InspireMD, Inc.
Form 10-Q
November 02, 2012

**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, 2012**

**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: 000-54335**

**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.) |

**4 Menorat Hamaor St.**

**Tel Aviv, Israel 67448**

(Address of principal executive offices)

(Zip Code)

**972-3-691-7691**

(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 (§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 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 ¨<br>(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 1, 2012: 71,374,976.

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**PART I - FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**INSPIREMD, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

(Unaudited)

(U.S. dollars in thousands)

| | September 30, 2012 | June 30, 2012 |
|---|---|---|
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 8,297 | $ 10,284 |
| Restricted cash | 37 | 37 |
| Accounts receivable: | | |
| Trade, net | 1,078 | 1,824 |
| Other | 408 | 264 |
| Prepaid expenses | 56 | 93 |
| Inventory: | | |
| On hand | 2,076 | 1,744 |
| On consignment | 22 | 63 |
| Total current assets | 11,974 | 14,309 |
| **PROPERTY, PLANT AND EQUIPMENT**, net of accumulated depreciation and amortization | 463 | 462 |
| OTHER NON-CURRENT ASSETS: | | |
| Deferred debt issuance costs | 874 | 961 |
| Funds in respect of employees rights upon retirement | 304 | 282 |
| Total other non-current assets | 1,178 | 1,243 |
| Total assets | $ 13,615 | $ 16,014 |

**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, 2012 | June 30, 2012 |
|---|---|---|
| LIABILITIES AND EQUITY (CAPITAL DEFICIENCY) | | |
| CURRENT LIABILITIES: | | |
| Accounts payable and accruals: | | |
| Trade | $ 556 | $ 441 |
| Other | 2,628 | 2,925 |
| Advanced payment from customers | 169 | 174 |
| Deferred revenues | 10 | 10 |
| Total current liabilities | 3,363 | 3,550 |
| LONG-TERM LIABILITIES: | | |
| Liability for employees rights upon retirement | 394 | 354 |
| Convertible loan | 5,635 | 5,018 |
| Contingently redeemable warrants | 4,979 | 1,706 |
| Total long-term liabilities | 11,008 | 7,078 |
| Total liabilities | 14,371 | 10,628 |
| EQUITY (CAPITAL DEFICIENCY): | | |
| Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 68,596,903 and 68,160,161 shares issued and outstanding at September 30, 2012 and June 30, 2012. | 7 | 7 |
| Additional paid-in capital | 50,464 | 49,101 |
| Accumulated deficit | (51,227) | (43,722) |
| Total equity (capital deficiency) | (756) | 5,386 |
| Total liabilities and equity | $ 13,615 | $ 16,014 |

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

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**INSPIREMD, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)

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

| | Three months ended September 30, | |
|---|---|---|
| | 2012 | 2011 |
| REVENUES | $ 509 | $ 1,986 |
| COST OF REVENUES | 230 | 801 |
| GROSS PROFIT | 279 | 1,185 |
| OPERATING EXPENSES: | | |
| Research and development | 946 | 547 |
| Selling and marketing | 402 | 302 |
| General and administrative | 2,212 | 2,486 |
| Total operating expenses | 3,560 | 3,335 |
| LOSS FROM OPERATIONS | (3,281) | (2,150) |
| **FINANCIAL EXPENSES,** net: | | |
| Interest on convertible loan and revaluation of Contingently redeemable warrants | 4,213 | |
| Other financial expenses | 5 | 108 |
| LOSS BEFORE TAX EXPENSES | (7,499) | (2,258) |
| TAX EXPENSES | 7 | 25 |
| NET LOSS | $ (7,506) | $ (2,283) |
| **NET LOSS PER SHARE -** basic and diluted | $ (0.11) | $ (0.04) |
| **WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE -** basic and diluted | 68,296,940 | 64,300,685 |

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

**INSPIREMD, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

(U.S. dollars in thousands)

| | 3 months ended September 30, 2012 | 2011 |
|---|---|---|
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | $(7,506) | $(2,283) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization of property, plant and equipment | 34 | 14 |
| Change in liability for employees right upon retirement | 40 | (25) |
| Financial expenses (income) | 3,984 | 204 |
| Share-based compensation expenses | 931 | 1,838 |
| Loss on amounts funded in respect of employee rights upon retirement, net | | 4 |
| Changes in operating asset and liability items: | | |
| Decrease (increase) in prepaid expenses | 37 | (32) |
| Decrease (increase) in trade receivables | 746 | (1,164) |
| Decrease (increase) in other receivables | (144) | 53 |
| Decrease (increase) in inventory on consignment | 41 | (20) |
| Increase in inventory on hand | (332) | (434) |
| Increase (decrease) in trade payables | 115 | (201) |
| (Increase) in other payables and advance payment from customers | (302) | (19) |
| Net cash (used in) operating activities | (2,356) | (2,065) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Decrease in restricted cash | | 303 |
| Purchase of property, plant and equipment | (35) | (56) |
| Amounts funded in respect of employee rights upon retirement | (22) | 17 |
| Net cash provided by (used in) investing activities | (57) | 264 |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Exercise of options and warrants | 432 | 1,500 |
| Repayment of long-term loan | | (93) |
| Net cash provided by financing activities | 432 | 1,407 |
| EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS | (6) | (191) |
| DECREASE IN CASH AND CASH EQUIVALENTS | (1,987) | (585) |
| BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD | 10,284 | 8,070 |
| BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD | $8,297 | $7,485 |
| Purchasing of property, plant and equipment on credit and in consideration of share-based payment | | $62 |

