INSPIREMD, INC.

FORM 8-K
(Current report filing)

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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 9, 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 August 9, 2016, InspireMD, Inc. issued a press release announcing its financial and operating results for the second fiscal quarter ended June 30, 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 August 9, 2016

* This exhibit is furnished pursuant to Item 2.02 and shall not be deemed to be "filed."

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 9, 2016

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Reports Financial Results for the Second Quarter Ended June 30, 2016

- Company to Host Conference Call Today at 4:30pm ET -

BOSTON, MA – August 9, 2016 – InspireMD, Inc. (NYSE MKT: NSPR, NSPR.WS) ("InspireMD" or the "Company"), a leader in embolic prevention systems (EPS), neurovascular devices and thrombus management technologies, today announced financial and operating results for the second quarter ended June 30, 2016, and provided a business update.

"We continue to see steady traction in sales of our CGUARD™ Embolic Prevention System, and are encouraged by the solid growth in second quarter sales for this product versus the same quarter last year. Notably, sales in Italy, one of the first countries in which we launched CGuard, grew more than 190% this quarter compared to the same quarter last year, and 20% compared to the first quarter of 2016," said James Barry, PhD, Chief Executive Officer of InspireMD. "In addition, our Micronet technology continues to gain recognition among industry experts, as evidenced by the selection of the investigator-initiated PARADIGM study for presentation in the late-breaking clinical trial session at the EuroPCR 2016 Conference, highlighting the clinical efficacy of routine use of the CGuard™ system, including use in high risk patients."

"The closing of our $14.6 million financing and recent debt restructuring provide us with the financial flexibility to advance the commercialization of CGuard™ EPS and MGuard Prime™ EPS in key markets," Dr. Barry continued. "We also continue to advance our robust product pipeline with the goal of utilizing our proprietary Micronet™ technology for other indications, including the development of our NGuard™ Flow Diverter for an anticipated 2017 CE Mark submission."

Recent Highlights:

COMMERCIAL

- Sales growth of CGuard ^{TM} increased by 112% in the second quarter of 2016 versus same quarter last year.
- Continued strong sales growth of CGuard ^{TM} in Italy, which grew 194% compared to the second quarter of 2015, and 20% compared to the first quarter of 2016.

REGULATORY / CLINICAL / PRODUCT DEVELOPMENT

- CGuard ^{TM} 's evaluation in the investigator-initiated PARADIGM-101 highlighted in the late-breaking clinical trial session at EuroPCR 2016 in Paris, France. This study found that CGuard may be a safe and effective treatment option for endovascular management in more than 90% of all-comer patients with carotid artery stenosis who require treatment.

FINANCIAL

- Closing of a $14.6 million public offering of approximately 442,424 shares of Series B Convertible preferred stock and warrants to purchase up to 44,242,400 shares of common stock.
- Restructuring of an outstanding loan with Hercules Capital, including four principal payment deferrals which began May 1st, 2016.

EXECUTIVE APPOINTMENT

- In June, James Barry, Ph.D. was appointed President and CEO of InspireMD. Prior to this appointment, Dr. Barry served as InspireMD's Chief Operating Officer for two years. For more than 18 years, Dr. Barry held senior roles at Boston Scientific Corporation, which included overseeing the development of Boston Scientific's Taxus™ stent which became the number one selling drug eluting stent worldwide.

Second Quarter 2016 Financial Results

Revenue for the second quarter ended June 30, 2016 was $0.5 million compared to $0.7 million during the same period in 2015. The decrease was primarily the result of 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 patients. This decrease was partially offset by an increase in sales of $0.2 million of CGuard™ EPS, the Company's carotid product.

The Company's gross profit for the quarter ended June 30, 2016 was $62,000 compared to a gross loss of $0.2 million for the same period in 2015. The increase in gross profit was largely attributable to a decrease of write-offs of MGuard™ Prime EPS inventory and a decrease in labor and material costs attributable to lower revenues, offset by a decrease in product revenues.

Total operating expenses for the quarter ended June 30, 2016 were $1.9 million, a decrease of 44.6% compared to $3.4 million for the same period in 2015. This decrease was primarily due to a reduction of compensation related expenses and other savings associated with our ongoing cost reduction plan.

The loss from operations for the quarter ended June 30, 2016 was $1.8 million, a decrease of 49.6% compared to a loss of $3.6 million for the same period in 2015.

Financial expenses for the quarter ended June 30, 2016 were $0.2 million, a decrease of 44.1% 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 June 30, 2016 totaled $2.0 million, or $0.19 per basic and diluted share, compared to a net loss of $3.9 million, or $0.51 per basic and diluted share, in the same period in 2015.

Non-GAAP net loss for the quarter ended June 30, 2016 was $1.7 million, or $0.16 per basic and diluted share, a decrease of 41.6% compared to a non-GAAP net loss of $2.9 million, or $0.38 per basic and diluted share, for the same period in 2015. The non-GAAP net loss for the quarter ended June 30, 2016 primarily excludes $0.3 million of share-based compensation. The non-GAAP net loss for the quarter ended June 30, 2015 primarily excludes $1.0 million of share-based compensation.

Six Months Ended June 30, 2016 Financial Results

Revenue for the six months ended June 30, 2016 was $1.1 million compared to $1.2 million during the same period in 2015. The decrease was predominantly driven 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 patients.

