424B4 1 form424b4.htm

Filed pursuant to Rule 424(b)(4)
Registration No. 333-233432

PROSPECTUS

539,000 Units (each Unit contains One Share of Common Stock and One Series E Warrant to purchase One Share of Common Stock)

2,238,777 Pre-funded Units (each Pre-funded Unit contains One Pre-funded Warrant to Purchase One Share of Common Stock and One Series E Warrant to purchase One Share of Common Stock)

Shares of Common Stock Underlying the Pre-funded Warrants and

Shares of Common Stock Underlying the Series E Warrants

We are offering 539,000 units (each unit consisting of one share of our common stock and one Series E Warrant to purchase one share of our common stock) pursuant to this prospectus. Each Series E Warrant contained in a unit has an exercise price of $1.80 per share of common stock. The Series E Warrants contained in the units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the Series E Warrants contained in the units.

We are also offering 2,238,777 pre-funded units to purchasers whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering (each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one Series E Warrant to purchase one share of our common stock) in lieu of units that would otherwise result in a purchaser's beneficial ownership exceeding 4.99% of our outstanding common stock (or at the election of the purchaser, 9.99%). Each pre-funded warrant contained in a pre-funded unit is exercisable for one share of our common stock. The purchase price of each pre-funded unit is equal to the price per unit being sold to the public in this offering, minus $0.01, and the exercise price of each pre-funded warrant included in the pre-funded unit is $0.01 per share. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants contained in the pre-funded units sold in this offering. Each Series E Warrant contained in a pre-funded unit has an exercise price of $1.80 per share of common stock. The Series E Warrants contained in the pre-funded units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the Series E Warrants contained in the pre-funded units.

Units and the pre-funded units will not be issued or certificated. The shares of common stock or pre-funded warrants, as the case may be, and the Series E Warrants included in the units or the pre-funded units, can only be purchased together in this offering, but the securities contained in the units or pre-funded units will be issued separately and will be immediately separable upon issuance.

Our common stock is traded on the NYSE American under the symbol "NSPR." On September 19, 2019, the last reported sale price of our common stock was $2.60 per share. There is no established public trading market for the pre-funded warrants or Series E Warrants, and we do not expect a market to develop. We do not intend to apply for listing of the pre-funded warrants or Series E Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants or the Series E Warrants will be limited.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 9 of this prospectus and in the documents incorporated by reference into this prospectus for a discussion of risks that should be considered in connection with an investment in our securities.

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

	Per Unit	Per Pre-funded Unit	Total
Public offering price	$ 1.800	$ 1.790	$4,977,611
Underwriting discounts and commissions (7%) (1)	$ 0.126	$ 0.126	$ 350,000
Proceeds, before expenses, to us	$ 1.674	$ 1.664	$4,627,611

(1) We have also agreed to pay the underwriter a management fee equal to 1.0% of the gross proceeds raised in this offering, a non-accountable expense allowance of $35,000 and reimbursement for legal fees and expenses in the amount of up to $100,000, and to issue the underwriter or its designees warrants to purchase a number of shares of common stock equal to 7.0% of the aggregate number of shares of common stock sold in this offering (including the number of shares of common stock issuable upon exercise of the pre-funded warrants), at an exercise price of $2.25 per share, which represents 125% of the public offering price per unit. For a description of the additional compensation to be received by the underwriter, see "Underwriting" for more information.

The offering is being underwritten on a firm commitment basis. The underwriter has an option exercisable within 30 days from the date of this prospectus to purchase up to 416,666 additional shares of common stock and/or Series E Warrants to purchase up to an additional 416,666 shares of common stock from us at the public offering price, less the underwriting discounts and commissions. If the underwriter exercises this option in full, the total underwriting discounts and commissions payable by us will be $402,500, and the total proceeds to us, before expenses, will be $5,325,110, excluding potential proceeds from the exercise of the Series E Warrants included in such option.

Delivery of the securities offered hereby is expected to be made on or about September 24, 2019.

H.C. Wainwright & Co.

The date of this prospectus is September 19, 2019

TABLE OF CONTENTS

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

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

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

PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus or incorporated by reference into this prospectus. This summary may not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus carefully, including the information discussed under "Risk Factors" and the documents incorporated by reference and our financial statements and related notes that are incorporated by reference in this prospectus before making an investment decision. In this prospectus, unless the context requires otherwise, all references to "we," "our" and "us" refer to InspireMD, Inc., a publicly traded Delaware corporation, and its direct and indirect subsidiaries, including InspireMD Ltd.

Overview

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

Our CGuard™ carotid embolic prevention system ("CGuard EPS") combines MicroNet and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013, and we launched its release on a limited basis in October 2014. In January 2015, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, we announced the full market launch of CGuard EPS in Europe. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, including India. We expect to receive approval to launch CGuard EPS in Brazil, and we are seeking strategic partners for potential launch of CGuard EPS in Japan and China.

We consider the addressable market for our CGuard EPS to consist 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 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 U.S. Food and Drug Administration agreed to our pre-clinical test plan and clinical trial design. On July 26, 2019, we submitted an IDE application for CGuard EPS. In connection with such application, on August 23, 2019, we received a request for additional information from the U.S. Food and Drug Administration in support of our application. We intend to continue to work closely with the U.S. Food and Drug Administration to resolve these additional requests. Following resolution of all comments from the U.S. Food and Drug Administration, we plan to submit a formal response for CGuard EPS, as IDE approval by the U.S. Food and Drug Administration would be a critical step toward the commencement of a human clinical trial using CGuard EPS in the United States.

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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 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 performance and 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 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 been participating in international trade shows and industry conferences in an attempt to gain market exposure and brand recognition.

Recent Developments

NYSE American Notification

Stockholder's Equity

On August 7, 2019, we received notification from the NYSE American that we do not meet continued listing standards of the NYSE American as set forth in Part 10 of the NYSE American Company Guide (the "Company Guide"). Specifically, we are 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, 2019, and net losses in our five most recent fiscal years ended December 31, 2018. As a result, we became subject to the procedures and requirements of Section 1009 of the Company Guide.

On August 25, 2019, we submitted our plan to regain compliance with Section 1003(a)(iii) of the Company Guide by August 7, 2020. If the plan is accepted by NYSE Regulation, we may be able to continue our listing during the plan period, during which time we will be subject to periodic review to determine whether we are making progress consistent with the plan.

If the plan is not accepted by NYSE Regulation, delisting proceedings will commence. Furthermore, if the plan is accepted but we are not in compliance with the continued listing standards by August 7, 2020, or if we do not make progress consistent with the plan during the plan period, the NYSE American will initiate delisting proceedings.

Low Trading Price

On January 7, 2019, we received notification from the NYSE American that we were not in compliance with the NYSE American continued listing standards because our shares of common stock had been selling for a low price per share for a substantial period of time. Pursuant to Section 1003(f)(v) of the Company Guide, the NYSE American staff determined that our continued listing was 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. In addition, the NYSE American 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.

