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): January 10, 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 7.01 Regulation FD Disclosure.

On January 10, 2018, InspireMD, Inc. (the " ***Company*** ") held a conference call for investors to discuss recent developments, preliminary unaudited fourth quarter 2017 sales results, and proposals under consideration for the upcoming shareholder meeting, followed by a "questions and answers" section. A copy of the script of the Company's management for the conference call is being furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and are incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "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, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Conference Call Script dated January 10, 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: January 10, 2018

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

CRESCENDO COMMUNICATIONS, LLC

To: **Jim Barry, Craig Shore**

From: **David Waldman, Natalya Rudman**

Subj: **Business Update Call**

Dial- in: **877-407-0781**

I. Introduction – David Waldman

Good morning and thank you for joining InspireMD's business update conference call.

On the call with us today is Jim Barry, Chief Executive Officer of InspireMD and Craig Shore, Chief Financial Officer.

At the conclusion of today's prepared remarks, we will open the call for your questions. If anyone has any questions after the call, please contact Crescendo Communications at 212-671-1021.
Before we begin, let me take a minute to note that this conference call may contain forward-looking statements. Forward-looking statements address future events and conditions and therefore involve inherent risks and uncertainties. Actual results may differ materially from those currently anticipated in such statements. Such information is subject to known and unknown risks, uncertainties and other factors that could influence actual results or events and cause actual results or events to differ materially from those stated, anticipated or implied in the forward-looking information. Listeners are cautioned not to place undue reliance on forward-looking information as no assurances can be given as to the future results, levels of activity or achievements.

With that out of the way, let me now turn the call over to Jim Barry, CEO. Please go ahead, Jim.

II. Business Overview – Jim Barry

Thank you, David, and thanks to everyone for joining us for today's conference call.

I know it's unusual for us to be holding a conference call in January, but given some of the recent developments, we thought it would be helpful to update shareholders on where we have been and where we are heading.

First, when I took the reigns as CEO, I was committed to focusing on the operations of the company and building the company as opposed to focusing on M&A, which in my experience, can be totally unpredictable. After eighteen months, I believe we are now very well positioned in the market, and this is evidenced by our stronger year-over-year growth. As you may recall, for the third quarter of 2017, we achieved a 90% year-over-year increase in sales of CGuard™ EPS. As announced this morning, I'm pleased to report preliminary unaudited CGuard sales of $606 thousand for the fourth quarter of 2017 which represents approximately a **211** % increase compared to the fourth quarter of 2016. The preliminary unaudited overall sales, including MGuard, for Q4 2017 are $833 thousand which represents approximately a 159% increase compared to the fourth quarter of 2016. Based on these numbers, we believe our strategy is working, we have momentum and we are poised to continue our turnaround. At this point, as we head into Q1 2018, we expect another strong quarter for CGuard.

Just last week, we announced we received regulatory approval for CGuard™ in India and that we had signed Hester Diagnostics as our exclusive distributor. This partnership comes on the heels of similar distribution agreements across Asia, including Hong Kong, Taiwan, Australia, New Zealand and Vietnam.

In addition, CGuard™ continues to be featured in leading publications and at the leading clinical conferences across both western and eastern Europe and the Middle East.

We recently announced the preliminary 24-month follow-up results in the PARADIGM 101 Clinical Study. Professor Musiałek presented these long-term follow-up results at both the 2017 VEITH Symposium and the 2017 ICI Meeting.

The results from this trial are consistent with four other published CGuard™ studies, and further demonstrate the sustained benefits of CGuard™ out to two years. To the best of our knowledge, this is the longest known clinical follow-up with any such carotid devices to date. And most importantly, without CGuard™, the majority of these patients would have otherwise had to undergo a carotid endarterectomy, an invasive surgical procedure to treat their carotid artery disease.

Patient enrollment is also continuing in an investigator initiated trial in Russia led by vascular surgeon Professor Karpenko comparing Abbott's RX ACCULINK Carotid Stent Versus CGuard™ EPS. The objective of the trial is to assess the superiority of CGuard™ EPS versus the market leading conventional carotid stent in patients at high risk for Carotid Endarterectomy or surgery.

