

# INSPIREMD, INC.

## **FORM 8-K** (Current report filing)

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

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**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

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Date of Report (Date of earliest event reported): September 24, 2018

**InspireMD, Inc.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction  
of incorporation)

001-35731

(Commission  
File Number)

26-2123838

(IRS Employer  
Identification No.)

321 Columbus Avenue  
Boston, MA

(Address of principal executive offices)

02116

(Zip Code)

Registrant's telephone number, including area code: (857) 305-2410

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(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On September 24, 2018, InspireMD, Inc. (the “*Company*”) and Agustin Gago, the Company’s executive vice president and chief commercial officer, entered into a General Release and Severance Agreement (the “*Separation Agreement*”), pursuant to which the parties mutually agreed that Mr. Gago’s employment shall cease for all positions, offices and authority with the Company, effective as of September 30, 2018 (the “*Separation Date*”). Mr. Gago fully and irrevocably released and discharged the Company, including all of its affiliates, parent companies, subsidiary companies, employees, owners, directors, officers, principals, agents, insurers, and attorneys from any and all claims arising or existing on, or at any time prior to, the date the Separation Agreement was signed by him, and the Company agreed to pay severance payments, in an amount equal to Mr. Gago’s base salary Mr. Gago would have earned if he had remained employed from the Separation Date through October 23, 2018, less applicable payroll deductions and tax withholdings, to be paid in equal installments in accordance with the Company’s standard payroll practices; and (ii) additional severance payments, in an amount equal to \$125,000, less applicable payroll deductions and tax withholdings, to be paid in equal installments in accordance with the Company’s standard payroll practices, commencing on the first payroll date following October 23, 2018 through March 23, 2019.

The foregoing summary of the Separation Agreement is not complete and is qualified in its entirety by reference to the full text of the Separation Agreement, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 8.01 Other Events.**

On September 24, 2018, the Company issued a press release announcing that its CGuard™ Embolic Prevention System has been granted regulatory approval by COFEPRIS (the Mexican Ministry of Health) for commercial sale in Mexico. A copy of such press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is hereby incorporated by reference herein.

On September 27, 2018, the Company issued a press release announcing that preliminary cumulative three-year follow-up safety, efficacy and stroke prevention durability data from the PARADIGM-Extend trial of CGuard™ EPS was presented at the Cardiovascular Research Foundation’s Transcatheter Cardiovascular Therapeutics (TCT) 2018 conference, which was held September 21-25 in San Diego. A copy of such press release is attached to this Current Report on Form 8-K as Exhibit 99.2 and is hereby incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
10.1	<a href="#">General Release and Severance Agreement, dated September 24, 2018, by and between InspireMD, Inc. and Agustin Gago</a>
99.1	<a href="#">Press release dated September 24, 2018</a>
99.2	<a href="#">Press release dated September 27, 2018</a>

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**InspireMD, Inc.**

Date: September 28, 2018

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

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## GENERAL RELEASE AND SEVERANCE AGREEMENT

This General Release and Severance Agreement (the “**Agreement**”), dated as of September 16, 2018, is made and entered into by and between Agustin Gago (“**Executive**”) and InspireMD, Inc. (the “**Company**”).

For good and valuable consideration, receipt of which is hereby acknowledged, in order to effect a mutually satisfactory and amicable separation of employment from the Company and to resolve and settle finally, fully and completely all matters and disputes that now or may exist between them, as set forth below, Executive and the Company agree as follows:

**1. Separation from Employment** . Effective September 30, 2018 (the “**Separation Date**”), Executive’s employment with the Company shall cease based upon the mutual agreement of the parties hereto and he shall, as of the Separation Date, relinquish all positions, offices, and authority with the Company. Executive acknowledges and agrees, except for the payments described hereunder, Executive has no rights to any other wages and other compensation or remuneration of any kind due or owed from the Company, including, but not limited, to all wages, reimbursements, bonuses (including for 2017 and 2018), advances, vacation pay, severance pay, vested or unvested equity or stock options, awards, and any other incentive-based compensation or benefits to which Executive was or may become entitled or eligible. Notwithstanding the foregoing, Executive shall (i) be reimbursed for any expenses reasonably incurred by Executive at any time prior to the Separation Date in accordance with applicable Company reimbursement policies and procedures, submitted for reimbursement on or before October 5, 2018; and (ii) receive payment for fifteen (15) accrued but unused vacation days, less applicable payroll deductions and tax withholdings, to be paid within the time period required by applicable law.

