

InspireMD, Inc.  
Form 424B5  
April 03, 2019

**Filed pursuant to Rule 424(b)(5)**

**Registration No. 333-223130**

**This preliminary prospectus supplement relates to an effective registration statement under the Securities Act of 1933, but the information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell and are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED APRIL 3, 2019**

**PRELIMINARY PROSPECTUS SUPPLEMENT  
(To Prospectus dated February 23, 2018)**

**Shares**

**Common Stock**

We are offering \_\_\_\_\_ shares of our common stock. Our common stock is listed on the NYSE American under the symbol "NSPR." On March 28, 2019, the last reported sale price of our common stock as reported on the NYSE American was \$6.875 per share.

**Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page S-6 of this prospectus supplement and page 4 of the accompanying prospectus.**

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

	Per Share	Total
Public offering price	\$	\$
Underwriting discounts and commissions (1)	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) In addition, we have agreed to reimburse the underwriter for certain offering-related expenses, including a management fee of 1% of the gross proceeds raised in this offering, and to issue the underwriter or its designees warrants to purchase a number of shares of common stock equal to 7% of the shares of common stock sold in this offering. See “Underwriting” for more information.

We have granted the underwriter an option for a period of 30 days from the date of this prospectus supplement to purchase up to an additional \_\_\_\_\_ shares of common stock at the public offering price less underwriting discounts and commissions. If the underwriter exercises the option in full, the total underwriting discounts and commissions payable by us will be \$ \_\_\_\_\_ and the total proceeds to us, before expenses, will be \$ \_\_\_\_\_.

The underwriter expects to deliver the shares of common stock on or about April \_\_\_\_\_, 2019.

As of April 3, 2019, the aggregate market value of our outstanding common stock held by non-affiliates was \$8,417,052 based on 871,872 shares of our common stock outstanding on April 3, 2019, of which 801,624 shares were held by non-affiliates, and a price of \$10.50 per share, the closing price of our common stock on February 7, 2019. During the 12 calendar months prior to and including the date of this prospectus, we have not sold any securities pursuant to General Instruction I.B.6 of Form S-3.

We filed an amendment to our amended and restated certificate of incorporation, which, effective as of 5:00 p.m. Eastern Time on March 29, 2019, effected a 1-for-50 reverse stock split of the issued and outstanding shares of our common stock. All share and per share prices in this prospectus supplement have been adjusted to reflect the reverse stock split.

**H.C. Wainwright & Co.**

The date of this prospectus supplement is \_\_\_\_\_, 2019.

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No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus supplement or the accompanying prospectus. You must not rely on any unauthorized information or representations. This prospectus supplement and the accompanying prospectus are an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus supplement and the accompanying prospectus is current only as of their respective dates.



## **ABOUT THIS PROSPECTUS SUPPLEMENT**

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the U.S. Securities and Exchange Commission utilizing a “shelf” registration process. This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference herein. The second part, the accompanying prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

You should rely only on the information contained in this prospectus supplement or the accompanying prospectus, or incorporated by reference herein. We have not authorized, and the underwriter has not authorized, anyone to provide you with information that is different. The information contained in this prospectus supplement or the accompanying prospectus, or incorporated by reference herein or therein is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our common stock. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled “Where you can find more information” and “Incorporation of certain information by reference” in this prospectus supplement and in the accompanying prospectus, respectively.

We are offering to sell, and seeking offers to buy, the securities offered by this prospectus supplement only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the securities offered by this prospectus supplement in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may

not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

All references in this prospectus supplement and the accompanying prospectus to “InspireMD,” the “Company,” “we,” “us,” “our,” or similar references refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries taken as a whole, except where the context otherwise requires or as otherwise indicated.

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## PROSPECTUS SUPPLEMENT SUMMARY

*This summary highlights selected information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents incorporated by reference herein and therein. This summary is not complete and does not contain all the information you should consider before investing in our securities pursuant to this prospectus supplement and the accompanying prospectus. Before making an investment decision, to fully understand this offering and its consequences to you, you should carefully read this entire prospectus supplement and the accompanying prospectus, including “Risk Factors,” the financial statements, and related notes, and the other information incorporated by reference herein and therein.*

### 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, including India. We consider the addressable market for our CGuard EPS consists of individuals with diagnosed, symptomatic high-grade carotid artery stenosis (HGCS, ≥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 (“FDA”) 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. The FDA agreed to our pre-clinical test plan and clinical trial design. We are currently in the process of obtaining an IDE approval for CGuard EPS, and we intend to ultimately seek FDA approval for commercial sales in the United States. We intend to make an IDE submission seeking approval to



conduct a human clinical trial in the United States in mid-2019.

While entering the U.S. market remains our top development priority and therefore we are focusing on, as our highest priority, completing the testing required for an IDE submission seeking approval to conduct a human clinical trial in the United States using CGuard EPS, we intend to continue to evaluate potential product enhancements and manufacturing enhancements for CGuard EPS expected to reduce cost of goods and/or provide the best-in-class performing delivery system. Among other delivery system improvements, we continue to evaluate the development of a smaller delivery catheter (5 French gauge) CGuard EPS product. If we receive sufficient proceeds from future financings, we may seek to develop CGuard EPS with a smaller delivery catheter (5 French gauge), which we would submit for CE mark approval. We cannot give any assurance that we will receive sufficient (or any) proceeds from 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 future financings, there is no assurance that we will be able to timely apply for CE mark approval following our receipt of such proceeds. We believe these improvements and a smaller delivery system may allow us to reduce cost of goods, increase penetration in our existing geographies and better position us for entry into the Asia Pacific market and for transradial catheterization, which, we believe, is gaining favor among interventionalists.

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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.

## **Recent Developments**

Effective as of 5:00 p.m. Eastern Time on March 29, 2019, we amended our amended and restated certificate of incorporation to effect a 1-for-50 reverse stock split of our outstanding shares of common stock. 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 or conversion 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 or conversion 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 InspireMD, Inc. 2011 UMBRELLA Option Plan, proportionately based on the reverse stock split ratio. The reverse stock split does 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 supplement and the accompanying prospectus have been retroactively adjusted to reflect the reduced number of shares outstanding and the increase in share price which resulted from this action.

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## Growth Strategy

Our primary business objective is to utilize our proprietary MicroNet technology and products to become the industry standard for treatment of stroke, 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 to convince vascular surgeons to use CGuard EPS in filter protected carotid artery stenting instead of vascular surgery in appropriate patients. 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 are continuing to focus on larger growing markets through this network by supporting our distributors with a comprehensive marketing and clinical education programs. In November 2018, we obtained approval for reimbursement and commercial sale for CGuard EPS in Australia and we are planning to launch there in 2019. 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. We intend to make an IDE submission seeking approval to conduct a human clinical trial in the United States in mid-2019.

**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 and MGuard DES, and other potential products that are based on our MicroNet technology.

**Continue to protect and expand our portfolio of patents.** Our MicroNet technology and the use of patents to protect it are critical to our success. We own numerous patents for our MicroNet technology. Twelve patent applications and patents are pending or in force (eight of which are issued patents) 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.

### **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](http://www.inspire-md.com). Information accessed through our website is not incorporated into this prospectus supplement and is not a part of this prospectus supplement.

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THE OFFERING

Issuer	InspireMD, Inc.
Securities offered by us in this offering	shares of our common stock, par value \$0.0001 per share
Offering price	\$ per share of common stock
Common stock outstanding immediately before this offering	871,872 shares
Common stock outstanding immediately after this offering	shares ( shares if the underwriter exercises its option to purchase additional shares in full).
Over-allotment option	We have granted the underwriter an option to purchase up to additional shares of common stock at the public offering price per share, less underwriting discounts and commissions. This option is exercisable, in whole or in part, for a period of 30 days from the date of this prospectus supplement.
Use of proceeds	We plan to use the net proceeds of this offering for research and development, capital expenditures, working capital, sales and marketing and other general corporate purposes. See “Use of Proceeds.”
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 involves a high degree of risk. You should carefully read and consider the information beginning on page S-6 of this prospectus supplement and page 4 of the accompanying prospectus set forth under the headings “Risk Factors” and all other information set forth in this prospectus supplement, the accompanying prospectus, and the documents incorporated herein and therein by reference before deciding to invest in our common stock.
NYSE American symbol for common stock	“NSPR.”

