EDGAR pro
by EDGAR Online

INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 06/01/18 for the Period Ending 05/30/18

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

Powered By EDGAR Online
http://www.edgar-online.com
© Copyright 2018, EDGAR Online, a division of Donnelley Financial Solutions. All Rights Reserved.
Distribution and use of this document restricted under EDGAR Online, a division of Donnelley Financial Solutions, Terms of Use.

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 30, 2018

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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(f) ***Determination of Bonus Awards for Year Ended December 31, 2017***

On May 30, 2018, the compensation committee of the board of directors (the "Compensation Committee") of InspireMD, Inc. (the "Company") approved bonus awards for the year ended December 31, 2017 for the Company's named executive officers identified in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on February 13, 2018 (the "Annual Report"). As of the filing of the Annual Report, the amounts of the bonus awards for the year ended December 31, 2017 for the named executive officers had not been determined and not calculable and, therefore, were not included in the 2017 summary compensation table included in the Annual Report. As indicated in the applicable footnotes to the 2017 summary compensation table included in the Annual Report, the Compensation Committee had planned to determine such bonus awards and make payment of such bonus awards, if any, upon closing of one or more equity financings in fiscal year 2018. All other compensation for the Company's named executive officers for the year ended December 31, 2017 was previously reported by the Company in the summary compensation table included in the Annual Report.

Pursuant to Item 5.02(f) of Form 8-K, the amounts of the bonus awards for the year ended December 31, 2017 and the total compensation for the year ended December 31, 2017 for the named executive officers, recalculated to include the bonus awards for the year ended December 31, 2017, are set forth below.

Name and Principal Position	Year	Bonus ($)	Total ($)
James Barry, Ph.D. *President and Chief Executive Officer*	2017	25,000	440,319
Craig Shore *Chief Financial Officer, Secretary and Treasurer*	2017	25,000(1)	370,286(1)
Agustin Gago *Executive Vice President And Chief Commercial Officer*	2017	25,000(2)	378,334

(1) Compensation amounts received in non-U.S. currency have been converted into U.S. dollars using the average exchange rate for the applicable period, except for bonus amounts which have been converted into U.S. dollars using 3.5997 NIS per dollar which was the average exchange rate for the twelve month period ended December 31, 2017. The average exchange rate for the twelve month period ended December 31, 2017 and 2016 were 3.5997 NIS per dollar and 3.8409 NIS per dollar, respectively.

(2) In addition to $50,000 of cash bonus earned by Mr. Gago in the 2017 calendar year previously reported in the summary compensation table included in the Annual Report.

Item 8.01 Other Events.

On May 30, 2018, the Company announced that Professor Piotr Musiałek, from the Department of Cardiac and Vascular Diseases, John Paul II Hospital, Kraków, Poland, presented the expanded 24 month follow-up results from the PARADIGM-Extend Clinical Study utilizing CGuard™ EPS at EuroPCR 2018, in Paris on May 24, 2018. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated May 30, 2018

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: June 1, 2018

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Reports on Expanded 2 Year Follow-up Results from the PARADIGM Clinical Study Using CGuard™ EPS

Results Presented at EuroPCR 2018
Confirm Sustained Safety and Cerebral Embolic Prevention out to 24 months

Tel Aviv, Israel— May 24, 2018 - InspireMD, Inc. (NYSE AMER:NSPR), a leader in embolic prevention systems (EPS), thrombus management technologies and neurovascular devices, today announced that Professor Piotr Musiałek, from the Department of Cardiac and Vascular Diseases, John Paul II Hospital, Kraków, Poland, presented the expanded 24 month follow-up results from the PARADIGM-Extend Clinical Study utilizing CGuard™ EPS at EuroPCR 2018, in Paris on May 24, 2018.

PARADIGM-Extend is the continuation of PARADIGM, an investigator-led clinical study evaluating the use of CGuard™ EPS in patients with symptomatic or asymptomatic carotid artery stenosis with increased stroke risk. The latest results include 251 patients, which is more than double the patient population of 101, which was previously reported in December 2017. Overall cumulative data showed no major strokes in the peri-procedural or post-procedural period up to 30 days (0%). There was one minor peri-procedural stroke (0.4%), and only one death (non-device related) at 30 days (0.4%). These results are consistent with earlier reported data in the first patient cohort. Importantly, there were no stroke or stroke-related deaths between 12 and 24 months.

Professor Musialek, commented, "The 24-month clinical and duplex ultrasound evidence is consistent with the unprecedented, sustained safety and cerebral embolism prevention efficacy of CGuard™ EPS in both symptomatic and asymptomatic patients with carotid stenosis."

"We feel privileged to have had Professor Musialek, one of the leading interventional cardiologists in Europe, present his expanded results of the PARADIGM study at EuroPCR 2018," said James Barry, PhD, Chief Executive Officer of InspireMD. "Professor Musialek's PARADIGM-Extend trial continues to demonstrate consistent and strong clinical evidence of durable protection against potential stroke that can result from post procedural embolization. In addition, the duplex ultrasound data confirms normal vessel healing with the CGuard ^{TM} EPS device and with no indication of any long term in-stent restenosis. These results include a significant proportion of challenging patients that would have otherwise been sent to surgery (carotid endarterectomy). Furthermore, these results are consistent with other CGuard™ EPS clinical trials including: CARENET, IRON-GUARD, WISSGOTT Study and CASANA Study. This excellent data continues to build on the extensive body of evidence supporting the clinical advantages of CGuard™ EPS in preventing stroke that can result from high grade carotid stenosis."

EuroPCR is the official annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI) and the world-leading course in interventional cardiovascular medicine. Bringing together over 12,000 clinicians and industry executives each year, EuroPCR is the global forum for sharing within and between all interventional communities. EuroPCR 2018 took place in Paris from May 22-25, 2018.

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 American under the ticker symbol NSPR and certain warrants are quoted on the NYSE American 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:

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

Crescendo Communications, LLC
David Waldman
Phone: (212) 671-1021
Email: NSPR@crescendo-ir.com