INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 11/10/15 for the Period Ending 11/10/15

Address	321 COLUMBUS AVENUE
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Telephone	(857) 453-6553
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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 10, 2015

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.)

321 Columbus Avenue Boston, MA	02116
(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 10, 2015, InspireMD, Inc. (the "Company") issued a press release announcing its financial and operating results for the fiscal quarter ended September 30, 2015. The Company will also host a conference call to review the Company's financial results and business outlook at 8:30 a.m. Eastern Time on November 10, 2015. 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 10, 2015

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 10, 2015

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1

InspireMD Reports Financial Results for the Third Quarter Ended September 30, 2015

BOSTON, MA – November 10, 2015 – InspireMD, Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic prevention systems (EPS), neurovascular devices and thrombus management technologies, today announced its financial and operating results for the third quarter ended September 30, 2015.

In its third full quarter of a strategic transition into the carotid and neuro interventional markets utilizing its proprietary MicroNet ™ technology, key activities included the announced strategic distributor agreement with global interventional therapies company Penumbra, Inc., strengthened intellectual property coverage, including the issuance of two US patents, and expanded regulatory footprint with CGuard approvals for both Argentina and Colombia. In addition, InspireMD's development program for its neurovascular flow diverter platform remains on track for pre-clinical results in December 2015 and CE Mark submission in 2H 2016. Broad collaboration discussions advanced steadily facilitated by an external financial and strategic advisor engaged to assist in the review of various strategic alternatives.

Alan Milinazzo, CEO of InspireMD, commented, "With 2015 being a transition year for InspireMD, we continue to execute on our strategic plan with clear focus and a sense of urgency. We highlight progress made in recent months and look forward to sustainable growth in 2016. Feedback from the CGuard ™ launch remains positive, aided by both the CARENET and PARADIGM clinical data sets that have received prominent attention at major clinical meetings this year. Recent approvals in Colombia and Argentina also allow us to bring this important technology to key markets around the world as we balance investments in the business with disciplined cash management."

Mr. Milinazzo continued, "We are pleased to note that our development efforts in the high value neurovascular field are tracking to expectations while we actively advance discussions across indications that leverage our MicroNet ™ technology. Finally, to ensure that we maximize InspireMD shareholder value, we have engaged TM Asante Healthcare Partners as an outside strategic advisor to further our business development activities."

Recent Operating Highlights:

COMMERCIAL

- Announced full European market launch of CGuard ™ in late September at CIRSE 2015 by Penumbra Inc., a global market leader in the interventional neuroradiology and peripheral vascular markets.
- Reported sequential revenue increase of 85% for CGuard ™ .
- On track for full Penumbra commercial launch of CGuard ™ in Q4 of 2015.

REGULATORY / CLINICAL / PRODUCT DEVELOPMENT

- Received regulatory approvals to commercialize CGuard ™ in Colombia and Argentina.
- Received two US patent issuances.
- Advanced next generation neurovascular flow diverter program with pre-clinical data on-track for December 2015 and CE Mark submission in 2H 2016.

- Reported positive results from the investigator led PARADIGM trial in an all comers patient population.
- Awarded 2015 Frost and Sullivan European Innovation Award for Product Development.
- Advanced broad collaboration discussions across indications – cardiovascular, carotid, and neurovascular – that leverage the MicroNet ™ technology, with facilitation from a recently engaged financial and strategic advisor.

FINANCIAL

- Announced one-for-ten reverse stock split effective October 1, 2015.
- Comprehensive cash management, with steady, measured declines in monthly cash use.
- Continued implementation of cost containment activities while supporting key development programs.

Quarter Ended September 30, 2015 Financial Results

Revenue for the third quarter ended September 30, 2015 increased $0.3 million to $0.6 million compared to $0.3 million during the same period in 2014. The increase was predominately driven by sales of $0.3 million of our new product CGuard™ EPS, our carotid product, which was launched in October 2014. Sales of CGuard™ EPS during the three months ended September 30, 2015 were predominately driven by initial sales to our new strategic distribution partner, Penumbra, Inc.

The company's gross profit for the quarter ended September 30, 2015 was $0.1 million compared to a gross loss of $0.1 million for the same period in 2014. The improvement of 217.1% was largely attributable to the increase in product revenues and a decrease of write-offs of inventory of MGuard™ Prime EPS. These improvements in gross profit, however, were partially offset by an increase in labor and material costs attributable to higher revenues.