The number of shares of common stock to be outstanding immediately after this offering is based on 871,872 shares of our common stock outstanding as of March 31, 2019 (subject to adjustment based on issuances of fractional shares

resulting from a 1-for-50 reverse stock split of the issued and outstanding shares of our common stock effected at 5:00 p.m. Eastern Time March 29, 2019) (unless otherwise indicated), and excludes, as of such date:

815,197 shares of common stock issuable upon the exercise of outstanding warrants with an exercise price ranging from \$15.00 to \$240,625 per share and having a weighted average exercise price of \$105.71 per share;

66,617 shares of common stock issuable upon the conversion of the outstanding Series B Convertible Preferred Stock (the "Series B Preferred Stock") (including the payment of the cumulative dividends accrued on the Series B Preferred Stock in an aggregate of 28,550 shares of common stock but excluding additional shares of common stock, if any, that we will be required to issue to the holders of our Series B Preferred Stock upon conversion of shares of our Series B Preferred Stock as a result of the full ratchet anti-dilution price protection in the certificate of designation for the Series B Preferred Stock if the public offering price of common stock in this offering is lower than \$15.00 per share) at the conversion price of \$15.00 per share and the stated value per share of \$33.00;

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25,355 shares of common stock issuable upon the conversion of the outstanding Series C Convertible Preferred Stock (the “Series C Preferred Stock”) (excluding additional shares of common stock, if any, that we will be required to issue to the holders 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 because the public offering price of common stock in this offering is lower than \$15.00 per share) at the conversion price of \$15.00 per share and the stated value per share of \$6.40;

additional shares of common stock that we will be required to issue to the holders of our Series B Preferred Stock upon conversion of shares of our Series B Preferred Stock (including the payment of the cumulative dividends thereunder in common stock) as a result of the full ratchet anti-dilution price protection in the certificate of designation for the Series B Preferred Stock, and additional shares of common stock that we will be required to issue to the holders of our Series C Preferred Stock 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, in each case based on shares of Series B Preferred Stock outstanding as of, 2019, and shares of Series C Preferred Stock outstanding as of, 2019, (see “*Risk Factors — Risks Related to Our Common Stock, Preferred Stock, Warrants and this Offering—If the public offering price per share of common stock in this offering is less than the respective current conversion price of our Series B or Series C Preferred Stock, we will be required to issue additional shares of common stock, as applicable, to the holders of the preferred stock, which will be dilutive to all of our other stockholders, including new investors in this offering.*”);

7,612 shares of common stock issuable upon conversion of the Series B Preferred Stock (including an aggregate of 3,260 shares of common stock for the payment of the cumulative dividends accrued on the Series B Preferred Stock issuable upon conversion of the Series B Preferred Stock) and exercise of the Series A Warrants 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;

additional shares of common stock that we will be required to issue to Dawson James upon conversion of shares of Series B Preferred Stock (including the payment of the cumulative dividends thereunder in common stock) included in the units issuable upon exercise of the unexercised portion of the unit purchase option that we issued to Dawson James, the placement agent in the public offering that closed on July 7, 2016, as a result of the full ratchet anti-dilution price protection in the certificate of designation for the Series B Preferred Stock, based on the adjusted Series B Preferred Stock conversion price equal to the public offering price per share of common stock (see “*Risk Factors — Risks Related to Our Common Stock, Preferred Stock, Warrants and this Offering—If the public offering price per share of common stock in this offering is less than the respective current conversion price of our Series B or Series C Preferred Stock, we will be required to issue additional shares of common stock, as applicable, to the holders of the preferred stock, which will be dilutive to all of our other stockholders, including new investors in this offering.*”);

184 shares of common stock issuable upon the exercise of outstanding options with exercise prices ranging from \$175.00 to \$3,675,000.00 and having a weighted average exercise price of \$348,625.00 per share;

607,796 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan; and

additional shares of common stock issuable upon the exercise of the underwriter’s warrants to be issued to the underwriter in connection with this offering.



Except as otherwise indicated, all information in this prospectus supplement assumes no exercise of the underwriter's option to purchase additional shares of common stock and no exercise of the underwriter's warrants to be issued to the underwriter in connection with this offering.

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## RISK FACTORS

*An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below, together with other information in this prospectus supplement, the accompanying 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 “Special 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 \$7.2 million for the fiscal year ended December 31, 2018, and had a net loss of approximately \$8.4 million during the fiscal year ended December 31, 2017. As of December 31, 2018, we had an accumulated deficit of \$148 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, 2018, 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 have sufficient capital to fund operations through the end of the third quarter of 2019. 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 FDA 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 public offering price per share of common stock in this offering is less than the respective current conversion price of our Series B or Series C Preferred Stock, we will be required to issue additional shares of common stock, as applicable, to the holders of the preferred stock, 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. 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. Such obligations may make any additional financing difficult to obtain or unavailable to us while any shares of our Series B Preferred Stock or Series C 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 or Series C Preferred Stock conversions or upon conversion of Series B Preferred Stock or Series C 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.

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***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.

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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 CGuard EPS and MGuard Prime 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 CGuard EPS or MGuard Prime 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 CGuard EPS or MGuard Prime 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 CGuard EPS or MGuard Prime 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, published peer reviewed journal articles and payor coverage policies, among other factors, 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 no growth in sales over the past three years. Such sales may never grow 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.

***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 long-term success measures have not been completely validated for our products, especially CGuard EPS, 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.

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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 U.S. Food and Drug Administration also requires that our sales and marketing efforts, as well as promotions, be consistent with various laws and regulations. Approved medical device promotions must be consistent with and not contrary to labeling, balanced, truthful and not false or misleading, adequately substantiated (when required), and include adequate directions for use. In addition to the requirements applicable to approved products, we may also be subject to enforcement action in connection with any promotion of an investigational new device. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, may not represent in a promotional context that an investigational new device is safe or effective for the purposes for which it is under investigation or otherwise promote the device.

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If the U.S. Food and Drug Administration investigates our marketing and promotional materials or other communications and finds that any of our investigational devices, or future commercial products, if any, are being marketed or promoted in violation of the applicable regulatory restrictions, we could be subject to the enforcement actions listed above, among others. Any enforcement action (or related lawsuit, which could follow such action) brought against us in connection with alleged violations of applicable device promotion requirements, or prohibitions, could harm our business and our reputation, as well as the reputation of any devices that may be approved for marketing in the U.S. in the future.

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.

***We are, or may be, 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 healthcare 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;

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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

state 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, healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended 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.

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Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our existing or future 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. Any such actions instituted against us could have a significant adverse 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. Even if we are successful in defending against such actions, we may nonetheless be subject to substantial costs, reputational harm and adverse effects on our ability to operate our business. 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 our employees, agents, or the physicians or other providers or entities with whom we expect to do business are found to have violated applicable laws, we may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, or, if we are not subject to such actions, we may suffer reputational harm for conducting business with persons or entities found, or accused of being, in violation of such laws. Any such events 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 intense competition from numerous

pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. Abbott Laboratories, Boston Scientific Corporation, Covidien Ltd. (currently part of Medtronic, Inc.), and Cordis Corporation (currently part of Cardinal Health, Inc.). Gore Medical and Terumo Medical Corporation produce a polytetrafluoroethylene mesh-covered stent and a double layer metal stent, respectively. 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 CGuard EPS and MGuard Prime 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. See "Business — Legal Proceedings" for more information. 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.

***Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.***

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, research data, our proprietary business information and that of our suppliers, technical information about our products, clinical trial plans and employee records. Similarly, our third-party providers possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, encrypted, lost or stolen. Any such access, inappropriate disclosure of confidential or proprietary information or other loss of information, including our data being breached at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disruption of our operations or our product development programs and damage to our reputation, which could adversely affect our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

***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.

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***Even if one or more of our products are approved by the U.S. Food and Drug Administration, we may fail to obtain an adequate level of reimbursement for our products by third party payors, such that 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 are factors that may impact 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 healthcare 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 European Union, our business could be significantly and adversely affected by healthcare reform initiatives and/or other legislation or judicial interpretations of existing or future healthcare laws and/or regulations.***

The Affordable Care Act, signed 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. Effective January 1, 2016, the excise tax was suspended until the end of 2017, and in January 2018, another temporary two-year suspension of the tax was passed, extending the suspension to December 31, 2019. If we obtain approval to commence sales of any of our applicable devices 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 asserted against the Affordable Care Act since its enactment and continue to evolve. While early challenges were largely unsuccessful, there have been renewed efforts to repeal and/or replace the Affordable Care Act following the 2017 changes in the U.S. presidential administration and U.S. Congress. Due to such efforts, certain elements of the Affordable Care Act have been invalidated or suspended, which has, in turn, led to additional challenges against the law as a whole. For example, the Tax Cuts and Jobs Act of 2017 included a provision repealing, effective January 1, 2019, the tax imposed by the Affordable Care Act's "individual mandate." As a result, at least one federal court has held that the entire Affordable Care Act must be invalidated. However, the ruling in that case, *Texas, et al, v. United States of America, et al.*, (N.D. Texas), has been stayed by the ruling judge pending appeal. Additionally, an Executive Order signed by the U.S. President directed 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.

We cannot predict the impact that such actions against the Affordable Care Act will have on our business, and there is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the United States, or the effect of any future legislation or regulation. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the United States in the future. For example, any changes that reduce, or impede the ability to obtain, reimbursement for the type of products we intend to commercialize in the United States (or our products more specifically, if approved) 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.