**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**

InspireMD, Inc., formerly Saguaro Resources, Inc., (the “Company”), a public company, is a Delaware corporation formed on February 29, 2008. On March 28, 2011, the Company changed its name to InspireMD, Inc. in connection with a share exchange transaction between the Company and InspireMD Ltd., a limited company incorporated under the laws of the State of Israel in April 2005.

The Company has had recurring losses and negative cash flows from operating activities and has significant future commitments. For the three months ended September 30, 2012, the Company had losses of approximately $7.5 million and negative cash flows from operating activities of approximately $2.4 million. Additionally, as of September 30, 2012, the Company has a capital deficiency of $756,000. The Company’s management believes that its working capital as of September 30, 2012 of approximately $8.6 million should enable it to continue funding the negative cash flows from operating activities until October 2013, when its senior secured convertible debentures (the “2012 Convertible Debentures”) are subject to a noncontingent redemption option that could require the Company to make a payment of $13.3 million, including accrued interest. Since the Company expects to continue incurring negative cash flows from operations and in light of the cash requirement in connection with the 2012 Convertible Debentures, there is substantial doubt about the Company’s ability to continue operating as a going concern. These financial statements include no adjustments of the values of assets and liabilities and the classification thereof, if any, that will apply if the Company is unable to continue operating as a going concern.

The Company will need to raise further capital at some future point in time, through the sale of additional equity securities or debt. The Company’s future capital requirements and the adequacy of the Company’s available funds will depend on many factors, including the Company’s ability to successfully commercialize the Company’s MGuard™ products, development of future products, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement the Company’s product offerings. However, the Company may be unable to raise sufficient additional capital when the Company needs it or with favorable terms. The terms of any securities issued by the Company in future financings may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of the Company’s securities then outstanding. If the Company is unable to obtain adequate funds on reasonable terms, the Company will need to curtail operations significantly, including possibly postponing or halting the Company's Unites States of America ("U.S.") Food and Drug Administration clinical trials or entering into financing agreements with unattractive terms.

**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 present 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 June 30, 2012, as found in the Company's Transition Report on Form 10-KT, filed with the Securities and Exchange Commission on September 11, 2012. The balance sheet for June 30, 2012 was derived from the Company's audited financial statements for the six month period ended June 30, 2012. The results of operations for the three months ended September 30, 2012 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- EQUITY:

On August 1, 2012, the Company’s board of directors issued to a consultant options with certain market conditions to purchase 200,000 shares of common stock at an exercise price of $1.18 per share, the closing price of the common stock on the date of grant.

On August 27, 2012, the Company’s board of directors issued to a member of the immediate family of the CEO options to purchase 243,483 shares of common stock at an exercise price of $1.45 per share, the closing price of the common stock on the date of grant. See Note 8.

On August 27, 2012, the Company's board of directors approved the extension of 121,740 options previously granted to a member of the immediate family of the CEO. The options were supposed to expire on October 2, 2012. Following the extension, the options can be exercised until September 30, 2014.

During the three months ended September 30, 2012, the Company issued a total of 436,742 shares of its common stock in connection with the exercise of 436,742 options and warrants. The Company received aggregate cash proceeds equal to approximately $432,000 in connection with such exercises.

Basic and diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of ordinary shares outstanding during the period. The calculation of diluted net loss per share excludes potential ordinary shares as the effect is anti-dilutive. Potential ordinary shares are comprised of incremental ordinary shares issuable upon the exercise of share options, warrants and convertible loans.

For the three month periods ended September 30, 2012 and 2011, all ordinary shares underlying outstanding options, warrants and convertible loans have been excluded from the calculation of the diluted loss per share since their effect was anti-dilutive. The total number of ordinary shares related to outstanding options, warrants and convertible loans excluded from the calculations of diluted loss per share were 32,190,854 and 17,122,793 for the three month periods ended September 30, 2012 and 2011, respectively.

