InspireMD, Inc.
Form 10-Q
May 11, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended: March 31, 2015

OR

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 001-35731

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2123838**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

321 Columbus Avenue

Boston, MA 02116
(Address of principal executive offices)
(Zip Code)

(857) 453-6553
(Registrant’s telephone number, including area code)

Indicate by check mark whether registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The number of shares of the registrant’s common stock, $0.0001 par value, outstanding as of May 11, 2015: 77,995,335.

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(Unaudited)

March 31, 2015

INSPIREMD, INC.

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

March 31, 2015

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The amounts are stated in U.S. dollars

INSPIREMD, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(U.S. dollars in thousands)

	March 31, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 13,186	$ 6,300
Accounts receivable:		
Trade	719	635
Other	278	359
Prepaid expenses	109	150
Inventory	1,750	1,924
Total current assets	16,042	9,368
NON-CURRENT ASSETS:		
Property, plant and equipment, net	584	622
Deferred issuance costs	136	153
Funds in respect of employees rights upon retirement	504	498
Long-term prepaid expenses	58	66
Royalties buyout	400	752
Total non-current assets	1,682	2,091
Total assets	$ 17,724	$ 11,459

The accompanying notes are an integral part of the condensed consolidated financial statements.

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INSPIREMD, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(U.S. dollars in thousands)

	March 31, 2015	December 31, 2014
LIABILITIES AND EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$665	$ 909
Other	2,766	3,576
Advanced payment from customers	162	179
Current maturity of loan	3,909	3,809
Total current liabilities	7,502	8,473
LONG-TERM LIABILITIES:		
Liability for employees rights upon retirement	699	687
Long-term loan	4,138	5,086
Total long-term liabilities	4,837	5,773
COMMITMENTS AND CONTINGENT LIABILITIES (Note 11)		
Total liabilities	12,339	14,246
EQUITY (CAPITAL DEFICIENCY):		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 75,940,566 and 41,368,889 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	7	4
Additional paid-in capital	118,001	104,620
Accumulated deficit	(112,623)	(107,411)
Total equity (capital deficiency)	5,385	(2,787)
Total liabilities and equity (net of capital deficiency)	$17,724	$ 11,459

The accompanying notes are an integral part of the condensed consolidated financial statements.

INSPIREMD, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(U.S. dollars in thousands, except share and per share data)

	Three months ended March 31,	
	2015	2014
REVENUES	$477	$1,482
COST OF REVENUES	514	625
GROSS PROFIT (LOSS)	(37)	857
OPERATING EXPENSES:		
Research and development	1,352	2,577
Selling and marketing	1,017	1,276
General and administrative	1,970	2,539
Restructuring and impairment expenses	514	-
Total operating expenses	4,853	6,392
LOSS FROM OPERATIONS	(4,890)	(5,535)
FINANCIAL EXPENSES, net:		
Interest expense	301	352
Other financial expenses	5	61
Total financial expenses	306	413
LOSS BEFORE INCOME TAXES	(5,196)	(5,948)
TAX EXPENSES	16	20
NET LOSS	$(5,212)	$(5,968)
NET LOSS PER SHARE - basic and diluted	$(0.10)	$(0.18)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	49,915,187	34,051,703

The accompanying notes are an integral part of the condensed consolidated financial statements.

INSPIREMD, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(U.S. dollars in thousands)

	Three months ended March 31, 2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,212)	$ (5,968)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	75	56
Impairment of royalties buyout	316	
Change in liability for employees right upon retirement	12	26
Financial expenses	102	93
Share-based compensation expenses	1,029	1,019
Loss on amounts funded in respect of employee rights upon retirement, net	4	
Changes in operating asset and liability items:		
Decrease in prepaid expenses	49	60
Decrease (increase) in trade receivables	(84)	361
Decrease (increase) in other receivables	81	(78)
Decrease in inventory	174	250
Decrease in trade payables	(244)	(218)
Increase (decrease) in other payables and advance payment from customers	(924)	690
Net cash used in operating activities	(4,622)	(3,709)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(1)	(13)
Amounts funded in respect of employee rights upon retirement, net	(10)	(21)
Net cash used in investing activities	(11)	(34)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Taxes withheld in respect of share issuance	(78)	(77)
Proceeds from issuance of shares and warrants, net of $1,315 issuance costs	12,529	
Repayment of long-term loan	(891)	
Net cash provided by (used in) financing activities	11,560	(77)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(41)	(9)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	6,886	(3,829)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	6,300	17,535
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	$ 13,186	$ 13,706