**2. Employment Agreement** . As of the Separation Date, the employment agreement between the parties dated October 18, 2016 (the “**Employment Agreement**”) shall terminate forever and no party shall have any further obligation or liability thereunder, except that Executive acknowledges and agrees that **ARTICLE IV RESTRICTIVE COVENANTS** of the Employment Agreement, and all sections and provisions thereunder, shall remain in full force and effect in accordance with their terms. With respect to the “Non-Disparagement” provisions set forth therein, the Company agrees to modify such provisions to also provide that following the Separation Date, the members of the Company’s Board of Directors and Executive Committee shall not in any way, directly or indirectly, disparage, libel or defame Executive.

**3. Consideration** . In consideration of this Agreement and the release herein becoming effective, and his compliance with his obligations hereunder, the Company shall provide Executive with (i) severance payments, in an amount equal to his base salary he would have earned if he had remained employed from the Separation Date through October 23, 2018, less applicable payroll deductions and tax withholdings, to be paid in equal installments in accordance with the Company’s standard payroll practices; and (ii) additional severance payments, in an amount equal to \$125,000, less applicable payroll deductions and tax withholdings, to be paid in equal installments in accordance with the Company’s standard payroll practices, commencing on the first payroll date following October 23, 2018 through March 23, 2019.

**4. Transition Services** . Through the Separation Date, Executive shall only perform such services as the Chief Executive Officer may reasonably request, including, without limitation, those relating to the transition of his positions, offices, authority, duties, or responsibilities with the Company. Employee also agrees to assist with the execution of all documents and all other instruments which the Chief Executive Officer shall deem necessary to accomplish any such transition.

**5. Release of Claims** . For and in consideration of the right to receive the consideration described in Section 3 of this Agreement, Executive fully and irrevocably releases and discharges the Company, including all of its affiliates, parent companies, subsidiary companies, employees, owners, directors, officers, principals, agents, insurers, and attorneys from any and all claims arising or existing on, or at any time prior to, the date this Agreement is signed by Executive. Such released claims include, without limitation, claims relating to or arising out of: (i) Executive's hiring, compensation, benefits and employment with the Company, (ii) Executive's separation from employment with the Company, and (iii) all claims known or unknown or which could or have been asserted by Executive against the Company, at law or in equity, or sounding in contract (express or implied) or tort, including claims arising under any federal, state, or local laws of any jurisdiction that prohibit age, sex, race, national origin, color, disability, religion, veteran, military status, pregnancy, sexual orientation, or any other form of discrimination, harassment, or retaliation, including, without limitation, age discrimination claims under the Age Discrimination in Employment Act; the Americans with Disabilities Act; claims under Title VII of the Civil Rights Act of 1964; the Rehabilitation Act; the Equal Pay Act; the Family and Medical Leave Act, 42 U.S.C. §1981; the Civil Rights Act of 1991; the Civil Rights Act of 1866 and/or 1871; the Sarbanes Oxley Act; the Executive Polygraph Protection Act; the Uniform Services and Employment and Re-Employment Rights Act; the Worker Adjustment Retraining Notification Act; the National Labor Relations Act and the Labor Management Relations Act; the New York State and City Human Rights Laws and any other similar or equivalent state laws; and any other federal, state, local, municipal or common law whistleblower protection claim, discrimination or anti-retaliation statute or ordinance; claims arising under the Executive Retirement Income Security Act; claims arising under the Fair Labor Standards Act; or any other statutory, contractual or common law claims. Executive does not release Executive's right to enforce the terms of this Agreement or release his rights to defense and indemnity or to liability insurance coverage.

**6. Review and Consultation.** Executive acknowledges that: (a) this Agreement is written in terms and sets forth conditions in a manner which he understands; (b) he has carefully read and understands all of the terms and conditions of this Agreement; (c) he agrees with the terms and conditions of this Agreement; and (d) he enters into this Agreement knowingly and voluntarily. Executive acknowledges that he does not waive rights or claims that may arise after the date this Agreement is executed, that he has been given twenty-one (21) days from receipt of this Agreement in which to consider whether he wanted to sign it, that any modifications, material or otherwise made to this Agreement do not restart or affect in any manner the original twenty-one (21) day consideration period, and that the Company advises Executive to consult with an attorney before he signs this Agreement. The Company agrees, and Executive represents that he understands, that he may revoke his acceptance of this Agreement at any time for seven (7) days following his execution of the Agreement and must provide notice of such revocation by giving written notice to the Company. If not revoked by written notice received on or before the eighth (8<sup>th</sup>) day following the date of his execution of the Agreement, this Agreement shall be deemed to have become enforceable and on such eighth (8<sup>th</sup>) day.

