plan as of June 22, 2018;

8,812 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan as of June 22, 2018;

10,416,666 shares of common stock issuable upon exercise of the pre-funded warrants offered hereby by us at an exercise price of \$0.01 per share;

10,416,666 shares of common stock issuable upon exercise of the Series D Warrants offered hereby by us at an exercise price of \$ per share; and

625,000 additional shares of common stock issuable upon the exercise of the underwriter’s warrants, with an exercise price of \$ to be issued to the underwriter in connection with this offering.

Except as otherwise indicated, all information in this prospectus assumes no exercise of the underwriter’s option to purchase additional securities and no exercise of the underwriter’s warrants to be issued to the underwriter in connection with 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 \$8.4 million for the fiscal year ended December 31, 2017, and had a net loss of approximately \$8.5 million during the fiscal year ended December 31, 2016. We had a net loss of approximately \$2.4 million during the three months ended March 31, 2018. As of March 31, 2018, we had an accumulated deficit of \$143 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 for the year ended December 31, 2017, includes an explanatory paragraph as to our potential inability 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 our stockholders' ownership interests.

Without materially curtailing our operations, we estimate that we only have sufficient capital to finance our operations for approximately 12 months from March 31, 2018. As such, in order for us to pursue our business objectives, we will need to raise additional capital, 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, including CGuard EPS with a smaller delivery catheter;

furthering our efforts to obtain an IDE approval for CGuard EPS, to ultimately seek the U.S. Food and Drug Administration approval for commercial sales in the United States;

pursuing growth opportunities, including more rapid expansion and funding regional distribution systems;

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. See "*Risk Factors—Risks Related to Our Common Stock, Preferred Stock and Warrants and this Offering —If the effective price per share of common stock included in the units or issuable upon exercise of the pre-funded warrants included in the pre-funded units being offered in this offering is less than the current conversion price of our Series C Preferred Stock, we will be required to issue additional shares of common stock, as applicable, to the holders of the Series C Preferred Stock that have not been converted into the securities we sell in this offering, which will be dilutive to all of our other stockholders, including new investors in this offering.*"

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. In connection with the Series D Private Placement, the certificate of designation for the Series B Preferred Stock was amended to provide that each share of outstanding Series B Preferred Stock will be automatically exchanged into the securities we sell in a Qualified Offering. The Series D Purchase Agreement, as amended, also requires us (i) to use 15% of the proceeds from any subsequent offering of our securities that is not a Qualified Offering to redeem a portion of our outstanding shares of the Series C Preferred Stock held by the Series D Investor, and (ii) upon closing of any subsequent offering that is a Qualified Offering, to exchange all remaining outstanding shares of Series C Preferred Stock held by the Series D Investor for any securities issued in such Qualified Offering. In the event that we fail, or are unable, to issue securities issued in the Qualified Offering to the Series D Investor in exchange for such investor's remaining Series C Preferred Stock due to limitations mandated by the NYSE American, the Securities and Exchange Commission, or for any other reason, we are required to offer to purchase from such investor those shares of Series C Preferred Stock not exchanged for the securities sold in the Qualified Offering. The holders of our Series D Preferred Stock also have the option to exchange their Series D Preferred Stock into the securities issued in a subsequent offering or into the securities we sell in a Qualified Offering upon consummation of a Qualified Offering. Furthermore, the respective certificate of designation for our Series B Preferred Stock and Series C Preferred Stock contains a full ratchet anti-dilution price protection to be triggered upon issuance of equity or equity-linked securities at an effective common stock purchase price of less than the conversion price in effect. Unless otherwise converted pursuant to the terms of the Series C Preferred Stock, shares of Series C Preferred Stock held by holders other than the Series D Investor would remain outstanding after the automatic exchange of shares of Series C Preferred Stock held by the Series D Investor into the securities we sell in a Qualified Offering. Such obligations may make any additional financing difficult to obtain or unavailable to us while any shares of our Series B Preferred Stock, Series C Preferred Stock or Series D Preferred Stock are outstanding. If we are unable to obtain 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. If we do not have a sufficient number of available shares for any Series B Preferred Stock, Series C Preferred Stock or Series D Preferred Stock conversions or upon exchange of Series B Preferred Stock, Series C Preferred Stock or Series D Preferred Stock, we will be required to increase our authorized shares, which may not be possible and will be time consuming and expensive.

Our products may in the future be subject to product notifications, recalls, or voluntary market withdrawals that could harm our reputation, business and financial results.

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.

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 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.

We expect to derive our revenue from sales of our CGuard EPS and MGuard Prime EPS stent products and other products we may develop, such as CGuard EPS with a smaller delivery catheter. 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 CGuard EPS and MGuard Prime 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 CGuard EPS with a smaller delivery catheter. 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.

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 has experienced a substantial reduction in sales over the past three years. 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 four 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 are laws and regulations specific to the healthcare industry which may affect all aspects of our business, including development, testing, marketing, sales, pricing, and reimbursement. Additionally, 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.

We may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation, ordering and utilization of any products for which we obtain regulatory approval. If we obtain U.S. Food & Drug Administration approval for any of our products and begin commercializing those products in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our potential sales, marketing and education programs. In addition, we may be subject to patient privacy

regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which may be pursued through civil whistleblower or qui tam actions, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

federal criminal statutes created through the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

the federal transparency requirements under The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, enacted into law in the United States in March 2010 (known collectively as the “Affordable Care Act”), including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we may be subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. Several states impose marketing restrictions or require medical device companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the False Claims Act as well as under the false claims laws of several states.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our products outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of the physicians or other providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. This could adversely affect our ability to operate our business and our results of operations.