Total operating expenses for the quarter ended September 30, 2015 were $3.5 million, a decrease of 45.3% compared to $6.4 million for the same period in 2014. This decrease was primarily due to a reduction of expenses related to MGuard™ Prime EPS's MASTER II trial, which was suspended in October 2014, a decrease in compensation related expenses and other savings associated with our cost reduction plan.

The loss from operations for the quarter ended September 30, 2015 was $3.4 million, a decrease of 47.4% compared to a loss of $6.5 million for the same period in 2014.

Financial expenses for the quarter ended September 30, 2015 was $0.2 million, a decrease of 27.2% compared to the same period in 2014. This decrease was primarily due to a decrease in interest expenses due to the reduction in principal of our outstanding indebtedness.

The net loss for the quarter ended September 30, 2015 totaled $3.6 million, or $0.48 per basic and diluted share, compared to a net loss of $6.8 million, or $1.96 per basic and diluted share, in the same period in 2014.

Non-GAAP net loss for the quarter ended September 30, 2015 was $2.8 million, or $0.36 per basic and diluted share, a decrease of 51.6% compared to a non-GAAP net loss of $5.7 million, or $1.65 per basic and diluted share, for the same period in 2014. The non-GAAP net loss for the quarter ended September 30, 2015 primarily excludes $0.6 million of share-based compensation and $0.3 million of expense related to the impairment of the value of our royalties buyout option associated with MGuard™ Prime EPS. The non-GAAP net loss for the quarter ended September 30, 2014 primarily excludes $1.1 million of share-based compensation.

Nine Months Ended September 30, 2015 Financial Results

Revenue for the nine months ended September 30, 2015 decreased $0.1 million to $1.8 million compared to $1.9 million during the same period in 2014. The 2015 period included an expected decline in sales of MGuard™ Prime EPS associated with the trend of doctors increasingly using drug eluting stents rather than bare metal stents in STEMI offset by sales of our new product CGuard™ EPS, which was launched in October 2014. The sales of CGuard™ EPS during the nine months ended September 30, 2015 included initial sales to our new strategic distribution partner, Penumbra, Inc. which commenced during the third quarter.

The company's gross loss for the nine months ended September 30, 2015 was $0.2 million, a decrease of 141.0% compared to a gross profit of $0.4 million for the same period in 2014. The decrease was largely attributable to an increase in labor and material costs attributable to higher costs for CGuard™ EPS and write-offs of inventory due to the trend of increased usage of DES stents in STEMI patients, longer shelf life requirements and the transition to the rapid exchange delivery system for CGuard from the over the wire platform.

Total operating expenses for the nine months ended September 30, 2015 were $11.7 million, a decrease of 40.4% compared to $19.6 million for the same period in 2014. This decrease was primarily due to a reduction of expenses related to MGuard's MASTER II trial, a decrease in compensation related expenses and other savings associated with our cost reduction plan.

The loss from operations for the nine months ended September 30, 2015 was $11.9 million, a decrease of 38.3% compared to a loss of $19.3 million for the same period in 2014.

Financial expenses for the nine months ended September 30, 2015 decreased 18.6% to $0.9 million from $1.1 million during the same period in 2014. This decrease was primarily due to a decrease in interest expenses due to the reduction in principal of our outstanding indebtedness.

The net loss for the nine months ended September 30, 2015 totaled $12.7 million, or $1.89 per basic and diluted share, compared to a net loss of $20.3 million, or $5.93 per basic and diluted share, in the same period in 2014.

Non-GAAP net loss for the nine months ended September 30, 2015 was $9.5 million, or $1.40 per basic and diluted share, a decrease of 44.7% compared to a non-GAAP net loss of $17.1 million, or $5.00 per basic and diluted share, for the same period in 2014. The non-GAAP net loss for the nine months ended September 30, 2015 primarily excludes $2.6 million of share-based compensation and $0.6 million of expense related to an impairment of a royalties buyout asset. The non-GAAP net loss for the nine months ended September 30, 2014 primarily excludes $3.2 million of share-based compensation.

Cash and Cash Equivalents

As of September 30, 2015, cash and cash equivalents were $6.5 million, compared to $6.3 million as of December 31, 2014.

