

INSPIREMD, INC.

FORM 8-K (Current report filing)

Filed 08/26/13 for the Period Ending 08/26/13

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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

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): August 26, 2013

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.)

800 Boylston Street, Suite 16041
Boston, MA
(Address of principal executive offices)

02199
(Zip Code)

Registrant's telephone number, including area code: (857) 453-6553

4 Menorat Hamaor St.
Tel Aviv, Israel 67448
(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))

Item 8.01 Other Events.

On August 26, 2013, InspireMD, Inc. (the "Company") issued a press release announcing that the Company (i) entered into an agreement with HealthLink Europe B.V. to provide logistical and customer support for the Company's commercial operations and (ii) consolidated its Israeli based manufacturing facilities into a single facility.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|-------------------------------------|
| 99.1 | Press release dated August 26, 2013 |

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: August 26, 2013

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

EXHIBIT INDEX

| Exhibit Number | Description |
|-----------------------|-------------------------------------|
| 99.1 | Press release dated August 26, 2013 |



InspireMD Completes First Phase of Manufacturing Upgrade and Partners with HealthLink for Global Logistics and Distribution Services

First stage of manufacturing strategy complete with consolidation of Israeli operations

Healthlink partnership advances commercial and clinical expansion strategy

BOSTON, MA – August 26, 2013 — InspireMD, Inc. (NYSE MKT: NSPR) (“InspireMD” or the “Company”), a leader in embolic protection stents, today announced it has completed the first phase of a manufacturing consolidation that the Company believes will improve its long term gross margins.

Simultaneously, the Company has signed an agreement with Healthlink Europe, a medical device support services and distribution company, to provide logistical and customer support for InspireMD’s commercial operations and clinical activities. Healthlink will provide InspireMD with customer service center capabilities for inquiries from hospitals and distributors. Healthlink will also handle all inventory controls, warehousing, shipping, and invoicing and receivables management for customers worldwide on behalf of InspireMD.

Alan Milinazzo, President and CEO of InspireMD, commented, “We have successfully completed the first stage of our manufacturing strategy through the consolidation of our Israeli manufacturing facilities. Over time, we believe that this will reduce our operating costs by streamlining our manufacturing operations.”

“As we prepare to announce the 12-month results from the MASTER trial in October, we continue to put in place the appropriate infrastructure to be able to meet the anticipated increase in demand for our lifesaving stent technology. The agreement with Healthlink Europe is intended to support both current commercial activities as well as ongoing clinical trials, and should provide us instant access to world-class customer logistics to support all of our customers through a single partner,” concluded Mr. Milinazzo.

Rick Hughes, President of HealthLink Europe, commented “For nearly 20 years Healthlink has built an impressive track record of providing superior customer service and logistics support to the medical device industry. We look forward to working with InspireMD as the Company prepares for increased demand for its MGuard™ stent technology throughout Europe.”

About Stenting and MGuard™ EPS

Standard stents were not 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 with regard to ST segment resolution, 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 seeks to utilize its proprietary MGuard technology to make its products the industry standard for embolic protection stents 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 technology in coronary, carotid and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

MGuard EPS is CE Mark approved. It is not approved for sale in the U.S. by the FDA 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, multinational 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 Form 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.



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