INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 09/18/13 for the Period Ending 09/16/13

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): September 16, 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, Suite 16041 Boston, Massachusetts (Address of principal executive offices)	02199 (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 September 17, 2013, InspireMD, Inc. (the "Company") issued a press release announcing its financial results for its fourth quarter and fiscal year ended June 30, 2013. A copy of this press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02, including Exhibit 99.1, 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 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

On September 16, 2013, the Company's board of directors approved a change in the Company's fiscal year-end from June 30 to December 31. The Company plans to report its financial results for the six month transition period of July 1, 2013 through December 31, 2013 on an Annual Report on Form 10-K/T and to thereafter file reports for each twelve month period ended December 31 of each year beginning with the twelve month period ended December 31, 2014.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Earnings release dated September 17, 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: September 18, 2013

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Earnings release dated September 17, 2013

FOR IMMEDIATE RELEASE

InspireMD Reports Fourth Quarter and Fiscal Year 2013 Results

BOSTON, MA – September 17, 2013 – InspireMD Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic protection stents, today announced financial results for its fourth quarter and fiscal year ended June 30, 2013.

Key Highlights

- Enhanced executive management team and Board with key new appointments
- Strengthened balance sheet with retirement of debt and $25 million capital raise in April 2013
- Announced superior MASTER trial results and positive 30-day and 6-month data
- Initiated enrollment in FDA-intended MASTER II trial

Upcoming Near-term Milestones

- 12-month MASTER trial results to be released at Transcatheter Cardiovascular Therapeutics (TCT) Conference on October 30, 2013
- Implementing tiered commercial strategy, including select direct sales activities in Europe
- Initiating clinical activities with CGuard™ Carotid stent system

Commenting on the Company's recent activity, Alan Milinazzo, President and Chief Executive Officer of InspireMD, stated, "Since joining the Company earlier this year, I've looked to realign our efforts across multiple areas of the business in order to create a solid foundation for future growth. We've identified four key areas of focus moving forward: clinical studies, development of new products in our pipeline, strategic partnerships and our commercial strategy. I believe these concentrated efforts will allow us to build broader awareness for our new generation of stent technologies with sales in countries where we already have market clearance, while working towards FDA approval."

"The 12-month follow up results for the MASTER trial are to be announced on October 30 th . This is the next major data point that most clinicians are looking for to validate use of the MGuard™ stent. As such, we believe these results will facilitate our sales and strategic partnership activities in key international markets. In terms of the U.S. market, we already began enrollment for our FDA-intended MASTER II trial. And as we expand our current clinical activities for the Coronary market, we continue to bolster our product pipeline with advances for the Carotid and Peripheral Vasculature target indications," concluded Mr. Milinazzo.

Operational Overview

In fiscal year 2013, the Company announced superior results from the MASTER trial for its MGuard Embolic Protection Stent (EPS). The findings show 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 30-day and 6-month data.

The MASTER trial is an important study for InspireMD, as it is the first large, randomized clinical trial for the MGuard to date. As such, the results have gained much more credence among those in the medical community. The 12-month follow up results for the MASTER trial, scheduled to be released on October 30 th , are expected to be an important data point for physicians evaluating the MGuard, as the first year is an important period for evaluating a patient that has received a stent during a heart attack.

The results disclosed thus far from the MASTER trial have allowed the Company to begin the transition to a new commercial strategy in countries where the MGuard has received regulatory clearance. This includes setting up the support structure for a direct sales team in certain European countries and advancing discussions with new strategic partners. The Company recently entered into 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.

The Company began enrollment with 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.

The ongoing progress and changes throughout the Company are being driven by new leadership brought in over the past year at the executive management and board levels. To lead the Company forward, Mr. Milinazzo was appointed President and CEO in January 2013, bringing fifteen years of experience in interventional cardiology to InspireMD. The Company also appointed Ms. Gwen Bame to a newly created position of Vice President of Corporate Development and charged her with identifying and executing strategic programs and partnerships designed to meet InspireMD's global growth objectives. As of yesterday, the Company appointed Mr. David Blossom as its Vice President of Global Marketing and Strategy and will be charged with creating and overseeing the implementation of a global strategic marketing plan. At the Board level, industry veterans, Mr. Michael Berman and Dr. Campbell Rogers recently joined to provide invaluable strategic guidance and support.

Fourth Quarter Financial Results

Revenue for the quarter ended June 30, 2013 was $1.5 million, an increase of 60.7% compared to $0.9 million for the same period in 2012. The increase was the result of recent expanded sales activities in key European and South American countries.

