InspireMD, Inc.
Form 10-Q
November 09, 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: September 30, 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 November 9, 2015: 7,785,268.

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Item 1. Financial Statements

INSPIREMD, INC.

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

September 30, 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)

	September 30, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 6,509	$ 6,300
Accounts receivable:		
Trade, net	664	635
Other	199	359
Prepaid expenses	108	150
Inventory	1,081	1,924
Total current assets	8,561	9,368
NON-CURRENT ASSETS:		
Property, plant and equipment, net	516	622
Deferred issuance costs	102	153
Funds in respect of employees rights upon retirement	466	498
Long-term prepaid expenses	20	66
Royalties buyout	96	752
Total non-current assets	1,200	2,091
Total assets	$ 9,761	$ 11,459

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

INSPIREMD, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(U.S. dollars in thousands)

	September 30, 2015	December 31, 2014
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 834	$ 909
Other	2,403	3,576
Advanced payment from customers	170	179
Current maturity of loan	4,123	3,809
Total current liabilities	7,530	8,473
LONG-TERM LIABILITIES:		
Liability for employees rights upon retirement	658	687
Long-term loan	2,147	5,086
Total long-term liabilities	2,805	5,773
COMMITMENTS AND CONTINGENT LIABILITIES		
(Note 11)		
Total liabilities	10,335	14,246
EQUITY (CAPITAL DEFICIENCY):		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 7,632,752 and 4,136,889 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	7	4
Additional paid-in capital	119,561	104,620
Accumulated deficit	(120,142)	(107,411)
Total capital deficiency	(574)	(2,787)
Total liabilities net of capital deficiency	$ 9,761	$ 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 September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
REVENUES	$632	$273	$1,794	$1,948
COST OF REVENUES	543	349	1,954	1,558
GROSS PROFIT (LOSS)	89	(76)	(160)	390
OPERATING EXPENSES:				
Research and development	781	2,460	2,880	7,485
Selling and marketing	588	1,806	2,600	5,030
General and administrative	1,713	2,139	5,270	7,126
Restructuring and impairment expenses	418		964	
Total operating expenses	3,500	6,405	11,714	19,641
LOSS FROM OPERATIONS	(3,411)	(6,481)	(11,874)	(19,251)
FINANCIAL EXPENSES, net:				
Interest expense	246	361	822	1,072
Other financial expenses (income)	(18)	(48)	34	(21)
Total financial expenses	228	313	856	1,051
LOSS BEFORE INCOME TAXES	(3,639)	(6,794)	(12,730)	(20,302)
TAX EXPENSES (INCOME)	2	(19)	1	3
NET LOSS	$(3,641)	$(6,775)	$(12,731)	(20,305)
NET LOSS PER SHARE - basic and diluted	$(0.48)	$(1.96)	$(1.89)	$(5.93)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	7,630,985	3,458,152	6,753,011	3,425,162

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

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INSPIREMD, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(U.S. dollars in thousands)

	Nine months ended September 30, 2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(12,731)	$(20,305)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	195	181
Impairment of royalties buyout	576	
Loss from sale of property, plant and equipment	3	
Change in liability for employees right upon retirement	(29)	109
Financial expenses	191	279
Share-based compensation expenses	2,600	3,151
Loss on amounts funded in respect of employee rights upon retirement, net	11	15
Changes in operating asset and liability items:		
Decrease in prepaid expenses	88	37
Decrease (increase) in trade receivables	(29)	1,458
Decrease (increase) in other receivables	160	(157)
Decrease (increase) in inventory	843	(89)
Decrease in trade payables	(75)	(75)
Increase (decrease) in other payables and advance payment from customers	(1,182)	1,124
Net cash used in operating activities	(9,379)	(14,272)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(12)	(105)
Decrease in restricted cash		93
Amounts funded in respect of employee rights upon retirement, net	21	(55)
Net cash provided by (used in) investing activities	9	(67)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Taxes withheld in respect of share issuance	(88)	(115)
Proceeds from issuance of shares and warrants, net of $1,315 and $46 issuance costs, respectively	12,432	2,229
Repayment of long-term loan	(2,739)	(290)
Net cash provided by financing activities	9,605	1,824
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(26)	(42)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	209	(12,557)
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	$6,509	$4,978

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 and Latin America.

b. Liquidity

The Company has an accumulated deficit as of September 30, 2015, as well as net losses and negative operating cash flows in recent years. The Company expects to continue incurring losses and negative cash flows from operations until its products (primarily CGuard™) reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with the Company's current cash position, the Company does not have sufficient resources to fund operations beyond the first half of 2016. Therefore, there is substantial doubt about the Company's ability to continue as a going concern.

