# INSPIREMD, INC.

## FORM 8-K
(Current report filing)

Filed 05/09/17 for the Period Ending 05/09/17

| | |
|---|---|
| Telephone | (888) 776-6804 |
| CIK | 0001433607 |
| Symbol | NSPR |
| SIC Code | 3841 - Surgical and Medical Instruments and Apparatus |
| Industry | Medical Equipment, Supplies & Distribution |
| 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 9, 2017

# 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.) |

| 4 Menorat Hamaor St. Tel Aviv, Israel | 6744832 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: (888) 776-6804

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

**Item 2.02 Results of Operations and Financial Condition.**

On May 9, 2017, InspireMD, Inc. issued a press release announcing its financial and operating results for the fiscal quarter ended March 31, 2017. 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 | Press release dated May 9, 2017 (furnished herewith pursuant to Item 2.02). |

**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 9, 2017

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

**InspireMD Provides Business Update for the First Quarter of 2017**

*New Commercial Roll-Out of CGuard™ EPS on Schedule*

*84% Sequential Increase in Sales of CGuard™*

Tel Aviv—May 9, 2017 - InspireMD, Inc. (NYSE MKT:NSPR) (NYSE MKT:NSPR.WS) ("InspireMD" or the "Company"), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today provided a business update, including an update on its new commercialization strategy. The Company also reported financial and operating results for the first quarter ended March 31, 2017.

James Barry, PhD, Chief Executive Officer of InspireMD, commented, "Earlier this year, we announced our transition away from a single distributor covering 18 European countries to a direct distribution model. In just a few short months, we have announced numerous distribution agreements covering markets across Europe, Asia and South America, fulfilling our commitment to relaunch both more broadly and more focused in Europe, as well as expanding our global footprint. We are extremely encouraged by the favorable response from our new partners and potential near-term future partners around the world. Not only have these distribution agreements expanded our geographic coverage, but in markets previously served by our former European distributor we are gaining deeper access into all four key clinical specialties that implant carotid stents."

"While it has been a short time since we began signing these new distributors, the feedback has been very encouraging. Specifically, each of our new distributors is targeting the key opinion leaders (KOL) in its respective markets, and the response from many of these KOLs has been extremely positive. In fact, many of these KOLs who have not had access to the device until now, have become strong advocates for the CGuard $^{TM}$ EPS device and have begun to present at leading industry conferences such as ICCA Stroke 2017 in Russia and the Leipzig Interventional Course (LINC) 2017 in Germany, where a live case procedure performed by a leading German KOL was transmitted."

"Despite the transition from our former distributor in the back half of the first quarter, we still managed to achieve 12% growth in year-over year sales of CGuard™ versus the same period last year. More importantly, we saw an 84% sequential increase in CGuard $^{TM}$ sales versus the fourth quarter of 2016, reflecting the beginning of our turnaround. Heading into the second quarter and balance of the year, we expect to generate both sequential and year-over-year growth in CGuard™ as we continue adding key hospitals and KOLs to our customer base around the world. As the device is put into the hands of new KOLs, it should, over time, lead to broader market adoption. As such, we expect more meaningful growth towards the end of this year and into 2018 as our primary customers shift from the small population of KOLs to the mainstream groups of vascular surgeons, interventional cardiologists, interventional radiologists and interventional neuroradiologists."

“As these initiatives begin to take hold, we continue to maintain strict financial discipline and remain extremely confident in the outlook for the business.”

**Financial Results**

Revenue for the first quarter ended March 31, 2017 was $569,000 compared to $563,000 during the same period in 2016. The increase was primarily due to an increase in sales of CGuard™ EPS as we entered new regional markets despite the negative impact of the transition from our prior exclusive distribution partner for most of Europe. The transition to local distributors reflects an effort to broaden our sales efforts from only interventional neuroradiologists to include vascular surgeons, interventional cardiologists and interventional radiologists, as well. The increase in sales of CGuard™ EPS was partially offset by a decrease in MGuard™ Prime EPS associated with the trend of doctors increasingly using drug eluting stents (DES) rather than bare metal stents in STEMI patients. In the meantime, based on positive feedback from physicians , the Company is evaluating potential partners to combine MGuard™ Prime EPS with DES technology. Total operating expenses for the quarter ended March 31, 2017 were $2,478,000, an increase of 18.2% compared to $2,096,000 for the same period in 2016. This increase was primarily due to an increase in sales and marketing expenses (primarily to support the commercialization of CGuard™ EPS), as well as an increase in corporate related expenses. Net loss for the quarter ended March 31, 2017 totaled $2,559,000, or $0.81 per basic and diluted share, compared to a net loss of $2,252,000, or $7.00 per basic and diluted share, in the same period in 2016.

