

InspireMD, Inc.  
Form 10-Q  
August 04, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended: June 30, 2014**

**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 (I.R.S. Employer  
incorporation or organization) 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  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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  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

Non-accelerated filer

Smaller reporting company

(Do not check if a 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

The number of shares of the registrant's common stock, \$0.0001 par value, outstanding as of August 4, 2014:  
35,181,465.



**TABLE OF CONTENTS**

|  | <b>Page</b> |
|--|-------------|
| <b><u>PART I</u></b>   |             |
| Item 1. <u>Financial Statements</u>  | 2           |
| Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 3           |
| Item 4. <u>Controls and Procedures</u>   | 9           |
| <b><u>PART II</u></b>  |             |
| Item 1. <u>Legal Proceedings</u>   | 9           |
| Item 1A. <u>Risk Factors</u>   | 9           |
| Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>                           | 11          |
| Item 6. <u>Exhibits</u>  | 12          |

**PART I - FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**INSPIREMD, INC.**

**INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

June 30, 2014

**INSPIREMD, INC.**

**INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

June 30, 2014

**TABLE OF CONTENTS**

|   | <b>Page</b> |
|---|-------------|
| <b>INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS:</b>     |             |
| <u>Condensed Consolidated Balance Sheets</u>                    | F-2 - F-3   |
| <u>Condensed Consolidated Statements of Operations</u>          | F-4         |
| <u>Condensed Consolidated Statements of Cash Flows</u>          | F-5         |
| <u>Notes to the Condensed Consolidated Financial Statements</u> | F-6 - F-11  |

The amounts are stated in U.S. dollars

**INSPIREMD, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(Unaudited)

(U.S. dollars in thousands)

|  | June 30,<br>2014 | December 31,<br>2013 |
|--|------------------|----------------------|
| <b>ASSETS</b>  |                  |                      |
| <b>CURRENT ASSETS:</b>                               |                  |                      |
| Cash and cash equivalents                            | \$8,988          | \$ 17,535            |
| Restricted cash                                      |                  | 93                   |
| Accounts receivable:                                 |                  |                      |
| Trade  | 493              | 1,855                |
| Other  | 420              | 387                  |
| Prepaid expenses                                     | 215              | 141                  |
| Inventory  | 1,514            | 1,593                |
| Total current assets                                 | 11,630           | 21,604               |
| <b>PROPERTY, PLANT AND EQUIPMENT, net</b>            | <b>663</b>       | <b>652</b>           |
| <b>NON-CURRENT ASSETS:</b>                           |                  |                      |
| Deferred issuance costs                              | 276              | 310                  |
| Funds in respect of employees rights upon retirement | 493              | 434                  |
| Long term prepaid expenses                           | 84               | 114                  |
| Royalties buyout                                     | 812              | 852                  |
| Total other non-current assets                       | 1,665            | 1,710                |
| Total assets   | \$13,958         | \$ 23,966            |

**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)

|   | June 30,<br>2014 | December 31,<br>2013 |
|---|------------------|----------------------|
| <b>LIABILITIES AND EQUITY (CAPITAL DEFICIENCY)</b>  |                  |                      |
| <b>CURRENT LIABILITIES:</b>   |                  |                      |
| Accounts payable and accruals:  |                  |                      |
| Trade   | \$1,529          | \$ 1,623             |
| Other   | 4,344            | 3,141                |
| Advanced payment from customers   | 214              | 179                  |
| Current maturity of loan  | 3,037            | 1,181                |
| Total current liabilities   | 9,124            | 6,124                |
| <b>LONG-TERM LIABILITIES:</b>   |                  |                      |
| Liability for employees rights upon retirement  | 745              | 610                  |
| Long term loan  | 6,886            | 8,593                |
| Total long-term liabilities   | 7,631            | 9,203                |
| <b>COMMITMENTS AND CONTINGENT LIABILITIES (Note 11)</b>   |                  |                      |
| Total liabilities   | 16,755           | 15,327               |
| <b>EQUITY (CAPITAL DEFICIENCY):</b>   |                  |                      |
| Common stock, par value \$0.0001 per share; 125,000,000 shares authorized; 34,159,043 and 33,983,346 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively | 3                | 3                    |
| Additional paid-in capital  | 93,046           | 90,952               |
| Accumulated deficit   | (95,846)         | (82,316 )            |
| Total equity (capital deficiency)   | (2,797 )         | 8,639                |
| Total liabilities and equity (less capital deficiency)  | \$13,958         | \$ 23,966            |

**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 |             | Six months ended |             |
|---|--------------------|-------------|------------------|-------------|
|   | June 30,           | 2013        | June 30,         | 2013        |
|   | 2014               |             | 2014             |             |
| REVENUES  | \$ 193             | \$ 1,500    | \$ 1,675         | \$ 3,014    |
| COST OF REVENUES  | 584                | 832         | 1,209            | 1,506       |
| GROSS PROFIT (LOSS)   | (391               | ) 668       | 466              | 1,508       |
| OPERATING EXPENSES:   |                    |             |                  |             |
| Research and development  | 2,448              | 1,047       | 5,025            | 1,954       |
| Selling and marketing   | 1,948              | 1,204       | 3,224            | 2,008       |
| General and administrative  | 2,448              | 2,632       | 4,987            | 4,972       |
| Total operating expenses  | 6,844              | 4,883       | 13,236           | 8,934       |
| LOSS FROM OPERATIONS  | (7,235             | ) (4,215    | ) (12,770        | ) (7,426    |
| <b>FINANCIAL EXPENSES, net:</b>   |                    |             |                  |             |
| Interest expense  | 359                | 884         | 711              | 2,160       |
| Other financial expenses (income)   | (34                | ) 9,871     | 27               | 10,287      |
| Total financial expenses  | 325                | 10,755      | 738              | 12,447      |
| LOSS BEFORE INCOME TAXES  | (7,560             | ) (14,970   | ) (13,508        | ) (19,873   |
| TAX EXPENSES (INCOME)   | 2                  | (23         | ) 22             | (41         |
| NET LOSS  | \$(7,562           | ) \$(14,947 | ) \$(13,530      | ) \$(19,832 |
| <b>NET LOSS PER SHARE</b> - basic and diluted   | \$(0.22            | ) \$(0.48   | ) \$(0.40        | ) \$(0.80   |
| <b>WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE</b> - basic and diluted | 34,115,814         | 31,033,657  | 34,083,936       | 24,650,333  |