The accompanying notes are an integral part of the condensed consolidated financial statements.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 1 - DESCRIPTION OF BUSINESS

a. General

InspireMD, Inc., a Delaware corporation (the "Company"), together with its subsidiaries, is a medical device company focusing on the development and commercialization of its proprietary MicroNet™ stent platform technology for the treatment of complex coronary and vascular disease. MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures. The Company's coronary products combining MicroNet and a bare-metal stent (MGuard Prime™ EPS) are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). In October 2014, the Company launched a limited market release of its carotid embolic prevention system (CGuard™ EPS), which combines MicroNet and a self-expandable nitinol stent in a single device to treat carotid artery disease, using an over-the-wire delivery system. In January 2015, the Company received CE mark approval for the rapid exchange delivery system and fully launched CGuard in countries in Europe. The Company markets its products through distributors in international markets, mainly in Europe, Southeast Asia, India, Latin America and Israel.

b. Liquidity

The Company has an accumulated deficit as of March 31, 2015, as well as net losses and negative operating cash flows in recent years and the current year. The Company expects to continue incurring losses and negative cash flows from operations. Management of the Company presently anticipates that it has sufficient resources to fund its operations for at least the next twelve months. During the next twelve months management expects that the Company will need to raise additional capital to finance its losses and negative cash flows from operations beyond the next twelve months and may continue to be dependent on additional capital raising as long as its products do not reach commercial profitability.

Management's plans include the continued commercialization of the MGuard™ and CGuard™ products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances, however, that the Company will be successful in obtaining the level of financing needed for its operations. If the Company is unsuccessful in commercializing its MGuard™ or CGuard™ products and raising capital, it may need to reduce activities, curtail or cease operations.

During the fourth quarter of 2014, the Company began implementing a focused spending plan. The plan included reducing the focus of clinical and development expenses related to the Company's bare metal stent product and increasing the focus on the Company's drug eluting stent product. Prior to the fourth quarter of 2014, a large portion of the Company's organization was supporting the MASTER II trial, in which the Company determined not to resume enrollment, and instead allocated resources to drug eluting stents and the CGuard platform.

During the first quarter of 2015, the board of directors approved to cease developing and promoting our bare metal stent platform and implementing another cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) limiting the focus of clinical and development expenses to only carotid and neurovascular products; (iii) limiting sales and marketing expenses to only those related to the CGuard EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, etc.). Prior to the cost reduction plan, a large portion of the Company's organization supported clinical trials and promotional activities related to the Company's bare metal stent platform. In light of the above noted change in focus, many positions related to the development and promotion of the Company's bare metal stent platform have since been elimated. The Company will invest in a next generation MGuard EPS drug eluting platform only upon entering into a strategic partnership.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

c. Fundraising

On March 9, 2015, the Company sold 34,369,675 shares of its common stock and warrants to purchase 34,369,675 shares of common stock in a registered direct offering. Each purchaser received a warrant to purchase one share of common stock for each share of common stock that it purchased in the offering. The warrants have a term of exercise of 5 years from the date of issuance and an exercise price of $0.55. This offering resulted in net proceeds to the Company of approximately $12.5 million after deducting placement agent fees and other offering expenses. See Note 4c.

NOTE 2 - BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, the financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the financial position and results of operations of the Company. These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company’s audited financial statements for the year ended December 31, 2014, as found in the Company’s Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 12, 2015. The balance sheet for December 31, 2014 was derived from the Company’s audited financial statements for the twelve months ended December 31, 2014. The results of operations for the three months ended March 31, 2015 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3 – RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In April, 2015, the Financial Accounting Standards Board (“FASB”) issued guidance related to the presentation of Debt Issuance Costs. The new guidance requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. The new guidance does not affect the recognition and measurement of debt issuance costs. The new guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The new guidance will be applied on a retrospective basis.

NOTE 4 - EQUITY:

a. During the three months ended March 31, 2015, the Company granted stock options to employees and directors to purchase a total of 1,492,525 shares of the Company's common stock. The options have exercise prices ranging from $0.32 to $0.83 per share, which were the fair market value of the Company's common stock on the date of each respective grant. Of the 1,492,525 options described above, 425,059 options are fully vested as of their grant date. The remaining options are subject to a three-year vesting period, with one-third of such awards vesting each year.

In calculating the fair value of the above options the Company used the following assumptions: dividend yield of 0%; expected term of 5-6.5 years; expected volatility of 62.68%-67.84%; and risk-free interest rate of 1.41%-1.71%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately $0.58 million.

b. During the three months ended March 31, 2015, the Company granted a total of 1,512,409 restricted shares of the Company's common stock to employees. Of the 1,512,409 restricted shares described above, 502,604 restricted shares are subject to a one-year vesting period, 92,500 restricted shares are fully vested as of their grant date and are subject to a 6 month lock up period and 917,305 restricted shares are subject to a three-year vesting period, with one-third of such awards vesting each year.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

The fair value of the above restricted shares was approximately $1.1 million.

c. On March 9, 2015, the Company sold 34,369,675 shares of its common stock and warrants to purchase 34,369,675 shares of common stock in a registered direct offering. Each purchaser received a warrant to purchase one share of common stock for each share of common stock that it purchased in the offering. The warrants, which are classified as equity, have a term of exercise of 5 years from the date of issuance and an exercise price of $0.55. This offering resulted in net proceeds to the Company of approximately $12.5 million after deducting placement agent fees and other offering expenses.

