# INSPIREMD, INC.

## FORM 8-K
(Current report filing)

Filed 11/12/13 for the Period Ending 11/11/13

| | |
|---|---|
| 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): November 11, 2013

**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.) |

| 800 Boylston Street, 16th Floor<br>Boston, MA | 02199 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

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

(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 2.02 Results of Operations and Financial Condition.**

On November 11, 2013, InspireMD, Inc. issued a press release announcing its financial results for the fiscal quarter ended September 30, 2013. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, that is furnished pursuant to this Item 2.02 shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit Number | Description |
|---|---|
| 99.1 | Earnings release dated November 11, 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: November 12, 2013

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

**FOR IMMEDIATE RELEASE**

**InspireMD Reports Financial Results for Quarter Ended September 30, 2013**

**BOSTON, MA** – November 11, 2013 – InspireMD Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic protection stents, today announced financial results for the quarter ended September 30, 2013.

**Key Highlights of Recent Events**

- MGuard™ outperformed bare metal and drug eluting stents in all-cause mortality in STEMI patients for the 12-month follow-up data from the MASTER Trial
- Secured $10 million in venture debt financing to support product development and clinical expansion
- Initiated direct selling activities in Germany

**Upcoming Near-term Milestones**

- Expanding direct selling organization and activities in other key European countries
- Accelerating product development and clinical programs to expand the MicroNet therapeutic platform to a drug eluting stent, as well as for carotid and peripheral artery
- CGuard™ first in man carotid stent trial initiation planned for Q1 2014

"The positive mortality data from the MASTER trial 12-month follow-up is being well received by physicians since the results were announced at the TCT conference just two weeks ago. We believe this data will be an important factor in our efforts to increase adoption rates for the MGuard and for recruitment in the MASTER II trial," stated Alan Milinazzo, President and Chief Executive Officer of InspireMD. "The acute benefits reported with the MGuard in ST segment resolution, improved TIMI flow and reduced infarct size, gives us the confidence that these improved clinical results are achieved due to the embolic protection benefits of our MicroNet technology."

"Encouraged by the MASTER trial 12-month data, we believe there is significant potential for our platform technology, MicroNet, to support a broader pipeline of devices in the coronary and vascular setting. We recently put into place a financing strategy that offers us greater flexibility to accelerate these programs," concluded Mr. Milinazzo.

**Operational Overview**

On October 29, 2013, the Company announced the 12-month follow up results from the MASTER trial for its MGuard Embolic Protection Stent (EPS). The findings showed that the novel MGuard EPS provides a significant acute advantage in reducing ST segment elevation versus traditional bare metal and drug eluting stents. As a result, MGuard may hold the potential to prolong the survival of heart attack victims, as evidenced by the 12-month data. The 12-month follow up results are an important data point for physicians evaluating the MGuard, as the first year is an important period for evaluating a patient who has received a stent during a heart attack. As the Company now has this data in hand, it intends to ramp commercial activity for the remainder of 2013 and 2014.

The Company continues enrollment in its MASTER II clinical trial to evaluate the safety and effectiveness of the MGuard™ Prime EPS in patients suffering from ST Elevation Myocardial Infarction (STEMI). In total, the multi-center, randomized trial is expected to include up to 70 sites in the U.S. and Europe and as many as 1,114 patients. The results are intended to support the Company's Investigational Device Exemption (IDE) application with the U.S. Food and Drug Administration (FDA) to market the MGuard™ Prime MicroNet™ covered coronary stent system in the U.S.

While the MASTER II trial is fully funded, the Company took additional steps to secure strategic financing and protect shareholder value. On October 24 th , the Company announced it had secured $10 million in venture debt to support expanding its emerging clinical research and product development efforts. The Company also put into place a one year stockholder rights plan which the Board believed was prudent in order to protect shareholders' interests.