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***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 executive office, sole manufacturing facility and certain of our key personnel are located in Israel. Our business is directly affected by the political, economic and military conditions in Israel and its neighbors. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. A state of hostility, varying in degree and intensity, has caused security and economic problems in Israel. Although Israel has entered into peace treaties with Egypt and Jordan, and various agreements with the Palestinian Authority, there has been a marked increase in violence, civil unrest and hostility, including armed clashes, between the State of Israel and the Palestinians since September 2000. The establishment in 2006 of a government in the Gaza Strip by representatives of the Hamas militant group has created heightened unrest and uncertainty in the region. In mid-2006, Israel engaged in an armed conflict with Hezbollah, a Shiite Islamist militia group based in Lebanon, and in June 2007, there was an escalation in violence in the Gaza Strip. From December 2008 through January 2009 and again in November and December 2012, Israel engaged in an armed conflict with Hamas, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In July 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. 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 2018 is 23% and in 2019 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.

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**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 this 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. 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 from the NYSE that we are not in compliance with Section 1003(a)(ii) of the Company Guide indicating that we are not in compliance with the stockholders' equity and net income continued listing standards.

On February 19, 2019 we received notice from NYSE American that we were back in compliance with three of the NYSE American continued listing standards set forth in Part 10 of the NYSE American Company Guide. We are subject to ongoing review for compliance with the NYSE American requirements and our stockholders' equity may decline and we may again fall out of compliance with Section 1003(a)(i), Section 1003(a)(ii) or Section 1003(a)(iii) of the Company Guide. If we are again determined to be below any of the continued listing standards within 12 months of the date of such notice, we have been advised that NYSE American will examine the relationship between the two incidents of noncompliance and re-evaluate our method of financial recovery. NYSE Regulation will then take the appropriate action, which, depending on the circumstances, may include truncating the compliance procedures described in Section 1009 of the Company Guide or immediately initiating delisting proceedings.

Delisting from NYSE American would adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

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

On January 7, 2019, we received notification from the NYSE American 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 could take action to delist our common stock in the event that our common stock trades at levels viewed as abnormally low for a substantial period of time. NYSE American has advised us that if our common stock trades below \$0.20 on a 30 trading day average, then it will be considered non-compliant with NYSE American's low selling price requirement. 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 7, 2019. We had previously received a notification of non-compliance of the same kind on January 16, 2018, effected a 1-for-35 reverse stock split of our common stock on February 7, 2018, and regained compliance on July 16, 2018.

On March 29, 2019, we effected a 1-for-50 reverse stock split of our common stock. One of the primary intents for each reverse stock split was that the anticipated increase in the price of our common stock immediately following and resulting from a reverse stock split due to the reduction in the number of issued and outstanding shares of common stock would help us meet the price criteria for continued listing on NYSE American. However, the increase in the price of our common stock from the reverse stock split effected on February 7, 2018, was not maintained, and our common stock again traded for a low price per share for a substantial period of time. There can be no assurance that the market price of our new common stock after our March 29, 2019 reverse stock split will remain above the levels viewed as abnormally low for a substantial period of time. It is not uncommon for the market price of a company's

common stock to decline in the period following a reverse stock split. If the market price of our common stock declines following the reverse stock split, the percentage decline may be greater than would occur in the absence of a reverse stock split. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock to fall below the levels viewed as low selling price for a substantial period of time and lead the NYSE American to immediately suspend trading in our common stock.

In addition, the NYSE American has advised us that its policy is to immediately suspend trading in shares of, and commence delisting procedures with respect to, a listed company if the market price of its shares falls below \$0.06 per share at any time during the trading day.

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***If you purchase our common stock sold in this offering you will experience immediate dilution in your investment as a result of this offering.***

Because the price per share of common stock being offered in this offering may be higher than the net tangible book value per share of our common stock, you will experience dilution to the extent of the difference between the public offering price per share of common stock you pay in this offering and the net tangible book value per share of our common stock immediately after this offering. Our net tangible book value as of December 31, 2018, was approximately \$8.7 million, or \$11.40 per share of common stock. Net tangible book value per share is equal to our total tangible assets minus total liabilities, all divided by the number of shares of common stock outstanding. See “Dilution” on page S-30 for a more detailed discussion of the dilution you will incur in this offering.

Furthermore, the anti-dilution provisions of our Series B and C Preferred Stock, may result in further dilution of your investment (see “*Risk Factors — Risks Related Our Common Stock, Preferred Stock and Warrants and this Offering —If the public offering price per share of common stock in this offering is less than the respective current conversion price of our Series B or Series C Preferred Stock, we will be required to issue additional shares of common stock, as applicable, to the holders of the preferred stock, which will be dilutive to all of our other stockholders, including new investors in this offering.*”)

***If the public offering price per share of common stock in this offering is less than the respective current conversion price of our Series B or Series C Preferred Stock, we will be required to issue additional shares of common stock, as applicable, to the holders of the preferred stock, which will be dilutive to all of our other stockholders, including new investors in this offering.***

The respective certificate of designation for our Series B Preferred Stock and Series C Preferred Stock contains anti-dilution provisions, which provisions require the lowering of the applicable conversion price, as then in effect, to the purchase price of equity or equity-linked securities issued in subsequent offerings. In accordance with this anti-dilution price protection, because the effective common stock purchase price in the March 2018 public offering, the April 2018 public offering and the July 2018 public offering was below the then current Series B Preferred Stock and the Series C Preferred Stock conversion price, we reduced the Series B Preferred Stock and the Series C Preferred Stock conversion price upon closing of each such public offering. As a result of these obligations, if the public offering price of our common stock in this offering is less than the respective current conversion price of our Series B or Series C Preferred Stock, each of these conversion prices shall be reduced, or effectively reduced, to such public offering price of our common stock. This reduction in the conversion prices will result in a greater number of shares of common stock being issuable upon conversion of the Series B Preferred Stock or Series C Preferred Stock for no additional consideration, causing greater dilution to our stockholders and investors in this offering. In addition, should we issue any securities following this offering at an effective common stock purchase price that is less than the then effective conversion price of our Series B Preferred Stock or Series C Preferred Stock, we will be required to further reduce the conversion prices of our Series B Preferred Stock and Series C Preferred Stock, which will result in a greater dilutive effect on our stockholders. In addition, as there is no floor price on the conversion price, we cannot

determine the total number of shares issuable upon conversion. As such, it is possible that we will not have a sufficient number of available shares to satisfy the conversion of the Series B Preferred Stock or the Series C Preferred Stock if we enter into a future transaction that reduces the applicable conversion price. The foregoing features will increase the number of shares of common stock issuable upon conversion, assuming that the effective offering price of our common stock in a subsequent financing is lower than the conversion price of these securities then in effect, of the Series B Preferred Stock or Series C Preferred Stock for no additional consideration, and will result in a greater dilutive effect on our shareholders.

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

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

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

Sales of a significant number of shares of our common stock or our warrants in the public market could harm the market prices of our common stock or warrants and make it more difficult for us to raise funds through future offerings of common stock or warrants. Our stockholders and the holders of our options and warrants may sell substantial amounts of our common stock or our publicly traded warrants in the public market. In addition, we will be required to issue additional shares of common stock to the holders of our Series B Preferred Stock upon conversion of shares of our Series B Preferred Stock and the payment of the dividends thereunder in common stock and to the holders of our Series C Preferred Stock upon conversion of such shares of our Series C Preferred Stock, as a result of the full ratchet anti-dilution price protection in the respective certificate of designation for the Series B Preferred Stock and the Series C Preferred Stock, if the effective common stock purchase price in a subsequent offering is less than the respective then current conversion price of the Series B Preferred Stock or the Series C Preferred Stock, which in turn will increase the number of shares of common stock available for sale. See “Risk Factors — Risks Related to Our Common Stock, Preferred Stock and Warrants and this Offering — If the public offering price per share of common stock in this offering is less than the respective current conversion price of our Series B or Series C Preferred Stock, we will be required to issue additional shares of common stock, as applicable, to the holders of the preferred stock, which will be dilutive to all of our stockholders, including new investors in this offering.

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

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

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

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



Each share of the Series B Preferred Stock is entitled to receive cumulative dividends at the rate per share of 15% per annum of the stated value per share, until the fifth anniversary of the date of issuance of the Series B Preferred Stock. The dividends are payable, at our discretion, in cash, out of any funds legally available for such purpose, or in pay-in-kind shares of common stock calculated based on the conversion price, subject to adjustment as provided in the certificate of designation for the Series B Preferred Stock. The conversion price is subject to reduction if in the future we issue securities for less than the conversion price of our Series B Preferred Stock, as then in effect. As there is no floor price on the conversion price, we cannot determine the total number of shares issuable upon conversion or in connection with the dividend. It is possible that we will not have a sufficient number of available shares to pay the dividend in common stock, which would require the payment of the dividend in cash. We will not be permitted to pay the dividend in cash unless we are legally permitted to do so under Delaware law, which requires cash to be available from surplus or net profits, which may not be available at the time payment is due. In light of our recurring losses and negative cash flows from operating activities, we do not expect to have cash available to pay the dividends on our Series B Preferred Stock or to be permitted to make such payments under Delaware law, and will be relying on having available shares of common stock to pay such dividends, which will result in dilution to our shareholders. If we do not have such available shares, we may not be able to satisfy our dividend obligations.