Effective as of 5:00 p.m. Eastern Time on March 29, 2019, we amended our amended and restated certificate of incorporation in order to effectuate a 1-for-50 reverse stock split of our outstanding shares of common stock.

On July 8, 2019, we received notice from NYSE American that we have resolved the continued listing deficiency with respect to low selling price pursuant to Section 1003(f)(v) of the Company Guide. We are subject to NYSE Regulation's normal continued listing monitoring. However, in accordance with Section 1009(h) of the Company Guide, if we are again determined to be below any of the continued listing standards within 12 months of July 8, 2019, NYSE American will examine the relationship between the two incidents of noncompliance and re-evaluate our method of financial recovery from the first incident. 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. If in the future we fall below the continued listing criterion of a minimum average share price of $0.20 over a 30-day trading period, our common stock will be subject to immediate review by NYSE American. There can be no assurance that the market price of our common stock will remain above the levels viewed as abnormally low for a substantial period of time.

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 expand the population of CGuard EPS patients in those countries in which CGuard EPS is commercially available. In particular, our focus is on establishing CGuard EPS as a viable alternative (in appropriate cases) to conventional carotid stents and vascular surgery within the applicable medical communities. We intend to accomplish this goal by continuing to publish and present our clinical data and support investigator-initiated clinical registries. We have partnered and will continue to seek out partnerships with organizations 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 our efforts to widen 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 immediately launched the product. We are also pursuing additional product registrations and distribution contracts with local distributors in other countries in Europe, Asia and Latin America.

- **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. Nineteen patent applications and patents are pending or in force (fifteen 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.

Risks Associated with Our Business

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

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern;

- our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute our stockholders' ownership interests;

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

- delisting of our common stock from NYSE American;

- our ability to adequately protect our intellectual property;

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

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

- market acceptance and adoption of our products;

- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;

- entry of new competitors and products and potential technological obsolescence of our products;

- loss of a key customer or supplier;

- technical problems with our research and products and potential product liability claims;
- adverse economic conditions;
- insufficient or inadequate reimbursement by governmental and other third-party payers for our products;
- adverse federal, state and local government regulation in the United States, Europe, Israel and other foreign jurisdictions;
- price increases for supplies and components;
- inability to carry out research, development and commercialization plans; and
- loss or retirement of key executives and research scientists.

Corporate Information

We were organized in the State of Delaware on February 29, 2008. Our principal executive offices are located at 4 Menorat Hamaor St., Tel Aviv, Israel 6744832. Our telephone number is (888) 776-6804. Our website address is www.inspire-md.com. Information accessed through our website is not incorporated into this prospectus and is not a part of this prospectus.

THE OFFERING

Units offered by us	539,000 units, each consisting of one share of our common stock and one Series E Warrant to purchase one share of our common stock
Pre-funded units offered by us in this offering	We are also offering 2,238,777 pre-funded units to purchasers whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding shares of common stock immediately following the consummation of this offering (each pre-funded unit consisting of one pre-funded warrant to purchase one share of common stock and one Series E Warrant to purchase one share of common stock) in lieu of units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding shares of common stock (or, at the election of the purchaser, 9.99%). The purchase price of each pre-funded unit is equal to the public offering price at which the units are being sold to the public in this offering, minus $0.01, and the exercise price of each pre-funded warrant included in each pre-funded unit is $0.01 per share. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering.
Series E Warrants offered by us in the offering	Series E Warrants to purchase an aggregate of 2,777,777 shares of common stock. Each unit and each pre-funded unit includes one Series E Warrant to purchase one share of our common stock. Each Series E Warrant entitles the holder to purchase one share of common stock at an exercise price of $1.80 per share, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the Series E Warrants.
Option to purchase additional securities	The underwriter has an option to purchase up to 416,666 additional shares of common stock and/or Series E Warrants to purchase up to an additional 416,666 shares of common stock from us at the public offering price, less underwriting discounts and commissions. The underwriter may exercise this option at any time and from time to time within 30 days from the date of this prospectus.
Common stock outstanding prior to this offering:	1,399,271 shares of common stock
Common stock outstanding after this offering:	1,938,271 shares of common stock, assuming no exercise of any pre-funded warrants (or 2,354,937 shares of common stock if the underwriter exercises in full its option to purchase additional securities, assuming no exercise of any pre-funded warrants).
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 securities involves a high degree of risk. See "Risk Factors" beginning on page 9 of this prospectus and the other information included or incorporated by reference in this prospectus.
NYSE American symbol for common stock:	"NSPR." We do not plan to list the pre-funded warrants or the Series E Warrants on the NYSE American or any other securities exchange or trading market. There is no established trading market for the pre-funded warrants or the Series E Warrants, and we do not expect a trading market to develop. Without a trading market, the liquidity of the pre-funded warrants and the Series E Warrants will be extremely limited.

The number of shares of common stock to be outstanding immediately after this offering is based on 1,399,271 shares of our common stock outstanding as of September 19, 2019, and excludes, as of such date:

- 850,151 shares of common stock issuable upon exercise of outstanding warrants, with an exercise price ranging from $6.25 to $240,625 per share and having a weighted average exercise price of $99.09 per share;
- 199,850 shares of common stock issuable upon 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 85,650 shares of common stock but excluding 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 as a result of the full ratchet anti-dilution price protection in the certificate of designation for the Series B Preferred Stock because the effective public offering price of common stock in this offering is lower than $5.00 per share), at the conversion price of $5.00 per share and the stated value per share of $33.00;
- 47,392 shares of common stock issuable upon conversion of the outstanding Series C Convertible Preferred Stock (the "Series C Preferred Stock") (excluding additional shares of common stock 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 effective public offering price of common stock in this offering is lower than $5.00 per share) at the conversion price of $5.00 per share and the stated value per share of $6.40;
- 355,288 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 88,305 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 and 37,025 shares of Series C Preferred Stock outstanding (see "*Risk Factors — Risks Related to Our Common Stock, Preferred Stock, Warrants and this Offering—Because the effective price per share of common stock included in the units or issuable upon exercise of the pre-funded warrants included in the pre-funded units being offered in this offering is less than the 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*.");

- 22,827 shares of common stock issuable upon conversion of the Series B Preferred Stock (including an aggregate of 9,781 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;

- 40,574 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 effective 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 effective price per share of common stock included in the units or issuable upon exercise of the pre-funded warrants included in the pre-funded units being offered in this offering is less than the 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.*");

- 178 shares of common stock issuable upon the exercise of outstanding options, with exercise prices ranging from $0.001 to $3,675,000 and having a weighted average exercise price of $336,056 per share;

- 608,449 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan;

- 2,238,777 shares of common stock issuable upon exercise of the pre-funded warrants offered hereby by us at an exercise price of $0.01 per share;

- 2,777,777 shares of common stock issuable upon exercise of the Series E Warrants offered hereby by us at an exercise price of $1.80 per share; and

- 194,444 additional shares of common stock, or, if the underwriter elects to exercise its option in full to purchase additional shares, then 223,611 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 assumes no exercise of the underwriter's option to purchase additional securities and no exercise of the underwriter's warrants to be issued to the underwriter in connection with this offering.