NOTE 5- NET LOSS PER SHARE:

Basic and diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share excludes potential share issuances of common stock upon the exercise of share options, warrants, convertible loans and restricted stocks as the effect is anti-dilutive.

The total number of shares of common stock related to outstanding options, warrants, convertible loans and restricted stock excluded from the calculations of diluted loss per share were 50,411,102 and 9,984,674 for the three month periods ended March 31, 2015 and 2014, respectively.

NOTE 6 - FAIR VALUE MEASURMENT:

The carrying amounts of financial instruments included in working capital approximate their fair value either because these amounts are presented at fair value or due to the relatively short-term maturities of such instruments. If measured at fair value in the financial statements, these financial instruments would be classified as Level 3 in the fair value hierarchy. As of March 31, 2015, the carrying amounts of financial instruments included in working capital approximate their fair value either because these amounts are presented at fair value or due to the relatively short-term maturities of such instruments. The fair value of the loan received on October 23, 2013 (the “Loan”) approximated its carrying amount since it bears interest at rates that approximate current market rates.

NOTE 7 - INVENTORY:

	March 31, 2015	December 31, 2014
	($ in thousands)	
Finished goods	$965	$ 1,273
Work in process	493	326
Raw materials and supplies	292	325
	$1,750	$ 1,924

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INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 8– IMPAIRMENT OF ROYALTIES BUYOUT

During the period ended March 31, 2015 the Company recorded expenses related to the impairment of our royalties buyout asset amounting to $316,000 due to anticipated lower sales of MGuard Prime in the future resulting from industry preferences for drug eluting stents. The expense is recorded under “Restructuring and impairment expenses” in the consolidated statements of operations.

NOTE 9 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	March 31, 2015	December 31, 2014
	($ in thousands)	
Employees and employee institutions	$ 608	$ 1,022
Accrued vacation and recreation pay	395	410
Accrued clinical trial expenses	691	1,016
Accrued expenses	958	993
Provision for sales commissions	94	120
Taxes payable	20	15
	$ 2,766	$ 3,576

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INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 10 - RELATED PARTIES:

a. During the three month period ended March 31, 2015, the Company’s chief executive officer was granted options to purchase 307,736 shares of common stock at an exercise price of $0.72 per share, as well as 517,583 shares of restricted stock. Of the 517,583 shares of restricted stock, 312,500 were in lieu of salary as part of his amendment for his base salary to be paid 50% in cash payments with the remaining 50% to be paid in an equivalent amount of shares of restricted common stock. See Note 4.

b. During the three month period ended March 31, 2015, directors of the Company were granted options to purchase an aggregate of 733,012 shares of common stock at exercise prices ranging from $0.32-$0.78, of which, 425,059 were in lieu of cash compensation that was owed to them for their servcies as directors for the third and fourth quarters of 2014 and the first quarter of 2015. See Note 4a.

NOTE 11 - COMMITMENT AND CONTINGENT LIABILITIES:

a. Litigation

In July 2012, a purported assignee of options in InspireMD Ltd. submitted a statement of claim against the Company, InspireMD Ltd., and the Company’s former CEO and President for a declaratory and enforcement order that it is entitled to options to purchase 83,637 shares of the Company’s common stock at an exercise price of $0.76 per share. In December 2014 the court accepted a motion to dismiss the former CEO and president from the lawsuit. After considering the views of its legal counsel as well as other factors, the Company’s management believes that a loss to the Company is neither probable nor in an amount or range of loss that is estimable.

In December 2012, a former service provider of InspireMD GmbH filed a claim with the Labor Court in Buenos Aires, Argentina in the amount of $193,378 plus interest (6% in dollars or 18.5% in pesos), social benefits, legal expenses and fees (25% of the award) against InspireMD Ltd. and InspireMD GmbH. The Company's management, after considering the views of its legal counsel as well as other factors, recorded a provision of $250,000 in the financial statements for the quarter ended December 31, 2012. In March 2015, the interest rate made by the Court of Appeal in Argentina was increased retroactively, which resulted in the provision increasing to $340,000. The related expense for the increase of $90,000 was recorded to “General and administrative” within the Consolidated Statements of

Operations. The Company's management estimates that the ultimate resolution of this matter could reasonably result in a loss of up to $110,000 in excess of the amount accrued.

b. Liens and pledges

The Company’s obligations under the Loan (as defined in Note 6) were secured by Israeli security agreements and deposit account control agreements on all of the assets and properties of the Company and InspireMD Ltd., other than the intellectual property of the Company and InspireMD Ltd.