**Quarter Ended September 30, 2013 Financial Results**

Revenue for the quarter ended September 30, 2013 was $1.6 million, an increase of 205% compared to $0.5 million for the same period in 2012. The increase year over year reflects the positive impact of recent steps taken to stabilize the global distribution strategy and the early success of targeted selling activities in Brazil as well as select European countries.

Gross profit for the quarter ended September 30, 2013 totaled $0.8 million, an increase of 187% compared to $0.3 million for same period in 2012. The increase in gross profit is attributable to an increase in revenue of approximately $1.1 million, as described above, partially offset by an increase in cost of revenues of approximately $0.5 million. Gross margin for the three months ended September 30, 2013 was 51.7%, a decrease from 54.8% in the three months ended September 30, 2012. If the non-recurring effects of the consolidation of our manufacturing facilities in the three months ended September 30, 2013 are removed, gross margin for the three months ended September 30, 2013 would have been 63.1%.

Total operating expenses for the quarter ended September 30, 2013 were $4.7 million, an increase of 31.7% compared to $3.6 million for the same period in 2012. The increase was primarily due to an increase in startup costs associated with initiating the MASTER II trial, as well as increased sales and marketing expenses, as the Company begins to build the appropriate sales infrastructure for future growth.

The loss from operations for the quarter ended September 30, 2013 was $3.9 million, an increase of 18.4% compared to a loss of $3.3 million for the same period in 2012.

Total financial expenses for the quarter ended September 30, 2013 were $0.1 million, a decrease of 98.6% compared to $4.2 million in the same period in 2012. The decrease in financial expenses resulted primarily from the absence of any non-cash revaluations of our warrants or amortization expenses during the three months ended September 30, 2013. In contrast, during the three months ended September 30, 2012, we recognized approximately $4.0 million in non-recurring, non-cash cost associated with the Company's previously retired convertible debt and associated warrants. If the non-cash effects in the three months ended September 30, 2012, as well as the non-cash effects in the three months ended September 30, 2013 are removed, financial expenses for the three months ended September 30, 2012 would have totaled approximately $0.2 million, as compared to approximately $20,000 of financial income for the three months ended September 30, 2013.

The net loss for the quarter ended September 30, 2013 totaled $3.9 million, or $0.12 per basic and diluted share, a decrease of 47.4% compared to a net loss of $7.5 million, or $0.44 per basic and diluted share in the same period in 2012.

Non-GAAP net loss for the quarter ended September 20, 2013 was $3.0 million, or $0.09 per basic and diluted share, an increase of 15.7% compared to a non-GAAP net loss of $2.6 million or $0.15 for the same period in 2012. The non-GAAP net loss for the quarter ended September 30, 2013 primarily excludes $0.9 million of share-based compensation. The non-GAAP net loss for quarter ended September 30, 2012 primarily excludes $4.0 million in non-recurring, non-cash cost associated with the Company's previously retired convertible debt and associated warrants and $1.0 million in share-based compensation.

**Cash and Cash Equivalents**

At September 30, 2013, cash and cash equivalents were $11.4 million, a decrease of 22.8% compared to $14.8 million at June 30, 2013. The Company's cash decreased in line with its anticipated burn rate.

On October 24, 2013, the Company secured $10 million in venture debt financing to support product development and clinical expansion.

**Change to Fiscal Year**

As announced on September 17 th , the Company will be changing its fiscal reporting year end from June 30 th to December 31 st . The three month period ending September 30 th was the first half of the transitional six-month fiscal year from July 1 st to December 31 st , 2013. Management believes that this change will allow the Company to better align its financial periods and annual budget planning with its business cycle, as well as assist the investment community in following the Company's progress moving forward.

**Investor Conference Call**

The Company will host a conference call today at 4:30 p.m. ET to review the Company's financial results and business outlook. Participants should call (877) 407-4018 (United States) or (201) 689-8471 (International) and request the InspireMD call or provide confirmation code 13572723. A live webcast of the call will also be available on the Investor Relations section of the Company's website at www.inspire-md.com/site_en/for-investors/ . Please allow 10 minutes prior to the call to visit this site to download and install any necessary audio software.