RISK FACTORS

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

Risks Related to Our Business

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

We have yet to establish any history of profitable operations. We reported a net loss of $7.2 million for the fiscal year ended December 31, 2018. We had a net loss of approximately $5.4 million during the six months ended June 30, 2019. As of June 30, 2019, we had an accumulated deficit of $153 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 until the end of the fourth 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:

- furthering our efforts to ultimately seek the U.S. Food and Drug Administration approval for commercial sales of CGuard EPS in the United States;
- development of our current and future products, including CGuard EPS enhancements;
- 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.

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. See "*Risk Factors—Risks Related to Our Common Stock, Preferred Stock and Warrants and this offering—Because the effective price per share of common stock included in the units or issuable upon exercise of the pre-funded warrants included in the pre-funded units being offered in this offering is less than the 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*." 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.

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 enhancements. 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 enhancements. If we fail to generate expected revenues from these products, our results of operations and the value of our business and securities would be materially and adversely affected.

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

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

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

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

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

We also rely on trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. In addition, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow competitors to learn our trade secrets and use the information in competition against us.

If our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We currently manufacture our 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.

Before we may conduct clinical trials for CGuard EPS in the United States, we must obtain the U.S. Food and Drug Administration's approval of our IDE application and meet a number of other regulatory requirements, and, if we obtain IDE approval and meet all other applicable requirements, all clinical trials must be conducted in compliance with the U.S. Food and Drug Administration's IDE regulations. Failure to complete the applicable prerequisites before beginning clinical trials and/or to maintain compliance with IDE regulations thereafter could have a material adverse effect on our business.

Clinical trials involve use of a medical device candidate (or drug, biological, or other product candidate, as applicable) on human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices, including the requirement that all research subjects provide informed consent for their participation in the clinical study. The U.S. Food and Drug Administration classifies medical device candidates into "significant risk" and "non-significant risk" devices. Significant risk devices present a potential for serious risk to the health, safety, or welfare of a subject. Examples may include implants, devices that support or sustain human life, and devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. If a medical device candidate presents a significant risk, an IDE application must be submitted and approved prior to commencing any human clinical trials in the United States in connection with such device. The U.S. Food and Drug Administration may approve, conditionally approve, or deny an IDE or it may require further information and, thus, delay approval.

IDE applications may be denied for a number of reasons. For example, commonly cited deficiencies in U.S. Food and Drug Administration disapproval letters include, but are not limited to, the following:

- Inadequate report of prior investigations due to:
  - Limited rationale and/or description of lab or animal studies;
  - No scientific justification for the number of animals selected in report of animal studies;
  - Failure to identify relevant information in literature research summary; or
  - Omission of adverse information in reports of prior publications;
- Inadequate investigational plan due to:
  - failure to clearly develop or define study objectives;
  - inadequate description of the protocol;
  - failure to identify all risks;
  - failure to develop proper monitoring procedures; or
  - inadequate informed consent documents;
- Inadequate characterization or description of the device and its operation due to inadequate or omitted:
  - Design/engineering drawing of device;
  - Rationale for device design;
  - Device and performance specifications;
  - Description of materials (including biocompatibility information); or
  - Description of function.

CGuard EPS is a significant risk device under the U.S. Food and Drug Administration's definition. Accordingly, to conduct clinical trials with human subjects in the U.S., we must obtain IDE approval from the U.S. Food and Drug Administration. On July 26, 2019, we submitted an original IDE application for CGuard EPS. In connection with such application, on August 23, 2019, we received a request for additional information from the U.S. Food and Drug Administration in support of our application. We intend to continue to work closely with the U.S. Food and Drug Administration to resolve these additional requests. Following resolution of all comments from the U.S. Food and Drug Administration, we plan to submit a formal response for CGuard EPS. There is no guarantee that we will obtain IDE approval from the U.S. Food and Drug Administration for CGuard EPS or any other current or future product candidate we may develop.

In addition to IDE approval, we must apply for and obtain IRB approval of the proposed CGuard EPS clinical study in connection with each clinical site before commencing any study activities. A written protocol with predefined end points, an appropriate sample size, and pre-determined patient inclusion and exclusion criteria, is also required before we may initiate or conduct the CGuard EPS trial. If we obtain IDE approval, IRB approval, and meet all of the other applicable requirements that must be met before beginning clinical trials in the United States, we will, then, be able to lawfully initiate the clinical investigation of the safety and effectiveness of CGuard EPS in the United States.

Importantly, the CGuard EPS clinical trial, if applicable, and any others that we may conduct in the future, must be conducted in accordance with the U.S. Food and Drug Administration's IDE regulations, which, among other things, establish requirements for investigational device labeling, prohibit pre-approval promotion of a device candidate, and specify recordkeeping, reporting, and monitoring responsibilities of study sponsors and study investigators.

We may not be able to obtain U.S. Food and Drug Administration and/or IRB approval to undertake clinical trials in the United States for CGuard EPS or any new devices we intend to market in the United States in the future. If we do

obtain such approvals, we may not be able to conduct studies which comply with the IDE and other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Failure to obtain such approvals or to comply with such regulations could have a material adverse effect on our business, financial condition and results of operations.

Relatedly, certainty that clinical trials will meet desired endpoints, produce meaningful or useful data, and be free of unexpected adverse effects, or that the U.S. Food and Drug Administration will accept the validity of foreign clinical study data, as applicable, cannot be guaranteed, and such uncertainty could preclude or delay regulatory approvals and commercialization, resulting in significant financial costs and reduced revenue. Moreover, the timing of the commencement, continuation, and completion of any future clinical trial may be subject to significant delays attributable to various causes, including, but not limited to, scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delay in or failure to meet regulatory and/or IRB requirements to conduct a clinical trial at a one or more prospective sites, and shortages of supply in the investigational device.

Though necessary to pursue U.S. Food and Drug Administration premarket approval, pre-clinical and clinical trials are inherently lengthy and expensive and subject to any number of regulatory and/or clinical difficulties that can cause further delays, additional costs, and/or rejection by the U.S. Food and Drug Administration, and any such delay, added cost, or failure in connection with any future clinical trials could prevent us from commercializing our MicroNet products in the United States, 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, among other standard-of-care considerations, 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. MGuard Prime EPS, our current coronary product, is not drug-eluting, 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 for coronary artery disease. 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.

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.

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;

● 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.

