BOSTON, Sept. 17, 2013 /PRNewswire/ -- InspireMD Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic protection stents, today announced financial results for its fourth quarter and fiscal year ended
June 30, 2013
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Key Highlights

- Enhanced executive management team and Board with key new appointments
- Strengthened balance sheet with retirement of debt and $25 million capital raise in April 2013
- Announced superior MASTER trial results and positive 30-day and 6-month data
- Initiated enrollment in FDA-intended MASTER II trial

Upcoming Near-term Milestones

- 12-month MASTER trial results to be released at Transcatheter Cardiovascular Therapeutics (TCT) Conference on October 29, 2013
- Implementing tiered commercial strategy, including select direct sales activities in Europe
- Initiating clinical activities with CGuard™ Carotid stent system

Commenting on the Company's recent activity, Alan Milinazzo, President and Chief Executive Officer of InspireMD, stated, "Since joining the Company earlier this year, I've looked to realign our efforts across multiple areas of the business in order to create a solid foundation for future growth. We've identified four key areas of focus moving forward: clinical studies, development of new products in our pipeline, strategic partnerships and our commercial strategy. I believe these concentrated efforts will allow us to build broader awareness for our new generation of stent technologies with sales in countries where we already have market clearance, while working towards FDA approval."

"The 12-month follow up results for the MASTER trial are to be announced on October 29th. This is the next major data point that most clinicians are looking for to validate use of the MGuard™ stent. As such, we believe these results will facilitate our sales and strategic partnership activities in key international markets. In terms of the U.S. market, we already began enrollment for our FDA-intended MASTER II trial. And as we expand our current clinical activities for the Coronary market, we continue to bolster our product pipeline with advances for the Carotid and Peripheral Vasculature target indications," concluded Mr. Milinazzo.

Operational Overview

In fiscal year 2013, the Company announced superior results from the MASTER trial for its MGuard Embolic Protection Stent (EPS).The findings show the novel MGuard EPS provides a significant acute advantage in reducing ST segment elevation versus traditional bare metal and drug eluting stents. As a result, MGuard may hold the potential to prolong the survival of heart attack victims, as evidenced by the 30-day and 6-month data.

The MASTER trial is an important study for InspireMD, as it is the first large, randomized clinical trial for the MGuard to date. As such, the results have gained much more credence among those in the medical community. The 12-month follow up results for the MASTER trial,

scheduled to be released on October 29th, are expected to be an important data point for physicians evaluating the MGuard, as the first year is an important period for evaluating a patient that has received a stent during a heart attack.

The results disclosed thus far from the MASTER trial have allowed the Company to begin the transition to a new commercial strategy in countries where the MGuard has received regulatory clearance. This includes setting up the support structure for a direct sales team in certain European countries and advancing discussions with new strategic partners. The Company recently entered into an agreement with Healthlink Europe, a medical device support services and distribution company, to provide logistical and customer support for InspireMD's commercial operations and clinical activities. Healthlink will provide InspireMD with customer service center capabilities for inquiries from hospitals and distributors. Healthlink will also handle all inventory controls, warehousing, shipping, and invoicing and receivables management for customers worldwide on behalf of InspireMD.

The Company began enrollment with its MASTER II clinical trial to evaluate the safety and effectiveness of the MGuard™ Prime EPS in patients suffering from ST Elevation Myocardial Infarction (STEMI). In total, the multi-center, randomized trial is expected to include up to 70 sites in the U.S. and Europe and as many as 1,114 patients. The results are intended to support the Company's Investigational Device Exemption (IDE) application with the U.S. Food and Drug Administration (FDA) to market the MGuard™ Prime MicroNet™ covered coronary stent system in the U.S.

The ongoing progress and changes throughout the Company are being driven by new leadership brought in over the past year at the executive management and board levels. To lead the Company forward, Mr. Milinazzo was appointed President and CEO in January 2013, bringing fifteen years of experience in interventional cardiology to InspireMD. The Company also appointed Ms.
Gwen Bame
to a newly created position of Vice President of Corporate Development and charged her with identifying and executing strategic programs and partnerships designed to meet InspireMD's global growth objectives. As of yesterday, the Company appointed Mr.
David Blossom
as its Vice President of Global Marketing and Strategy and will be charged with creating and overseeing the implementation of a global strategic marketing plan. At the Board level, industry veterans, Mr.
Michael Berman
and Dr. Campbell Rogers recently joined to provide invaluable strategic guidance and support.

