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): June 25, 2020

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)

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

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of exchange on which registered**
Common Stock, par value $0.0001 per share	NSPR	NYSE American
Warrants, exercisable for one share of Common Stock	NSPR.WS	NYSE American
Series B Warrants, exercisable for one share of Common Stock	NSPR.WSB	NYSE American

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 8.01 Other Events.

On June 25, 2020, InspireMD, Inc. (the "**Company**") issued a press release announcing that the results from an investigator-initiated SIBERIA randomized clinical trial of the Company's CGuard™ Embolic Prevention System (EPS) are being featured as a late-breaking presentation in an EuroPCR e-Course, which is being held June 25-27, 2020.

The trial, which evaluated 30-day silent brain infarcts associated with the use of the Acculink™ conventional open-cell nitinol stent vs the CGuard™ Micronet™-covered stent, displayed that CGuard™ had a statistically significant (greater than three-fold) reduction in the procedure-generated mean cerebral lesion volume relative to Acculink™. At 30 days, there were zero new cerebral lessons in the CGuard™ arm, compared to six in the Acculink™ arm, also statistically significant.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press release dated June 25, 2020

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 25, 2020

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1

InspireMD Announces Late-Breaking Presentation of Early SIBERIA Clinical Trial Results to be Featured in an e-Course at EuroPCR

In a head-to-head evaluation, significantly fewer silent brain infarcts were associated with CGuard™ EPS versus Acculink™ at 30 days post-procedure

Tel Aviv, Israel — June 25, 2020 – InspireMD, Inc. (NYSE American: NSPR), developer of the CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by carotid artery disease treatment, announced today that early results from the investigator-initiated SIBERIA randomized clinical trial of CGuard™ EPS are being featured as a late-breaking presentation in an EuroPCR e-Course, which is being held June 25-27, 2020. The study evaluated 30-day silent brain infarcts associated with the use of the Acculink™ conventional open-cell nitinol stent vs the CGuard™ Micronet™-covered stent.

Title: The SIBERIA trial for carotid artery stenosis: A randomized controlled trial of conventional versus Micronet™-covered stent use in percutaneous neuroprotected carotid artery revascularization: Peri-procedural and 30-day diffusion-weighted magnetic resonance imaging and clinical outcomes

Presenter: Pavel Ignatenko, MD, E.N. Meshalkin Siberian Federal Biomedical Research Center, Ministry for Public Health of the Russian Federation, Novosibirsk, Russia

Date: June 25, 2020

Time: 4:00pm CEST (10:00am EDT)

The SIBERIA trial evaluated one hundred patients who qualified for carotid revascularization with high risk for surgery and were randomized 1:1 to either CGuard or Acculink™. Primary endpoints were incidence and volume of new cerebral embolic post-procedural lesions (24-48 hours) as determined by diffusion weighted magnetic resonance imaging (DW-MRI). Principal secondary endpoints included incidence of periprocedural or postprocedural stroke, myocardial infarction and death at 30 days.

- Post Procedure (24-48 hours), the CGuard™ arm was observed to have a 78% reduction in the average volume of new cerebral lesions (157 mm^3 vs. 700 mm^3), a statistically significant improvement (p=0.007)
- At 30 days, DW-MRI showed zero new cerebral lessons in the CGuard™ arm versus six in the Acculink™ arm (p=0.03)
- At 30 days, there were zero strokes, myocardia infarctions or deaths in the CGuard arm and three events the Acculink™ arm (two strokes and one myocardial infarction)

Dr. Ignatenko stated, "CGuard™ Micronet™-covered stent use in consecutive unselected patients subjected to neuroprotected carotid artery stenting was associated with a greater than three-fold reduction in the procedure-generated mean cerebral lesion volume, and with zero post-procedural cerebral embolisms observed."

“The SIBERIA trial is the first randomized, controlled clinical trial to directly compare CGuard™ EPS head-to-head against a widely used conventional stent, and needless to say, we are very pleased with the results,” said Marvin Slosman, Chief Executive Officer of InspireMD. “The data from this important study provide critical validation and adds to the growing body of evidence as we work to make CGuard™ EPS the standard of care not only in carotid stenting, but also as a safe and less-invasive alternative to carotid endarectomy, which accounts for more than 75% of carotid artery revascularization procedures. We are grateful to Prof. Karpenko, Dr. Ignatenko, their colleagues and the patients who made this trial possible.”

About EuroPCR

EuroPCR is the official annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI) and the world-leading course in interventional cardiovascular medicine.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet® technology to make its products the industry standard for the treatment of carotid artery disease by providing outstanding acute results and durable stroke-free long-term outcomes.

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 symbols NSPR.WS and NSPR.WSB.

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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