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

Our management will have broad discretion over the use of proceeds from this offering. We intend to use the proceeds of this offering for research and development, capital expenditures, working capital, sales and marketing and other general corporate purposes. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business and cause the price of our common stock to decline.

***The reverse stock split may decrease the liquidity of the shares of our common stock.***

The liquidity of the shares of our common stock may be affected adversely by the reverse stock split given the reduced number of shares that are outstanding following the reverse stock split. In addition, the reverse stock split increased the number of stockholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

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

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

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

The ongoing internal control provisions of Section 404 of the Sarbanes-Oxley Act of 2002 require us to identify material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Our management, including our chief executive officer and chief financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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

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

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

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

***We have a staggered board of directors, which could impede an attempt to acquire us or remove our management.***

Our board of directors is divided into three classes, each of which serves for a staggered term of three years. This division of our board of directors could have the effect of impeding an attempt to take over our company or change or remove management, since only one class will be elected annually. Thus, only approximately one-third of the existing board of directors could be replaced at any election of directors.

*As a former shell company, resales of shares of our restricted common stock in reliance on Rule 144 of the Securities Act are subject to the requirements of Rule 144(i).*

We previously were a “shell company” and, as such, sales of our securities pursuant to Rule 144 under the Securities Act of 1933, as amended, cannot be made unless, among other things, at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, and have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 as amended, as applicable, during the preceding 12 months, other than Form 8-K reports. Because, as a former shell company, the reporting requirements of Rule 144(i) will apply regardless of holding period, restrictive legends on certificates for shares of our common stock cannot be removed except in connection with an actual sale that is subject to an effective registration statement under, or an applicable exemption from the registration requirements of, the Securities Act of 1933, as amended. Because our unregistered securities cannot be sold pursuant to Rule 144 unless we continue to meet such requirements, any unregistered securities we issue will have limited liquidity unless we continue to comply with such requirements.

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***No industry analyst publishes research about our business.***

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. Because no industry analyst publishes research about us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***Aspects of the tax treatment of the securities may be uncertain.***

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

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern;
- our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders’ ownership interests;
- our ability to regain compliance with NYSE American listing standards;
- our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products;
- our ability to adequately protect our intellectual property;

our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;

the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products;

market acceptance of our products;

negative clinical trial results or lengthy product delays in key markets;

an inability to secure and maintain regulatory approvals for the sale 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;

inability to carry out research, development and commercialization plans;

loss of a key customer or supplier;

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

product malfunctions;

price increases for supplies and components;

adverse economic conditions;

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

our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful;

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

the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction;

the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and

loss or retirement of key executives and research scientists.

You should review carefully the section entitled “Risk Factors” beginning on page S-6 of this prospectus supplement for a discussion of these and other risks that relate to our business and investing in our securities. The forward-looking statements contained or incorporated by reference in this prospectus supplement are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

## USE OF PROCEEDS

We estimate that the net proceeds from the sale of the securities offered in this offering will be approximately \$ \_\_\_\_\_, or approximately \$ \_\_\_\_\_ if the underwriter exercises in full its option to purchase additional shares of common stock, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds of this offering for research and development, capital expenditures, working capital, sales and marketing and other general corporate purposes.

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

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



a change in development plan or strategy;

the addition of new products or applications;

technical delays;

delays or difficulties with our clinical trials;

negative results from our clinical trials;

difficulty obtaining regulatory approval;

failure to achieve sales as anticipated; and

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

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

Information regarding the market for our common stock

Our common stock trades on the NYSE American under the symbol “NSPR.” The last reported sale price for our common stock on March 28, 2019, was \$6.875 per share. As of March 30, 2019, we had approximately 265 holders of record of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers and registered clearing agencies.

#### DIVIDEND POLICY

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

#### DILUTION

Our net tangible book value as of December 31, 2018, was approximately \$8.7 million, or \$11.40 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of December 31, 2018. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to (i) the sale of \_\_\_\_\_ shares of common stock in the aggregate amount of \$ \_\_\_\_\_ in this offering at a public offering price of \$ \_\_\_\_\_ per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, and (ii) the issuance of \_\_\_\_\_ additional shares of common stock that we will be required to issue to the holders of our Series B Preferred Stock upon conversion of shares of our Series B Preferred Stock (including the payment of the cumulative dividends thereunder in common stock) and \_\_\_\_\_ additional shares of common stock that we will be required to issue to the holders of our Series C Preferred Stock upon conversion of shares of our Series C Preferred Stock, each as a result of the full ratchet anti-dilution price protection in the respective certificate of designation for the Series B Preferred Stock and the Series C Preferred Stock, based on 17,303 shares of Series B Preferred Stock outstanding as of December 31, 2018, and 61,423 shares of Series C

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Preferred Stock outstanding as of December 31, 2018, our as adjusted net tangible book value as of December 31, 2018, would have been approximately \$        million, or \$        per share, based        on shares of common stock outstanding on a pro forma basis at that time. This represents an immediate increase in net tangible book value of \$        per share to existing stockholders and immediate dilution of \$        per share to investors purchasing our common stock in this offering at the public offering price. The following table illustrates this dilution on a per share basis:

Public offering price per share	\$
Net tangible book value per share of as December 31, 2018	\$11.40
Increase in net tangible book value per share attributable to this offering	\$
As adjusted net tangible book value per share as of December 31, 2018, after giving effect to this offering	\$
Dilution per share to new investors purchasing our common stock in this offering	\$

If the underwriter exercises in full its option to purchase an additional        shares of common stock at the public offering price of \$        per share, less underwriting discounts and commissions, our as adjusted net tangible book value after this offering would be approximately \$        , or \$        per share, representing an increase in net tangible book value of approximately \$        per share to existing shareholders and immediate dilution in net tangible book value of approximately \$        per share to investors purchasing our shares of common stock in this offering at the public offering price.

The above discussion and table are based on 768,615 shares outstanding as of December 31, 2018 (subject to adjustment based on issuances of fractional shares resulting from a 1-for-50 reverse stock split of the issued and outstanding shares of our common stock effected at 5:00 p.m. Eastern Time March 29, 2019), and excludes as of that date:

32,034 shares of common stock issuable upon the exercise of pre-funded warrants with an exercise price of \$0.50 per share, all of which have since been exercised;

815,197 shares of common stock issuable upon the exercise of other outstanding warrants with an exercise price ranging from \$15.00 to \$240,625.00 per share and having a weighted average exercise price of \$105.71 per share;

66,617 shares of common stock issuable upon the conversion of the outstanding Series B Preferred Stock (including the payment of the cumulative dividends accrued on the Series B Preferred Stock in an aggregate of 28,550 shares of common stock but excluding additional shares of common stock, if any, that we will be required to issue to the holders of our Series B Preferred Stock upon conversion of shares of our Series B Preferred Stock as a result of the full ratchet anti-dilution price protection in the certificate of designation for the Series B Preferred Stock if the public offering price of common stock in this offering is lower than \$15.00 per share) at the conversion price of \$15.00 per share and the stated value per share of \$33.00;

26,208 shares of common stock issuable upon the conversion of the outstanding Series C Preferred Stock (excluding additional shares of common stock, if any, that we will be required to issue to the holders 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 because the public offering price of common stock in this offering is lower than \$15.00 per share) at the conversion price of \$15.00 per share and the stated value per share of \$6.40;

additional shares of common stock that we will be required to issue to the holders of our Series B Preferred Stock upon conversion of shares of our Series B Preferred Stock (including the payment of the cumulative dividends thereunder in common stock) as a result of the full ratchet anti-dilution price protection in the certificate of designation for the Series B Preferred Stock, and additional shares of common stock that we will be required to issue to the holders of our Series C Preferred Stock 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, in each case based on 17,303 shares of Series B Preferred Stock outstanding as of, December 31, 2018, and 61,423 shares of Series C Preferred Stock outstanding as of December 31, 2018, (see “*Risk Factors — Risks Related to Our Common Stock, Preferred Stock, Warrants and this Offering—If the public offering price per share of common stock in this offering is less than the respective current conversion price of our Series B or Series C Preferred Stock, we will be required to issue additional shares of common stock, as applicable, to the holders of the preferred stock, which will be dilutive to all of our other stockholders, including new investors in this offering.*”);

7,612 shares of common stock issuable upon conversion of the Series B Preferred Stock (including an aggregate of 3,260 shares of common stock for the payment of the cumulative dividends accrued on the Series B Preferred Stock issuable upon conversion of the Series B Preferred Stock) and exercise of the Series A Warrants included in the units issuable upon exercise of the unexercised portion of the unit purchase option that we issued to Dawson James, the placement agent in the public offering that closed on July 7, 2016;

additional shares of common stock that we will be required to issue to Dawson James upon conversion of shares of Series B Preferred Stock (including the payment of the cumulative dividends thereunder in common stock)

included in the units issuable upon exercise of the unexercised portion of the unit purchase option that we issued to Dawson James, the placement agent in the public offering that closed on July 7, 2016, as a result of the full ratchet anti-dilution price protection in the certificate of designation for the Series B Preferred Stock, based on the adjusted Series B Preferred Stock conversion price equal to the public offering price per share of common stock (see “*Risk Factors — Risks Related to Our Common Stock, Preferred Stock, Warrants and this Offering—If the public offering price per share of common stock in this offering is less than the respective current conversion price of our Series B or Series C Preferred Stock, we will be required to issue additional shares of common stock, as applicable, to the holders of the preferred stock, which will be dilutive to all of our other stockholders, including new investors in this offering*”);

184 shares of common stock issuable upon the exercise of outstanding options with exercise prices ranging from \$175.00 to \$3,675,000.00 and having a weighted average exercise price of \$348,625.00 per share;

607,796 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan; and

additional shares of common stock issuable upon the exercise of the underwriter’s warrants to be issued to the underwriter in connection with this offering.