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

F-4

**INSPIREMD, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

(U.S. dollars in thousands)

|  | Six months ended<br>June 30, |            |
|--|------------------------------|------------|
|  | 2014                         | 2013       |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>   |                              |            |
| Net loss   | \$(13,530)                   | \$(19,832) |
| Adjustments required to reconcile net loss to net cash used in operating activities: |                              |            |
| Depreciation and amortization  | 122                          | 113        |
| Change in liability for employees right upon retirement                              | 135                          | 149        |
| Financial expenses   | 149                          | 12,156     |
| Share-based compensation expenses  | 2,099                        | 2,408      |
| Loss (Gains) on amounts funded in respect of employee rights upon retirement, net    | 6                            | (3 )       |
| Changes in operating asset and liability items:                                      |                              |            |
| Increase in prepaid expenses   | (44 )                        | (178 )     |
| Decrease (increase) in trade receivables   | 1,362                        | (466 )     |
| Increase in other receivables  | (33 )                        | (176 )     |
| Decrease in inventory on consignment   |                              | 20         |
| Decrease (increase) in inventory   | 79                           | 384        |
| Increase (decrease) in trade payables  | (94 )                        | 330        |
| Increase in other payables and advance payment from customers                        | 1,394                        | 594        |
| Net cash used in operating activities  | (8,354 )                     | (4,501 )   |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>   |                              |            |
| Purchase of property, plant and equipment  | (93 )                        | (115 )     |
| Decrease in restricted cash  | 93                           |            |
| Amounts funded in respect of employee rights upon retirement, net                    | (65 )                        | (68 )      |
| Net cash used in investing activities  | (65 )                        | (183 )     |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>   |                              |            |
| Taxes withheld in respect of share issuance  | (115 )                       | (27 )      |
| Proceeds from issuance of shares   |                              | 22,880     |
| Exercise of options and warrants   |                              | 8          |
| Induced conversion of convertible debt   |                              | (8,787 )   |
| Net cash provided (used) by financing activities                                     | (115 )                       | 14,074     |

Edgar Filing: InspireMD, Inc. - Form 10-Q

|   |          |          |
|---|----------|----------|
| EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS    | (13 )    | (3 )     |
| INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS                | (8,547 ) | 9,387    |
| BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD | 17,535   | 5,433    |
| BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD       | \$8,988  | \$14,820 |

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

F-5

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

**NOTE 1 - DESCRIPTION OF BUSINESS**

InspireMD, Inc., a Delaware corporation (the “Company”), together with its subsidiaries, is a medical device company focused on the development and commercialization of its proprietary stent platform technology, MGuard™. MGuard provides embolic protection in stenting procedures by placing a micron mesh sleeve over a stent. The Company’s initial products are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). The Company markets its products through distributors in international markets, mainly in Europe, Latin America and the Middle East, and through direct sales to hospitals in Europe.

The Company has an accumulated deficit of \$95.8 million as of June 30, 2014, as well as net losses and negative operating cash flows in recent years and the current quarter. The Company expects to continue incurring losses and negative cash flows from operations until its MGuard™ products 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 for the next twelve months. Therefore, there is substantial doubt about the Company’s ability to continue as a going concern.

Management’s plans include the continued commercialization of the MGuard™ products and raising capital through the sale of additional equity securities or debt, including through the Company’s “At-the-Market” equity program. 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™ 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.

On April 30, 2014, the Company initiated a voluntary field corrective action (“VFA”) of its MGuard Prime EPS to address the issue of stent retention following reports of MGuard Prime EPS stent dislodgements. The Company received approval from the European regulatory agency on June 18, 2014 for its plan to modify its MGuard Prime EPS stents in order improve stent retention and performance, and has begun modifying existing units of the MGuard Prime EPS. The VFA had an adverse impact on both the commercial and clinical activities relating to the MGuard Prime EPS in the three months ended June 30, 2014.

The expense associated with the modifications performed, and the modifications that will be performed as a result of the VFA is estimated to be \$400,000 and was recorded in “Cost of revenues” in the three months ended June 30, 2014.

## **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 six month period ended December 31, 2013, as found in the Company’s Transition Report on Form 10-KT, filed with the Securities and Exchange Commission on February 26, 2014. The balance sheet for December 31, 2013 was derived from the Company’s audited financial statements for the six month period ended December 31, 2013. The results of operations for the six months ended June 30, 2014 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 May 2014, the FASB issued ASC 606, Revenue from contracts with customers. The objective of the new revenue standard is to provide a single, comprehensive revenue recognition model for all contracts with customers to improve comparability within industries, across industries, and across capital markets. The revenue standard contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services, based on a five step model that includes the identification of the contract with the customer and the performance obligations in the contract, determination of the transaction price, allocation of the transaction price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies a performance obligation. The revenue standard is effective for annual periods beginning on or after January 1, 2017. Early adoption is permitted.