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 the appropriate governing body in each applicable country. The approval processes vary 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, Medtronic, Inc., and Johnson and Johnson, 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 enforcing their intellectual property rights against us or 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 Bosti Trading Ltd. ("Bosti") in July 2019, seeking €1,830,000 (which is approximately $2 million), the amount Bosti was due to receive from its Russian subsidiary, or alternatively, €1,024,000 (which is approximately $1.1 million), the amount Bosti paid to InspireMD Ltd., for the MGuard Prime EPS returned to InspireMD Ltd. in connection with the voluntary field corrective action of our MGuard Prime EPS we initiated in 2014. See "*Part II, Item 1 — Legal Proceedings*" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the Securities and Exchange Commission on August 5, 2019, 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.

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.

In May 2017, the European parliament and the council of the European Union approved a new Medical Device Regulation (EU) 2017/745 which has replaced the existing medical device directives (93/42/EEC). The new regulations will come into full application in May 2020. The new Medical Device Regulation imposes stricter requirements on medical device manufacturers and strengthens the supervising competences of the competent authorities of European Union member states, the notified bodies and the authorized representatives. As a result, the new legislation can prevent or delay the CE marking and certifications of our products under development or impact our ability to modify our currently CE marked products on a timely basis. If we fail to comply with the modified regulation and requirements it can adversely affect our business, operating results and prospects.

Risks Related to Operating in Israel

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

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

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

Our 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.

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. 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 7, 2019, 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, 2019, and had net losses in our five most recent fiscal years ended December 31, 2018. As a result, we had become subject to the procedures and requirements of Section 1009 of the Company Guide. On August 25, 2019, we submitted a plan of compliance to NYSE Regulation, addressing how we intend to regain compliance with Section 1003(a)(iii) of the Company Guide by August 7, 2020. However, there is no assurance that our compliance plan will be accepted by NYSE American. If the plan is not accepted by NYSE Regulation, delisting proceedings will commence.

Furthermore, if the plan is accepted but if we do not regain compliance by August 7, 2020, or fail to remain in compliance as of August 7, 2020, or anytime thereafter, with Section 1003(a)(iii) of the Company Guide, or if we do not maintain our progress consistent with the plan during the applicable plan period, the NYSE American will initiate delisting proceedings. There is no assurance that we will be able to regain compliance with Section 1003(a)(iii) of the Company Guide as of August 7, 2020. Even if the net proceeds from our capital raises provide us with sufficient stockholders' equity to regain compliance with Section 1003(a)(iii) of the Company Guide by August 7, 2020, we will be subject to ongoing review for compliance with NYSE American requirements, and there can be no assurance that we will continue to remain in compliance with this standard.

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 had 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. On March 29, 2019, we effected a 1-for-50 reverse stock split of our common stock.

Although on July 8, 2019, we received notice from NYSE American that we have resolved the continued listing deficiency with respect to low selling price pursuant to Section 1003(f)(v) of the Company Guide, in accordance with Section 1009(h) of the Company Guide, if we are again determined to be below any of the continued listing standards within 12 months of July 8, 2019, NYSE American will examine the relationship between the two incidents of noncompliance and re-evaluate our method of financial recovery from the first incident. 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. If in the future we fall below the continued listing criterion of a minimum average share price of $0.20 over a 30-day trading period, our common stock will be subject to immediate review by NYSE American. There can be no assurance that the market price of our common stock will remain above the levels viewed as abnormally low for a substantial period of time. 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.

Because the effective price per share of common stock included in the units or issuable upon exercise of the pre-funded warrants included in the pre-funded units being offered in this offering is less than the 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 each of the March 2018 public offering, the April 2018 public offering, the July 2018 public offering and the April 2019 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, because the effective price per share of common stock included in the units or issuable upon exercise of the pre-funded warrants included in the pre-funded units being offered in this offering is less than the respective current conversion price of our Series B or Series C Preferred Stock, each of these conversion prices shall be reduced to the effective price per share of common stock included in the units or issuable upon exercise of the pre-funded warrants included in the pre-funded units being offered in this offering. 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. Furthermore, 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 may 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 stockholders.

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 may 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 — Because the effective price per share of common stock included in the units or issuable upon exercise of the pre-funded warrants included in the pre-funded units being offered in this offering is less than the 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*."

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.

There is no public market for the pre-funded warrants or the Series E Warrants being offered by us in this offering.

There is no established public trading market for the pre-funded warrants or the Series E Warrants and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants or the Series E Warrants on any national securities exchange or other nationally recognized trading system, including NYSE American. Without an active market, the liquidity of the pre-funded warrants and the Series E Warrants will be limited, which may adversely affect their value.

Holders of pre-funded warrants or Series E Warrants purchased in this offering will have no rights as common stockholders until such holders exercise their pre-funded warrants or Series E Warrants and acquire our common stock.

Until holders of pre-funded warrants or Series E Warrants acquire shares of our common stock upon exercise thereof, such holders will have no rights with respect to the shares of our common stock underlying the pre-funded warrants and Series E Warrants. Upon exercise of the pre-funded warrants or Series E Warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Series E Warrants are speculative in nature.

The Series E Warrants do not confer any rights of common stock ownership on its holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the Series E Warrants may exercise their right to acquire the common stock and pay an exercise price of $1.80 per share of common stock, subject to certain adjustments, prior to five years from the date of issuance, after which date any unexercised Series E Warrants will expire and have no further value. Moreover, following this offering, the market value of the Series E Warrants, if any, is uncertain and there can be no assurance that the market value of the Series E Warrants will equal or exceed their imputed offering price. The Series E Warrants will not be listed or quoted for trading on any market or exchange. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the Series E Warrants, and consequently, it may not ever be profitable for holders of the Series E Warrants to exercise the Series E Warrants.

There is no public market for our preferred stock.

There is no established trading market for our preferred stock. A trading market for our preferred stock is not expected to develop, and even if a market develops for our preferred stock, it may not provide meaningful liquidity. The absence of a trading market or liquidity for our preferred stock may adversely affect their value.

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.

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

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

Aspects of the 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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. You should review carefully the section entitled "Risk Factors" beginning on page 9 of this prospectus for a discussion of these and other risks that relate to our business and investing in our securities. The forward-looking statements contained or incorporated by reference in this prospectus are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

USE OF PROCEEDS

The net proceeds from this offering will be approximately $4.1 million from the sale of our securities in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriter exercises its option to purchase additional shares of common stock and/or Series E Warrants to purchase common stock in full, we estimate the net proceeds from this offering will be approximately $4.8 million from the sale of our securities, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. These estimates exclude the proceeds, if any, from the exercise of Series E Warrants and the pre-funded warrants sold in this offering. If all of the Series E Warrants sold in this offering were to be exercised in cash at the exercise price of $1.80 per share of common stock, we would receive additional net proceeds of approximately $5 million, and if all of the pre-funded warrants sold in this offering were to be exercised in cash at an exercise price of $0.01 per share of common stock, we would receive additional net proceeds of approximately $22,388. We cannot predict when or if these Series E Warrants or pre-funded warrants will be exercised. It is possible that these Series E Warrants or pre-funded warrants may expire and may never be exercised.