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

## UNDERWRITING

We have entered into an underwriting agreement with H.C. Wainwright & Co., LLC, as underwriter, with respect to the common stock being offered hereby. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase from us the number of shares of our common stock set forth opposite its name below.

<b>Underwriter</b>	<b>Number of Shares</b>
H.C. Wainwright & Co., LLC	
Total	

The underwriting agreement provides that the obligations of the underwriter are subject to certain conditions precedent and that the underwriter has agreed to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased.

We have agreed to indemnify the underwriter against specified liabilities, including liabilities under the Securities Act of 1933, as amended (the "Securities Act"), and to contribute to payments the underwriter may be required to make in respect thereof.

The underwriter is offering the shares, subject to prior sale, when, as and if issued to and accepted by it, subject to approval of legal matters by its counsel and other conditions specified in the underwriting agreement. The underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

*Option to Purchase Additional Shares.* We have granted to the underwriter an option, exercisable for 30 days from the date of this prospectus supplement, to purchase, from time to time, in whole or in part, up to an aggregate of shares of common stock from us at the public offering price set forth on the cover page of this prospectus supplement, less underwriting discounts and commissions. If the underwriter exercises this option, it will be obligated, subject to certain conditions, to purchase a number of additional shares of common stock approximately proportionate to that underwriter's initial purchase commitment as indicated in the table above.

*Underwriting Discounts and Commissions.* The following table shows the public offering price, underwriting discounts and commissions and proceeds, before expenses to us.

We estimate that the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$ \_\_\_\_\_ and is payable by us. We have agreed to reimburse the expenses of the underwriter in the non-accountable sum of \$35,000 and the other actual expenses of the underwriter, including its legal fees, up to \$100,000 in connection with this offering. We have also agreed to pay the underwriter a management fee equal to 1% of the aggregate gross proceeds in this offering.

	<b>Per Share</b>	<b>Total</b>
Public offering price	\$	\$
Underwriting discounts and commissions	\$	\$
Proceeds, before expenses	\$	\$

The underwriter proposes to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus. The underwriter may offer the shares of common stock to securities dealers at the public offering price less a concession not in excess of \$ \_\_\_\_\_ per share. If all of the shares are not sold at the public offering price, the underwriter may change the offering price and other selling terms.

In addition, we have agreed to issue to the underwriter warrants to purchase up to \_\_\_\_\_ shares of common stock (representing 7% of the aggregate number of shares of common stock sold in this offering), at an exercise price of \$ \_\_\_\_\_ per share (representing 125% of the public offering price for a share of common stock to be sold in this offering). The underwriter warrants will be exercisable immediately and for five years from the date of the underwriting agreement. Pursuant to FINRA Rule 5110(g), the underwriter warrants and any shares issued upon exercise of the underwriter warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the underwriter or related persons do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

We have also agreed to pay the underwriter a tail fee equal to the cash and warrant compensation in this offering, if any investor, who was contacted or introduced to us by the underwriter during the five month term of engagement beginning March 27, 2019, provides us with capital in any public or private offering or other financing or capital raising transaction, during the twelve month period following expiration or termination of our engagement of the underwriter.

We have also granted the underwriter certain right of first refusal to act as sole book-running manager, sole underwriter or sold placement agent for each and every future public or private equity offering by us or any of our successors or subsidiaries, under certain circumstances.

*Discretionary Accounts.* The underwriter does not intend to confirm sales of the shares to any accounts over which they have discretionary authority.

*Stabilization.* In connection with this offering, the underwriter may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions and penalty bids in connection with our common stock.

Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum.

Overallotment transactions involve sales by the underwriter of shares of common stock in excess of the number of shares the underwriter is obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriter is not greater than the number of shares that it may purchase in the overallotment option. In a naked short position, the number of shares involved is greater than the number of shares in the overallotment option. The underwriter may close out any short position by exercising its overallotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.

Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our



common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the NYSE American, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

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In connection with this offering, the underwriter also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

*Lock-Up Agreements.* We and each of our directors and executive officers have entered into lock-up agreements that prevent them from selling any shares of our common stock or any securities convertible into or exercisable or exchangeable into share of common stock, subject to certain exceptions, for a period of 90 days after the date of this prospectus. The underwriter, in its sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release the common stock and other securities from lock-up agreements, the underwriter will consider, among other factors, the holder's reasons for requesting the release and the number of shares of common stock or other securities for which the release is being requested.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on our behalf, other than offers made by the underwriter and its respective affiliates, with a view to the final placement of the securities as contemplated in this prospectus supplement. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of shares on our behalf or on behalf of the underwriter.

*Electronic Offer, Sale and Distribution of Shares.* A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representatives may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

*Other Relationships.* The underwriter and its affiliates have provided, and may in the future provide, various other investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees. The underwriter acted as our underwriter in connection with public offerings in March 2018, April 2018 and July 2018, for which it received cash compensation.

*Offers outside the United States.* Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the shares offered by this prospectus in any jurisdiction where action for that purpose is required. The shares offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such shares be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any shares offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

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## LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus supplement has been passed upon for us by Haynes and Boone, LLP, New York, New York. McDermott Will & Emery LLP, New York, New York, is acting as counsel for the underwriter in connection with the shares of common stock offered hereby.

## EXPERTS

The financial statements incorporated in this prospectus supplement by reference to the Annual Report on Form 10-K for the year ended December 31, 2018 have been so incorporated in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1b to the financial statements) of Kesselman & Kesselman, an independent registered public accounting firm and a member firm of PricewaterhouseCoopers International Limited, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and in accordance therewith we file annual, quarterly, and other reports, proxy statements and other information with the SEC under the Exchange Act. Such reports, proxy statements and other information, including the Registration Statement, and exhibits and schedules thereto, are available to the public through the SEC's website at <http://www.sec.gov>.

We make available free of charge on or through our website at [www.inspire-md.com](http://www.inspire-md.com), our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with or otherwise furnish it to the Securities and Exchange Commission.

We have filed with the Securities and Exchange Commission a registration statement under the Securities Act of 1933, as amended, relating to the offering of these securities. The registration statement, including the attached exhibits, contains additional relevant information about us and the securities. This prospectus does not contain all of the information set forth in the registration statement. You can obtain a copy of the registration statement, at prescribed rates, from the Securities and Exchange Commission at the address listed above, or for free at

www.sec.gov. The registration statement and the documents referred to below under “Incorporation of Certain Information By Reference” are also available on our website, [www.inspire-md.com](http://www.inspire-md.com).

We have not incorporated by reference into this prospectus supplement the information on our website, and you should not consider it to be a part of this prospectus supplement.

#### INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The Securities and Exchange Commission allows us to “incorporate by reference” the information we have filed with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus, and later information that we file with the Securities and Exchange Commission will automatically update and supersede this information. We incorporate by reference the documents listed below and any future documents (in each case excluding information furnished pursuant to Items 2.02 and 7.01 of Form 8-K) we file with the Securities and Exchange Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, subsequent to the date of this prospectus supplement and prior to the termination of the offering:

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the Securities and Exchange Commission on February 19, 2019;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 11, 2019;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 14, 2019;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 22, 2019;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 24, 2019;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 6, 2019;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 7, 2019;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on March 21, 2019,

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on March 28, 2019,

The description of our common stock, which is contained in our registration statement on Form 8-A, filed with the Securities and Exchange Commission on March 12, 2013, as updated or amended in any amendment or report filed for such purpose.

You should rely only on the information incorporated by reference or provided in this prospectus supplement. We have not authorized anyone else to provide you with different information. Any statement contained in a document incorporated by reference into this prospectus supplement will be deemed to be modified or superseded for the purposes of this prospectus supplement to the extent that a later statement contained in this prospectus supplement or in any other document incorporated by reference into this prospectus supplement modifies or supersedes the earlier statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus. You should not assume that the information in this prospectus supplement is accurate as of any date other than the date of this prospectus supplement or the date of the documents incorporated by reference in this prospectus supplement.

