InspireMD, Inc.
Form S-1/A
February 17, 2017

As filed with the Securities and Exchange Commission on February 17 , 2017

Registration No. 333- 215682

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

AMENDMENT NO.1

TO

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

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

4 Menorat Hamaor St.

Tel Aviv, Israel 6744832
(888) 776-6804

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

James Barry, Ph.D.
President and Chief Executive Officer
InspireMD, Inc.
4 Menorat Hamaor St.

Tel Aviv, Israel 6744832
(888) 776-6804

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

Rick A. Werner, Esq.
Haynes and Boone, LLP
30 Rockefeller Plaza, 26th Floor
New York, New York 10112
Tel. (212) 659-7300
Fax (212) 884-8234

Ralph V. De Martino
Cavas S. Pavri
Schiff Hardin LLP
901 K Street NW Suite 700
Washington, D.C. 20001
Phone (202) 778-6400
Fax: (202) 778-6460

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer [ ]	Accelerated filer [ ]
Non-accelerated filer [ ] (Do not check if a smaller reporting company)	Smaller reporting company [X]

Title of Each Class of Securities to be Registered [(1)]	**Proposed Maximum Aggregate Offering Price**	**Amount of Registration Fee(2)**
Units consisting of:	$ 7,500,000.00	$ 869.25
(i) Series C Convertible Preferred Stock, $0.0001 par value per share	—	(3)
(ii) Warrants to purchase shares of common stock, $0.0001 par value per share (4)	—	(5)
Common Stock, $0.0001 par value per share, issuable upon conversion of the Series C Convertible Preferred Stock	—	(3)
Common Stock, $0.0001 par value per share, issuable upon exercise of warrants included in the units (6)	$ 16,875,000.00	$ 1,955.81
Placement Agent’s Warrant		
Warrants to purchase shares of Common Stock included in Placement Agent Warrant [(7)]	—	(5)
Common stock, par value $0.0001 per share, issuable upon exercise of warrants included in Placement Agent Warrant [(7)]	$ 468,750.00	$ 54.33
Total	$ 24,843,750.00	$ 2,879.39(8)

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended , this registration statement also covers any additional shares of common stock that may be offered or issued in connection with any stock split, stock dividend or similar transaction.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. The fee table assumes offering price of $10.00 per unit.

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

(4) The warrants included in the units will consist of two separate classes of warrants, with each unit allocated an equal number of warrants of each such class, as described in this registration statement.

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

(6) Each unit will include (i) a five-year warrant to purchase 4 shares of common stock at an assumed initial exercise price of $3.13 per share, and (ii) a six-month warrant to purchase 4 shares of common stock at an assumed initial exercise price of $2.50 per share, based on an assumed offering price of $10.00 per unit and an assumed Series C Convertible Preferred Stock conversion price of $2. 50 per share of common stock.

(7) Represents a placement agent warrant to purchase up to 5% of the number of shares of common stock underlying the securities sold in this offering (including the number of shares of common stock issuable upon conversion of the Series C Convertible Preferred Stock but excluding any shares of common stock underlying the warrants issued in this offering) at an exercise price equal to 125% of the conversion price of the Series C Convertible Preferred Stock.

(8) $2,868.53 of which has been previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED FEBRUARY 17 , 2017

InspireMD, Inc.

750,000 Units

Each Consisting of 1 Share of Series C Convertible Preferred Stock

One Warrant to Purchase 4 Shares of Common Stock

and

One Short-Term Warrant to Purchase 4 Shares of Common Stock

3,000,000 Shares of Common Stock Underlying the Series C Convertible Preferred Stock

3,000,000 Shares of Common Stock Underlying the Warrants

3,000,000 Shares of Common Stock Underlying the Short-Term Warrants

We are offering up to 750,000 units, with each unit consisting of (i) one share of our Series C Convertible Preferred Stock (the “Preferred Stock ”), (ii) a five-year warrant (the “Series B Warrant ”) to purchase 4 shares of our common stock, and (iii) a six-month warrant (the “Series C Warrant” and together with the Series B Warrants, the “Warrants”) to purchase 4 shares of our common stock (and the shares of common stock issuable from time to time upon conversion of the Preferred Stock and the shares of common stock upon exercise of the Warrants). We currently estimate that the initial exercise price for the Series B Warrants will be equal to 125% of the conversion price of the Preferred Stock and that the initial exercise price for the Series C Warrants will be equal to the conversion price of the Preferred Stock.