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.

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.

CAPITALIZATION

The following table summarizes our cash and cash equivalents, certain other items from our historical consolidated balance sheet, and capitalization as of June 30, 2019:

- on an actual basis; and
- on an as adjusted basis, giving effect to the sale by us of 539,000 units in this offering at a public offering price of $1.80 per unit and the sale by us of 2,238,777 pre-funded units in this offering at a public offering price of $1.79 per pre-funded unit, after deducting the estimated underwriting discounts and commissions and estimated offering expenses and excluding the proceeds, if any, from the exercise of Series E Warrants or pre-funded units issued in this offering.

For the purposes of this capitalization discussion on an as adjusted basis, we also took into account the issuance of 355,288 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 88,305 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 June 30, 2019, and 38,806 shares of Series C Preferred Stock outstanding as of June 30, 2019. You should read this table together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes incorporated by reference into this prospectus.

	June 30, 2019 (in thousands) (unaudited)	
	Actual	**As Adjusted**
Cash and cash equivalents	$ 4,823	$ 9,066
Equity:		
Common stock, par value $0.0001 per share – 150,000,000 shares authorized; 1,397,133 shares issued and outstanding actual and 2,379,726 shares outstanding as adjusted	$ -	$ -
Preferred stock, par value $0.0001 per share - 5,000,000 shares authorized:		
Series A Preferred Stock, par value $0.0001 per share; none issued and outstanding actual and as adjusted	-	-
Series B Convertible Preferred Stock, par value $0.0001 per share; 17,303 shares issued and outstanding actual and as adjusted	-	-
Series C Convertible Preferred Stock, par value $0.0001 per share; 38,806 shares issued and outstanding actual and as adjusted	-	-
Additional paid-in capital	158,579	162,822
Accumulated deficit	(153,005)	(153,005)
Total equity	$ 5,574	$ 9,817

The above discussion and table are based on 1,397,133 shares outstanding as of June 30, 2019, and excludes as of that date:

- 850,152 shares of common stock issuable upon exercise of outstanding warrants, with an exercise price ranging from $6.25 to $240,625 per share and having a weighted average exercise price of $101.62 per share;

- 199,850 shares of common stock issuable upon 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 85,650 shares of common stock but excluding 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 as a result of the full ratchet anti-dilution price protection in the certificate of designation for the Series B Preferred Stock because the effective public offering price of common stock in this offering is lower than $5.00 per share), at the conversion price of $5.00 per share and the stated value per share of $33.00;

- 49,672 shares of common stock issuable upon 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 effective public offering price of common stock in this offering is lower than $5.00 per share) at the conversion price of $5.00 per share and the stated value per share of $6.40;

- 22,827 shares of common stock issuable upon conversion of the Series B Preferred Stock (including an aggregate of 9,781 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;

- 40,574 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 effective 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 effective price per share of common stock included in the units or issuable upon exercise of the pre-funded warrants included in the pre-funded units being offered in this offering is less than the 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.”);

- 181 shares of common stock issuable upon the exercise of outstanding options with exercise prices ranging from $0.001 to $3,675,000 and having a weighted average exercise price of $354,315 per share;

- 608,307 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan;

- 2,238,777 shares of common stock issuable upon exercise of the pre-funded warrants offered hereby by us at an exercise price of $0.01 per share;

- 2,777,777 shares of common stock issuable upon exercise of the Series E Warrants offered hereby by us at an exercise price of $1.80 per share; and

- 194,444 additional shares of common stock, or, if the underwriter elects to exercise its option in full to purchase additional shares, then 223,611 shares of common stock, issuable upon the exercise of the underwriter’s warrants to be issued to the underwriter in connection with this offering.

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 September 19, 2019, was $2.60 per share. As of September 19, 2019, we had approximately 264 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.

DESCRIPTION OF SECURITIES

We are offering (i) 539,000 units, each unit consisting of one share of our common stock and one Series E Warrant to purchase one share of our common stock and (ii) 2,238,777 pre-funded units, each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one Series E Warrant to purchase one share of our common stock. The share of common stock and accompanying Series E Warrant included in each unit will be issued separately and will be immediately separable upon issuance, and the pre-funded warrant to purchase one share of common stock and the accompanying Series E Warrant included in each pre-funded unit will be issued separately and will be immediately separable upon issuance. The units and pre-funded units will not be issued or certificated. We are also registering the shares of common stock included in the units and the shares of common stock issuable from time to time upon exercise of the pre-funded warrants included in pre-funded units and Series E Warrants included in the units and the pre-funded units offered hereby.

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 September 19, 2019, there were 1,399,271 shares of common stock, 17,303 shares of Series B Preferred Stock and 37,025 shares of Series C Preferred Stock issued and outstanding. We currently have 20,000 shares of preferred stock designated as Series A Preferred Stock, 500,000 shares of preferred stock designated as Series B Preferred Stock, 1,172,000 shares of preferred stock designated as Series C Preferred Stock and 750 shares of preferred stock designated as Series D Convertible Preferred Stock (the "Series D 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 foregoing description is intended as a summary and is qualified in its entirety by reference to our amended and restated certificate of incorporation, the bylaws, and the respective certificates of designations for our Series B Preferred Stock and Series C Preferred Stock.

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."

Pre-Funded Warrants Being Offered in this Offering

The following summary of certain terms and provisions of pre-funded warrants included in the pre-funded units that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration and Exercise Price

Each pre-funded warrant offered hereby will have an initial exercise price per share equal to $0.01. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The pre-funded warrants will be issued separately from the accompanying Series E Warrants, and may be transferred separately immediately thereafter.

Exercisability

The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded warrants in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Cashless Exercise

If, at the time a holder exercises its pre-funded warrants, a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Transferability

Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the pre-funded warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Trading Market

There is no trading market available for the pre-funded warrants on any securities exchange or nationally recognized trading system. We do not intend to list the pre-funded warrants on any securities exchange or nationally recognized trading system. The common stock issuable upon exercise of the pre-funded warrants is currently listed on the NYSE American under the symbol "NSPR."

Right as a Stockholder

Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

Series E Warrants Being Offered in this Offering

The following summary of certain terms and provisions of Series E Warrants included in the units and the pre-funded units that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Series E Warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Series E Warrant for a complete description of the terms and conditions of the Series E Warrants.

Duration and Exercise Price

Each Series E Warrant included in the units and the pre-funded units offered hereby will have an initial exercise price equal to $1.80 per share of common stock. The Series E Warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The Series E Warrants will be issued separately from the common stock included in the units, or the pre-funded warrants included in the pre-funded units, as the case may be. A Series E Warrant to purchase one share of our common stock will be included in each unit or pre-funded unit purchased in this offering.