An archive of the webcast will be available approximately one hour after completion of the live event and will be accessible on the Investor Relations section of the Company's website at www.inspire-md.com/site_en/for-investors/ . A dial-in replay of the call will also be available to those interested. To access the replay, dial (877) 870-5176 (United States) or (858) 384-5517 (International) and enter code 13572723.

**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.

**Use of Non-GAAP Financial Measures**

To supplement the Company's consolidated financial statements presented on a GAAP basis, the Company discloses a non-GAAP measure as non-GAAP net loss because management uses this supplemental non-GAAP financial measure to evaluate performance period over period, to analyze the underlying trends in its business, and to establish operational goals and forecasts that are used in allocating resources. In addition, many investors use this non-GAAP measure to monitor the Company's performance. This non-GAAP measure should not be considered as an alternative to GAAP measures as an indicator of the Company's operating performance.

Non-GAAP net loss is defined by the Company as net loss excluding non-cash financial expenses, share-based compensation expenses and royalties buyout amortization. Non-cash financial expenses are items that are related to the amortization of discount on convertible debt and related issuance costs, the revaluation of warrants and expenses related to the anti-dilution rights of our March 2011 investors.

Generally, a non-GAAP financial measure is a numerical measure of a company's performance, financial position or cash flow that either excludes or includes amounts that are not normally excluded or included in the most directly comparable measure calculated and presented in accordance with GAAP. The non-GAAP measures discussed above, however, should be considered in addition to, and not as a substitute for or superior to operating loss, cash flows, or other measures of financial performance prepared in accordance with GAAP. A reconciliation of non-GAAP to GAAP financial measure is set forth in the table below.

The Company believes that presenting a non-GAAP net loss, in addition to the corresponding GAAP financial measures, provides investors greater transparency to the information used by management for financial and operational decision-making and allows investors to see the Company's results "through the eyes" of management. The Company further believes that providing this information assists investors in understanding the Company's operating performance and the methodology used by management to evaluate and measure such performance.

**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 the Company's 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 the Company's products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) the Company's limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payers for the Company's products, (viii) the Company's efforts to successfully obtain and maintain intellectual property protection covering its products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) the Company's reliance on single suppliers for certain product components, (xi) the fact that the Company will need to raise additional capital to meet its business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xii) the fact that the Company conducts business in multiple foreign jurisdictions, exposing the Company 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:**
Todd Fromer / Garth Russell
KCSA Strategic Communications
Phone: 212-896-1215 / 212-896-1250
Email: tfromer@kcsa.com / grussell@kcsa.com

**Media Contacts:**
Lewis Goldberg / Samantha Wolf
KCSA Strategic Communications
Phone: 212-896-1216 / 212-896-1220
Email: lgoldberg@kcsa.com / swolf@kcsa.com

######

**CONSOLIDATED STATEMENTS OF OPERATIONS** [1]
(U.S. dollars in thousands, except per share data)

| | Three months ended September 30, | |
|---|---|---|
| | **2013** | **2012** |
| **Revenues** | $ 1,552 | $ 509 |
| Cost of Revenues | 750 | 230 |
| **Gross Profit** | 802 | 279 |
| Operating Expenses: | | |
| Research and development expenses | 1,544 | 946 |
| Selling and marketing | 830 | 402 |
| General and administrative | 2,313 | 2,212 |
| Total operating expenses | 4,687 | 3,560 |
| Loss from Operations | (3,885) | (3,281) |
| Financial expenses | 57 | 4,218 |
| Loss before income taxes | (3,942) | (7,499) |
| Tax expenses | 3 | 7 |
| **Net Loss** | $ (3,945) | $ (7,506) |
| Net loss per share – basic and diluted | $ (0.12) | $ (0.44) |
| Weighted average number of shares of common stock used in computing net loss per share – basic and diluted | 33,959,773 | 17,074,235 |

