INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 05/10/16 for the Period Ending 05/10/16

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): May 10, 2016

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) 305-2410

(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 May 10, 2016, InspireMD, Inc. (the "Company") issued a press release announcing its financial and operating results for the fiscal quarter ended March 31, 2016. 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 May 10, 2016

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: May 10, 2016

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1

InspireMD Reports Financial Results for the First Quarter Ended March 31, 2016

BOSTON, MA – May 10, 2016 – 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 first quarter ended March 31, 2016.

During the first quarter, InspireMD announced initiatives to support ongoing commercial operations and development programs. Key activities include announced:

- Completed private placement and public offering;
- Strengthened Board of Directors with appointment of Isaac Blech as Vice Chairman; and
- Continued operational and financial alignment, with ongoing implementation of a comprehensive cash management program.

Sol Barer, Chairman of the Board of InspireMD, commented, "In line with our focused execution of our strategy, a key priority is our ongoing management transition plan with attention on our European commercial and development activities. These efforts were aided by our recent capital raise and addition to the board. We look for timely and continuous updates as we execute on our plans."

Dr. Barer continued, "We remain pleased with consistent, positive feedback with our CGuard ^{TM} commercial activities, noting progress with our early efforts to drive market traction. We look forward to continued clinical presentations of CGuard ^{TM} patient evaluations at relevant medical industry conferences, including the investigator-led PARADIGM-101 at the Late-Breaking Clinical Trial session at EuroPCR on May 17 th."

Recent Operating Highlights:

COMMERCIAL

- Continued focus on expanding European commercial activities in new geographies.
- Successful CGuard ^{TM} commercial efforts across distributor network, particularly in select European regions, such as Italy.

REGULATORY / CLINICAL / PRODUCT DEVELOPMENT

- CGuard ^{TM} evaluation on 101 consecutive all comer patients in PARADIGM-101 or PARADIGM-EXTEND study selected for Late-Breaking Clinical Trial presentation at EuroPCR conference from May 17-20, 2016 in Paris, France.

FINANCIAL

- Comprehensive and active cash management program, including a March 16 th, 2016 pricing of an underwritten public offering of 1,900,000 shares of its common stock and warrants to purchase up to 950,000 shares of common stock and a concurrent private placement of 1,033,051shares of its common stock and warrants to purchase up to 516,526 shares of common stock to certain of the Company's directors.

- Continued implementation of cost containment activities while supporting key development programs.

Quarter Ended March 31, 2016 Financial Results

Revenue for the first quarter ended March 31, 2016 increased $0.1 million to $0.6 million compared to $0.5 million during the same period in 2015. The increase was predominantly driven by sales of $0.3 million of CGuard™ EPS, our carotid product. This increase, however, was partially offset by 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.

The Company's gross profit for the quarter ended March 31, 2016 was $66,000 compared to a gross loss of $37,000 for the same period in 2015. This increase in gross profit was largely attributable to the increase in product revenues and a decrease of write-offs of MGuard™ Prime EPS inventory offset by expenses related to the underutilization of our manufacturing resources.

Total operating expenses for the quarter ended March 31, 2016 were $2.5 million, a decrease of 49.5% compared to $4.9 million for the same period in 2015. This decrease was primarily due to a reduction of compensation related expenses, restructuring and impairment costs and other savings associated with our ongoing cost reduction plan.

The loss from operations for the quarter ended March 31, 2016 was $2.4 million, a decrease of 51.2% compared to a loss of $4.9 million for the same period in 2015.

Financial expenses for the quarter ended March 31, 2016 were $0.2 million, a decrease of 27.8% compared to the same period in 2015. This decrease was primarily due to a reduction in interest expense of our outstanding loan.

The net loss for the quarter ended March 31, 2016 totaled $2.6 million, or $0.32 per basic and diluted share, compared to a net loss of $5.2 million, or $1.04 per basic and diluted share, in the same period in 2015.

Non-GAAP net loss for the quarter ended March 31, 2016 was $1.9 million, or $0.23 per basic and diluted share, a decrease of 51.6% compared to a non-GAAP net loss of $3.8 million, or $0.77 per basic and diluted share, for the same period in 2015. The non-GAAP net loss for the quarter ended March 31, 2016 primarily excludes $0.7 million of share-based compensation. The non-GAAP net loss for the quarter ended March 31, 2015 primarily excludes $1.0 million of share-based compensation and $0.3 million of expense related to an impairment of a royalties buyout asset.

