

InspireMD, Inc.  
Form 424B5  
April 08, 2019

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

**Registration No. 333-223130**

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

**486,957 Shares**

### **Common Stock**

We are offering 486,957 shares of our common stock. Our common stock is listed on the NYSE American under the symbol "NSPR." On April 3, 2019, the last reported sale price of our common stock as reported on the NYSE American was \$7.14 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	\$ 5.00	\$ 2,434,785
Underwriting discounts and commissions (1)	\$ 0.35	\$ 170,435
Proceeds, before expenses, to us	\$ 4.65	\$ 2,264,350

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 (1) 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 73,043 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 \$196,000 and the total proceeds to us, before expenses, will be \$2,604,000.

The underwriter expects to deliver the shares of common stock on or about April 8, 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 April 4, 2019.

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**PROSPECTUS**

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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 did not otherwise affect any of the rights currently accruing to holders of our common stock, or options or warrants exercisable for our common stock. All share and related option and warrant information presented in this prospectus 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	486,957 shares of our common stock, par value \$0.0001 per share
Offering price	\$5.00 per share of common stock
Common stock outstanding immediately before this offering	871,872 shares
Common stock outstanding immediately after this offering	1,358,829 shares (1,431,872 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 73,043 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 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 \$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;

133,233 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 50,708 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 April 4, 2019, and 59,423 shares of Series C Preferred Stock outstanding as of April 4, 2019, (see “*Risk Factors — Risks Related to Our Common Stock, Preferred Stock, Warrants and this Offering—Because 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 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 because the public offering price of common stock in this offering is lower than \$15.00 per share) 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;

15,216 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—Because 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.*”);

183 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

34,087 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—Because 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