Fourth Quarter Financial Results

Revenue for the quarter ended June 30, 2013 was $1.5 million, an increase of 60.7% compared to $0.9 million for the same period in 2012. The increase was the result of recent expanded sales activities in key European and South American countries.

Gross profit for the quarter ended June 30, 2013 totaled $0.7 million, an increase of 414% compared to $0.1 million for same period in 2012. The increase in gross profit is primarily attributable to a non-recurring write-off of $0.4 million of slow moving inventory in the twelve months ended June 30, 2012, which did not occur in the same period in 2013, and an increase of $0.4 million primarily due to the increase in sales of $0.6 million, as discussed above. This was partially offset by $0.2 million of expenses related to the integration of our R&D center into a streamlined manufacturing facility intended to increase efficiency and support anticipated commercial demand. Gross margins for the quarter increased to 44.5% compared to 13.9% for the same period in 2012.

Total operating expenses for the quarter ended June 30, 2013 were $4.9 million, an increase of 17.3% compared to $4.2 million for the same period in 2012. The increase was primarily due to an increase in General & Administrative and Sales & Marketing expenses, as the Company builds the appropriate sales infrastructure and management team for future growth.

The loss from operations for the quarter ended June 30, 2013 was $4.2 million, a slight increase of 4.5% compared to $4.0 million for the same period in 2012.

The net loss for the quarter ended June 30, 2013 totaled $14.9 million, or $0.48 per basic and diluted share, an increase of 279% compared to a net loss of
$3.9 million
, or
$0.23
per basic and diluted share in the same period in 2012. The net loss was driven by
$10.6 million
of non-recurring, non-cash costs associated with the conversion and retirement of the Company's convertible debt in conjunction with the
April 2013
capital raise.

Non-GAAP net loss for the quarter ended June 30, 2013 was $3.2 million, or $0.10 per basic and diluted share, a decrease of 8.6% compared to a non-GAAP net loss of
$3.5 million
or
$0.21
for the same period in 2012. The non-GAAP net loss for the quarter ended
June 30, 2013
primarily excludes the
$10.6 million
non-recurring, non-cash costs associated with the conversion and retirement of the Company's convertible debt in conjunction with the
April 2013
capital raise.

Fiscal Year End Financial Results

Revenue for the fiscal year ended June 30, 2013 totaled $4.9 million, a decrease of 8.9% compared to $5.3 million
for the same period in 2012. The
$0.4 million
decrease in sales volume was due primarily to the process of restructuring the Company's commercial strategy in key countries by developing direct sales channels and eliminating certain non-performing third party distributors.

Gross profit for the fiscal year ended June 30, 2013 totaled $2.6 million, an increase of 3.6% compared to $2.5

million for the same period in 2012. The increase in gross profit is attributable to a decrease in cost of revenues, primarily from a non-recurring write-off of $0.4 million of slow moving inventory in the twelve months ended June 30, 2012, which did not occur in the same period in 2013. These decreases were partially offset by expenses related to the integration of our R&D center into a streamlined manufacturing facility intended to increase efficiency and support anticipated commercial demand. Gross margins increased to 53.2% for the fiscal year ended June 30, 2013 compared to 46.7% for the same period in 2012.

Total operating expenses for the fiscal year ended June 30, 2013 were $17.7 million, a decrease of 11.9% compared to $20.0 million for the same period in 2012. The decrease was primarily due to a decrease in share-based compensation of $6.7 million, which was partially offset by an increase in Sales and Marketing, as the Company builds the appropriate sales infrastructure for future growth.

The loss from operations for the fiscal year ended June 30, 2013 was $15.1 million, a decrease of 14.1% compared to $17.5 million for the same period in 2012.

The net loss for the fiscal year ended June 30, 2013 totaled $29.3 million, or $1.39 per basic and diluted share, an increase of 66.3% compared to a net loss of $17.6 million, or $1.04 per basic and diluted share in the period in 2012. The increase in net loss resulted primarily from an increase of $14.1 million in financial expenses, of which, $13.4 million were non-recurring, non-cash costs associated with the Company's convertible debt.