Cash and Cash Equivalents

As of March 31, 2016, cash and cash equivalents were $2.0 million, compared to $3.3 million as of December 31, 2015.

No Conference Call Scheduled

The Company is not hosting a conference call to discuss first quarter March 31, 2016 results. Additional updates will be provided as they become available.

About PARADIGM

PARADIGM is an investigator-initiated **P** rospective evaluation of **A** ll-comer pe **R** cutaneous c **A** roti **D** revascularization **I** n symptomatic and increased-risk asymptomatic carotid artery stenosis, using C **G** uard™ **M** esh-covered embolic prevention stent system. At EuroPCR 2015, Dr. Musialek summarized the results of his PARADIGM evaluation of 71 CGuard ™ procedures in unselected all-comer patients: 1) stent system success and procedure success rate of 100%; 2) periprocedural complications of 0%, and remained at 0% at 30 days; and 3) no MACNE occurred periprocedurally or at 30 days, by operator-independent neurologist and non-invasive cardiologist evaluation.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MGuard™ with MicroNet ™ 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 ™), 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.

Investor Contacts:
InspireMD, Inc.
Craig Shore
Chief Financial Officer
Phone: 1-888-776-6804 FREE
Email: craigs@inspiremd.com

PCG Advisory
Vivian Cervantes
Investor Relations
Phone: (212) 554-5482

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

	Three months ended March 31,	
	2016	**2015**
Revenues	$ 563	$ 477
Cost of revenues	497	514
Gross Profit (Loss)	66	(37)
Operating Expenses:		
Research and development	478	1,352
Selling and marketing	386	1,017
General and administrative	1,589	1,970
Restructuring and impairment	-	514
Total operating expenses	2,453	4,853
Loss from operations	(2,387)	(4,890)
Financial expenses	221	306
Loss before tax expenses	(2,608)	(5,196)
Tax expenses	1	16
Net Loss	$ (2,609)	$ (5,212)
Net loss per share – basic and diluted	$ (0.32)	$ (1.04)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	8,042,082	4,991,519

RECONCILIATION OF NON-GAAP NET LOSS [(2)]

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

	Three months ended March 31,	
	2016	**2015**
GAAP Net Loss	$ (2,609)	$ (5,212)
Non-GAAP Adjustments:		
Share-based compensation expenses	741	1,029
Impairment of royalties buyout	-	316
Royalties buyout amortization	12	36
Total Non-GAAP Adjustments	934	1,381
Non-GAAP Net Loss	$ (1,856)	$ (3,831)
Non-GAAP net loss per share – basic and diluted	$ (0.23)	$ (0.77)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	8,042,082	4,991,519

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

ASSETS	**March 31, 2016**	**December 31, 2015**
Current Assets:		
Cash and cash equivalents	$ 1,999	$ 3,257
Accounts receivable:		
Trade, net	546	405
Other	204	142
Prepaid expenses	62	75
Inventory	511	753
Total current assets	3,322	4,632
Non-current assets:		
Property, plant and equipment, net	436	472
Funds in respect of employee rights upon retirement	411	502
Royalties buyout	75	87
Total non-current assets	922	1,061
Total assets	$ 4,244	$ 5,693

LIABILITIES (NET OF CAPITAL DEFICIENCY)	March 31, 2016	December 31, 2015
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 453	$ 512
Other	2,139	2,006
Advanced payment from customers	169	167
Current maturity of loan	4,294	4,149
Total current liabilities	7,055	6,834
Long-term liabilities:		
Liability for employees rights upon retirement	584	706
Long -term loan	-	1,099
Total long-term liabilities	584	1,805
Total liabilities	7,639	8,639
Equity:		
Common stock, par value $0.0001 per share; 50,000,000 shares authorized; 7,676,074 and 4,136,890 shares issued and outstanding at December 31, 2015 and 2014, respectively	1	1
Additional paid-in capital	122,209	120,049
Accumulated deficit	(125,605)	(122,996)
Total capital deficiency	(3,395)	(2,946)
Total liabilities net of capital deficiency	$ 4,244	$ 5,693

(1) All 2016 financial information is derived from the Company's 2016 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission, 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.

(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) All March 31, 2016 financial information is derived from the Company's 2016 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, 2015 financial information is derived from the Company’s 2015 audited financial statements as disclosed in the Company’s Annual Report on Form 10-K, for the twelve months ended December 31, 2015 filed with the Securities and Exchange Commission.