NOTE 4 - EQUITY:

During the six months ended June 30, 2014, the Company granted stock options to employees and directors to purchase a total of 1,346,515 shares of the Company's common stock. The options have exercise prices ranging from a.\$2.41-\$3.23 per share, which were the fair market value of the Company's common stock on the date of each respective grant. The 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% and expected term of 5.5-6.5 years; expected volatility of 64.9%-67.9%; and risk-free interest rate of 1.64%-2.18%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately \$2.5 million.



During the six months ended June 30, 2014, the Company granted a total of 487,757 restricted shares of the Company's common stock to employees. The 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 \$1.5 million.

**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 9,943,540 and 8,006,837 for the six and three month periods ended June 30, 2014 and 2013, respectively.

**NOTE 6 - FAIR VALUE MEASUREMENT:**

**Financial Assets and Liabilities Not Measured Using Fair Value Method**

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 June 30, 2014, the carrying amount of cash and cash equivalents, accounts receivable, other current assets and accounts payables and accrued expenses approximated their fair values due to the short-term maturities of these instruments. The fair value of the loan received on October 23, 2013 (the "Loan") approximated its carrying amount.

**INSPIREMD, INC.****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(UNAUDITED)

**NOTE 7 - INVENTORY:**

|                            | June<br>30,<br>2014 | December<br>31,<br>2013 |
|----------------------------|---------------------|-------------------------|
|                            | (\$ in thousands)   |                         |
| Finished goods             |                     | \$ 1,097                |
| Work in process            | \$ 1,372            | 341                     |
| Raw materials and supplies | 142                 | 155                     |
|                            | \$ 1,514            | \$ 1,593                |

As of June 30, 2014 all "Finished goods" have been classified as "Work in process" due to the modifications being performed as part of the VFA. See Note 1.

**NOTE 8 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:**

|                                     | June<br>30,<br>2014 | December<br>31,<br>2013 |
|-------------------------------------|---------------------|-------------------------|
|                                     | (\$ in thousands)   |                         |
| Employees and employee institutions | \$ 1,292            | \$ 1,133                |
| Accrued vacation and recreation pay | 442                 | 325                     |
| Accrued clinical trial expenses     | 1,292               | 622                     |
| Accrued expenses                    | 1,014               | 886                     |
| Provision for sales commissions     | 257                 | 139                     |
| Other                               | 47                  | 36                      |
|                                     | \$ 4,344            | \$ 3,141                |

F-8

**INSPIREMD, INC.****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(UNAUDITED)

**NOTE 9 - FINANCIAL EXPENSES, NET:**

|  | Three months<br>ended<br>June 30,<br>2014 |          | Six months<br>ended<br>June 30,<br>2014 |          |
|--|---|----------|---|----------|
|  | 2013                                      |          | 2013                                    |          |
|  | <b>(\$ in thousands)</b>                  |          |   |          |
| Bank commissions   | \$11                                      | \$13     | \$21                                    | \$19     |
| Interest income  |   | (5 )     |   | (12 )    |
| Exchange rate differences  | 13  | 7        | 53                                      | 13       |
| 2013 Exchange agreement:   |   |          |   |          |
| Induced conversion of convertible debt                           |   | 9,330    |   | 9,330    |
| Issuance of warrants   |   | 568      |   | 568      |
| Interest expense (including debt issuance costs)                 | 359                                       | 884      | 711                                     | 2,160    |
| Change in fair value of warrants, embedded derivatives and other | (41 )                                     | (42 )    | (47 )                                   | 369      |
| Other  |   | (17 )    |   |          |
|  | \$325                                     | \$10,755 | \$738                                   | \$12,447 |

**NOTE 10 - RELATED PARTIES:**

During the six month period ended June 30, 2014, the Company's chief executive officer was granted options to purchase 399,675 shares of common stock at exercise prices ranging from \$2.97-\$3.10 per share, as well as 182,725 shares of restricted stock. See Note 3.

During the six month period ended June 30, 2014, directors of the Company were granted options to purchase an aggregate of 335,000 shares of common stock at an exercise price of \$3.10 per share. See Note 3a.

**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 chief executive officer and president for a declaratory and enforcement order that this purported assignee is entitled to options to purchase 83,637 shares of the Company's common stock at an exercise price of \$0.76 per share. 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. The Company's management estimates that the ultimate resolution of this matter could result in a loss of up to \$80,000 in excess of the amount accrued.

F-9

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

**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.

**NOTE 12 - ENTITY WIDE DISCLOSURE:**

The Company operates in one operating segment.

Disaggregated financial data is provided below as follows:

- (1) Revenues by geographic area and
- (2) Revenues from principal customers.

Revenues are attributed to geographic areas based on the location of the customers. The following is a summary of revenues by geographic areas:

| Three months ended |      | Six months ended |      |
|--------------------|------|------------------|------|
| June 30,           |      | June 30,         |      |
| 2014               | 2013 | 2014             | 2013 |

(\$ in thousands)

|             |        |          |          |          |
|-------------|--------|----------|----------|----------|
| Belarus     | \$ 110 | \$ 62    | \$ 142   | \$ 199   |
| Russia      |        | 277      | 3        | 712      |
| Spain       |        | 255      | 201      | 412      |
| Brazil      |        | 167      |          | 290      |
| Middle East |        | 75       | 624      | 183      |
| Other       | 83     | 664      | 705      | 1,218    |
|             | \$ 193 | \$ 1,500 | \$ 1,675 | \$ 3,014 |

The following is a summary of revenues by principal customers:

|            | Three months ended |      | Six months ended |      |
|------------|--------------------|------|------------------|------|
|            | June 30,           |      | June 30,         |      |
|            | 2014               | 2013 | 2014             | 2013 |
| Customer A | 57 %               | 4 %  | 8 %              | 7 %  |
| Customer B |                    | 18 % | 0 %              | 24 % |
| Customer C |                    | 17 % | 12 %             | 14 % |
| Customer D |                    | 11 % | 0 %              | 10 % |
| Customer E |                    | 5 %  | 37 %             | 6 %  |

All tangible long-lived assets are located in Israel.