Management's plans include the continued commercialization of their 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 products and raising capital, it may need to reduce activities, curtail or cease operations.

These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

During the first quarter of 2015, the board of directors approved to curtail 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 primarily to 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, rent, etc.).

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 nine months ended September 30, 2015 are not necessarily indicative of results that could be expected for the entire fiscal year.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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.

On July 9, 2015, the FASB approved a one-year deferral of the effective date of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers, such that it is effective beginning on or after December 15, 2017 for public entities. Reporting entities may choose to adopt the standard as of the original effective date.

On July 22, 2015, the FASB issued Accounting Standards Update 2015-11, Simplifying the Measurement of Inventory, which requires that inventory within the scope of the guidance be measured at the lower of cost and net realizable value. Inventory measured using last-in, first-out (LIFO) and the retail inventory method (RIM) are not impacted by the new guidance. The new guidance will be effective for public business entities in fiscal years beginning after December 15, 2016, including interim periods within those years. Prospective application is required. Early adoption is permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the impact of the standard on its consolidated financial statements.

NOTE 4 - EQUITY:

a. During the nine months ended September 30, 2015, the Company granted stock options to employees and directors to purchase a total of 214,520 shares of the Company's common stock. The options have exercise prices ranging from $1.7 to $8.3 per share, which were the fair market value of the Company's common stock on the date of each respective grant. Of the 214,520 options described above, 107,744 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%-71.12%; 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 $0.66 million.

b. During the nine months ended September 30, 2015, the Company granted a total of 132,353 restricted shares of the Company's common stock to employees, of which 43,300 restricted shares are subject to a one-year vesting period, 9,250 restricted shares are fully vested as of their grant date and are subject to a 6 month lock up period, 32,914 restricted shares are subject to a six-month vesting period and 46,889 restricted shares are subject to a three-year vesting period, with one-third of such awards vesting each year.

The fair value of the above restricted shares was approximately $0.96 million.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

c. On March 9, 2015, the Company sold 3,436,968 shares of its common stock and warrants to purchase 3,436,968 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 $5.50. This offering resulted in net proceeds to the Company of approximately $12.4 million after deducting placement agent fees and other offering expenses.

d. On September 9, 2015, the stockholders approved the amendment of its Long Term Incentive Plan which was adopted by our board of directors on July 16, 2015 to increase the total number of shares of common stock issuable under such plan by 470,000 shares.

e. On September 9, 2015, the stockholders approved the authorization of the board of directors, in its discretion, to amend the Amended and Restated Certificate of Incorporation of the Company to effect a reverse stock split of the Company’s common stock at a ratio of one-for-ten and to reduce the number of authorized shares of our common stock from 125 million shares to 50 million shares.

f. On September 30, 2015, the Company filed with the Secretary of State of Delaware a Certificate of Amendment to the Company’s Amended and Restated Certificate of Incorporation to effect a one-for-ten reverse stock split of its common stock, par value $0.0001 per share (the “Reverse Stock Split”), effective as of October 1, 2015, which decreased the number of issued and outstanding shares of common stock and restricted shares of common stock from 78 million shares to 7.8 million shares. The Company’s authorized common stock was decreased from 125 million shares to 50 million shares. All related share and per share data have been retroactively applied to the financial statements and their related notes for all periods presented.

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, and restricted stocks as the effect is anti-dilutive.

The total number of shares of common stock related to outstanding options, warrants and restricted stock excluded from the calculations of diluted loss per share were 5,010,580 and 1,048,402 for the nine and three month periods ended September 30, 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 September 30, 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.

As of September 30, 2015 and December 31, 2014, allowance for doubtful accounts was $349,000 and 337,000, respectively.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 7 - INVENTORY:

	September 30, 2015	December 31, 2014
	($ in thousands)	
Finished goods	$275	$ 1,273
Work in process	529	326
Raw materials and supplies	277	325
	$1,081	$ 1,924

NOTE 8– IMPAIRMENT OF ROYALTIES BUYOUT

During the nine month period ended September 30, 2015 the Company recorded expenses related to the impairment of our royalties buyout asset amounting to $576,000 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:

	September 30, 2015	December 31, 2014
	($ in thousands)	
Employees and employee institutions	$494	$ 1,022
Accrued vacation and recreation pay	352	410
Accrued clinical trial expenses	589	1,016

Accrued expenses	863	993
Provision for sales commissions	96	120
Taxes payable	9	15
	$2,403	$ 3,576

NOTE 10 - RELATED PARTIES:

a. During the nine month period ended September 30, 2015, the Company's chief executive officer was granted options to purchase 30,777 shares of common stock at an exercise price of $7.2 per share, as well as 51,759 shares of restricted stock. Of the 51,759 shares of restricted stock, 31,250 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.