With this trial, being led by a vascular surgeon, we believe there are continued signs the market may finally be recognizing the advantages of CGuard™ versus not only traditional stents, but the gold standard, more invasive, carotid endarterectomy surgical procedure. We recently presented the preliminary results of a 50-patient study at the 7th Munich Vascular Conference, which demonstrated improved outcomes using CGuard™ versus carotid endarterectomy. The study showed cranial nerve injury was significantly lower in patients treated with CGuard™ versus patients undergoing carotid endarterectomy and it further showed that hospital discharge was faster in the CGuard™ group compared to carotid endarterectomy. This trial was also conducted by a leading vascular surgeon, Professor Ralf Kolvenbach, in Germany.

These clinical trials illustrate that CGuard™ EPS is not only gaining acceptance among key opinion leaders that treat carotid artery disease, but these physicians are approaching us, unsolicited, to be involved with our program. They are even spending their own time and money to run independent trials around our technology.

We believe this positions us for even stronger sales growth as these KOLs publish their findings, which in turn may influence the mainstream group of users and thus support a broader expansion into the larger group of vascular surgeons, interventional cardiologists, interventional radiologists and interventional neuroradiologists. We have had to make some significant and difficult decisions to get where we are in this short period of time, and it appears to be paying off. For this reason, we are extremely encouraged heading into 2018.

Moreover, we have always defined the target market for CGuard™ as those patients more likely to undergo carotid artery stenting. But based on the preliminary results of these ongoing clinical studies, and the level of interest we are getting from the vascular surgery community, we believe we may be able to start making inroads into those patients that would otherwise undergo surgery. We believe such expansion would broaden the addressable market for our device from the reported approximately $500 million to well over a billion in the carotid market alone.

We continue to focus our resources on CGuard, where we see the most immediate near-term opportunity. Once we are on sounder financial footing, we can exploit the full potential of CGuard in the United States, further develop CGuard product extensions that can help accelerate penetration into the surgical market, and further exploit our platform technology by developing products for the neurovascular and peripheral device markets. It is important to note that we expect these projects to have relatively low development risk and thus expense, as we would be leveraging our existing product configuration of our MicroNet mesh technology.

Given that the fundamentals of the company are now in a better place, and we had an improved third quarter in 2017, as previously reported, we felt it was time to turn our attention to our capital structure. In November, we announced a plan to begin the process of recapitalizing the company and I'd like to take a moment to discuss the rationale behind this move.

Over the course of our last 2 capital raises, we were just beginning our turnaround and changing our focus. Unfortunately, that limited our funding options and resulted in a complicated capital structure.

Despite the growth and operational success we have achieved since our last financing, our capital structure turned out to be a continued impediment to driving shareholder value and completing our turnaround. Specifically, many of the larger institutional investors and fundamental healthcare funds have expressed their unwillingness to invest in our stock, despite their interest in the company, due to the complicated share structure and multiple preferred share series, which carry certain preferential features, especially the Series B Preferred Stock, which I will refer to as "Series B shares" in this call.

The rationale for the sale of $750,000 of Series D Preferred Stock, which was announced on November 29, was to reset the conversion price on the Series B shares, with the goal of eliminating all of the outstanding Series B shares by having the current Series B shareholders convert their preferred holdings into common stock. Without eliminating the Series B shares, we believed that it would be difficult, if not impossible, to attract any new institutional or fundamental investors as well as potential strategic investors.

As a result, all Series B shareholders eligible to convert, have fully converted all of their Series B holdings. The one remaining Series B shareholder's shares will convert in a qualified financing with the identical terms of the new investors. In addition, the holder of more than 60% of the outstanding shares of Series C Preferred Stock has agreed to convert their Series C Preferred Stock into the securities offered in such qualified financing with the identical terms of the new investors. This is very important since new investors will no longer have to worry about the vast majority of the preferred shareholders holding preferential terms over them.

So as of today, the shares outstanding, assuming conversion of all the preferred shares is 66.5 million. We strongly believe the steps we have taken are necessary and will ultimately prove beneficial for shareholders given the operational success we are now experiencing.