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

**NOTE 13 - SUBSEQUENT EVENTS:**

On July 14, 2014, the Company appointed a COO. In connection to his appointment, the Company granted the COO stock options to purchase 450,000 shares of the Company's common stock and 150,000 shares of restricted stock. Both the options and the restricted stock are subject to a three-year vesting period subject to the COO's continued service with the Company, with one-third (1/3rd) of such awards vesting on the first, second and third anniversary of the grant date.

The options have an exercise price of \$2.61 per share, which was the fair market value of the Company's common stock on the date of grant. In calculating the fair value of the above options the Company used the following assumptions: dividend yield of 0% and expected term of 5.5-6.5 years; expected volatility of 63.8%-66.7%; and risk-free interest rate of 1.80%-2.05%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately \$700,000.

The fair value of the above restricted shares was approximately \$400,000.

F-11



## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.*

*Unless the context requires otherwise, references in this Form 10-Q to the "Company," "InspireMD," "we," "our" and "us" refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries.*

### Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements," which include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "estimates," and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and will probably not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or our good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;
- our ability to complete clinical trials as anticipated and obtain and maintain regulatory approvals for our products;
- our ability to adequately protect our intellectual property;
- disputes over ownership of intellectual property;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;

Edgar Filing: InspireMD, Inc. - Form 10-Q

the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that the MGuard™ technology is an attractive alternative to other procedures and products;

intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;

- entry of new competitors and products and potential technological obsolescence of our products;

- loss of a key customer or supplier;

- technical problems with our research and products and potential product liability claims;

- adverse economic conditions;

- adverse federal, state and local government regulation, in the United States, Europe, Asia or Israel;

- price increases for supplies and components;

inability to carry out research, development and commercialization plans; and

loss or retirement of key executives and research scientists.

For a discussion of these and other risks that relate to our business and investing in our common stock, you should carefully review the risks and uncertainties described under the heading “Part II – Item 1A. Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q and the Transition Report on Form 10-KT for the six month period ended December 31, 2013, and those described from time to time in our future reports filed with the Securities and Exchange Commission. The forward-looking statements contained in this Quarterly Report on Form 10-Q are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

## **Overview**

We are a medical device company focused on the development and commercialization of our proprietary stent platform technology, MGuard with MicroNet technology. MGuard provides embolic protection in stenting procedures by using MicroNet technology, which is a single fiber knitted mesh wrapped on an open cell stent platform designed to trap debris that can dislodge and travel downstream after a patient is treated with traditional stenting methods. This technology seeks to protect patients from plaque debris and blood clots breaking off and which can lead to life threatening coronary events as well as strokes. Our initial products were marketed for use mainly in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). We also intend to pursue other applications of the MicroNet technology in carotid (CGuard) and peripheral artery procedures.

## **Recent Events**

On April 30, 2014, we initiated a voluntary field corrective action with respect to our MGuard Prime embolic protection systems (“EPS”) to address reports of stent dislodgement. In connection with such action, we ceased shipments of all MGuard Prime EPS units and suspended enrollment in our MASTER II trial pending a review by the U.S. Food and Drug Administration. On June 23, 2014, we publicly announced that we received European regulatory approval to resume the manufacturing of our MGuard Prime EPS stent with a modified stent securement process. We also received approval to modify and re-deploy all the MGuard Prime EPS stents that were returned from clinical and commercial sites. As a result of the voluntary field action, we have not executed any new customer sales agreements and remain subject to numerous risks and uncertainties as discussed more fully in the section entitled “Risk Factors.”

## **Critical Accounting Policies**

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies are more fully described in both (i) the Management's Discussion and Analysis of Financial Condition and Results of Operations section and (ii) Note 2 of the Notes to the Consolidated Financial Statements included in our Transition Report on Form 10-KT for the six month period ended December 31, 2013. There have not been any material changes to such critical accounting policies since December 31, 2013.

The currency of the primary economic environment in which our operations are conducted is the U.S. dollar (" \$" or "dollar"). Accordingly, our currency is the dollar.

## Results of Operations

*Three months ended June 30, 2014 compared to the three months ended June 30, 2013*

*Revenues.* For the three months ended June 30, 2014, revenue decreased by \$1.3 million, or 87.2%, to \$0.2 million from \$1.5 million during the same period in 2013. This decrease was driven by a decrease in sales volume of \$1.3 million, or 87.5%, partially offset by price increases to our repeat distributors of \$5,000, or 0.3%. The decrease is due to our voluntary field action (VFA) which resulted in a temporary suspension of MGuard™ Prime EPS sales, our primary commercial product. On June 18, 2014, we received European regulatory approval to modify, redeploy and resume the manufacturing of our MGuard™ Prime EPS.

With respect to regions, the decrease in revenue was primarily attributable to a decrease of \$1.0 million in revenue from our distributors in Europe, \$0.2 million in revenue from our distributors in Latin America and \$0.1 million in revenue from our distributors in the Middle East.

*Gross Profit (Loss).* For the three months ended June 30, 2014, we had a gross loss (revenue less cost of revenues) of \$0.4 million, as compared to a gross profit of \$0.7 million during the same period in 2013, representing a decrease of 158.5%, or \$1.1 million. This decrease in gross profit was attributable to the impact of the VFA which included a decrease in revenues of \$1.3 million (see above for explanation), partially offset by a decrease in cost of revenues of \$0.2 million. The cost of revenues for the three months ended June 30, 2014 included \$0.4 million of costs associated with the VFA. Gross margin (gross profits as a percentage of revenue) decreased from 44.5% in the three months ended June 30, 2013 to (202.6)% in same period in 2014.