The Company's gross profit for the six months ended June 30, 2016 was $0.1 million compared to a gross loss of $0.3 million for the same period in 2015. This increase in gross profit was largely attributable to 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 six months ended June 30, 2016 were $4.3 million, a decrease of 47.5% compared to $8.2 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 six months ended June 30, 2016 was $4.2 million, a decrease of 50.5% compared to a loss of $8.5 million for the same period in 2015.

Financial expenses for the six months ended June 30, 2016 were $0.4 million, a decrease of 36.1% 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 six months ended June 30, 2016 totaled $4.6 million, or $0.49 per basic and diluted share, compared to a net loss of $9.1 million, or $1.44 per basic and diluted share, in the same period in 2015.

Non-GAAP net loss for the six months ended June 30, 2016 was $3.5 million, or $0.38 per basic and diluted share, a decrease of 47.3% compared to a non-GAAP net loss of $6.7 million, or $1.07 per basic and diluted share, for the same period in 2015. The non-GAAP net loss for the six months ended June 30, 2016 primarily excludes $1.0 million of share-based compensation. The non-GAAP net loss for the six months ended June 30, 2015 primarily excludes $2.0 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 June 30, 2016, cash and cash equivalents were $0.9 million, compared to $3.3 million as of December 31, 2015. This amount does not include the net proceeds from the Company's public offering which closed on July 7, 2016. The aggregate net proceeds to InspireMD from the financing were $13.0 million.

Conference Call

The company has scheduled a conference call to discuss second quarter 2016 financial results for today at 4:30 PM Eastern. To participate in the conference call, please dial 866-652-5200 (United States) or 412-317-6060 (International) and request the InspireMD call. A live webcast will be available in the Investor Relations section of the Company's website or by clicking here. 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 following the call and will be accessible in the Investor Relations section of the Company's website or by clicking here. A dial-in replay of the call will also be available to those interested until August 23, 2016.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary 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 and certain warrants are quoted on the NYSE MKT under the ticker symbol NSPR.WS.

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 June 30,		Six months ended June 30,	
	2016	**2015**	**2016**	**2015**
Revenues	$ 540	$ 685	$ 1,103	$ 1,162
Cost of revenues	478	897	975	1,411
Gross Profit (Loss)	62	(212)	128	(249)
Operating Expenses:				
Research and development	301	747	779	2,099
Selling and marketing	401	995	787	2,012
General and administrative	1,160	1,587	2,749	3,557
Restructuring and impairment	-	32	-	546
Total operating expenses	1,862	3,361	4,315	8,214
Loss from operations	(1,800)	(3,573)	(4,187)	(8,463)
Financial expenses	180	322	401	628
Loss before tax expenses	(1,980)	(3,895)	(4,588)	(9,091)
Tax expenses (Income)	-	(17)	1	(1)
Net Loss	$ (1,980)	$ (3,878)	$ (4,589)	$ (9,090)
Net loss per share – basic and diluted	$ (0.19)	$ (0.51)	$ (0.49)	$ (1.44)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	10,674,410	7,603,572	9,358,246	6,306,745

RECONCILIATION OF NON-GAAP NET LOSS [2]

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

	Three months ended June 30,		Six months ended June 30,	
	2016	**2015**	**2016**	**2015**
GAAP Net Loss	$ (1,980)	$ (3,878)	$ (4,589)	$ (9,090)
Non-GAAP Adjustments:				
Share-based compensation expenses	283	970	1,024	1,999
Impairment of royalties buyout	-	-	-	316
Royalties buyout expenses and amortization	13	22	25	58
Total Non-GAAP Adjustments	296	992	1,049	2,373
Non-GAAP Net Loss	$ (1,684)	$ (2,886)	$ (3,540)	$ (6,717)
Non-GAAP net loss per share – basic and diluted	$ (0.16)	$ (0.38)	$ (0.38)	$ (1.07)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	10,674,410	7,603,572	9,358,246	6,306,745

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

	June 30, 2016	December 31,2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 885	$ 3,257
Accounts receivable:		
Trade	432	405
Other	130	142
Prepaid expenses	41	75
Inventory	387	753
Total current assets	1,875	4,632
Non-current assets:		
Property, plant and equipment, net	412	472
Funds in respect of employee rights upon retirement	380	502
Deferred issuance costs	290	-
Royalties buyout	63	87
Total non-current assets	1,145	1,061
Total assets	$ 3,020	$ 5,693
LIABILITIES (NET OF CAPITAL DEFICIENCY)		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 1,198	$ 512
Other	2,223	2,006
Advanced payment from customers	111	167
Current maturity of loan	3,919	4,149
Total current liabilities	7,451	6,834
Long-term liabilities:		
Liability for employees rights upon retirement	539	706
Warrant liability	123	-
Long -term loan	-	1,099
Total long-term liabilities	662	1,805
Total liabilities	8,113	8,639
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 and 50,000,000 shares authorized at June 30, 2016 and December 31, 2015, respectively; 10,675,586 and 7,676,074 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	1	1
Additional paid-in capital	122,491	120,049
Accumulated deficit	(127,585)	(122,996)
Total capital deficiency	(5,093)	(2,946)
Total liabilities net of capital deficiency	$ 3,020	$ 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 June 30, 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.