Non-GAAP net loss for the fiscal year ended June 30, 2013 was $11.0 million, or $0.53 per share, compared to
$7.4 million
, or
$0.44
per share, for the same period in 2012. The non-GAAP net loss for fiscal year 2013 primarily excludes the
$13.4 million
non-recurring, non-cash costs associated with the Company's convertible debt, and
$3.8 million
in share-based compensation. The non-GAAP net loss for fiscal year 2012 primarily excludes
$10.6 million
in share-based compensation.

Cash and Cash Equivalents

At June 30, 2013, cash and cash equivalents were $14.8 million, an increase of 44.1% compared to $10.3 million at June 30, 2012. The Company's cash increased mainly due to the April 2013 capital raise with net proceeds of $14.1 million.

Change to Fiscal Year

The Company announced today that it will be changing its fiscal reporting year end from June 30th to December 31st. It will run a transitional six-month fiscal year from July 1st to December 31st, 2013. Management believes that this change will allow the Company to better align its

financial periods and annual budget planning with its business cycle, as well as assist the investment community with following its progress moving forward.

Investor Conference Call

The Company will host a conference call today at 4:30 p.m. ET to review the Company's financial results and business outlook. Participants should call (877) 375-4189 (United States / Canada) or (973) 935-2046 (International) and request the InspireMD call or provide confirmation code 45736242. A live webcast of the call will be available on the Investor Relations section of the Company's website at www.inspire-md.com/site_en/for-investors/ . Please allow 10 minutes prior to the call to visit this site to download and install any necessary audio software.

A replay of the conference call will be available approximately two hours after completion of the live conference call and will be accessible until 11:59 p.m. ET on October 1, 2013. To listen to the replay, dial (855) 859-2056 (United States / Canada) or (404) 537-3406 (International) and enter code 45736242. The webcast of the event will also be archived for two weeks on the Investor Relations section of the Company's website at www.inspire-md.com/site_en/for-investors/ .

About Stenting and MGuard™ EPS

Standard stents were not engineered for heart attack patients. They were designed for treating stable angina patients whose occlusion is different from that of an occlusion in a heart attack patient.

In acute heart attack patients, the plaque or thrombus is unstable and often breaks up as the stent is implanted causing downstream blockages (some of which can be fatal) in a significant portion of heart attack patients.

The MGuard EPS is integrated with a precisely engineered micro net mesh that prevents the unstable arterial plaque and thrombus (clots) that caused the heart attack blockage from breaking off.

While offering superior performance relative to standard stents in STEMI patients with regard to ST segment resolution, the MGuard EPS requires no change in current physician practice – an important factor in promoting acceptance and general use in time-critical emergency settings.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MGuard technology to make its products the industry standard for embolic protection stents and to provide a superior solution to the key clinical issues of current stenting in patients with a high risk of distal embolization, no reflow and major adverse cardiac events.

InspireMD intends to pursue applications of this technology in coronary, carotid and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

MGuard EPS is CE Mark approved. It is not approved for sale in the U.S. by the FDA at this time.

Use of Non-GAAP Financial Measures

To supplement the Company's consolidated financial statements presented on a GAAP basis, the Company discloses a non-GAAP measure as non-GAAP net loss because management

uses this supplemental non-GAAP financial measure to evaluate performance period over period, to analyze the underlying trends in its business, and to establish operational goals and forecasts that are used in allocating resources. In addition, many investors use this non-GAAP measure to monitor the Company's performance. This non-GAAP measure should not be considered as an alternative to GAAP measures as an indicator of the Company's operating performance.

Non-GAAP net loss is defined by the Company as net loss excluding non-cash financial expenses, share-based compensation expenses and royalties buyout expenses and amortization. Non-cash financial expenses are items that are related to the induced conversion of the convertible debt, amortization of discount on convertible debt and related issuance costs.

Generally, a non-GAAP financial measure is a numerical measure of a company's performance, financial position or cash flow that either excludes or includes amounts that are not normally excluded or included in the most directly comparable measure calculated and presented in accordance with GAAP. The non-GAAP measures discussed above , however, should be considered in addition to, and not as a substitute for or superior to; operating loss, cash flows, or other measures of financial performance prepared in accordance with GAAP. A reconciliation of non-GAAP to GAAP financial measure is set forth in the table below.

The Company believes that presenting a non-GAAP net loss, in addition to the corresponding GAAP financial measures, provides investors greater transparency to the information used by management for financial and operational decision-making and allows investors to see the Company's results "through the eyes" of management. The Company further believes that providing this information assists investors in understanding the Company's operating performance and the methodology used by management to evaluate and measure such performance.