*Research and Development Expenses.* For the three months ended June 30, 2014, research and development expenses increased 133.8%, or \$1.4 million, to \$2.4 million, from \$1.0 million during the same period in 2013. This increase in research and development expenses resulted primarily from increases of \$0.2 million in related salaries, \$0.3 million in miscellaneous expenses and \$0.5 million in clinical trial expenses associated with our MASTER II trial moving from the pre-clinical stage to the set-up and enrollment phases. In addition, clinical trial expenses associated with our CARENET trial increased by \$0.3 million and expenditures related to our stent retention program increased by \$0.2 million. This increase in research and development expenses, however, was partially offset by a decrease of \$0.1 million in expenses associated with our MASTER I trial that was concluded in 2013. Research and development expense as a percentage of revenue increased to 1,268.4% for the three months ended June 30, 2014, from 69.8% in the same period in 2013.

*Selling and Marketing Expenses.* For the three months ended June 30, 2014, selling and marketing expenses increased 61.8%, or \$0.7 million, to \$1.9 million, from \$1.2 million during the same period in 2013. This increase in selling and

marketing expenses resulted primarily from an increase of \$0.5 million in salaries and an increase of \$0.1 million in share based compensation, as we hired additional sales personnel in an effort to expand our sales activities worldwide and an increase of \$0.1 million in travel expenses for our increased sales force. Much of these sales initiatives were driven by efforts to support the new sales strategies in key European and Latin American countries. Selling and marketing expenses as a percentage of revenue increased to 1,009.3% in the three months ended June 30, 2014 from 80.3% in the same period in 2013.

*General and Administrative Expenses.* For the three months ended June 30, 2014, general and administrative expenses decreased 7.0%, or \$0.2 million, to \$2.4 million from \$2.6 million during the same period in 2013. The decrease in general and administrative expenses resulted primarily from a decrease of \$0.2 million in share based compensation, a decrease in rent expense of \$0.1 million and a decrease in miscellaneous expenses of \$0.1 million. This decrease was partially offset by an increase in salaries of \$0.1 million and an increase of \$0.1 million in legal expenses. General and administrative expenses as a percentage of revenue increased to 1,268.4% in the three months ended June 30, 2014 from 175.5% in the same period in 2013.

*Financial Expenses.* For the three months ended June 30, 2014, financial expenses decreased 97.0%, or \$10.4 million, to \$0.3 million from \$10.7 million during the same period in 2013. The decrease in financial expenses partially resulted from a decrease of \$0.5 million of amortization and interest expenses. In the three months ended June 30, 2014, we recognized \$0.4 million in amortization and interest expense, in contrast to the three months ended June 30, 2013, during which we recognized \$0.9 million of amortization and interest expense pertaining to our previously outstanding senior convertible debentures and their related issuance costs (of which \$0.8 million represented the non-cash amortization of the discount of the convertible debentures and their related issuance costs). In addition, we incurred \$0.2 million of non-cash expense in the three months ended June 30, 2013 pertaining to our obligation to issue shares of common stock without new consideration to the investors in our March 2011 private placement due to certain anti-dilution rights held by such stockholders and the non-cash revaluations of our warrants, as well as \$9.9 million in non-recurring, non-cash effects of the adjustment of the conversion ratio of our convertible debentures prior to their retirement in April 2013. No such expenses occurred during the three months ended June 30, 2014. This decrease in expenses was partially offset by the absence of any non-cash revaluations of our warrants during the three months ended June 30, 2014. During the three months ended June 30, 2013, we recognized \$0.2 million of financial income pertaining to the non-cash revaluation of certain of our warrants due to our stock price decreasing from \$2.52 to \$2.21 during such period. No such income was recognized during the three months ended June 30, 2014. Financial expense as a percentage of revenue decreased to 168.4% in the three months ended June 30, 2014, from 717.0% in the same period in 2013.

*Tax Expenses.* For the three months ended June 30, 2014, tax expenses increased \$25,000 to \$2,000 from \$23,000 of tax income during the same period in 2013.

*Net Loss.* Our net loss decreased by \$7.4 million, or 49.4%, to \$7.6 million for the three months ended June 30, 2014 from \$15.0 million during the same period in 2013. The decrease in net loss resulted primarily from a decrease of \$10.4 million in financial expenses, of which \$10.7 million were non-cash (see above for explanation), partially offset by an increase of \$1.9 million in operating expenses primarily associated with research and development and sales and marketing expansion (see above for explanation), and a decrease of \$1.1 million in gross profit (see above for explanation). If the non-cash effects of the debt inducement, warrant revaluation, amortization expense and effects of the anti-dilution rights in the three months ended June 30, 2013 are removed our net loss would be \$4.2 million for the three months ended June 30, 2013, as compared to a net loss of \$7.6 million for the same period in 2014.

*Six months ended June 30, 2014 compared to the six months ended June 30, 2013*

*Revenues.* For the six months ended June 30, 2014, revenue decreased by \$1.3 million, or 44.4%, to \$1.7 million from \$3.0 million during the same period in 2013. This decrease was driven by a decrease in sales volume of \$1.3 million, or 44.5%, partially offset by price increases to our repeat distributors of \$2,000, or 0.1%. The decrease is due to our VFA which resulted in a temporary suspension of MGuard™ Prime EPS sales, our primary commercial product. On June 18, 2014, we received European regulatory approval to resume the manufacturing of our MGuard™ Prime EPS.

With respect to regions, the decrease in revenue was primarily attributable to a decrease of \$1.5 million in revenue from our distributors in Europe, \$0.3 million in revenue from our distributors in Latin America and \$0.1 million in revenue from our distributors in Africa, partially offset by an increase of \$0.5 million in revenue from our distributors in the Middle East and an increase of \$0.1 million in revenue from our distributors in the rest of the world.

