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): June 7, 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 June 7, 2017, InspireMD, Inc. announced the publication of an independent clinical study entitled, "Long term Outcomes of MGuard™ Stent Deployment in Saphenous Vein Grafts and Native Coronary Arteries: A Single Center Experience," in the Israel Medical Association Journal. 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 June 7, 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: June 7, 2017

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Announces the Publication of an Investigator Initiated Clinical Registry Reaffirming MGuard ^{TM} Prime as a Highly Effective Tool to Prevent Heart Damage in Coronary Artery Blockages with High Thrombotic Content

Study Entitled "Long term Outcomes of MGuard™ Stent Deployment in Saphenous Vein Grafts and Native Coronary Arteries: A Single Center Experience"

Tel Aviv, Israel—June 7, 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 an independent clinical study entitled, "Long term Outcomes of MGuard™ Stent Deployment in Saphenous Vein Grafts and Native Coronary Arteries: A Single Center Experience," in the Israel Medical Association Journal.

The study was published by the Department of Cardiology, Rabin Medical Center, affiliated with the Sacker Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel. The study followed 163 consecutive patients who underwent MGuard™ stent deployment during the period 2009 to 2014. The MGuard™ stent was used in 67% of patients who underwent Saphenous Vein Grafts (SVG) procedure while 33% were treated for native coronary artery disease, the majority during ST-Elevation Myocardial Infarction (STEMI) in the latter group.

One of the lead authors, Dr. Ran Kornowski, commented: "Our study is one of the largest and longest running analysis of MGuard™ charting the outcomes of these patients for up to one year. We have found MGuard™ to be a highly effective solution to prevent no-reflow syndrome. No-reflow syndrome manifests itself by the absence of blood flow in the capillary system after a blocked coronary artery has been opened and is related to heart damage that may increase post-interventional mortality rates. Revascularization rates in the study were 7% in the native vessel group and 15% in the SVG group. In the native vessel group, this rate is satisfactory where the presence of thrombus and possible no-reflow syndrome is a major concern. In the SVG group, revascularization levels were comparable to drug eluting stents (DES) stents. We have thus concluded that the MGuard ^{TM} Prime stent remains a very effective treatment option in patients with Saphenous Vein Grafts and in STEMI patients with vessels with high thrombotic content."

James Barry, PhD, Chief Executive Officer of InspireMD, commented: "This study clearly shows that MGuard™ remains an important, potentially live saving tool in the treatment paradigm of STEMI with highly thrombotic lesions and Saphenous Vein Grafts, and is consistent with previous clinical trial results using MGuard ^{TM} Prime. This is an important message on the benefits of MGuard™ in treating complex coronary artery disease and we intend to continue to re-enforce this clinical data within the clinical community in the coming months."

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 (MGuard™ Prime), 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.

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