**RECONCILIATION OF NON-GAAP NET LOSS** [2]
(U.S. dollars in thousands, except per share data)

| | Three months ended September 30, | |
|---|---|---|
| | **2013** | **2012** |
| **GAAP Net Loss** | $ (3,945) | $ (7,506) |
| Non-GAAP Adjustments: | | |
| Non-cash financial expenses [4] | 77 | 3,977 |
| Share-based compensation expenses | 851 | 931 |
| Royalties buyout expenses and amortization | 11 | 0 |
| Total Non-GAAP Adjustments | 939 | 4,908 |
| **Non-GAAP Net Loss** | $ (3,006) | $ (2,598) |
| Non-GAAP net loss per share – basic and diluted | $ (0.09) | $ (0.15) |
| Weighted average number of shares of common stock used in computing net loss per share – basic and diluted | 33,959,773 | 17,074,235 |

**CONSOLIDATED BALANCE SHEETS [3]**
(U.S. dollars in thousands)

| ASSETS | September 30, 2013 | June 30, 2013 |
|---|---|---|
| Current Assets: | | |
| Cash and cash equivalents | $ 11,440 | $ 14,820 |
| Restricted cash | 93 | 93 |
| Accounts receivable: | | |
| Trade | 2,128 | 1,739 |
| Other | 447 | 388 |
| Prepaid expenses | 144 | 272 |
| Inventory | 1,392 | 1,593 |
| **Total current assets** | 15,644 | 18,905 |
| Property, plant and equipment, net | 591 | 550 |
| Non-current assets: | | |
| Funds in respect of employee rights upon retirement | 436 | 406 |
| Long term prepaid expenses | 143 | |
| Royalties buyout | 873 | 884 |
| **Total non-current assets** | 1,452 | 1,290 |
| **Total assets** | $ 17,687 | $ 20,745 |

**CONSOLIDATED BALANCE SHEETS (Cont.) [3]**
(U.S. dollars in thousands)

# LIABILITIES AND EQUITY

| | September 30, 2013 | June 30, 2013 |
|---|---|---|
| Current liabilities: | | |
| Accounts payable and accruals: | | |
| Trade | $ 850 | $ 831 |
| Other | 3,016 | 3,028 |
| Advanced payment from customers | 176 | 174 |
| Deferred revenues | | 10 |
| **Total current liabilities** | 4,042 | 4,043 |
| Long-term liabilities - | | |
| Liability for employees rights upon retirement | 637 | 600 |
| **Total long-term liabilities** | 637 | 600 |
| **Total liabilities** | 4,679 | 4,643 |
| Equity: | | |
| Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 33,965,950 and 33,888,845 shares issued and outstanding at September 30, 2013 and June 30, 2013, respectively. | 3 | 3 |
| Additional paid-in capital | 89,930 | 89,079 |
| Accumulated deficit | (76,925) | (72,980) |
| **Total equity** | 13,008 | 16,102 |
| **Total liabilities and equity** | $ 17,687 | $ 20,745 |

(1) All 2013 financial information is derived from the Company's 2013 unaudited financial statements and all 2012 financial information is derived from the Company's 2012 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission.

(2) Our non-GAAP net loss is presented as management uses this supplemental non-GAAP financial measure to evaluate performance period over period, analyze the underlying trends in our business, and establish operational goals and forecasts that are used in allocating resources. We believe by presenting this additional measurement, we our providing investors with greater transparency to the information used by our management for our financial and operational decision-making, as well as allowing investors to see our results "through the eyes" of management. We further believe that providing this information assists our investors in understanding our operating performance and the methodology used by management to evaluate and measure such performance.

(3) All September 30, 2013 financial information is derived from the Company's 2013 unaudited financial statements and all June 30, 2013 financial information is derived from the Company's 2013 audited financial statements, as disclosed in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission.

(4) Non-cash financial expenses are items related to the amortization of the discount on the convertible loan and its related issuance costs, the revaluation of warrants and the issuance of shares as a result of the anti-dilution rights of the Company's March 2011 investors.