*Gross Profit.* For the six months ended June 30, 2014, gross profit (revenue less cost of revenues) decreased 69.1%, or \$1.0 million, to \$0.5 million from \$1.5 million during the same period in 2013. This decrease in gross profit was attributable to the impact of the VFA which included a decrease in revenues of \$1.3 million (see above for explanation), partially offset by a decrease in cost of revenues of \$0.3 million. The cost of revenues for the six months ended June 30, 2014 included \$0.4 million of costs associated with the VFA. Gross margin (gross profits as a percentage of revenue) decreased from 50.0% in the six months ended June 30, 2013 to 27.8% in same period in 2014.



*Research and Development Expenses.* For the six months ended June 30, 2014, research and development expenses increased 157.2%, or \$3.1 million, to \$5.0 million, from \$1.9 million during the same period in 2013. This increase in research and development expenses resulted primarily from increases of \$0.4 million in related salaries, \$0.1 million in related travel expenses, \$0.2 million in miscellaneous expenses and \$1.9 million in clinical trial expenses associated with our MASTER II trial moving from the pre-clinical stage to the set-up and enrollment phases. In addition, clinical trial expenses associated with our CARENET trial increased by \$0.3 million, expenditures related to our stent retention program increased by \$0.3 million, expenditures related to the development of a drug eluting mesh product increased by \$0.1 million and expenditures related to our Emaster registry increased by \$0.1 million. This increase in research and development expenses, however, was partially offset by a decrease of \$0.3 million in expenses associated with our MASTER I trial that concluded in 2013. Research and development expense as a percentage of revenue increased to 300.0% for the six months ended June 30, 2014, from 64.8% in the same period in 2013.

*Selling and Marketing Expenses.* For the six months ended June 30, 2014, selling and marketing expenses increased 60.6%, or \$1.2 million, to \$3.2 million, from \$2.0 million during the same period in 2013. This increase in selling and marketing expenses resulted primarily from an increase of \$0.9 million in salaries and an increase of \$0.1 million in share based compensation, as we hired additional sales personnel in an effort to expand our sales activities worldwide, an increase of \$0.2 million in travel expenses for our increased sales force and an increase of \$0.2 million in miscellaneous expenses. Much of these sales initiatives were driven by our increased efforts to support the new sales strategies in key European and Latin American countries. This increase in selling and marketing expenses, however, was partially offset by a decrease of \$0.2 million in product promotion expenses. Selling and marketing expenses as a percentage of revenue increased to 192.5% in the six months ended June 30, 2014 from 66.6% in the same period in 2013.

*General and Administrative Expenses.* For the six months ended June 30, 2014, general and administrative expenses remained relatively flat at \$5.0 million compared to the same period in 2013. The significant changes in general and administrative expenses for the six months ended June 30, 2014 were a decrease of \$0.5 million in share based compensation, partially offset by an increase of in salaries and director's compensation of \$0.3 million, an increase of \$0.1 million in legal fees and an increase of \$0.1 million in miscellaneous expenses. General and administrative expenses as a percentage of revenue increased to 297.7% in the six months ended June 30, 2014 from 165.0% in the same period in 2013.

*Financial Expenses.* For the six months ended June 30, 2014, financial expenses decreased 94.1%, or \$11.7 million, to \$0.7 million from \$12.4 million during the same period in 2013. The decrease in financial expenses partially resulted from a decrease of \$1.5 million of amortization and interest expenses. In the six months ended June 30, 2014, we recognized \$0.7 million in amortization and interest expense, in contrast to the six months ended June 30, 2013, during which we recognized \$2.2 million of amortization and interest expense pertaining to our previously outstanding senior convertible debentures and their related issuance costs (of which \$1.9 million represented the non-cash amortization of the discount of the convertible debentures and their related issuance costs). In addition, we incurred \$1.5 million of non-cash expense in the six months ended June 30, 2013 pertaining to our obligation to issue shares of common stock without new consideration to the investors in our March 2011 private placement due to certain anti-dilution rights held by such stockholders and the non-cash revaluations of our warrants, as well as \$9.9 million in non-recurring, non-cash effects of the adjustment of the conversion ratio of our convertible debentures prior

to their retirement in April 2013. No such expenses occurred during the six months ended June 30, 2014. This decrease in expenses was partially offset by the absence of any non-cash revaluations of our warrants during the six months ended June 30, 2014. During the six months ended June 30, 2013, we recognized \$1.1 million of financial income pertaining to the non-cash revaluation of certain of our warrants due to our stock price decreasing from \$3.90 to \$2.21 during such period. No such income was recognized during the six months ended June 30, 2014. Financial expense as a percentage of revenue decreased to 44.5% in the six months ended June 30, 2014, from 413.0% in the same period in 2013.

*Tax Expenses.* For the six months ended June 30, 2014, tax expenses increased \$63,000 to \$22,000 from \$41,000 of tax income during the same period in 2013.

*Net Loss.* Our net loss decreased by \$6.3 million, or 31.8%, to \$13.5 million for the six months ended June 30, 2014 from \$19.8 million during the same period in 2013. The decrease in net loss resulted primarily from a decrease of \$11.7 million in financial expenses, of which \$12.2 million were non-cash (see above for explanation), partially offset by an increase of \$4.3 million in operating expenses primarily associated with research and development and sales and marketing expansion (see above for explanation), and a decrease of \$1.0 million in gross profit (see above for explanation). If the non-cash effects of the debt inducement, warrant revaluation, amortization expense and effects of the anti-dilution rights in the six months ended June 30, 2013 are removed our net loss would be \$7.7 million for the six months ended June 30, 2013, as compared to a net loss of \$13.6 million for the same period in 2014.