Quarterly Conference Call Details

The company has scheduled a conference call to discuss third quarter 2015 financial results for today at 8:30 AM Eastern. To participate in the conference call, please dial (888) 243-4451 (United States) or (412) 542-4135 (International) and request the InspireMD call. A live webcast of the call will also be available on the Investor Relations section of the Company's website at http://www.inspiremd.com/en/investors/investor-relations/. 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 two hours after completion of the live event and will be accessible on the Investor Relations section of the Company's website at http://www.inspiremd.com/en/investors/investor-relations/ for a limited time. A dial-in replay of the call will also be available to those interested until November 24, 2015. To access the replay, dial (877) 344-7529 (United States) or (412) 317-0088 (International) and enter code: 10075630.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MGuard™ with MicroNet ^{TM} 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, carotid (CGuard ^{TM}), neurovascular, and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

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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CONSOLIDATED STATEMENTS OF OPERATIONS [1]

(U.S. dollars in thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2015	**2014**	**2015**	**2014**
Revenues	$ 632	$ 273	$ 1,794	$ 1,948
Cost of revenues	543	349	1,954	1,558
Gross Profit (Loss)	89	(76)	(160)	390
Operating Expenses:				
Research and development	781	2,460	2,880	7,485
Selling and marketing	588	1,806	2,600	5,030
General and administrative	1,713	2,139	5,270	7,126
Restructuring and impairment expenses	418	-	964	-
Total operating expenses	3,500	6,405	11,714	19,641
Loss from operations	(3,411)	(6,481)	(11,874)	(19,251)
Financial expenses	228	313	856	1,051
Loss before tax expenses	(3,639)	(6,794)	(12,730)	(20,302)
Tax expenses (Income)	2	(19)	1	3
Net Loss	$ (3,641)	$ (6,775)	$ (12,731)	$ (20,305)
Net loss per share – basic and diluted	$ (0.48)	$ (1.96)	$ (1.89)	$ (5.93)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	7,630,985	3,458,152	6,753,011	3,425,162

RECONCILIATION OF NON-GAAP NET LOSS [2]

(U.S. dollars in thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2015	**2014**	**2015**	**2014**
GAAP Net Loss	$ (3,641)	$ (6,775)	$ (12,731)	$ (20,305)
Non-GAAP Adjustments:				
Share-based compensation expenses	601	1,052	2,600	3,151
Impairment of royalties buyout	260	-	576	-
Royalties buyout expenses and amortization	22	20	80	60
Non-cash financial expenses (income) [3]	-	-	-	(47)
Total Non-GAAP Adjustments	883	1,072	3,256	3,164
Non-GAAP Net Loss	$ (2,758)	$ (5,703)	$ (9,475)	$ (17,141)
Non-GAAP net loss per share – basic and diluted	$ (0.36)	$ (1.65)	$ (1.40)	$ (5.00)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	7,630,985	3,458,152	6,753,011	3,425,162

CONSOLIDATED BALANCE SHEETS [4]
(U.S. dollars in thousands)

ASSETS	September 30, 2015	December 31, 2014
Current Assets:		
Cash and cash equivalents	$ 6,509	$ 6,300
Accounts receivable:		
Trade, net	664	635
Other	199	359
Prepaid expenses	108	150
Inventory	1,081	1,924
Total current assets	8,561	9,368
Non-current assets:		
Property, plant and equipment, net	516	622
Deferred issuance costs	102	153
Funds in respect of employee rights upon retirement	466	498
Long term prepaid expenses	20	66
Royalties buyout	96	752
Total non-current assets	1,200	2,091
Total assets	$ 9,761	$ 11,459

LIABILITIES (NET OF CAPITAL DEFICIENCY)	September 30, 2015	December 31, 2014
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 834	$ 909
Other	2,403	3,576
Advanced payment from customers	170	179
Current maturity of loan	4,123	3,809
Total current liabilities	7,530	8,473
Long-term liabilities:		
Liability for employees rights upon retirement	658	687
Long -term loan	2,147	5,086
Total long-term liabilities	2,805	5,773
Total liabilities	10,335	14,246
Equity:		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 7,632,752 and 4,136,889 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	7	4
Additional paid-in capital	119,561	104,620
Accumulated deficit	(120,142)	(107,411)
Total capital deficiency	(574)	(2,787)
Total liabilities net of capital deficiency	$ 9,761	$ 11,459

(1) All 2015 financial information is derived from the Company's 2015 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission, all 2014 financial information is derived from the Company's 2014 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 are 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) Non-cash financial income relates to the issuance of shares as a result of the anti-dilution rights of our March 2011 investors.

(4) All September 30, 2015 financial information is derived from the Company's 2015 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission. All December 31, 2014 financial information is derived from the Company’s 2014 audited financial statements as disclosed in the Company’s Annual Report on Form 10-K, for the twelve months ended December 31, 2014 filed with the Securities and Exchange Commission.