INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 07/23/20 for the Period Ending 07/23/20

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): July 23, 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 July 23, 2020, InspireMD, Inc. (the "**Company**") issued a press release announcing that it has obtained registration from the Brazilian registration authority for the Company's CGuard™ MicroNet®- covered stents, thereby clearing them for commercial sale and distribution in Brazil.

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 July 23, 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: July 23, 2020

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1

InspireMD Gains Registration Clearance of its CGuard™ Embolic Prevention System (EPS) in Brazil

Tel Aviv, Israel — July 23, 2020 – InspireMD, Inc. (NYSE American: NSPR), the developer of the CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by carotid artery disease (CAD), today announced it has obtained registration from the Brazilian registration authority, Agéncia Nacional de Vigiláncia Sanitária (ANVISA), for its CGuard™ MicroNet®- covered stent, clearing it for sale and distribution in Brazil.

"As the largest market for medical devices in Latin America and one of the top overall global markets for carotid artery disease, the Brazilian registration clearance for CGuard™ is an important accomplishment for our company and represents a significant opportunity to serve an emerging healthcare system. The global carotid artery disease market is expected to reach up to $11.6 billion by 2023, and with an expected 12% CAGR in the overall stent market in Brazil, it is a pillar of our 2020 and 2021 growth strategy," said Marvin Slosman, InspireMD's CEO. "We look forward to working with our Brazilian partner, *SUPRI Artigos Médicos Hospitalares Ltda*, to reach and serve this crucial market with our advanced technology."

Regulatory approval of CGuard™ EPS in Brazil reflects not only the ANVISA'S recognition of CGuard's differentiating features versus conventional carotid stents, but also the need for safer treatments for carotid artery disease. Brazil ranks as the sixth largest populated country in world and the largest healthcare market in Latin America. With a population over 213 million, Brazil represents an important step toward expanding commercial availability of InspireMD products into new territories.

"The Brazilian clearance further supports our goals of broader expansion into South America, particularly into adjacent markets such as Argentina, Mexico and Columbia, and as part of our global expansion strategy, capitalizing on the potential of CGuard™ EPS – and its novel MicroNet® technology – to fundamentally disrupt the current standard of care in carotid artery disease. While the COVID-19 related interruptions have had an impact on elective surgeries worldwide, we expect a resumption in elective procedures as the healthcare system gains a foothold in returning to more normalized operations, as is occurring in our key markets in Europe and other parts of the world. The Brazilian clearance for our CGuard™ EPS represents a milestone in our broader strategy to continue growing our market share in existing markets while expanding in growth markets such as South America, Asia/Pacific, and the U.S. We are also continuing our concerted focus on numerous opportunities for growing our pipeline, leveraging new indications for use of CGuard™ and MicroNet® along with our research into a peri procedural protection device technology as we seek to build upon our strong growth performance in the first quarter of 2020," Mr. Slosman concluded.

Marcos Ramin of SUPRI Artigos Médicos Hospitalares Ltda, added, "At SUPRI, we strive to bring the latest technologies to health care professionals across Brazil, and we are pleased to add CGuard™ EPS to our portfolio, the most innovative and effective carotid stent available today to prevent embolic stroke of Brazilians."

The CGuard® Embolic Protection System is an advanced platform solution designed to deliver the flexibility of the traditional open cell stent with an advanced protection from peri procedural and post procedural embolic events caused by plaque prolapse through the stent strut that can lead to stroke. CGuard's unique MicroNet® technology mitigates the prolapse and associated embolization and has shown superior clinical outcomes for patients against alternative carotid stent types, conventional or next generation double layer stents, as well as invasive procedures such as endarterectomy, a major surgical procedure. InspireMD's CGuard™ has created a new dimension in protected treatment of carotid artery disease with the potential to truly establish a new standard of care for management of carotid artery disease and stroke prevention.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet® technology to make its products the industry standard for carotid stenting 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 symbol 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.

Investor Contacts:

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