## Liquidity and Capital Resources

We had an accumulated deficit of \$95.8 million as of June 30, 2014, as well as net losses and negative operating cash flows in recent years and the current quarter. We expect to continue incurring losses and negative cash flows from operations until our MGuard products reach profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we do not have sufficient resources to fund operations for the next twelve months. Therefore, there is substantial doubt about our ability to continue as a going concern.

Our plans include the continued successful commercialization of the MGuard product and raising capital through the sale of additional equity securities or debt, including through our “At-the-Market” equity program. There are no assurances, however, that we will be successful in obtaining sufficient financing to fund our operations. If we are unsuccessful in commercializing our MGuard products to the level of profitability and raising capital, we may need to reduce activities, curtail or cease operations.

On October 23, 2013, we entered into a loan and security agreement, pursuant to which we received a loan of \$10 million, before deduction of issuance costs. Interest on the loan is determined on a daily basis at a variable rate equal to the greater of either (i) 10.5%, or (ii) the sum of (A) 10.5% plus (B) the prime rate minus 5.5%. Payments under the loan and security agreement are interest only for 9 months, followed by 30 monthly payments of principal and interest through the scheduled maturity date on February 1, 2017. Our obligations under the loan and security agreement are secured by a grant of a security interest in all of our assets (other than our intellectual property). In addition, in connection with the loan and security agreement, we issued the lender a five year warrant to purchase 168,351 shares of our common stock at a per share exercise price of \$2.97.

### *Six months ended June 30, 2014 compared to the six months ended June 30, 2013*

*General.* At June 30, 2014, we had cash and cash equivalents of \$9.0 million, as compared to \$17.5 million as of December 31, 2013. We have historically met our cash needs through a combination of issuing new shares, borrowing activities and product sales. Our cash requirements are generally for clinical trials, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was \$8.4 million for the six months ended June 30, 2014 and \$4.5 million for the same period in 2013. The principal reason for the usage of cash in our operating activities for the six months ended June 30, 2014 was a net loss of \$13.5 million, offset by a decrease in working capital of \$2.8 million, \$2.1 million in non-cash share-based compensation that was largely paid to our directors and chief executive officer, \$0.1 million of non-cash financial expense and \$0.1 million of depreciation and amortization expenses. The principal reasons for the usage of cash in our operating activities for the six months ended June 30, 2013 included a net loss of \$19.8 million

offset by \$12.2 million in non-cash financial expenses, \$2.4 million in non-cash share-based compensation, a decrease in working capital of \$0.6 million and \$0.1 million in depreciation and amortization expenses.

Cash used in our investing activities was \$65,000 during the six months ended June 30, 2014, compared to \$183,000 during the same period in 2013. The principal reason for the decrease in cash used in investing activities during 2014 was the \$93,000 decrease in restricted cash upon the removal of fixed liens in connection with our credit cards.

Cash used by financing activities for the six months ended June 30, 2014 was \$115,000, compared to \$14.1 million of cash provided by financing activities during the same period in 2013. The reason for the increase in cash used by financing activities relates to funds received from the issuance of shares in connection with the underwritten public offering of our common stock of approximately \$22.9 million, partially offset by the partial satisfaction of our convertible debentures for approximately \$8.8 million during the six months ended June 30, 2013.

As of June 30, 2014, our current assets exceeded our current liabilities by a multiple of 1.3. Current assets decreased \$10.0 million during the period, mainly due to cash used in operations, and current liabilities increased by \$3.0 million during the period. As a result, our working capital surplus decreased by \$13.0 million to \$2.5 million at June 30, 2014.

### **Off Balance Sheet Arrangements**

We have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

### **Recent Accounting Pronouncements**

In May 2014, the FASB issued ASC 606, Revenue from contracts with customers. The objective of the new revenue standard is to provide a single, comprehensive revenue recognition model for all contracts with customers to improve comparability within industries, across industries, and across capital markets. The revenue standard contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services, based on a five step model that includes the identification of the contract with the customer and the performance obligations in the contract, determination of the transaction price, allocation of the transaction price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies a performance obligation. The revenue standard is effective for annual periods beginning on or after January 1, 2017. Early adoption is permitted.

### **Item 4. Controls and Procedures**

#### **Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures**

As of June 30, 2014, we conducted an evaluation, under the supervision and participation of management including our chief executive officer and chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of June 30, 2014.

### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the fiscal quarter ended June 30, 2014 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II - OTHER INFORMATION**

### **Item 1. Legal Proceedings**

From time to time, we may be involved in litigation that arises through the normal course of business. As of the date of this filing, we are not a party to any material litigation nor are we aware of any such threatened or pending litigation.

### **Item 1A. Risk Factors**

During the fiscal quarter ended June 30, 2014, there were no material changes to the risk factors disclosed in our Transition Report on Form 10-KT for the six month period ended December 31, 2013, except for the following:

## Risks Related to Our Business

*The voluntary field action of our MGuard Prime embolic protection systems (“MGuard Prime EPS”), and any future recalls and/or product withdrawals, could have a significant adverse impact on us.*

The manufacturing of medical devices involves an inherent risk that our products may prove to be defective and cause a health risk even after regulatory clearances have been obtained. Medical devices may also be modified after regulatory clearance is obtained to such an extent that additional regulatory clearance is necessary before the device can be further marketed. In these events, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority.