Units will not be issued or certificated . The shares of Preferred Stock and the Warrants will be issued separately but can only be purchased together in this offering. Each Warrant will be immediately exercisable.

Our common stock is traded on the NYSE MKT under the symbol “NSPR,” and our warrants sold in our public offering that closed on July 7, 2016 (the “Series A Warrants”), are traded on the NYSE MKT under the symbol “NSPR.WS.” We do not intend to apply for listing of either the Preferred Stock or the Warrants on any securities exchange, and we do not expect that the Preferred Stock or the Warrants will be quoted on the NYSE MKT. On February 15 , 2017, the last reported sale price of our common stock and our Series A Warrants as reported on the NYSE MKT was $2.35 per share and $0.59 per warrant.

We have retained Dawson James Securities, Inc. to act as placement agent in connection with this offering and to use its “best efforts” to solicit offers to purchase the units . We have agreed to pay the placement agent a cash fee equal to 8.0% of the gross proceeds of the offering and 5.0% of the proceeds from the exercise of the Series C Warrants . There are no minimum purchase requirements. We may not sell the entire amount of the securities being offered pursuant to this prospectus. The placement agent is not purchasing or selling any securities pursuant to this offering, nor are we requiring any minimum purchase or sale of any specific number of securities. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual public offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth below. See “Plan of Distribution” beginning on page 107 of this prospectus for more information regarding these arrangements.

Investing in our Preferred Stock and Warrants (and the common stock underlying such securities) involves a high degree of risk. See "Risk Factors" beginning on page 8 of this prospectus before making a decision to purchase our securities.

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

	Per Unit	Total
Public offering price	$	$
Placement agent fees [(1)]	$	$
Proceeds, before expenses, to us	$	$

(1) In addition, we have agreed to reimburse the placement agent for certain offering-related expenses and to issue the placement agent or its designees warrants to purchase common stock. See "Plan of Distribution" for more information.

Because there is no minimum offering amount required as a condition to closing this offering, we may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus. In addition, because there is no escrow account and no minimum offering amount in this offering, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Also, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. See "Risk Factors" for more information. The offering will be terminated by March 31, 2017, and may not be extended.

Affiliates and associated persons of Dawson James Securities, Inc. may invest in this offering on the same terms and conditions as the public investors participating in this offering.

The placement agent expects to deliver the securities against payment in New York, New York on or about , 2017.

DAWSON JAMES SECURITIES, INC.

The date of this prospectus is , 2017

TABLE OF CONTENTS

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

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

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

PROSPECTUS SUMMARY

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

Unless otherwise indicated, all information in this prospectus reflects a 1-for-10 reverse stock split of our common stock that occurred on October 1, 2015, a 1-for-25 reverse stock split of our common stock that occurred on October 7, 2016, and a 1-for-25 reverse stock split of our Series A Warrants that occurred on November 7, 2016.

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 Argentina and Colombia, and have received regulatory approval to commercialize CGuard EPS in Russia. If we receive sufficient proceeds from the exercise of the Series C Warrants, we plan to develop CGuard EPS with a smaller delivery catheter (5 French gauge), which we intend to submit for CE mark approval within three calendar quarters of receiving such proceeds. We believe that CGuard EPS with a smaller delivery catheter will enable us to meet the market demand for minimally invasive devices, have a competitive advantage in penetrating the Asia Pacific market and offer our product for transradial catheterization, which, we believe, is gaining favor among interventionalists. We cannot give any assurance that we will receive sufficient (or any) proceeds from the exercise of the Series C Warrants or the timing of receipt of such proceeds, if ever. We cannot predict when or if the Series C Warrants will be

exercised. It is possible that the Series C Warrants may expire and may never be exercised.

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 and, together with our first generation MGuard stent combining MicroNet with a bare-metal stainless steel stent, unless otherwise indicated, we refer to both kinds of bare-metal stents as our MGuard coronary products. We market and sell MGuard Prime EPS for the treatment of coronary disease in the European Union. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. However, as a result of a shift in industry preferences away from bare-metal stents in favor of drug-eluting (drug-coated) stents, in 2014 we decided to curtail further development of this product in order to focus on the development of a drug-eluting stent product, MGuard DES™. Due to limited resources, though, our efforts have been limited to testing drug-eluting stents manufactured by potential partners for compatibility with MicroNet and seeking to incorporate MicroNet onto a drug-eluting stent manufactured by a potential partner.