Forward-looking Statements:

This press release contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results

may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) market acceptance of the Company's existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of the Company's products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) the Company's limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payers for the Company's products, (viii) the Company's efforts to successfully obtain and maintain intellectual property protection covering its products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) the Company's reliance on single suppliers for certain product components, (xi) the fact that the Company will need to raise additional capital to meet its business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xii) the fact that the Company conducts business in multiple foreign jurisdictions, exposing the Company to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction. More detailed information about the Company and the risk factors that may affect the realization of forward looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov . The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three months ended		Twelve months ended	
	June 30,		June 30,	
	2013	2012	2013	2012
Revenues				

$1,500

$933

$4,873

$5,349

Cost of Revenues

832

803

2,283

2,849

Gross Profit

668

130

2,590

2,500

Operating Expenses:

Royalties buyout expenses

918

Other research and development expenses

1,047

1,258

4,156

3,988

Selling and marketing

1,204

801

3,616

2,174

General and administrative

2,632

2,103

8,973

13,883

Total operating expenses

4,883

4,162

17,663

20,045

Loss from Operations

(4,215)

(4,032)

(15,073)

(17,545)

Financial expenses (income)

10,755

(98)

14,177

38

Loss before tax expenses (income)

(14,970)

(3,934)

(29,250)

(17,583)

Tax expenses (income)

(23)

7

8

14

Net Loss

($14,947)

($3,941)

($29,258)

($17,597)

Net loss per share – basic and diluted

($0.48)

($0.23)

($1.39)

($1.04)

Weighted average number of shares of common stock used in computing net loss per share – basic and

31,033,657

17,043,704

20,995,887

16,707,599

RECONCILIATION OF NON-GAAP NET LOSS[3]

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

Three months ended

Twelve months ended

June 30,

 June 30,

2013

2012

2013

2012

GAAP Net Loss

($14,947)

($3,941)

($29,258)

($17,597)

Non-GAAP Adjustments:

Non-cash financial expenses (income)[3]

10,627

(314)

13,416

(314)

Share-based compensation expenses

1,109

755

3,839

10,554

Royalties buyout expenses and amortization

13

0

964

0

Total Non-GAAP Adjustments

11,749

441

18,219

10,240

Non-GAAP Net Loss

($3,198)

($3,500)

($11,039)

($7,357)

Non-GAAP net loss per share – basic and diluted

($0.10)

($0.21)

($0.53)

($0.44)

Weighted average number of shares of common stock used in computing net loss per share – basic and

31,033,657

17,043,704

20,995,887

16,707,599

CONSOLIDATED BALANCE SHEETS(1)

(U.S. dollars in thousands)

ASSETS

June 30,

June 30,

2013

2012

Current Assets:

Cash and cash equivalents

$14,820

$10,284

Restricted cash

93

37

Accounts receivable:

Trade

1,739

1,824

Other

388

264

Prepaid expenses

272

93

Inventory:

On hand

1,593

1,744

On consignment

63

Total current assets

18,905

14,309

Property, plant and equipment, net

550

462

Non-current assets:

Deferred debt issuance costs

961

Funds in respect of employee rights upon retirement

406

282

Royalties buyout

884

Total non-current assets

1,290

1,243

Total assets

$20,745

$16,014

CONSOLIDATED BALANCE SHEETS (Cont.)[1]

(U.S. dollars in thousands)

LIABILITIES AND EQUITY

June 30,

June 30,

2013

2012

Current liabilities:

Accounts payable and accruals:

Trade

$831

$441

Other

3,028

2,925

Advanced payment from customers

174

174

Deferred revenues

10

10

Total current liabilities

4,043

3,550

Long-term liabilities:

Liability for employees rights upon retirement

600

354

Convertible loan

5,018

Contingently redeemable warrants

1,706

Total long-term liabilities

600

7,078

Total liabilities

4,643

10,628

Equity:

Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 33,888,845 and 17,040,0

3

2

Additional paid-in capital

89,079

49,106

Accumulated deficit

(72,980)

(43,722)

Total equity

16,102

5,386

Total liabilities and equity

$20,745

$16,014

(1) All 2013 financial information is derived from the Company's 2013 audited financial statements and a

(2) The Company's non-GAAP net loss is presented as management uses this supplemental non-GAAP

(3) Non-cash financial expenses are items related to the induced conversion of the convertible loan, amo

SOURCE InspireMD

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