We will provide without charge to each person to whom a copy of this prospectus supplement is delivered, upon written or oral request, a copy of any or all of the information that has been incorporated by reference in this prospectus supplement but not delivered with this prospectus supplement (other than an exhibit to these filings, unless we have specifically incorporated that exhibit by reference in this prospectus supplement). Any such request should be addressed to us at: 4 Menorat Hamaor St., Tel Aviv, Israel 6744832, Attention: Craig Shore, Chief Financial Officer, or made by phone at (888) 776-6804. You may also access the documents incorporated by reference in this prospectus supplement through our website at [www.inspire-md.com](http://www.inspire-md.com). Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus supplement or the registration statement of which it forms a part.

## **PROSPECTUS**

### **InspireMD, Inc.**

**\$30,000,000**

**Common Stock**

**Preferred Stock**

**Warrants**

**Units**

We may offer and sell from time to time, in one or more series or issuances and on terms that we will determine at the time of the offering, any combination of the securities described in this prospectus, up to an aggregate amount of \$30,000,000.

We will provide specific terms of any offering in a supplement to this prospectus. Any prospectus supplement may also add, update, or change information contained in this prospectus. You should carefully read this prospectus and the applicable prospectus supplement as well as the documents incorporated or deemed to be incorporated by reference in this prospectus before you purchase any of the securities offered hereby.

These securities may be offered and sold in the same offering or in separate offerings; to or through underwriters, dealers, and agents; or directly to purchasers. The names of any underwriters, dealers, or agents involved in the sale of our securities, their compensation and any over-allotment options held by them will be described in the applicable prospectus supplement. See “Plan of Distribution.”

Our common stock is listed on the NYSE American under the symbol “NSPR.” On February 20, 2018, the last reported sale price of our common stock as reported on the NYSE American was \$4.46 per share. We recommend that you

obtain current market quotations for our common stock prior to making an investment decision. We will provide information in any applicable prospectus supplement regarding any listing of securities other than shares of our common stock on any securities exchange.

**As of February 14, 2018, the aggregate market value of our outstanding common stock held by non-affiliates, or the public float, was approximately \$9,120,979, which was calculated based on 1,634,584 shares of our outstanding common stock held by non-affiliates and a price of \$5.58 per share, the last reported sale price for our common stock on February 14, 2018. We have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar months prior to and including the date of this prospectus.**

**You should carefully read this prospectus, any prospectus supplement relating to any specific offering of securities, and all information incorporated by reference herein and therein.**

**Investing in our securities involves a high degree of risk. These risks are discussed in this prospectus under “Risk Factors” beginning on page 4 and in the documents incorporated by reference into this prospectus.**

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

The date of this prospectus is February 23, 2018



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## **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission using a “shelf” registration process. Under this shelf process, we may, from time to time, sell any combination of the securities described in this prospectus in one or more offerings up to a total amount of \$30,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add to, update or change information contained in the prospectus and, accordingly, to the extent inconsistent, information in this prospectus is superseded by the information in the prospectus supplement.

The prospectus supplement to be attached to the front of this prospectus may describe, as applicable: the terms of the securities offered; the public offering price; the price paid for the securities; net proceeds; and the other specific terms related to the offering of the securities.

You should only rely on the information contained or incorporated by reference in this prospectus and any prospectus supplement or issuer free writing prospectus relating to a particular offering. No person has been authorized to give any information or make any representations in connection with this offering other than those contained or incorporated by reference in this prospectus, any accompanying prospectus supplement and any related issuer free writing prospectus in connection with the offering described herein and therein, and, if given or made, such information or representations must not be relied upon as having been authorized by us. Neither this prospectus nor any prospectus supplement nor any related issuer free writing prospectus shall constitute an offer to sell or a solicitation of an offer to buy offered securities in any jurisdiction in which it is unlawful for such person to make such an offering or solicitation. This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits.

You should read the entire prospectus and any prospectus supplement and any related issuer free writing prospectus, as well as the documents incorporated by reference into this prospectus or any prospectus supplement or any related issuer free writing prospectus, before making an investment decision. Neither the delivery of this prospectus or any prospectus supplement or any issuer free writing prospectus nor any sale made hereunder shall under any circumstances imply that the information contained or incorporated by reference herein or in any prospectus supplement or issuer free writing prospectus is correct as of any date subsequent to the date hereof or of such prospectus supplement or issuer free writing prospectus, as applicable. You should assume that the information appearing in this prospectus, any prospectus supplement or any document incorporated by reference is accurate only as of the date of the applicable documents, regardless of the time of delivery of this prospectus or any sale of securities. Our business, financial condition, results of operations and prospects may have changed since that date.



## PROSPECTUS SUMMARY

*This summary provides an overview of selected information contained elsewhere or incorporated by reference in this prospectus and does not contain all of the information you should consider before investing in our securities. You should carefully read the prospectus, the information incorporated by reference and the registration statement of which this prospectus is a part in their entirety before investing in our securities, including the information discussed under “Risk Factors” in this prospectus and the documents incorporated by reference and our financial statements and related notes that are incorporated by reference in this prospectus. As used in this prospectus, unless the context otherwise indicates, the terms “we,” “our,” “us,” or “the Company” refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries taken as a whole.*

### 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 January 2018, received regulatory approval to commercialize CGuard EPS in India.

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 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 any such 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 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.

We are also developing a neurovascular flow diverter, which is an endovascular device that directs blood flow away from cerebral aneurysms in order to ultimately seal the aneurysms. Our flow diverter would utilize an open cell, highly flexible metal scaffold to which MicroNet would be attached. We have completed initial pre-clinical testing of this product in both simulated bench models and standard in vivo pre-clinical models. However, we have currently suspended further development of this product as we plan to focus our resources primarily on the further expansion of our sales and marketing activities for CGuard EPS.

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.

## **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](http://www.inspire-md.com). Information accessed through our website is not incorporated into this prospectus and is not a part of this prospectus.

## **The Securities We May Offer**

We may offer up to \$30,000,000 of common stock, preferred stock, warrants and/or units in one or more offerings and in any combination. This prospectus provides you with a general description of the securities we may offer. A prospectus supplement, which we will provide each time we offer securities, will describe the specific amounts, prices and terms of these securities.

## **Common Stock**

We may issue shares of our common stock from time to time. The holders of our common stock are entitled to one vote per share. Our certificate of incorporation does not provide for cumulative voting. Our directors are divided into three classes. At each annual meeting of stockholders, directors elected to succeed those directors whose terms expire are elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election. The holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds; however, the current policy of our board of directors is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all assets that are legally available for distribution. The holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock, which may be designated solely by action of our board of directors and issued in the future.

### **Preferred Stock**

We may issue shares of our preferred stock from time to time, in one or more series. Our board of directors will determine the rights, preferences, privileges and restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, without any further vote or action by stockholders. Convertible preferred stock will be convertible into our common stock or exchangeable for our other securities. Conversion may be mandatory or at your option or both and would be at prescribed conversion rates.

If we sell any series of preferred stock under this prospectus and applicable prospectus supplements, we will fix the rights, preferences, privileges and restrictions of the preferred stock of such series in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the Securities and Exchange Commission, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. We urge you to read the applicable prospectus supplement related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

## **Warrants**

We may issue warrants for the purchase of common stock or preferred stock in one or more series. We may issue warrants independently or together with common stock or preferred stock, and the warrants may be attached to or separate from these securities. We will evidence each series of warrants by warrant certificates that we will issue under a separate agreement. We may enter into warrant agreements with a bank or trust company that we select to be our warrant agent. We will indicate the name and address of the warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

In this prospectus, we have summarized certain general features of the warrants. We urge you, however, to read the applicable prospectus supplement related to the particular series of warrants being offered, as well as the warrant agreements and warrant certificates that contain the terms of the warrants. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the Securities and Exchange Commission, the form of warrant agreement or warrant certificate containing the terms of the warrants we are offering before the issuance of the warrants.

## **Units**

We may issue units consisting of common stock, preferred stock and/or warrants for the purchase of common stock or preferred stock in one or more series. In this prospectus, we have summarized certain general features of the units. We urge you, however, to read the applicable prospectus supplement related to the series of units being offered, as well as the unit agreements that contain the terms of the units. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference reports that we file with the Securities and Exchange Commission, the form of unit agreement and any supplemental agreements that describe the terms of the series of units we are offering before the issuance of the related series of units.





## **RISK FACTORS**

An investment in our securities involves a high degree of risk. The prospectus supplement applicable to each offering of our securities will contain a discussion of the risks applicable to an investment in our securities. Before deciding whether to invest in our securities, you should carefully consider the specific factors discussed under the heading "Risk Factors" in the applicable prospectus supplement, together with all of the other information contained or incorporated by reference in the prospectus supplement or appearing or incorporated by reference in this prospectus. You should also consider the risks, uncertainties and assumptions discussed under Item 1A, "Risk Factors," in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, all of which are incorporated herein by reference, as updated or superseded by the risks and uncertainties described under similar headings in the other documents that are filed after the date hereof and incorporated by reference into this prospectus and any prospectus supplement related to a particular offering. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. If any of these risks actually occurs, our business, business prospects, financial condition or results of operations 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. Please also read carefully the section below entitled "Special Note Regarding Forward-Looking Statements."

## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

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

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern;
- our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests;
- our ability to regain compliance with NYSE American listing standards;
- our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products;

our ability to adequately protect our intellectual property;  
our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;  
the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products;  
market acceptance of our products;  
negative clinical trial results or lengthy product delays in key markets;  
an inability to secure and maintain regulatory approvals for the sale 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;  
inability to carry out research, development and commercialization plans;  
loss of a key customer or supplier;  
technical problems with our research and products and potential product liability claims;

product malfunctions;  
price increases for supplies and components;  
adverse economic conditions;  
insufficient or inadequate reimbursement by governmental and other third-party payers for our products;  
our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful;  
adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions;  
the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction;  
the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and  
loss or retirement of key executives and research scientists.

You should review carefully the section entitled “Risk Factors” beginning on page 4 of this prospectus for a discussion of these and other risks that relate to our business and investing in our securities. The forward-looking statements contained or incorporated by reference in this prospectus or any prospectus supplement are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

## **USE OF PROCEEDS**

Unless we specify another use in the applicable prospectus supplement, we will use the net proceeds from the sale of the securities offered by us for general corporate purposes, including funding of our development programs, commercial planning and sales and marketing expenses, general and administrative expenses, acquisition or licensing of additional product candidates or businesses and working capital.

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

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

a change in development plan or strategy;  
the addition of new products or applications;  
technical delays;  
delays or difficulties with our clinical trials;  
negative results from our clinical trials;  
difficulty obtaining U.S. Food and Drug Administration approval;  
failure to achieve sales as anticipated; and  
the availability of other sources of cash including cash flow from operations and new bank debt financing arrangements, if any.

Pending other uses, we intend to invest the proceeds to us in investment-grade, interest-bearing securities such as money market funds, certificates of deposit, or direct or guaranteed obligations of the U.S. government, or hold as cash. We cannot predict whether the proceeds invested will yield a favorable, or any, return.

## **DESCRIPTION OF CAPITAL STOCK**

The following description of common stock and preferred stock summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus, but is not complete. For the complete terms of our common stock and preferred stock, please refer to our amended and restated certificate of incorporation, as amended, any certificates of designation for our preferred stock, and our amended and restated bylaws, as may be amended from time to time. While the terms we have summarized below will apply generally to any future common stock or preferred stock that we may offer, we will describe the specific terms of any series of preferred stock in more detail in the applicable prospectus supplement. If we so indicate in a prospectus supplement, the terms of any preferred stock we offer under that prospectus supplement may differ from the terms we describe below.

We have authorized 155,000,000 shares of capital stock, par value \$0.0001 per share, of which 150,000,000 are shares of common stock and 5,000,000 are shares of “blank check” preferred stock. On February 13, 2018, there were 1,675,592 shares of common stock, 17,303 shares of Series B Convertible Preferred Stock, 741,651 shares of Series C Convertible Preferred Stock and 750 shares of Series D Convertible Preferred Stock issued and outstanding. We currently have 200,000 shares of preferred stock designated as Series A Preferred Stock, 500,000 shares of preferred stock designated as Series B Convertible Preferred Stock, 1,172,000 shares of preferred stock designated as Series C Convertible Preferred Stock and 750 shares of preferred stock designated as Series D Convertible Preferred Stock. The authorized and unissued shares of common stock and the authorized and undesignated shares of preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. Unless approval of our stockholders is so required, our board of directors does not intend to seek stockholder approval for the issuance and sale of our common stock or preferred stock.

The discussion below gives effect to the one-for-thirty-five reverse stock split of our common stock that occurred on February 7, 2018.

### **Common Stock**

The holders of our common stock are entitled to one vote per share. Our certificate of incorporation does not provide for cumulative voting. Our directors are divided into three classes. At each annual meeting of stockholders, directors elected to succeed those directors whose terms expire are elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election. The holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds; however, the current policy of our board of directors is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all assets that are legally available for distribution. The holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to, and may be

adversely affected by, the rights of the holders of any series of preferred stock, which may be designated solely by action of our board of directors and issued in the future.

The transfer agent and registrar for our common stock is Action Stock Transfer Corp. The transfer agent's address is 2469 E. Fort Union Blvd., Suite 214, Salt Lake City, Utah 84121. Our common stock is listed on the NYSE American under the symbol "NSPR."

### **Preferred Stock**

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

Prior to the issuance of shares of each series of preferred stock, the board of directors is required by the Delaware General Corporation Law and our certificate of incorporation to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Delaware. The certificate of designation fixes for each class or series the designations, powers, preferences, rights, qualifications, limitations and restrictions, including, but not limited to, some or all of the following:

- the number of shares constituting that series and the distinctive designation of that series, which number may be increased or decreased (but not below the number of shares then outstanding) from time to time by action of the board of directors;
- the dividend rate and the manner and frequency of payment of dividends on the shares of that series, whether dividends will be cumulative, and, if so, from which date;
- whether that series will have voting rights, in addition to any voting rights provided by law, and, if so, the terms of such voting rights;
- whether that series will have conversion privileges, and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as the board of directors may determine;
- whether or not the shares of that series will be redeemable, and, if so, the terms and conditions of such redemption;
- whether that series will have a sinking fund for the redemption or purchase of shares of that series, and, if so, the terms and amount of such sinking fund;
- whether or not the shares of the series will have priority over or be on a parity with or be junior to the shares of any other series or class in any respect;
- the rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the corporation, and the relative rights or priority, if any, of payment of shares of that series; and
- any other relative rights, preferences and limitations of that series.

Once designated by our board of directors, each series of preferred stock may have specific financial and other terms that will be described in a prospectus supplement. The description of the preferred stock that is set forth in any prospectus supplement is not complete without reference to the documents that govern the preferred stock. These include our certificate of incorporation and any certificates of designation that our board of directors may adopt.

All shares of preferred stock offered hereby will, when issued, be fully paid and nonassessable, including shares of preferred stock issued upon the exercise of preferred stock warrants or subscription rights, if any.

Although our board of directors has no intention at the present time of doing so, it could authorize the issuance of a series of preferred stock that could, depending on the terms of such series, impede the completion of a merger, tender offer or other takeover attempt.

**Delaware Anti-Takeover Law, Provisions of our Certificate of Incorporation and Bylaws and our Stockholder Rights Agreement**



*Delaware Anti-Takeover Law*

We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

any merger or consolidation involving the corporation and the interested stockholder;  
any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;  
subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; or  
the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with, or controlling, or controlled by, the entity or person. The term “owner” is broadly defined to include any person that, individually, with or through that person’s affiliates or associates, among other things, beneficially owns the stock, or has the right to acquire the stock, whether or not the right is immediately exercisable, under any agreement or understanding or upon the exercise of warrants or options or otherwise or has the right to vote the stock under any agreement or understanding, or has an agreement or understanding with the beneficial owner of the stock for the purpose of acquiring, holding, voting or disposing of the stock.

The restrictions in Section 203 do not apply to corporations that have elected, in the manner provided in Section 203, not to be subject to Section 203 of the Delaware General Corporation Law or, with certain exceptions, which do not have a class of voting stock that is listed on a national securities exchange or held of record by more than 2,000 stockholders. Our certificate of incorporation and bylaws do not opt out of Section 203.

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

### ***Certificate of Incorporation and Bylaws***

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might

otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our certificate of incorporation and bylaws:

permit our board of directors to issue up to 5,000,000 shares of preferred stock, without further action by the stockholders, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;

provide that the authorized number of directors may be changed only by resolution of the board of directors;

provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

divide our board of directors into three classes, with each class serving staggered three-year terms;

do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);

provide that special meetings of our stockholders may be called only by our board of directors; and

set forth an advance notice procedure with regard to the nomination, other than by or at the direction of our board of directors, of candidates for election as directors and with regard to business to be brought before a meeting of stockholders.

## DESCRIPTION OF WARRANTS

As of February 13, 2018, there were 181,912 shares of common stock that may be issued upon exercise of outstanding warrants.

We may issue warrants for the purchase of common stock or preferred stock in one or more series. We may issue warrants independently or together with common stock or preferred stock, and the warrants may be attached to or separate from these securities.