Cashless Exercise

If, at the time a holder exercises its Series E Warrants, a registration statement registering the issuance of the shares of common stock underlying the Series E Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Series E Warrants.

Exercisability

The Series E Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Series E Warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Series E Warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series E Warrants. Purchasers of Series E Warrants in this offering may also elect prior to the issuance of the Series E Warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Series E Warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Transferability

Subject to applicable laws, the Series E Warrants may be offered for sale, sold, transferred or assigned without our consent. There is currently no trading market for the Series E Warrants.

Exchange Listing

There is no trading market available for the Series E Warrants on any securities exchange or nationally recognized trading system. We do not intend to list the Series E Warrants on any securities exchange or nationally recognized trading system. The common stock issuable upon exercise of the Series E Warrants is currently listed on the NYSE American under the symbol "NSPR."

Right as a Stockholder

Except as otherwise provided in the Series E Warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Series E Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Series E Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Series E Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the Series E Warrants will be entitled to receive upon exercise of the Series E Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Series E Warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our Board, the holders of the Series E Warrants have the right to require us or a successor entity to redeem the Series E Warrant for cash in the amount of the Black-Scholes value of the unexercised portion of the Series E Warrant as of the date of the consummation of the fundamental transaction; provided, however, in the event of a fundamental transaction which is not approved by our Board and not within the control of the Company, neither we nor a successor entity will be required to redeem the Series E Warrant for such amount.

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.

Series B Convertible Preferred Stock

On July 7, 2016, we issued 442,424 shares of Series B Preferred Stock in a public offering. Our Series B Preferred Stock has a stated value of $33.00 and was initially convertible into 0.00229 shares of common stock (subject to the beneficial ownership limitations as provided in the related certificate of designation of preferences) reflecting a conversion price equal to $14,437.50 per share, subject to adjustment as provided in the certificate of designation. In accordance with the anti-dilution price protection contained in the certificate of designation for the Series B Preferred Stock, we reduced the Series B Preferred Stock conversion price upon closing of the March 2017 offering to $2,800.00 per share of common stock, which was further reduced to $350.00 per share in connection with the private placement of 750 shares of Series D Preferred Stock in December 2017 (the "Series D Private Placement"), to $150.00 per share in connection with the underwritten public offering that closed on March 1, 2018, to $87.50 per share in connection with the underwritten public offering that closed on April 2, 2018, to $15.00 per share in connection with the underwritten public offering that closed on July 3, 2018, then to $5.00 per share in connection with the underwritten public offering that closed on April 8, 2019.

The Series B Preferred Stock is convertible at any time at the option of the holder prior to the fifth anniversary of the date of issuance, at which time all shares of outstanding Series B Preferred Stock shall automatically and without any further action by the holder be converted into shares of our common stock at the then effective conversion price, provided that the holder will be prohibited from converting Series B Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of our common stock then issued and outstanding.

As of September 19, 2019, there were 17,303 shares of Series B Preferred Stock outstanding.

The holders of Series B Preferred Stock are 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 become payable, at our option, in either cash, out of any funds legally available for such purpose, or in shares of common stock, (i) upon any conversion of the Series B Preferred Stock, (ii) on each such other date as our board of directors may determine, subject to written consent of the holders of Series B Preferred Stock holding a majority of the then issued and outstanding Series B Preferred Stock, (iii) upon our liquidation, dissolution or winding up, and (iv) upon occurrence of a fundamental transaction, including any merger or consolidation, sale of all or substantially all of our assets, exchange or conversion of all of our common stock by tender offer, exchange offer or reclassification; provided, however, that if Series B Preferred Stock is converted into shares of common stock at any time prior to the fifth anniversary of the date of issuance of the Series B Preferred Stock, the holder will receive a make-whole payment in an amount equal to all of the dividends that, but for the early conversion, would have otherwise accrued on the applicable shares of Series B Preferred Stock being converted for the period commencing on the conversion date and ending on the fifth anniversary of the date of issuance, less the amount of all prior dividends paid on such converted Series B Preferred Stock before the date of conversion. Make-whole payments are payable at our option in either cash, out of any funds legally available for such purpose, or in shares of common stock.

With respect to any dividend payments and make-whole payments paid in shares of common stock, the number of shares of common stock to be issued to a holder of Series B Preferred Stock will be an amount equal to the quotient of (i) the amount of the dividend payable to such holder divided by (ii) the conversion price then in effect.

We are not obligated to redeem or repurchase any shares of Series B Preferred Stock. Shares of Series B Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provision.

The Series B Preferred Stock, to the extent that it has not been converted previously, is subject to full ratchet anti-dilution price protection upon the issuance of equity or equity-linked securities at an effective common stock purchase price of less than the conversion price then in effect, subject to adjustment as provided in the certificate of designation.

In the event of our liquidation, dissolution, or winding up, holders of our Series B Preferred Stock will be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Series B Preferred Stock if such shares had been converted to common stock immediately prior to such event (without giving effect for such purposes to the 9.99% beneficial ownership limitation, as applicable) subject to the preferential rights of holders of any class or series of our capital stock specifically ranking by its terms senior to the Series B Preferred Stock as to distributions of assets upon such event, whether voluntarily or involuntarily.

The holders of the Series B Preferred Stock have no voting rights, except as required by law. Any amendment to our certificate of incorporation, bylaws or certificate of designation that adversely affects the powers, preferences and rights of the Series B Preferred Stock requires the approval of the holders of a majority of the shares of Series B Preferred Stock then outstanding.

We have not listed, and we do not plan on making an application to list, the Series B Preferred Stock on the NYSE American, any other national securities exchange or any other nationally recognized trading system. The common stock issuable upon conversion of the Series B Preferred Stock is listed on the NYSE American under the symbol "NSPR."

Shares of Series B Preferred Stock were issued in book-entry form under a transfer agency and service agreement between Action Stock Transfer Corp., as transfer agent, and us, and are represented by one or more book-entry certificates deposited with DTC and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

The transfer agent and registrar for our Series B Preferred Stock is Action Stock Transfer Corp. The transfer agent's address is 2469 E. Fort Union Blvd., Suite 214, Salt Lake City, Utah 84121.

You should review the certificate of designation of the Series B Preferred Stock, which has been filed as an exhibit to our Quarterly Report on Form 10-Q, for the quarter ended June 30, 2016, filed with the Securities and Exchange Commission on August 9, 2016, and the certificates of amendment to the certificate of designation of the Series B Preferred Stock, which were filed as an exhibit to our Current Reports on Form 8-K, filed with the Securities and

Exchange Commission on December 12, 2017, December 22, 2017, and July 5, 2018, respectively, for a complete description of the terms and conditions of the Series B Preferred Stock.