As of March 31, 2017, cash and cash equivalents were $8,572,000, compared to $7,516,000 as of December 31, 2016.

**Conference Call**

The Company will host a conference call on Wednesday, May 10 at 8:00 a.m. Eastern Time. The conference call will be available via telephone by dialing toll free 866-682-6100 for U.S. callers or +1 862-255-5401 for international callers, or on the Company’s Investor Relations section of the website: http://www.inspiremd.com/en/investors/investor-relations/.

A webcast will also be archived on the Company’s website and a telephone replay of the call will be available approximately one hour following the call, through midnight May 24, 2017, and can be accessed by dialing 877-481-4010 for U.S. callers or +1 919-882-2331 for international callers and entering conference ID: 10378.

**About InspireMD, Inc.**

InspireMD seeks to utilize its proprietary 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 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.*

**Investor Contacts:**

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**CONSOLIDATED STATEMENTS OF OPERATIONS** [1]

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

| | Three months ended March 31, | |
|---|---|---|
| | **2017** | **2016** |
| **Revenues** | $ 569 | $ 563 |
| Cost of revenues | 495 | 497 |
| **Gross Profit** | 74 | 66 |
| Operating Expenses: | | |
| Research and development | 350 | 379 |
| Selling and marketing | 532 | 365 |
| General and administrative | 1,596 | 1,352 |
| Total operating expenses | 2,478 | 2,096 |
| Loss from operations | (2,404) | (2,030) |
| Financial expenses | 154 | 221 |
| Loss before tax expenses | (2,558) | (2,251) |
| Tax expenses (Income) | 1 | 1 |
| **Net Loss** | $ (2,559) | $ (2,252) |
| Net loss per share – basic and diluted | $ (0.81) | $ (7.00) |
| Weighted average number of shares of common stock used in computing net loss per share – basic and diluted | 3,946,434 | 321,684 |

**CONSOLIDATED BALANCE SHEETS** [2]

(U.S. dollars in thousands)

| | March 31, 2017 | December 31, 2016 |
|---|---|---|
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 8,572 | $ 7,516 |
| Accounts receivable: | | |
| Trade, net | 471 | 356 |
| Other | 189 | 157 |
| Prepaid expenses | 21 | 65 |
| Inventory | 329 | 500 |
| **Total current assets** | 9,582 | 8,594 |
| Non-current assets: | | |
| Property, plant and equipment, net | 496 | 379 |
| Funds in respect of employee rights upon retirement | 402 | 399 |
| Royalties buyout | 32 | 38 |
| **Total non-current assets** | 930 | 816 |
| **Total assets** | $ 10,512 | $ 9,410 |

| | March 31, 2017 | December 31, 2016 |
|---|---|---|
| **LIABILITIES AND EQUITY (NET OF CAPITAL DEFICIENCY)** | | |
| Current liabilities: | | |
| Current maturity of long-term loan | $ - | $ 2,680 |
| Accounts payable and accruals: | | |
| Trade | 351 | 618 |
| Other | 1,884 | 1,447 |
| Advanced payment from customers | 23 | 33 |
| **Total current liabilities** | 2,258 | 4,778 |
| Long-term liabilities: | | |
| Liability for employees rights upon retirement | 540 | 587 |
| **Total long-term liabilities** | 540 | 587 |
| **Total liabilities** | 2,798 | 5,365 |
| Equity: | | |
| Common stock, par value $0.0001 per share; 150,000,000 and 50,000,000 shares authorized at March 31, 2017 and December 31, 2016, respectively; 6,830,070 and 1,475,318 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively | 1 | - |
| Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at March 31, 2017 and December 31, 2016, respectively; 191,993 and 311,521 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively | - | - |
| Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at March 31, 2017 and December 31, 2016, respectively; 808,612 and 0 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively | - | - |
| Additional paid-in capital | 142,186 | 135,959 |
| Accumulated deficit | (134,473) | (131,914) |
| **Total equity** | 7,714 | 4,045 |
| **Total liabilities and equity** | $ 10,512 | $ 9,410 |

(1) All 2017 financial information is derived from the Company's 2017 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission, 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.

(2) All March 31, 2017 financial information is derived from the Company's 2017 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, 2016 financial information is derived from the Company's 2016 audited financial statements as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2016 filed with the Securities and Exchange Commission.