# INSPIREMD, INC.

## FORM 8-K
(Current report filing)

Filed 12/04/12 for the Period Ending 12/04/12

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|---|---|
| Address | 321 COLUMBUS AVENUE |
| | BOSTON, MA 02116 |
| Telephone | (857) 453-6553 |
| CIK | 0001433607 |
| Symbol | NSPR |
| SIC Code | 3841 - Surgical and Medical Instruments and Apparatus |
| Industry | Medical Equipment & Supplies |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

**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): December 4, 2012

**InspireMD, Inc.**

(Exact name of registrant as specified in its charter)

| Delaware | 000-54335 | 26-2123838 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| 4 Menorat Hamaor St.<br>Tel Aviv, Israel | 67448 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: 972-3-691-7691

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

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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))

**Item 8.01 Other Events.**

On December 4, 2012, InspireMD, Inc. (the "Company") issued a press release announcing its presentation of thirty-day results of the randomized 432-patient MASTER trial of its embolic protective MGuard ™ stent at a satellite symposium on such date at the ICI, Innovations in Cardiovascular Innovation, Meeting in Tel-Aviv. 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.

Certain statements contained in the press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and involve a number of risks and uncertainties. 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 InspireMD, Inc.'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, multi-national companies, (v) product liability claims, (vi) our limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (viii) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) our reliance on single suppliers for certain product components, (xi) 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 (xii) 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, including the Company's Transition Report on Form 10-KT For the transition period from January 1, 2012 to June 30, 2012 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.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release dated December 4, 2012. |

**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: December 4, 2012

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

**EXHIBIT INDEX**

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Press release dated December 4, 2012. |

**InspireMD to Discuss MGuard ™ and the MASTER Randomized Trial Results at the ICI 2012 Meeting**

***InspireMD Will Present 30 Days Results of the MASTER Randomized Trial at a Scientific Symposium, Tuesday December 4 th at 12:30PM***

***Tel-Aviv, Israel, December 4, 2012*** -- InspireMD, Inc. (OTC BB: NSPR) ("Inspire" or the "Company"), the developer of the MGuard™ Embolic Protection Stent (EPS), will sponsor a satellite symposium on December 4th at the ICI, Innovations in Cardiovascular Innovation, Meeting at the David Intercontinental Hotel, Tel-Aviv.

InspireMD's symposium will be chaired by Dr. Gregg W. Stone, and the meeting faculty includes Drs. Martin Leon, Sigmund Silber and Chaim Lotan. The session, titled "MGuard Embolic Protection Stent (EPS) Outperforms BMS and DES in STEMI Treatment", will show the 30 days MASTER trial randomized data of MGuard in STEMI patients, as well challenging cases that give insights into the uses and benefits of the MGuard MicroNet® EPS technology.

The MASTER trial findings were presented for the first time at the Late Breaking Clinical Trials session of the 24th Annual Transcathater Cardiovascular Therapeutics (TCT) scientific meeting in Miami on October 24. The results showed the novel MGuard EPS provided a statistically and clinically significant acute advantage and, as a result, may hold the potential to lower the incidence of adverse sequela and prolong survival of heart attack victims.

The MASTER trial randomized 432-patient data was published in the November 6, 2012 print edition of the peer-reviewed *Journal of American College of Cardiology*, Vol. 60, No. 19.

The online version of the paper, authored by Gregg W. Stone, MD and others, appeared Wednesday (October 24) at: http://content.onlinejacc.org/article.aspx?articleid=1377008 , coinciding with Dr. Stone's presentation of the findings at TCT.

**About Stenting and MGuard EPS**
Standard stents weren't engineered for heart attack patients. They were designed for treating stable angina patients whose occlusion is different from that of an occlusion in a heart attack patient.

In acute heart attack patients, the plaque or thrombus is unstable and often breaks up as the stent is implanted causing downstream blockages (some of which can be fatal) in a significant portion of heart attack patients.

The MGuard EPS is integrated with a precisely engineered micro net mesh that prevents the unstable arterial plaque and thrombus (clots) that caused the heart attack blockage from breaking off.

While offering superior performance relative to standard stents in STEMI patients, the MGuard EPS requires no change in current physician practice – an important factor in promoting acceptance and general use in time-critical emergency settings.

**About InspireMD, Inc.**
InspireMD is a medical device company focusing on the development and commercialization of its proprietary stent system technology, MGuard™. InspireMD intends to pursue applications of this technology in coronary, carotid and peripheral artery procedures. InspireMD's common stock is quoted on the OTC under the ticker symbol NSPR.

**About MGuard™ Embolic Protection Coronary Stent**
MGuard™ EPS combines a coronary stent merged with an embolic protection specifically designed for acute MI patients. The embolic protection is comprised of an ultra-thin polymer micron net that is integrated with the stent. The MGuard EPS is designed to provide outstanding and lifelong embolic protection, without affecting deliverability. MGuard EPS is CE Mark approved. MGuard™ is not approved for sale in the U.S. by the U.S. Food and Drug Administration at this time.

**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, multi-national companies, (v) product liability claims, (vi) our limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (viii) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) our reliance on single suppliers for certain product components, (xi) 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 (xii) 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 Transition Report on From 10-K/T 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.

**For additional information:**
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