On April 30, 2014 we initiated a voluntary field corrective action of our MGuard Prime EPS to address the issue of stent retention following reports of MGuard Prime EPS stent dislodgements in patients. Although there have been no reports of death or serious injury as a result of such dislodgements, we decided to suspend shipments of the MGuard Prime EPS and implement a field corrective action to enhance the reliability and performance of the affected product units in the field. As a result of our voluntary field action, we are subject to numerous risks and uncertainties, including the following:

although we received European regulatory approval to resume manufacturing and distribution of our MGuard Prime EPS stent with a modified stent securement process, our suspension of shipments has and will continue to adversely impact revenue until we are able to fully upgrade the existing inventory of MGuard Prime EPS units and resume shipments in the market;

as a result of the voluntary field action, we have suspended enrollment in our MASTER II clinical trial pending a review by the U.S. Food and Drug Administration of the proposed manufacturing improvements to the MGuard Prime EPS, which could cause an increase in costs and delays or result in the failure of the clinical trial which would prevent us from entering the U.S. market;

we are more susceptible to products liability claims and class action lawsuits as a result of the reported product malfunction and voluntary field action, which could significantly increase our costs and may have a material adverse effect on our business, financial condition and results of operations;

the direct and indirect costs associated with the voluntary field action and re-launch of our product are difficult to predict and will likely divert significant managerial, financial and other resources, which could have an adverse effect on our financial condition and operating results and could hinder our ability to carry out initiatives relating to other new products or product enhancements; and

our decision to implement the voluntary field action and discontinue shipments, and any future action, may harm our reputation or the market's perception of our products, which could have a negative impact on our future sales and our ability to generate profits.

In the European Economic Area, we must comply with the EU Medical Device Vigilance System. Under this system, manufacturers are required to take Field Safety Corrective Actions ("FSCAs") to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. A FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

Any adverse event involving our products could result in other future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events, such as the MGuard Prime EPS stent dislodgements, have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.



*Our financial statements for the six months ended June 30, 2014 contain an explanatory paragraph in the footnotes that expresses substantial doubt as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.*

Because we have had recurring losses and negative cash flows from operating activities and have significant future commitments, substantial doubt exists regarding our ability to continue as a going concern. Such doubts regarding our ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all.

### **Risks Related to Operating in Israel**

*If there are significant shifts in the political, economic and military conditions in Israel and its neighbors, it could have a material adverse effect on our business relationships and profitability.*

Our sole manufacturing facility and certain of our key personnel are located in Israel. Our business is directly affected by the political, economic and military conditions in Israel and its neighbors. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. A state of hostility, varying in degree and intensity, has caused security and economic problems in Israel. Although Israel has entered into peace treaties with Egypt and Jordan, and various agreements with the Palestinian Authority, there has been a marked increase in violence, civil unrest and hostility, including armed clashes, between the State of Israel and the Palestinians since September 2000. The establishment in 2006 of a government in the Gaza Strip by representatives of the Hamas militant group has created heightened unrest and uncertainty in the region. In mid-2006, Israel engaged in an armed conflict with Hezbollah, a Shiite Islamist militia group based in Lebanon, and in June 2007, there was an escalation in violence in the Gaza Strip. From December 2008 through January 2009 and again in November and December 2012, Israel engaged in an armed conflict with Hamas, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In July 2014, Israel launched an additional operation against Hamas operatives in the Gaza strip in response to Palestinian groups launching rockets at Israel. Recent political uprisings and social unrest in Syria are affecting its political stability, which has led to the deterioration of the political relationship between Syria and Israel and have raised new concerns regarding security in the region and the potential for armed conflict. Similar civil unrest and political turbulence is currently ongoing in many countries in the region. The continued political instability and hostilities between Israel and its neighbors and any future armed conflict, terrorist activity or political instability in the region could adversely affect our operations in Israel and adversely affect the market price of our shares of common stock. In addition, several countries restrict doing business with Israel and Israeli companies have been and are today subjected to economic boycotts. The interruption or curtailment of trade between Israel and its present trading partners could result in damage to our facility and likewise have a material adverse effect on our business, financial condition and results of operations.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

The following table sets forth information with respect to purchases by us of our equity securities during the fiscal quarter ended June 30, 2014:

11

## Issuer's Purchases of Equity Securities

| Period                | Total number of shares (or units) purchased <sup>(1)</sup> | Average price paid per share (or unit) <sup>(1)</sup> | Total number of shares (or units) purchased as part of publicly announced plans or programs | Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs |
|-----------------------|--|---|---|---|
| 4/1/2014 to 4/30/2014 | 16,398   | \$ 2.30   | —   | —   |
| 5/1/2014 to 5/31/2014 | —  | —   | —   | —   |
| 6/1/2014 to 6/30/2014 | —  | —   | —   | —   |
| <b>Total</b>          | 16,398   | \$ 2.30   | —   | —   |

Includes 16,398 shares of our common stock surrendered by Alan Milinazzo in order to satisfy tax withholding obligations in connection with the vesting of restricted stock on April 25, 2014. For purposes of determining the (1) number of shares to be surrendered by Mr. Milinazzo to meet tax withholding obligations, the price per share deemed to be paid was the closing price of our common stock on the NASDAQ Capital Market on the applicable vesting date.

**Item 6. Exhibits**

See Index to Exhibits.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INSPIREMD, INC.

Date: August 4, 2014 By: /s/ Alan Milinazzo

Name: Alan Milinazzo  
Title: President and Chief Executive Officer

Date: August 4, 2014 By: /s/ Craig Shore

Name: Craig Shore  
Title: Chief Financial Officer, Secretary and Treasurer

**EXHIBIT INDEX**

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 3.1                | Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)  |
| 3.2                | Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)  |
| 3.3                | Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2012)  |
| 3.4                | Certificate of Designation, Preferences and Rights of Series A Preferred Stock (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)  |
| 10.1               | Amended and Restated Employment Agreement, dated May 5, 2014, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 7, 2014)   |
| 31.1*              | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 31.2*              | Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 32.1*              | Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.  |
| 32.2*              | Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.  |
| 101**              | The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, formatted in XBRL (eXtensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (v) the Notes to the Condensed Consolidated Financial Statements |

---

\* Filed herewith.

\*\* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