Potential Common Stock Issuances to the Holders of Our Series B Preferred Stock

Pursuant to the anti-dilution provisions contained in the certification of designation for our Series B Preferred Stock, in the event that, while any of our Series B Preferred Stock is outstanding, we issue equity or equity-linked securities at an effective common stock purchase price of less than the Series B Preferred Stock conversion price then in effect, we are required, subject to certain limitations and adjustments as provided in the certificate of designation, to reduce the Series B Preferred Stock conversion price to equal the effective common stock purchase price. This reduction in the Series B Preferred Stock conversion price will result in a greater number of shares of common stock becoming issuable upon conversion of the Series B Preferred Stock for no additional consideration. In accordance with this anti-dilution price protection, because the effective purchase price per share of common stock in this offering is below the current Series B Preferred Stock conversion price of $5.00 per share of common stock, it will result in additional shares of common stock becoming issuable to the holders of our Series B Preferred Stock upon conversion of the Series B Preferred Stock. As a result of this offering, based on 17,303 shares of Series B Preferred Stock outstanding as of September 19, 2019, the conversion price for the Series B Preferred Stock will be adjusted to $1.80, and we would be required to issue 355,288 additional shares of common stock (including the payment of the cumulative dividends accrued on the Series B Preferred Stock in an aggregate of 152,267 shares of common stock) to the holders of Series B Preferred Stock upon conversion of their Series B Preferred Stock.

Series C Convertible Preferred Stock

On March 14, 2017, we issued 1,069,822 shares of Series C Preferred Stock in a public offering. Our Series C Preferred Stock has a stated value of $6.40, and each share of Series C Preferred Stock was initially convertible into 0.00229 of a share of common stock at an initial conversion price equal to $2,800 per share of common stock. Series C Preferred Stock, to the extent that it has not been converted previously, is subject to full ratchet anti-dilution price protection upon the issuance of equity or equity-linked securities at an effective common stock purchase price of less than the conversion price then in effect, subject to adjustment as provided in the certificate of designation. In accordance with the anti-dilution price protection contained in the certificate of designation for the Series C Preferred Stock, we reduced the Series C Preferred Stock conversion price to $150.00 per share in connection with the underwritten public offering that closed on March 1, 2018, to $87.50 per share in connection with the underwritten public offering that closed on April 2, 2018, to $15.00 per share in connection with the underwritten public offering that closed on July 3, 2018, then to $5.00 per share in connection with the underwritten public offering that closed on April 8, 2019.

The Series C Preferred Stock is convertible at any time at any time at the option of the holder, provided that the holder will be prohibited from converting Series C Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us.

As of September 19, 2019 there were 37,025 shares of Series C Preferred Stock outstanding.

In the event of our liquidation, dissolution, or winding up, holders of our Series C Preferred Stock will be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Series C Preferred Stock if such shares had been converted to common stock immediately prior to such event (without giving effect for such purposes to the 4.99% or 9.99% beneficial ownership limitation, as applicable) subject to the preferential rights of holders of any class or series of our capital stock specifically ranking by its terms senior to the Series C Preferred Stock as to distributions of assets upon such event, whether voluntarily or involuntarily.

Shares of Series C Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by our board of directors. However, holders of our Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock equal (on an as-if-converted-to-common-stock basis, and without giving effect for such purposes to the 4.99% or 9.99% beneficial ownership limitation, as applicable) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by our board of directors. We are not obligated to redeem or repurchase any shares of Series C Preferred Stock. Shares of Series C Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provision.

The holders of the Series C Preferred Stock have no voting rights, except as required by law. Any amendment to our certificate of incorporation, bylaws or certificate of designation that adversely affects the powers, preferences and rights of the Series C Preferred Stock requires the approval of the holders of a majority of the shares of Series C Preferred Stock then outstanding.

We have not listed, and we do not plan on making an application to list, the Series C Preferred Stock on the NYSE American, any other national securities exchange or any other nationally recognized trading system. The common stock issuable upon conversion of the Series C Preferred Stock is listed on the NYSE American under the symbol "NSPR."

Shares of Series C Preferred Stock were issued in book-entry form under a transfer agency and service agreement between Action Stock Transfer Corp., as transfer agent, and us, and are represented by one or more book-entry certificates deposited with DTC and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

The transfer agent and registrar for our Series C Preferred Stock is Action Stock Transfer Corp. The transfer agent's address is 2469 E. Fort Union Blvd., Suite 214, Salt Lake City, Utah 84121.

You should review the certificate of designation of the Series C Preferred Stock, which has been filed as an exhibit to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on March 15, 2017, and the certificate of amendment to the certificate of designation of the Series C Preferred Stock, which were filed as an exhibit to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 29, 2017, for a complete description of the terms and conditions of the Series C Preferred Stock.

Potential Common Stock Issuances to the Holders of Our Series C Preferred Stock

Pursuant to the anti-dilution provisions contained in the certification of designation for our Series C Preferred Stock, in the event that, while any of our Series C Preferred Stock is outstanding, we issue equity or equity-linked securities at an effective common stock purchase price of less than the Series C Preferred Stock conversion price then in effect, we are required, subject to certain limitations and adjustments as provided in the certificate of designation, to reduce the Series C Preferred Stock conversion price to equal the effective common stock purchase price. This reduction in the Series C Preferred Stock conversion price will result in a greater number of shares of common stock becoming issuable upon conversion of the Series C Preferred Stock for no additional consideration. In accordance with this anti-dilution price protection, because the effective purchase price per share of common stock in this offering is below the current Series C Preferred Stock conversion price of $5.00 per share of common stock, it will result in additional shares of common stock becoming issuable to the holders of our Series C Preferred Stock upon conversion of the Series C Preferred Stock. As a result of this offering, based on 37,025 shares of Series C Preferred Stock outstanding as of September 19, 2019, the conversion price for the Series C Preferred Stock will be adjusted to $1.80, and we would be required to issue 88,305 additional shares of common stock to the holders of Series C Preferred Stock upon conversion of their Series C Preferred Stock.

Delaware Anti-Takeover Law, Provisions of our Certificate of Incorporation and Bylaws

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.

UNDERWRITING

We have entered into an underwriting agreement dated September 19, 2019 with H.C. Wainwright & Co., LLC, as underwriter, with respect to the securities being offered hereby. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriter and the underwriter has agreed to purchase from us, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, 539,000 units and 2,238,777 pre-funded units.

A copy of the form of underwriting agreement has been filed as an exhibit to the registration statement of which this prospectus is a part. The units and pre-funded units we are offering are being offered by the underwriter subject to certain conditions specified in the underwriting agreement.

We have been advised by the underwriter that it proposes to offer the units and pre-funded units, as the case may be, directly to the public at the public offering prices set forth on the cover page of this prospectus. Any units and pre-funded units sold by the underwriter to securities dealers will be sold at the public offering price less a selling concession not in excess of $0.081 per unit or pre-funded unit.