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

We market our products in international markets. In order to market our products in other foreign jurisdictions, we must obtain separate regulatory approvals from those obtained in the 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 or any future U.S. Food and Drug Administration 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 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. We face intense competition from Boston Scientific Corporation, Guidant Corporation, Medtronic, Inc., Abbott Vascular Devices, Johnson & Johnson, Terumo

Corporation, Covidien Ltd., Cordis Corporation (currently part of Cardinal Health, Inc.) 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.

Our competitors 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 products 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 the market or clinical trials. We may also be exposed to product liability claims based on the sale of any products under development 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 new products or existing products in new territories, 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, fraud and abuse, personal injury and product liability matters.

We are subject to a lawsuit filed by Medpace Inc. in July 2016, seeking \$1,967,822 in damages plus interest, costs, attorneys' fees and expenses. While we believe that the claims in this suit are without merit, due to the uncertainties of litigation, however, we can give no assurance that we will prevail on the claims made against us in 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. Adverse outcomes in some or all of these claims may result in significant monetary damages that could adversely affect our ability to conduct our business.

The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists and laboratory and field personnel could adversely affect our business.

We depend on the skills, experience and performance of our senior management and research personnel. The efforts of each of these persons will be critical to us as we continue to further develop our products, increase sales and broaden our product offerings. If we were to lose one or more of these key employees, we may experience difficulties

in competing effectively, developing our technologies and implementing our business strategies. Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses. There can be no assurance that we will be able to attract and retain necessary personnel on acceptable terms given the intense 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 to accomplish our business objectives, we may experience constraints that will adversely affect our ability to support our operations, 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 market 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.

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 products 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 products. The efficacy, safety, performance and cost-effectiveness of our products 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 and limit our ability to sell our products 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 Affordable Care Act, enacted into law in the United States in March 2010, contains certain provisions which are not yet fully implemented and for which it is unclear what the full impact will be from the legislation. The legislation levies a 2.3% excise tax 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 on or after January 1, 2013, 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. The tax has not been applied yet as it is subject to a moratorium. If we commence sales of our MGuard Prime EPS or CGuard EPS stent in the United States, this tax may materially and adversely affect our business and results of operations. The legislation also focuses on a number of provisions aimed at improving quality, broadening access to health insurance, enhancing remedies for fraud and abuse, adding transparency requirements, and decreasing healthcare costs, among others. Uncertainties remain regarding what negative unintended consequences these provisions will have on patient access to new technologies, pricing and the market for our products, and the healthcare industry in general. The Affordable Care Act includes provisions affecting the Medicare program, such as 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. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Judicial challenges as well as legislative initiatives to modify, limit, or repeal the Affordable Care Act have been initiated and continue to evolve, including an Executive Order signed by the U.S. President directing executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of provisions of the Affordable Care Act that would impose a fiscal or regulatory burden on individuals and certain entities to the maximum extent permitted by law. Recently, there have been renewed efforts to repeal or replace the Affordable Care Act following the 2017 changes in the U.S. presidential administrations and U.S. Congress. 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. Most recently, in July and August 2014, an armed conflict took place between Israel and Hamas, and since September 2015, there has been an increase in sporadic terror incidents conducted by individuals not necessarily associated with terror organizations. 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, many 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.

Many 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. 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 other than cash 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 to eight 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 2017 is 24% and in 2018 is 23% 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 tax benefit period is twelve years from the year of election, which means that after a year of election, the two-year exemption and eight years of reduced tax rate can only be used within the next twelve years. The Company elected the year 2007, as a year of election and 2011 as an additional year of election. 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, Preferred Stock and Warrants and the Offering

The market prices of our common stock and our publicly traded warrants are subject to fluctuation and have been and may continue to be volatile, which could result in substantial losses for investors.

The market prices of our common stock and our Series A Warrants and Series B Warrants have been and are 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 prices of our common stock and our publicly traded warrants.

Our common stock could be delisted from the NYSE American if we fail to regain compliance with the NYSE American's stockholders' equity continued listing standards on the schedule required by the NYSE American or if our common stock continues to trade for a substantial period of time at low selling prices. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from the NYSE American.

On August 17, 2017, we received a notice indicating that we do not meet certain of the NYSE American's continued listing standards as set forth in Part 10 of the Company Guide. Specifically, we were not in compliance with Section 1003(a)(iii) of the Company Guide because we reported stockholders' equity of less than \$6 million as of June 30, 2017, and had net losses in our five most recent fiscal years ended December 31, 2016. As a result, we have become subject to the procedures and requirements of Section 1009 of the Company Guide. The notice also included an early warning of our potential noncompliance with Section 1003(a)(iv) of the Company Guide because the uncertainty regarding our ability to generate sufficient cash flows and liquidity to fund operations raises substantial doubt about its ability to continue as a going concern. In order to maintain our listing on NYSE American, we submitted a plan of compliance to NYSE American addressing how we intend to regain compliance with Section 1003(a)(iii) of the Company Guide, which was accepted by NYSE American on October 19, 2017. On November 22, 2017, we received an additional letter