**7. Confidentiality** . Executive agrees that he will keep both the fact of this Agreement and the terms of this Agreement confidential, and will not disclose the fact of this Agreement or the terms of this Agreement to anyone other than the Executive's spouse/registered domestic partner, attorney or accountant/tax advisor, unless otherwise required to under applicable law or regulation after providing reasonable notice in writing to the Company and a reasonable opportunity to challenge any such disclosure.

**8. Governing Law/Venue** . The parties agree that the Agreement shall be governed by and construed under the laws of the State of New York. In the event of any dispute regarding this Agreement or Executive's employment, the parties hereby irrevocably agree to submit to the federal and state courts situated in New York, New York, and Executive agrees that he shall not challenge personal or subject matter jurisdiction in such courts.

**9. Voluntary**. This Agreement is executed voluntarily and without any duress or undue influence on the part or behalf of the parties hereto. The parties acknowledge that they have had ample opportunity to have this Agreement reviewed by the counsel of their choice.

**10. Acknowledgment** . Executive acknowledges and agrees that the severance payments and other consideration provided herein are consideration to which Executive is not otherwise entitled except pursuant to the terms of this Agreement, and are being provided in exchange for Executive's compliance with his obligations set forth hereunder.

**11. No Admission of Liability** . This Agreement shall not in any way be construed as an admission by the Company or Executive of any acts of wrongdoing or violation of any statute, law or legal right.

**12. Successors and Assigns** . This Agreement is binding upon, and shall inure to the benefit of the parties themselves, as well as their respective representatives, successors, permitted assigns, heirs and estates.

**13. Sole Agreement and Severability** . Except as set forth herein, this Agreement is the sole, entire and complete agreement of the parties relating in any way to the subject matter hereof. No statements, promises or representations have been made by any party to any other party, or relied upon, and no consideration has been offered, promised, expected or held out other than as expressly set forth herein, provided only that the release of claims in any prior agreement or release shall remain in full force and effect. The covenants contained in this Agreement are intended by the parties hereto as separate and divisible provisions, and in the event that any or all of the covenants expressed herein shall be determined by a court of competent jurisdiction to be invalid or unenforceable, the remaining parts, terms or provisions of this Agreement shall not be affected and such provisions shall remain in full force and effect.

SIGNATURE PAGE FOLLOWS



PLEASE READ CAREFULLY. THIS GENERAL RELEASE AND SEVERANCE AGREEMENT INCLUDES A RELEASE OF ANY AND ALL CLAIMS, KNOWN OR UNKNOWN, AGAINST INSPIREMD, INC.

INSPIREMD, INC.

AGUSTIN GAGO

By: /s/ James Barry

/s/ Agustin Gago

Title: President & CEO

Date: 9/16/2018

Date: 9/24/2018





## **InspireMD Announces Regulatory Approval of CGuard™ Embolic Prevention System in Mexico**

*Commercial Launch to Occur Immediately*

**Tel Aviv, Israel— September 24, 2018** – InspireMD, Inc. (NYSE American: NSPR), developer of the CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by the treatment of carotid artery disease, today announced that its novel CGuard™ Embolic Prevention System (EPS) has been granted regulatory approval by COFEPRIS (the Mexican Ministry of Health) for commercial sale in Mexico.

“The expansion of our commercial footprint into new key geographies is a fundamental component of our growth strategy,” said James Barry, PhD, Chief Executive Officer of InspireMD. “We are pleased to have received regulatory approval for the commercial sale of CGuard EPS in Mexico, and very grateful for the support provided by our distribution partner, LevBeth Medical, throughout this rigorous approval process.”

Mr. Mauro Levinton, Managing Director of LevBeth Medical S.A. de C.V, noted, “We have been eagerly following the clinical data being generated on CGuard™ as it continues to demonstrate its superiority over conventional stents, and we look forward to launching this innovative product and technology and making it available to patients in Mexico who suffer from carotid artery disease.”