Gross profit for the quarter ended June 30, 2013 totaled $0.7 million, an increase of 414% compared to $0.1 million for same period in 2012. The increase in gross profit is primarily attributable to a non-recurring write-off of $0.4 million of slow moving inventory in the twelve months ended June 30, 2012, which did not occur in the same period in 2013, and an increase of $0.4 million primarily due to the increase in sales of $0.6 million, as discussed above. This was partially offset by $0.2 million of expenses related to the integration of our R&D center into a streamlined manufacturing facility intended to increase efficiency and support anticipated commercial demand. Gross margins for the quarter increased to 44.5% compared to 13.9% for the same period in 2012.

Total operating expenses for the quarter ended June 30, 2013 were $4.9 million, an increase of 17.3% compared to $4.2 million for the same period in 2012. The increase was primarily due to an increase in General & Administrative and Sales & Marketing expenses, as the Company builds the appropriate sales infrastructure and management team for future growth.

The loss from operations for the quarter ended June 30, 2013 was $4.2 million, a slight increase of 4.5% compared to $4.0 million for the same period in 2012.

The net loss for the quarter ended June 30, 2013 totaled $14.9 million, or $0.48 per basic and diluted share, an increase of 279% compared to a net loss of $3.9 million, or $0.23 per basic and diluted share in the same period in 2012. The net loss was driven by $10.6 million of non-recurring, non-cash costs associated with the conversion and retirement of the Company's convertible debt in conjunction with the April 2013 capital raise.

Non-GAAP net loss for the quarter ended June 30, 2013 was $3.2 million, or $0.10 per basic and diluted share, a decrease of 8.6% compared to a non-GAAP net loss of $3.5 million or $0.21 for the same period in 2012. The non-GAAP net loss for the quarter ended June 30, 2013 primarily excludes the $10.6 million non-recurring, non-cash costs associated with the conversion and retirement of the Company's convertible debt in conjunction with the April 2013 capital raise.

Fiscal Year End Financial Results

Revenue for the fiscal year ended June 30, 2013 totaled $4.9 million, a decrease of 8.9% compared to $5.3 million for the same period in 2012. The $0.4 million decrease in sales volume was due primarily to the process of restructuring the Company's commercial strategy in key countries by developing direct sales channels and eliminating certain non-performing third party distributors.

Gross profit for the fiscal year ended June 30, 2013 totaled $2.6 million, an increase of 3.6% compared to $2.5 million for the same period in 2012. The increase in gross profit is attributable to a decrease in cost of revenues, primarily from a non-recurring write-off of $0.4 million of slow moving inventory in the twelve months ended June 30, 2012, which did not occur in the same period in 2013. These decreases were partially offset by expenses related to the integration of our R&D center into a streamlined manufacturing facility intended to increase efficiency and support anticipated commercial demand. Gross margins increased to 53.2% for the fiscal year ended June 30, 2013 compared to 46.7% for the same period in 2012.

Total operating expenses for the fiscal year ended June 30, 2013 were $17.7 million, a decrease of 11.9% compared to $20.0 million for the same period in 2012. The decrease was primarily due to a decrease in share-based compensation of $6.7 million, which was partially offset by an increase in Sales and Marketing, as the Company builds the appropriate sales infrastructure for future growth.

The loss from operations for the fiscal year ended June 30, 2013 was $15.1 million, a decrease of 14.1% compared to $17.5 million for the same period in 2012.

The net loss for the fiscal year ended June 30, 2013 totaled $29.3 million, or $1.39 per basic and diluted share, an increase of 66.3% compared to a net loss of $17.6 million, or $1.04 per basic and diluted share in the period in 2012. The increase in net loss resulted primarily from an increase of $14.1 million in financial expenses, of which, $13.4 million were non-recurring, non-cash costs associated with the Company's convertible debt.

Non-GAAP net loss for the fiscal year ended June 30, 2013 was $11.0 million, or $0.53 per share, compared to $7.4 million, or $0.44 per share, for the same period in 2012. The non-GAAP net loss for fiscal year 2013 primarily excludes the $13.4 million non-recurring, non-cash costs associated with the Company's convertible debt, and $3.8 million in share-based compensation. The non-GAAP net loss for fiscal year 2012 primarily excludes $10.6 million in share-based compensation.

Cash and Cash Equivalents

At June 30, 2013, cash and cash equivalents were $14.8 million, an increase of 44.1% compared to $10.3 million at June 30, 2012. The Company's cash increased mainly due to the April 2013 capital raise with net proceeds of $14.1 million.

Change to Fiscal Year

The Company announced today that it will be changing its fiscal reporting year end from June 30 th to December 31 st. It will run a 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 with following its 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) 375-4189 (United States/Canada) or (973) 935-2046 (International) and request the InspireMD call or provide confirmation code 45736242. A live webcast of the call will 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.