We will evidence each series of warrants by warrant certificates that we may issue under a separate agreement. We may enter into a warrant agreement with a warrant agent. Each warrant agent may be a bank that we select which has its principal office in the United States. We may also choose to act as our own warrant agent. We will indicate the name and address of any such warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

- the offering price and aggregate number of warrants offered;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
- in the case of warrants to purchase common stock or preferred stock, the number or amount of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which and currency in which these shares may be purchased upon such exercise;
- the manner of exercise of the warrants, including any cashless exercise rights;
- the warrant agreement under which the warrants will be issued;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;
- anti-dilution provisions of the warrants, if any;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire or, if the warrants are not continuously exercisable during that period, the specific date or dates on which the warrants will be exercisable;
- the manner in which the warrant agreement and warrants may be modified;
- the identities of the warrant agent and any calculation or other agent for the warrants;

federal income tax consequences of holding or exercising the warrants;  
the terms of the securities issuable upon exercise of the warrants;  
any securities exchange or quotation system on which the warrants or any securities deliverable upon exercise of the warrants may be listed or quoted; and  
any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including, in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

### **Exercise of Warrants**

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to 5:00 P.M. eastern time, the close of business, on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required exercise price by the methods provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate, and in the applicable prospectus supplement, the information that the holder of the warrant will be required to deliver to the warrant agent.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants.

### **Enforceability of Rights By Holders of Warrants**

Any warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action the holder's right to exercise, and receive the securities purchasable upon exercise of, its warrants in accordance with their terms.

### **Warrant Agreement Will Not Be Qualified Under Trust Indenture Act**

No warrant agreement will be qualified as an indenture, and no warrant agent will be required to qualify as a trustee, under the Trust Indenture Act. Therefore, holders of warrants issued under a warrant agreement will not have the protection of the Trust Indenture Act with respect to their warrants.

### **Governing Law**

Each warrant agreement and any warrants issued under the warrant agreements will be governed by New York law.

### **DESCRIPTION OF UNITS**

We may issue units comprised of one or more of the other securities described in this prospectus or any prospectus supplement in any combination. Each unit will be issued so that the holder of the unit is also the holder, with the rights and obligations of a holder, of each security included in the unit. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any times before a specified date or upon the occurrence of a specified event or occurrence.

The applicable prospectus supplement will describe:

- the designation and the terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any unit agreement under which the units will be issued;
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and
- whether the units will be issued in fully registered or global form.

## PLAN OF DISTRIBUTION

We may sell the securities being offered pursuant to this prospectus to or through underwriters, through dealers, through agents, or directly to one or more purchasers or through a combination of these methods. The applicable prospectus supplement will describe the terms of the offering of the securities, including:

- the name or names of any underwriters, if any, and if required, any dealers or agents;
- the purchase price of the securities and the proceeds we will receive from the sale;
- any underwriting discounts and other items constituting underwriters' compensation;
- any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchange or market on which the securities may be listed or traded.

We may distribute the securities from time to time in one or more transactions at:

- a fixed price or prices, which may be changed;
- market prices prevailing at the time of sale, directly by us or through a designated agent;
- prices related to such prevailing market prices; or
- negotiated prices.

Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement.

If underwriters are used in an offering, we will execute an underwriting agreement with such underwriters and will specify the name of each underwriter and the terms of the transaction (including any underwriting discounts and other terms constituting compensation of the underwriters and any dealers) in a prospectus supplement. The securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by one or more investment banking firms or others, as designated. If an underwriting syndicate is used, the managing underwriter(s) will be specified on the cover of the prospectus supplement. If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time. Unless otherwise set forth in the prospectus supplement, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent, and the underwriters will be obligated to purchase all of the offered securities, if any are purchased.



We may grant to the underwriters options to purchase additional securities to cover over-allotments, if any, at the public offering price, with additional underwriting commissions or discounts, as may be set forth in a related prospectus supplement. The terms of any over-allotment option will be set forth in the prospectus supplement for those securities.

If we use a dealer in the sale of the securities being offered pursuant to this prospectus or any prospectus supplement, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. The names of the dealers and the terms of the transaction will be specified in a prospectus supplement.

We may sell the securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, any agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

In connection with the sale of the securities, underwriters, dealers or agents may receive compensation from us or from purchasers of the securities for whom they act as agents, in the form of discounts, concessions or commissions. Underwriters may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agents. Underwriters, dealers and agents that participate in the distribution of the securities, and any institutional investors or others that purchase securities directly for the purpose of resale or distribution, may be deemed to be underwriters, and any discounts or commissions received by them from us and any profit on the resale of the common stock by them may be deemed to be underwriting discounts and commissions under the Securities Act of 1933, as amended.

We may provide agents, underwriters and other purchasers with indemnification against particular civil liabilities, including liabilities under the Securities Act of 1933, as amended, or contribution with respect to payments that the agents, underwriters or other purchasers may make with respect to such liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

To facilitate the public offering of a series of securities, persons participating in the offering may engage in transactions that stabilize, maintain, or otherwise affect the market price of the securities. This may include over-allotments or short sales of the securities, which involves the sale by persons participating in the offering of more securities than have been sold to them by us. In addition, those persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to underwriters or dealers participating in any such offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. We make no representation or prediction as to the direction or magnitude of any effect that the transactions described above, if implemented, may have on the price of our securities.

Unless otherwise specified in the applicable prospectus supplement, any common stock sold pursuant to a prospectus supplement will be eligible for listing on the NYSE American, subject to official notice of issuance. Any underwriters to whom securities are sold by us for public offering and sale may make a market in the securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice.

In order to comply with the securities laws of some states, if applicable, the securities offered pursuant to this prospectus will be sold in those states only through registered or licensed brokers or dealers. In addition, in some states securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and complied with.

## **LEGAL MATTERS**

The validity of the securities offered by this prospectus will be passed upon by Haynes and Boone, LLP, New York, New York.

## **EXPERTS**

The financial statements incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2017 have been so incorporated in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the financial statements) of Kesselman & Kesselman, an independent registered public accounting firm and a member firm of PricewaterhouseCoopers International Limited, given on the authority of said firm as experts in auditing and accounting.

## **WHERE YOU CAN FIND MORE INFORMATION**

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and in accordance therewith file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. Such reports, proxy statements and other information can be read and copied at the Securities and Exchange Commission's public reference facilities at 100 F Street, N.E., Washington, D.C. 20549, at prescribed rates. Please call the Securities and Exchange Commission at 1-800-732-0330 for further information on the operation of the public reference facilities. In addition, the Securities and Exchange Commission maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Securities and Exchange Commission. The address of the Securities and Exchange Commission's website is [www.sec.gov](http://www.sec.gov).

We make available free of charge on or through our website at [www.inspire-md.com](http://www.inspire-md.com), our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with or otherwise furnish it to the Securities and Exchange Commission.

We have filed with the Securities and Exchange Commission a registration statement under the Securities Act of 1933, as amended, relating to the offering of these securities. The registration statement, including the attached exhibits, contains additional relevant information about us and the securities. This prospectus does not contain all of the information set forth in the registration statement. You can obtain a copy of the registration statement, at prescribed rates, from the Securities and Exchange Commission at the address listed above, or for free at [www.sec.gov](http://www.sec.gov). The registration statement and the documents referred to below under “Incorporation of Certain Information By Reference” are also available on our website, [www.inspire-md.com](http://www.inspire-md.com).

We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

## **INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The Securities and Exchange Commission allows us to “incorporate by reference” the information we have filed with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus, and later information that we file with the Securities and Exchange Commission will automatically update and supersede this information. We incorporate by reference the documents listed below and any future documents (excluding information furnished pursuant to Items 2.02 and 7.01 of Form 8-K) we file with the Securities and Exchange Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, subsequent to the date of this prospectus and prior to the termination of the offering:

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the Securities and Exchange Commission on February 13, 2018;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 8, 2018 (two reports);

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 19, 2018;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 26, 2018;

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Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 1, 2018;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 7, 2018;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 14, 2018;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 20, 2018;

Our Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 21, 2018; and

The description of our common stock, which is contained in our registration statement on Form 8-A, filed with the Securities and Exchange Commission on March 12, 2013, as updated or amended in any amendment or report filed for such purpose.

All filings filed by us pursuant to the Securities Exchange Act of 1934, as amended, after the date of the initial filing of this registration statement and prior to the effectiveness of such registration statement (excluding information furnished pursuant to Items 2.02 and 7.01 of Form 8-K) shall also be deemed to be incorporated by reference into the prospectus.

You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide you with different information. Any statement contained in a document incorporated by reference into this prospectus will be deemed to be modified or superseded for the purposes of this prospectus to the extent that a later statement contained in this prospectus or in any other document incorporated by reference into this prospectus modifies or supersedes the earlier statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus. You should not assume that the information in this prospectus is accurate as of any date other than the date of this prospectus or the date of the documents incorporated by reference in this prospectus.

We will provide without charge to each person to whom a copy of this prospectus is delivered, upon written or oral request, a copy of any or all of the reports or documents that have been incorporated by reference in this prospectus but not delivered with this prospectus (other than an exhibit to these filings, unless we have specifically incorporated that exhibit by reference in this prospectus). Any such request should be addressed to us at: 4 Menorat Hamaor St., Tel Aviv, Israel 6744832, Attention: Craig Shore, Chief Financial Officer, or made by phone at (888) 776-6804. You may also access the documents incorporated by reference in this prospectus through our website at [www.inspire-md.com](http://www.inspire-md.com). Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

**Shares**

**Common Stock**

**H.C. Wainwright & Co.**

, 2019