NOTE 4 - FAIR VALUE MEASURMENT:

**a.** **Financial Assets and Liabilities Measured at Fair Value.** The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

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**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 4 - FAIR VALUE MEASURMENT (continued):

The following table summarizes the balances for those financial liabilities where fair value measurements are estimated utilizing Level 2 and Level 3 inputs:

| | Level | September 30 2012 | June 30 2012 |
|---|---|---|---|
| | | ($ in thousands) | |
| 2012 Warrants at fair value | 2 | $4,979 | $1,706 |
| Embedded derivative | 3 | - | 49 |
| | | $4,979 | $1,755 |

The following table summarizes the activity for those financial liabilities where fair value measurements are estimated utilizing Level 3 inputs:

| | Embedded Derivative ($ in thousands) |
|---|---|
| Balance as of July 1, 2012 | $ 49 |
| Total losses (gains) (realized and unrealized) - included in earnings - financial expenses , net | (49) |
| Balance as of September 30, 2012 | $ - |

Level 3 liabilities include an embedded derivative related to the Company’s 2012 Convertible Debentures. The Company values the Level 3 embedded derivative using an internally developed valuation model, whose inputs include recovery rates, credit spreads, stock prices, and volatilities, as described below.

The fair value of the warrants included in Level 2 is estimated using the Black Scholes model.

In calculating the fair value of warrants at September 30, 2012, the Company used the following assumptions: expected term of 4.52 years; expected volatility of 69.9%; risk-free interest rate of 0.54%; and dividend yield of 0%.

**b. 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. The carrying amount of the Company's other financial long-term assets approximate their fair value.

The fair value of the Company's 2012 Convertible Debentures approximates the carrying amount (after considering the beneficial conversion feature). If measured at fair value in the financial statements, these financial instruments would be classified as Level 3 in the fair value hierarchy.

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

**NOTE 5 - INVENTORY ON HAND:**

| | September 30, 2012 | June 30, 2012 |
|---|---|---|
| | ($ in thousands) | |
| Finished goods | $752 | $479 |
| Work in process | 1,201 | 1,115 |
| Raw materials and supplies | 123 | 150 |
| | $2,076 | $1,744 |

**NOTE 6 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:**

| | September 30, 2012 | June 30, 2012 |
|---|---|---|
| | ($ in thousands) | |
| Employees and employee institutions | $442 | $438 |
| Accrued vacation and recreation pay | 256 | 272 |
| Accrued clinical trial expenses | 333 | 607 |
| Provision for sales commissions | 188 | 194 |
| Accrued expenses | 1,259 | 1,197 |
| Due to government institutions | 23 | 22 |
| Provision for returns | 55 | 139 |
| Taxes payable | 72 | 56 |
| | $2,628 | $2,925 |

**NOTE 7 - FINANCIAL EXPENSES, NET:**

| | September 30, 2012 | September 30, 2011 |
|---|---|---|
| | ($ in thousands) | |
| Bank commissions | $ 9 | $ 8 |
| Interest income | (9 ) | (20 ) |
| Exchange rate differences | 5 | 105 |
| Interest expense (including debt issuance costs) | 988 | 15 |
| Change in fair value of warrants and embedded derivatives | 3,225 | |
| | $ 4,218 | $ 108 |

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**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

**NOTE 8 - RELATED PARTIES:**

On July 2, 2012, effective August 1, 2012, InspireMD Ltd. (a wholly-owned subsidiary of the Company) entered into a consultancy agreement (the “First Consultancy Agreement”) with a member of the immediate family of the CEO, pursuant to which the consultant would be retained for sales services. Pursuant to the agreement, she would be entitled to a fixed fee of $625 (2,500 NIS) for each full working day and a bonus fee up to $10,000 (40,000 NIS) upon 100% achievement of set objectives. The First Consultancy Agreement was terminated on September 30, 2012.

On August 27, 2012, InspireMD Ltd. entered into a revised consultancy agreement (the “Second Consultancy Agreement”) with a member of the immediate family of the CEO, pursuant to which, the consultant would be retained for sales and marketing services. Pursuant to the agreement, she is entitled to options to purchase 243,483 shares of common stock at an exercise price of $1.45 per share. The revised agreement also extended to September 2014 the exercise date on 121,740 options scheduled to expire upon the termination of the First Consultancy Agreement

**NOTE 9 - COMMITMENT AND CONTINGENT LIABILITIES:**

**a. Commitment**

In March 2010, the Company entered into a license agreement to use a stent design (“MGuard Prime™”). Pursuant to the agreement, the licensor is entitled to receive royalty payments of 7% of net sales outside the United States and, for sales within the United States, royalty payments as follows: 7% of net sales for the first $10,000,000 of net sales and 10% of net sales for net sales exceeding $10,000,000.

On October 22, 2012, the Company, InspireMD Ltd. and the licensor entered into the First Amendment to License Agreement, which amended the license agreement described above. Pursuant to the amendment, amongst other things, the licensor agreed to reduce the royalty owed with respect to sales of MGuard Prime™ to 2.9% of all net sales both inside and outside the U.S. in exchange for (i) InspireMD Ltd. waiving $85,000 in regulatory fees for the CE Mark that are owed by the licensor to InspireMD Ltd., (ii) InspireMD Ltd. making full payment of royalties in the amount