INSPIREMD, INC.

FORM 8-K
(Current report filing)

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

FORM 8-K

CURRENT REPORT

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

Date of report (Date of earliest event reported): November 26, 2019

InspireMD, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-35731**	**26-2123838**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4 Menorat Hamaor St. **Tel Aviv, Israel** (Address of principal executive offices)	**6744832** (Zip Code)

(888) 776-6804
(Registrant's telephone number, including area code)

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of exchange on which registered**
Common Stock, par value $0.0001 per share	NSPR	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Item 8.01 Other Events.

On November 26, 2019, InspireMD, Inc. (the "Company") issued a press release reporting on updated registry study data presented at the 2019 VEITH Symposium, which was held November 19-23 in New York City. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 26, 2019

SIGNATURES

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

InspireMD Inc.

Date: November 26, 2019

By: */s/ Craig Shore*
Name: Craig Shore
Title: Chief Financial Officer

Exhibit 99.1

InspireMD Reports Updated Positive CGuard™ EPS Data Presented at VEITH 2019

CGuard™ EPS clinical data featured as a prominent discussion point in multiple key presentations

Data from investigator-initiated multicenter, 729-patient IRONGUARD 2 study suggests that the use of CGuard™ EPS in routine clinical practice is associated with no major periprocedural, 30-day or one-year neurological complications

Tel Aviv, Israel — November 26, 2019 – InspireMD, Inc. (NYSE American: NSPR), the developer of the CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by carotid artery disease, today reported on updated registry study data presented at the 2019 VEITH Symposium, which was held November 19-23 in New York City.

"The annual VEITH symposium is among the most prestigious gatherings of vascular surgeons, cardiologists, cardiac surgeons and vascular medicine specialists. We are pleased to once again see that the data presented at the symposium further demonstrates the clinical advantages of CGuard™ EPS," said James Barry, Ph.D., chief executive officer. "The data from long term investigator-initiated multi-center studies presented at VEITH continue to suggest that treatment of carotid artery stenosis with CGuard™ EPS results in lower rates of stroke and restenosis than other treatments presented, including first generation carotid stents, novel double carotid layer stents, and surgical or hybrid techniques. In particular, we were pleased to see the data presented from a greater than 700 patient, real-world, 20 center clinical study conducted by physicians of three major specialties including vascular surgeons, interventional cardiologist and interventional radiologists. This was complimented by a study that showed equally impressive results at 30 days and long-term follow-up out to four years.

"These data are driving a growing consensus among vascular specialists that CGuard™ EPS may be the safest treatment available today for the treatment of carotid artery disease. We continue to believe that CGuard™ EPS can redefine the treatment paradigm for patients with carotid artery disease, and we continue to work diligently to drive our growth plan forward and expand the availability of this novel technology," concluded Dr. Barry.

Summary of the presentations are as follows:

Title: **Preliminary Results from a Prospective Real World Multicenter Clinical Practice of Carotid Artery Stenting Using the CGuard Embolic Prevention System: The IRONGUARD 2 Study**

Presenter: Dr. Pasqualino Sirignano, Assistant Professor of Vascular Surgery, Department of Surgery "Paride Stefanini", Vascular and Endovascular Surgery Unit, Policlinico Umberto, Sapienza University of Rome

Highlights:

- Procedural success was achieved in 100% of patients
- At 24 hours post-procedure, the complication rate was **0.73%** (two minor strokes, six TIAs and one myocardial infarction)
- Data from 529 patients at one-month follow-up showed a stroke complication rate of **0.54%** (one minor stroke and one hemorrhagic). The accumulated neurologic event rate at 30 days was **1.63%**
- Data from 253 patients at one-year follow-up showed no further neurologic events

Conclusion: Data from this study suggests that the use of CGuard™ EPS in routine clinical practice is associated with no major periprocedural, 30-day or one-year neurological complications.

Title: **Update on the C-Guard MicroNet Mesh Covered Stent for CAS: Longer Term Results: Advantages and Are There Late Downsides Like ISR or Late Thrombosis**

Presenter: Dr. Piotr Musialek, Associate Professor of Cardiovascular Medicine, Jagiellonian University Department of Cardiac & Vascular Diseases, Krakow, Poland

Highlights:

- The PARADIGM-Extend study enrolled 402 patients (436 arteries), all of whom were treated using CGuard™ EPS.
- Peri-procedural outcome included one minor stroke and one type 2 myocardial infarction, yielding a neurological event rate of **0.5%**. There were no deaths or major strokes
- At 30 days follow-up, the neurological event rate was **0.5%**, including one hemorrhagic transformation of prior ischemic cerebral infarct leading to death and one bleeding-related death
- The 30-day accumulated neurological event rate was **1.0%** (4/402)
- There were no reported post procedural ischemic strokes
- Patient follow-up data at 12, 24, 36 and 48 months suggest that CGuard™ EPS continues to maintain a favorable safety profile

CONCLUSION: Long-term patient follow-up out to 48 months show that CGuard™ EPS maintains a long-term clinical benefit.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet® technology to make its products the industry standard for carotid stenting 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 and NSPR.WSB.

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.

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