

InspireMD, Inc.
Form 8-K
October 11, 2011

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): October 4, 2011

InspireMD, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or other
jurisdiction of
incorporation)

333-162168
(Commission File
Number)

26-2123838
(IRS Employer
Identification No.)

3 Menorat Hamaor St.
Tel Aviv, Israel
(Address of principal executive offices)

67448
(Zip Code)

Registrant's telephone number, including area code: 972-3-691-7691

(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 1.01 Entry into a Material Definitive Agreement.

On October 4, 2011, InspireMD Ltd. (“InspireMD”), our wholly-owned subsidiary, entered into a clinical trial services agreement (the “Clinical Trial Services Agreement”) with Harvard Clinical Research Institute, Inc. (“Harvard”), pursuant to which Harvard will conduct a study entitled “MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction” (the “Study”) on behalf of InspireMD. InspireMD will pay Harvard an estimated fee of \$6,994,456 for conducting the Study, subject to adjustment dependent upon changes in the scope and nature of the Study, which is expected to last 37 months, as well as other costs to be determined by the parties. The Clinical Trial Services Agreement will expire upon the final payment by InspireMD to Harvard for work performed by Harvard on the Study, unless earlier terminated pursuant to the terms therein. The Study is expected to enroll a total of 654 patients in 50 clinical sites in the United States and Europe. InspireMD is entering into a separate agreement with a third party to monitor and oversee the European clinical sites involved in the Study and to share the data from the European sites with Harvard.

InspireMD will have exclusive rights to the data produced by the Study and Harvard will transfer to InspireMD all rights to any intellectual property developed during the Study or relating to the Study or to InspireMD’s products being used during the Study. Harvard will, however, own all rights to the procedures, methodologies, computer programs and other know-how used and/or generated by Harvard in conducting analyses related to the Study. Harvard will not be responsible for any adverse reactions by any of the patient subjects taking part in the Study. All data produced by the Study will be kept confidential by both parties, however, there are provisions by which an independent publications committee can publish results of the Study while providing InspireMD an opportunity to first publish and protect its intellectual property rights.

The foregoing summary of the Clinical Trial Services Agreement is not complete, and is qualified in its entirety by reference to the full text of the Clinical Trial Services Agreement that is attached as an exhibit to this Current Report on Form 8-K as Exhibit 10.1. Readers should review the Clinical Trial Services Agreement for a more complete understanding of the terms and conditions associated with this transaction.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
10.1	Clinical Trial Services Agreement, dated as of October 4, 2011, by and between InspireMD Ltd. and Harvard Clinical Research Institute, Inc.

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: October 11, 2011

By: /s/ Craig Shore
Name: Craig Shore
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
10.1	Clinical Trial Services Agreement, dated as of October 4, 2011, by and between InspireMD Ltd. and Harvard Clinical Research Institute, Inc.