On December 15, we filed a preliminary proxy statement that we will be holding a shareholder meeting on February 7 to approve certain proposals that we believe are necessary to complete the recapitalization plan and take advantage of strategic financing opportunities as they may arise.

First, we are seeking approval for a reverse split of our common stock at a ratio in the range of 1-for-25 to 1-for-50. We realize this is not popular for existing shareholders and this is not something we would do if we had any other options. But the truth is, we do not believe we have other reasonable options. Without the option of a reverse split, we believe we will be unable to raise capital in the future because we would not have sufficient authorized, unissued and unreserved shares and we will likely be delisted from the NYSE for the lack of shareholder equity. We also risk being delisted for low trading price if the stock were to remain under $0.20 for an extended period. The consequences of either of these events would put the Company in serious jeopardy.

That said, we have received positive feedback from a variety of groups given the progress we have made. However, it was also conveyed to us that the stock would need to be over $1, and in some cases $5, in order for the key healthcare funds to invest, and for many of the brokers to recommend our stock to their clients.

Obviously, we do not believe the current share price is reflective of the fundamental value we have built. For this reason, we will be prudent in how, when and on what terms we would contemplate any potential future financing. It would not make sense to work this hard to clean up our cap structure only to put the company back into a difficult situation.

Second, we are seeking approval to issue more than 19.99% of the Company's common stock at a price per share of $0.20 upon conversion of the Series D convertible preferred stock, which was less than the greater of book or market value of the Company's common stock on the date of the purchase agreement for the Series D.

Lastly, we are seeking approval to adjourn the shareholders meeting if we need additional time to solicit proxies related to the shareholder meeting.

We would greatly appreciate your support on these measures which we recognize on the face of it are difficult and frustrating, but we believe it is not only beneficial, but will be critical for the long-term sustainability and success of the Company.

As I noted above, when I took over as CEO in June of 2016, the focus of the company was different and thus parts of the operations were overlooked. We took the last 18 months to get focused on the business and get it to a place where we can execute on the potential we believe this company has. We believe we have accomplished that goal and this recapitalization is one of the last steps we think will be required for completing the turnaround and realizing the true potential of our company. We believe we now have the ability to build this company as opposed to fixing it.

I got involved with InspireMD when I joined the Board in 2012 because I fundamentally believed in the enormous potential of this technology and my now coming into the company in an operating role to rebuild things should be a further indicator to you all that my view of the potential here has not only not changed, but has in fact increased, as we continue to validate the technology with every clinical trial and editorial that has been published over this past year, and every physician I have spoken with.

Many of you know, prior to InspireMD, I was at Boston Scientific, where I had the good fortune to personally lead the development and supported the global commercialization of the company's first drug eluting stent, which to date I believe remains the most successful commercial launch of a medical device in the history of the industry. While the drug eluting stent was vitally important to the treatment of coronary artery disease, and it remains an achievement in which I take great pride, I believe InspireMD's products and pipeline can have a greater impact on saving lives and preventing catastrophic events, such as stroke, that occur with conventional devices.

If you look at the team we have built, and our board of directors, as well as our major investors, these are people that would not tie their name to a company unless they strongly believed in the underlying technology, products and market potential. This confidence and perseverance is finally proving out, as illustrated by our growth this year and the 211% growth in CGuard sales this quarter.

To wrap up, we have put the company in a much better position, allowing and requiring us to make difficult decisions like we did with the recapitalization, and thus we continue to fight and believe our best days are ahead of us.

We expect 2018 will be another transformative year. We have already seen adoption of CGuard among the leading KOLs and expect to begin seeing greater uptake among mainstream vascular surgeons, interventional cardiologists, interventional radiologists and interventional neuroradiologists. We believe we may be able to make inroads into the surgical market based on the positive clinical results comparing CGuard against surgery or carotid endarterectomy. We look forward to reporting the results of a number of ongoing trials, including the trial comparing CGuard™ head to head with Abbott's RX ACCULINK Carotid Stent.

We appreciate the support of our shareholders and would appreciate your continued support at the upcoming shareholder meeting, which we believe will allow us to complete our turnaround and help us to realize the full potential of the company and our technology.

At this point, we'll now open the call to your questions.