The underwriting agreement provides that the underwriter's obligation to purchase the securities we are offering is subject to conditions contained in the underwriting agreement. The underwriter is obligated to purchase and pay for all of the units and/or pre-funded units offered by this prospectus, if any of these units and/or pre-funded are purchased, other than those shares and/or warrants covered by the option to purchase additional securities described below.

No action has been taken by us or the underwriter that would permit a public offering of the units or pre-funded units in any jurisdiction where action for that purpose is required. None of the securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities 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 who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of units and pre-funded units and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the units or pre-funded units in any jurisdiction where that would not be permitted or legal.

Underwriting Discounts, Commissions and Expenses

The following table shows the public offering price, underwriting discounts and commissions and proceeds, before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriter's option to purchase additional shares of common stock and/or Series E Warrants to purchase shares of common stock.

	Per Unit	Per Pre-funded Unit	Total Without Option	Total With Option
Public offering price	$ 1.800	$ 1.790	$ 4,977,611	$ 5,727,610
Underwriting discounts and commissions	$ 0.126	$ 0.126	$ 350,000	$ 402,500
Proceeds before expenses	$ 1.674	$ 1.664	$ 4,627,611	$ 5,325,110

We have also agreed to pay to the underwriter a management fee equal to 1.0% of the aggregate gross proceeds raised in this offering. We estimate the total expenses payable by us for this offering, excluding the underwriting discounts and commissions, to be approximately $335,111, which includes (i) $10,000 clearing agent settlement and financing cost payable to the underwriter, (ii) $35,000 non-accountable expense allowance payable to the underwriter, (iii) reimbursement of the accountable expenses of the underwriter equal to $100,000, including the legal fees of the underwriter being paid by us and the costs and expenses of the "road show", and (iv) other estimated expenses of approximately $200,111 which include legal, accounting, printing costs and various fees associated with the registration and listing of our securities sold in this offering.

In addition, we have agreed to issue to the underwriter warrants to purchase up to 194,444 shares of common stock, or, if the underwriter elects to exercise its option to purchase additional shares in full, then 223,611 shares of common stock, which represents 7% of the aggregate number of shares of common stock sold in this offering (including the number of shares of common stock issuable upon exercise of the pre-funded warrants), at an exercise price of $2.25 per share (representing 125% of the public offering price for a unit to be sold in this offering). The underwriter warrants will be exercisable immediately and for five years from the effective date of the registration statement. 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.

Option to Purchase Additional Securities

We have granted to the underwriter an option, exercisable not later than 30 days after the date of this prospectus, to purchase up to additional 416,666 shares of common stock at a purchase price of $1.79 per share and/or 416,666 additional Series E Warrants to purchase 416,666 shares of common stock at a purchase price of $0.01 per Series E Warrant, less the underwriting discounts and commissions of $0.1253 per share and $0.0007 per Series E Warrant. If any additional shares of common stock and/or Series E Warrants are purchased pursuant to such option, the underwriter will offer these securities on the same terms as those on which the securities are being offered hereby.

Right of First Refusal

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.

Tail Financing Payments

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 term of the underwriter's engagement, provides us with capital in any public or private offering or other financing or capital raising transaction, subject to certain conditions and exceptions, during the 12 month period following expiration or termination of our engagement of the underwriter.

Lock-up Agreements

Our officers and directors have agreed with the underwriter to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any of our shares of common stock or any securities convertible into, or exercisable or exchangeable for, shares of common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our shares of common stock for 90 days following the closing of this offering, although we will be permitted to issue stock options or stock awards to directors, officers, employees and consultants under our existing plans. The underwriter may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

Stabilization, Short Positions and Penalty Bids

The underwriter may engage in syndicate covering transactions, stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our shares of common stock:

- Syndicate covering transactions involve purchases of securities 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.

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.

- 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 syndicate covering transactions, stabilizing transactions and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result, the price of our shares of common stock may be higher than the price that might otherwise exist in the open market. 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 shares of common stock. These transactions may be effected on the NYSE American, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter also may engage in passive market making transactions in our shares of common stock in accordance with Regulation M during a period before the commencement of offers or sales of our shares of 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.

Neither we nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriter make any representation that the underwriter will engage in these transactions or that any transactions, once commenced, will not be discontinued without notice.

Indemnification

We have agreed to indemnify the underwriter against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the underwriter may be required to make for these liabilities.

Determination of Offering Price

The actual offering price of the securities we are offering will be negotiated between us and the underwriter based on the trading of our shares of common stock prior to the offering, among other things, and may be at a discount to the current market price.

Electronic Offer, Sale and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by the underwriter, if any, participating in this offering and the underwriter may distribute prospectuses electronically. 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 form a part, has not been approved or endorsed by us or the underwriter, and should not be relied upon by investors.

Other Relationships

The underwriter and its respective affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. The underwriter acted as our underwriter in connection with public offerings in March 2018, April 2018, July 2018 and April 2019 for which it received compensation.

Listing

Our shares are listed on the NYSE American under the symbol “NSPR.” We do not plan to list the Series E Warrants or pre-funded warrants on the NYSE American or any other securities exchange or trading market.

NOTICE TO INVESTORS

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the securities offered hereby is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

LEGAL MATTERS

The validity of the securities offered by this prospectus will be 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 securities offered hereby.

EXPERTS

The financial statements incorporated in this prospectus 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 Securities and Exchange Commission. Such reports, proxy statements and other information, including the Registration Statement, and exhibits and schedules thereto, are available to the public through the Securities and Exchange Commission's website at http://www.sec.gov.

We make available free of charge on or through our website at *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 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*.

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.

This prospectus incorporates by reference the documents set forth below that have been previously filed with the Securities and Exchange Commission:

- 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;

- The portions of our definitive proxy statement on Schedule 14A that are deemed "filed" with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, filed on February 19, 2019;

- Our Quarterly Reports on Form 10-Q for the fiscal quarter ended March 31, 2019, filed with the Securities and Exchange Commission on May 13, 2019, and for the fiscal quarter ended June 30, 2019, filed with the Securities and Exchange Commission on August 5, 2019;

- Our Current Reports on Form 8-K (other than portions thereof furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits accompanying such reports that relate to such items) filed with the Securities and Exchange Commission on January 11, 2019, January 14, 2019, January 22, 2019, January 24, 2019, February 6, 2019, February 7, 2019, March 21, 2019, March 28, 2019, April 4, 2019, April 8, 2019, May 15, 2019, August 9, 2019, and September 9, 2019.

We also incorporate by reference all 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.

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*. 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.

539,000 Units (each Unit contains One Share of Common Stock and One Series E Warrant to purchase One Share of Common Stock)

2,238,777 Pre-funded Units (each Pre-funded Unit contains One Pre-funded Warrant to Purchase One Share of Common Stock and One Series E Warrant to purchase One Share of Common Stock)

Common Stock Underlying the Pre-funded Warrants and

Common Stock Underlying the Series E Warrants

H.C. Wainwright & Co.

September 19, 2019