INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 05/17/17 for the Period Ending 05/17/17

Telephone	(888) 776-6804
CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

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): May 17, 2017

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	6744832
(Address of principal executive offices)	(Zip Code)

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

(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))

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 May 17, 2017, InspireMD, Inc. announced the publication of the investigator initiated IRON-GUARD Italian clinical registry in the peer reviewed journal EuroIntervention, which appeared in the May 9th issue. 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 Number	Description
99.1	Press release dated May 17, 2017

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: May 17, 2017

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

InspireMD Announces Publication of the IRON-GUARD Registry in EuroIntervention

Zero incidence of major adverse cardiovascular events including no major strokes

BOSTON, MA—May 17, 2017 - InspireMD, Inc. (NYSE MKT:NSPR) (NYSE MKT:NSPR.WS) ("InspireMD" or the "Company"), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced the publication of the Investigator Initiated IRON-GUARD Italian clinical registry in the peer reviewed journal EuroIntervention, which appeared in the May 9th issue. IRON-GUARD was an independent, multicentre, multi-disciplinary clinical study treating patients with carotid artery disease using the CGuard ™ EPS (embolic prevention system) in 12 Italian centers.

The IRON-GUARD registry enrolled 200 patients, and showed results of 100% technical success placing the device, and zero incidence of major adverse cardiovascular events (MACE), comprised of death, major stroke or myocardial infarction, in all patients at 30 days. Five (2.5%) minor strokes and two transient ischemic attacks (1%) were observed, which were resolved by 30 days.

Study authors included Professor Carlo Setacci, MD, Francesco Spezialie, MD; Laura Capoccia, MD; Pasqualino Sirignano, MD; Wassim Mansour, MD: Chiara Pranteda, MD; and Renato Casana, MD.

Dr. Francesco Spezialie, stated, "In our multi-center, multi-specialty experience, use of the CGuard EPS in routine clinical practice was associated with no major peri-procedural neurologic complications and a total elimination of post-procedural neurologic complications after 30 days. The CGuard EPS has shown itself to be a promising treatment for carotid lesions."

James Barry, PhD, Chief Executive Officer of InspireMD, commented, "We were pleased to see the results of the IRON-GUARD registry accepted and published in EuroIntervention. These results further validate the positive clinical outcomes of other trials and registries utilizing CGuard ™ EPS and the data is quite consistent with those other clinical trials. To our knowledge, this now appears to be the largest registry utilizing CGuard. Following on from the very successful Paradigm 101 study, IRON-GUARD is a further high quality independent registry which continues to give us confidence in CGuard becoming the standard-of-care for treatment of carotid artery disease due to the significant safety advantages of our device."

EuroIntervention is a monthly peer-reviewed journal of interventional cardiovascular medicine that has become one of the benchmarks in its field. EuroIntervention is the official journal of EuroPCR and the European Association of Percutaneous Cardiovascular Interventions (EAPCI). The Journal is endorsed by the European Society of Cardiology (ESC) and has a distinguished European and International editorial board led by Prof Patrick W. Serruys from the Erasmus MC, Rotterdam.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet™ technology to make its products the industry standard for embolic protection and to provide a superior solution to the key clinical issues of current stenting in patients with a high risk of distal embolization, no reflow and major adverse cardiac events.

InspireMD intends to pursue applications of this MicroNet technology in coronary, carotid (CGuard™), neurovascular, and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR and certain warrants are quoted on the NYSE MKT under the ticker symbol NSPR.WS.

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:

InspireMD, Inc.
Craig Shore
Chief Financial Officer
Phone: 1-888-776-6804 FREE
Email: craigs@inspiremd.com

Crescendo Communications, LLC
David Waldman
Phone: (212) 671-1021
Email: NSPR@crescendo-ir.com