A replay of the conference call will be available approximately two hours after completion of the live conference call and will be accessible until 11:59 p.m. ET on October 1, 2013. To listen to the replay, dial (855) 859-2056 (United States/Canada) or (404) 537-3406 (International) and enter code 45736242. The webcast of the event will also be archived for two weeks on the Investor Relations section of the Company's website at www.inspire-md.com/site_en/for-investors/.

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 expenses and amortization. Non-cash financial expenses are items that are related to the induced conversion of the convertible debt, amortization of discount on convertible debt and related issuance costs.

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 June 30,		Twelve months ended June 30,	
	2013	**2012**	**2013**	**2012**
Revenues	$ 1,500	$ 933	$ 4,873	$ 5,349
Cost of Revenues	832	803	2,283	2,849
Gross Profit	668	130	2,590	2,500
Operating Expenses:				
Royalties buyout expenses			918	
Other research and development expenses	1,047	1,258	4,156	3,988
Selling and marketing	1,204	801	3,616	2,174
General and administrative	2,632	2,103	8,973	13,883
Total operating expenses	4,883	4,162	17,663	20,045
Loss from Operations	(4,215)	(4,032)	(15,073)	(17,545)
Financial expenses (income)	10,755	(98)	14,177	38
Loss before tax expenses (income)	(14,970)	(3,934)	(29,250)	(17,583)
Tax expenses (income)	(23)	7	8	14
Net Loss	$ (14,947)	$ (3,941)	$ (29,258)	$ (17,597)
Net loss per share – basic and diluted	$ (0.48)	$ (0.23)	$ (1.39)	$ (1.04)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	31,033,657	17,043,704	20,995,887	16,707,599

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

	Three months ended June 30,		Twelve months ended June 30,	
	2013	**2012**	**2013**	**2012**
GAAP Net Loss	$ (14,947)	$ (3,941)	$ (29,258)	$ (17,597)
Non-GAAP Adjustments:				
Non-cash financial expenses (income) [3]	10,627	(314)	13,416	(314)
Share-based compensation expenses	1,109	755	3,839	10,554
Royalties buyout expenses and amortization	13	0	964	0
Total Non-GAAP Adjustments	11,749	441	18,219	10,240
Non-GAAP Net Loss	$ (3,198)	$ (3,500)	$ (11,039)	$ (7,357)
Non-GAAP net loss per share – basic and diluted	$ (0.10)	$ (0.21)	$ (0.53)	$ (0.44)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	31,033,657	17,043,704	20,995,887	16,707,599

CONSOLIDATED BALANCE SHEETS [1]
(U.S. dollars in thousands)

ASSETS

	June 30, 2013	June 30, 2012
Current Assets:		
Cash and cash equivalents	$ 14,820	$ 10,284
Restricted cash	93	37
Accounts receivable:		
Trade	1,739	1,824
Other	388	264
Prepaid expenses	272	93
Inventory:		
On hand	1,593	1,744
On consignment		63
Total current assets	18,905	14,309
Property, plant and equipment, net	550	462
Non-current assets:		
Deferred debt issuance costs		961
Funds in respect of employee rights upon retirement	406	282
Royalties buyout	884	
Total non-current assets	1,290	1,243
Total assets	$ 20,745	$ 16,014

CONSOLIDATED BALANCE SHEETS (Cont.) [1]

(U.S. dollars in thousands)

LIABILITIES AND EQUITY

	June 30, 2013	June 30, 2012
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 831	$ 441
Other	3,028	2,925
Advanced payment from customers	174	174
Deferred revenues	10	10
Total current liabilities	4,043	3,550
Long-term liabilities:		
Liability for employees rights upon retirement	600	354
Convertible loan		5,018
Contingently redeemable warrants		1,706
Total long-term liabilities	600	7,078
Total liabilities	4,643	10,628
Equity:		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 33,888,845 and 17,040,040 shares issued and outstanding at June 30, 2013 and 2012, respectively.	3	2
Additional paid-in capital	89,079	49,106
Accumulated deficit	(72,980)	(43,722)
Total equity	16,102	5,386
Total liabilities and equity	$ 20,745	$ 16,014

(1) All 2013 financial information is derived from the Company's 2013 audited financial statements and all 2012 financial information is derived from the Company's 2012 audited financial statements, as disclosed in the Company's Amended Transition Report on Form 10-KT/A, filed with the Securities and Exchange Commission on January 3, 2013.

(2) The Company's 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 its business, and establish operational goals and forecasts that are used in allocating resources. The Company believes by presenting this additional measurement, they are providing investors with greater transparency to the information used by management for financial and operational decision-making, as well as allowing 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.

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