### **About InspireMD, Inc.**

InspireMD seeks to utilize its proprietary MicroNet<sup>®</sup> technology to make its products the industry standard for treatment of carotid arter disease by providing outstanding acute results and durable stroke free long-term outcomes.

InspireMD’s common stock is quoted on the NYSE American under the ticker symbol NSPR and certain warrants are quoted on the NYSE American under the ticker symbol NSPR.WS.

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## Forward-looking Statements

This press release contains “forward-looking statements.” Such statements may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “potential” or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company’s control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) market acceptance of our existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of our products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xiii) 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. More detailed information about the Company and the risk factors that may affect the realization of forward looking statements is set forth in the Company’s filings with the Securities and Exchange Commission (SEC), including the Company’s Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC’s web site at <http://www.sec.gov>. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

## Investor Contacts:

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Chief Financial Officer  
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888-776-6804  
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Jeremy Feffer  
LifeSci Advisors, LLC  
212-915-2568  
[jeremy@lifesciadvisors.com](mailto:jeremy@lifesciadvisors.com)

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**InspireMD Announces Presentation of Preliminary Cumulative Three-Year CGuard™ EPS Safety and Efficacy Data at the Transcatheter Cardiovascular Therapeutics 2018 Conference**

*Preliminary Three-Year Data Continue to Show Unprecedented Safety, Efficacy and Durability of Stroke Prevention in Treating Carotid Artery Stenosis*

**Tel Aviv, Israel— September 27, 2018** – InspireMD, Inc. (NYSE American: NSPR), developer of the CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by the treatment of carotid artery disease, today announced that preliminary cumulative three-year follow-up safety, efficacy and stroke prevention durability data from the PARADIGM-Extend trial of CGuard™ EPS was presented at the Cardiovascular Research Foundation’s Transcatheter Cardiovascular Therapeutics (TCT) 2018 conference, which was held September 21-25 in San Diego.

Overall cumulative data showed no stroke or stroke-related deaths between 24 and 36 months and the absence of any device related issues in the first 93 of the 251 patients in the PARADIGM-Extend cohort.

PARADIGM-Extend is the continuation of PARADIGM, an investigator-led clinical study evaluating the use of CGuard™ EPS in patients with symptomatic or asymptomatic carotid artery stenosis (CAD) with increased stroke risk.

“These preliminary three-year follow-up data continue to show very compelling safety, stroke prevention efficacy and long-term durability of CGuard™ EPS in an all-comer symptomatic and asymptomatic carotid artery stenosis patient population with various stages of disease progression,” said Prof. Piotr Musiałek, MD, Department of Cardiac and Vascular Diseases, John Paul II Hospital, Kraków, Poland, and lead investigator in the PARADIGM-Extend trial. “The risk of stroke and other serious complications post-procedure remains a significant consideration in the treatment of CAS, and these results reflect the sustained, long term potential of CGuard™ EPS to significantly improve patient outcomes and evolve into the new standard of care.”

“We are grateful to Prof. Musiałek for his continued interest in CGuard™ EPS for treating all his patients with carotid artery disease, and we are pleased that the data from this investigator-led study continues to demonstrate strong safety and efficacy up to 36 months post-procedure,” said James Barry, PhD, Chief Executive Officer of InspireMD. “With this latest presentation, we are compiling a significant body of evidence suggesting that treatment with CGuard™ EPS could result in sustained, long term normal vessel healing with no device-related issues. We look forward to the presentation of additional three-year data at the 45th Annual Symposium on Vascular and Endovascular Issues, Techniques, Horizons (VEITHsymposium) in New York in November.”

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The poster, entitled “PARADIGM-Extend Prospective Academic Trial of the CGuard™ MicroNET-Covered Embolic Prevention Stent in All-comer Symptomatic and Increased-Stroke-Risk Asymptomatic Carotid Stenosis: Cumulative 3-Year Evidence for Safety, Efficacy and Stroke Prevention Durability,” was recognized by TCT as among the “Best of Moderated Endovascular Intervention and Structural Heart Disease” poster presentations at this year’s conference.

InspireMD previously reported two-year PARADIGM-Extend follow up data on 251 patients in May at the EuroPCR 2018.

### **About the TCT Conference**

Transcatheter Cardiovascular Therapeutics (TCT) is the world’s largest and most important educational meeting specializing in interventional cardiovascular medicine. For 30 years, TCT has been the center of cutting-edge educational content, showcasing the latest advances in current therapies and clinical research.

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### **Investor Contacts:**

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