We are also developing a neurovascular flow diverter ("NGuard"), which is an endovascular device that directs blood flow away from cerebral aneurysms in order to ultimately seal the aneurysms. Our flow diverter would utilize an open cell, highly flexible metal scaffold to which MicroNet would be attached. We have completed initial pre-clinical testing of this product in both simulated bench models and standard in vivo pre-clinical models. However, as we plan to focus our resources on the further expansion of our sales and marketing activities for CGuard EPS and MGuard Prime EPS and, provided that we have sufficient resources, the development of CGuard EPS with a smaller delivery catheter (5 French gauge) and its submission for CE mark approval, we do not intend to resume further development of NGuard until at least the third quarter of 2018.

We also intend to develop a pipeline of other products and additional applications by leveraging our MicroNet technology to new applications to improve peripheral vascular and neurovascular procedures, such as the treatment of the superficial femoral artery disease, vascular disease below the knee and neurovascular stenting to open diseased vessels in the brain.

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

1

During the first quarter of 2015, we implemented a cost reduction/focused spending plan. The plan had four components: (i) reducing headcount; (ii) limiting the focus of clinical and development expenses to only carotid and neurovascular products; (iii) limiting sales and marketing expenses to those related to the CGuard EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, rent, etc.). In addition, we decided to alter our commercial strategy by using third party distributors to drive future sales, as opposed to direct sales to hospitals and clinics, which had previously been our focus. However, we have decided to shift our commercial strategy to focus on direct sales of our products through our own internal sales initiatives as well as through distribution partners. In addition, we have begun to participate in international trade shows and industry conferences in an attempt to gain market exposure and brand recognition.

Recent Developments

On July 7, 2016, we closed a public offering of 442,424 shares of Series B Convertible Preferred Stock and Series A Warrants to purchase up to 1,769,696 shares of common stock. Each share of Series B Convertible Preferred Stock and the accompanying Series A Warrants were sold at a price of $33.00. Each share of Series B Convertible Preferred Stock is convertible into 4 shares of common stock reflecting a conversion price equal to $8.25 per share. The holders of Series B Convertible Preferred Stock will be entitled to receive cumulative dividends at the rate per share of 15% per annum of the stated value for five years, payable in cash or common stock, at our discretion. The Series A Warrants are exercisable immediately and have a term of exercise of five years from the date of issuance and have an exercise price of $5.00 per share of common stock. The Series A Warrants commenced trading on the NYSE MKT under the ticker symbol “NSPR.WS” on August 1, 2016. We received gross proceeds of approximately $14.6 million from the offering, before deducting placement agent fees and offering expenses payable by us.

Growth Strategy

Our primary business objective is to utilize our proprietary technology to become the industry standard for treatment of complex vascular and coronary disease and to provide a superior solution to the common acute problems caused by current stenting procedures, such as restenosis, embolic showers and late thrombosis. We are pursuing the following business strategies in order to achieve this objective.

Grow our presence in existing and new markets for CGuard EPS. We have fully launched CGuard EPS in most European and Latin American countries, through a combination of distributor sales organizations. We are also pursuing additional registrations and contracts with local distributors in other countries in Europe, Asia and Latin America.

Continue to leverage MicroNet technology to develop additional applications for interventional cardiologists and vascular surgeons. In addition to the applications described above, we believe that we will eventually be able to utilize our proprietary 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 NGuard, as well as future efforts with MGuard Prime EPS, MGuard DES, and other potential products that are based on our MicroNet technology.

Continue to protect and expand our portfolio of patents. Our MicroNet technology and the use of patents to protect it are critical to our success. We own numerous patents for our MicroNet technology. Twelve separate patent applications have been filed in the United States, some of which have corresponding patent applications and/or issued patents in Canada, China, Europe, Israel, India, and South Africa. We believe these patents and patent applications collectively cover all of our existing products, and may be useful for protecting our future 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 carotid and neurovascular 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;

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;