EDGAR Online

INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 05/08/14 for the Period Ending 05/07/14

Address	321 COLUMBUS AVENUE BOSTON, MA 02116
Telephone	(857) 453-6553
CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	12/31

Powered By EDGAR Online
http://www.edgar-online.com
© Copyright 2015, EDGAR Online, Inc. All Rights Reserved.
Distribution and use of this document restricted under EDGAR Online, Inc. Terms of Use.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 7, 2014

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35731	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

321 Columbus Avenue Boston, Massachusetts (Address of principal executive offices)	02116 (Zip Code)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On May 7, 2014, InspireMD, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended March 31, 2014. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, that is furnished pursuant to this Item 2.02 shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On May 7, 2014, the Company issued a press release announcing new results from the Company's International MGuard Observational Study Prime Registry for the MGuard ™ Prime embolic protection stent.

A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Earnings release dated May 7, 2014
99.2	Press release dated May 7, 2014

SIGNATURES

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

INSPIREMD, INC.

Date: May 8, 2014

By: /s/ Craig Shore
Name: Craig Shore
Title: Chief Financial Officer

InspireMD Reports Financial Results for the First Quarter Ended March 31, 2014

BOSTON, MA – May 7, 2014 – InspireMD, Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic protection systems ("EPS"), today announced financial and operating results for the quarter ended March 31, 2014.

Recent Events

- Initiated enrollment of patients into the CARENET (CARotid Embolic protection study using microNET) for the CGuard ™ EPS
  - Data from the CARENET trial is anticipated in the third quarter of 2014
- Positive clinical results for the iMOS Prime Registry for the MGuard ™ Prime EPS
  - Complete ST-resolution in approximately 75% of cases, and 2.2% MACE rate at 30 days, including zero cases of mortality
- Development work on a next generation Drug Eluding Stent ("DES") MGuard continued on track with favorable technical test results from all DES product candidates
- Implemented a Voluntary Field Action ("VFA") for the MGuard Prime EPS that is expected to have a short-term impact on both commercial and clinical activities
  - VFA does not apply to or impact the MGuard stainless steel EPS or CGuard nitinol products
  - VFA is expected to have a neutral impact on cash utilization in the near-term

"As expected, overall revenue for the quarter was relatively flat at $1.5 million compared to the same period last year. Importantly, countries with direct sales reps reported an increase in revenue compared to the prior quarter and the majority of these territories outperformed the prior year period, which is an encouraging early indicator that our strategy is working in these key markets," stated Alan Milinazzo, Chief Executive Officer of InspireMD. "We also announced positive clinical results from the iMOS Prime Registry for the MGuard Prime EPS, which reported complete ST-resolution in approximately 75% of cases, and a 2.2% MACE rate at 30 days, including zero cases of mortality. This study enrolled 97 acute STEMI patients undergoing PCI from two sites in the Netherlands over the course of approximately 15 months."

Mr. Milinazzo concluded, "Finally, our recent decision to initiate a Voluntary Field Action has been communicated to all of our customers and we are in the process of working through the regulatory approval processes which would allow us to begin shipping modified MGuard Primes back into the marketplace and to restart enrollment in our MASTER II trial. This action underscores the Company's strong commitment to quality and we feel confident the modified product will be well received once commercial and clinical activities resume."

Operational Overview

The Company continues to move forward with the CARENET (CARotid Embolic protection using microNET) study, which is a multi-specialty trial to evaluate the safety and efficacy of the CGuard EPS. The CGuard uses the Company's proprietary MicroNet technology and is designed for the treatment of carotid lesions in order to protect patients from plaque debris, blood clots and reduce the risk of stroke. Enrollment in the CARENET trial started ahead of schedule and the Company is on track to release initial results of the trial in the third quarter of 2014.

InspireMD is in the process of conducting pre-clinical studies for the viability of combining its proprietary MicroNet(TM) technology with several already CE Marked or FDA approved drug eluting coronary stents. These tests are evaluating the safety and efficacy of the stent when it is combined with the Company's MicroNet technology. This is an important phase in the development of the Company's next generation embolic protection system and management is carefully evaluating opportunities in this area on an ongoing basis. The Company is currently in negotiations with several stent manufacturers regarding next steps in the development of a combined product.

The Company recently became aware of reports of stent dislodgements occurring in the MGuard Prime EPS, leading to the precautionary measure of initiating a VFA. Although there were no reports of patients being harmed, management believed that proactively addressing the issue was important to uphold the Company's standards of quality and safety. The Company believes that it has identified the root cause of these dislodgements and, upon approval from the European regulatory agency, intends to modify all existing units of the MGuard Prime EPS in order to improve stent retention and performance. InspireMD has notified its clinical and commercial partners worldwide of the VFA for the MGuard Prime EPS and intends to modify all units in the field once regulatory approval is received.

As previously announced, the Company has temporarily suspended enrollment in its MASTER II FDA trial pending a review by the FDA of the manufacturing improvements to the MGuard Prime EPS. This is likely to delay enrollment in the trial for approximately 3 to 6 months. The Company intends to focus on site activation activities during this review period in order to accelerate enrollment once the study resumes.

Quarter Ended March 31, 2014 Financial Results

Revenue for the quarter ended March 31, 2014 was relatively flat at $1.5 million compared to $1.5 million during the same period in 2013. The 2014 period included a decline in sales volume associated with the move away from sales distributors as we transition towards direct sales channels, which was mostly offset by new customer sales in the Middle East.

Gross profit for the quarter ended March 31, 2014 totaled $0.9 million, an increase of 2.0% or $17,000, compared to $0.8 million for same period in 2013. Gross margin for the three months ended March 31, 2014 was 57.8%, an increase from 55.5% in the three months ended December 31, 2013. This increase in gross profit was attributable to a decrease in cost of revenues that was partially offset by a write-off of slow moving inventory of $52,000. If the non-recurring effects of the write-off of slow moving inventory in the three months ended March 31, 2014, are removed, gross margin for the three months ended March 31, 2014 would have been 61.3%.

Total operating expenses for the quarter ended March 31, 2014 were $6.4 million, an increase of 57.8% compared to $4.1 million for the same period in 2013. This was primarily due to increased research and development expenses attributable to the MASTER II trial and expenditures in sales and marketing as the Company increased its efforts to support the new sales strategies in key European countries.

The loss from operations for the quarter ended March 31, 2014 was $5.5 million, an increase of 72.4% compared to a loss of $3.2 million for the same period in 2013.

Financial expenses for the three months ended March 31, 2014 decreased 75.6%, or $1.3 million, to $0.4 million from $1.7 million during the same period in 2013. The decrease in financial expenses resulted primarily from a decrease of $1.3 million of anti-dilution rights expense associated with the April 2013 fund raising of $25 million.

The net loss for the quarter ended March 31, 2014 totaled $6.0 million, or $0.18 per basic and diluted share, compared to a net loss of $4.9 million, or $0.27 per basic and diluted share, in the same period in 2013.

Non-GAAP net loss for the quarter ended March 31, 2014 was $4.9 million, or $0.15 per basic and diluted share, an increase of 132.1% compared to a non-GAAP net loss of $2.1 million, or $0.12 per basic and diluted share, for the same period in 2013. The non-GAAP net loss for the quarter ended March 31, 2014 primarily excludes $1.0 million of share-based compensation. The non-GAAP net loss for quarter ended December 31, 2013 primarily excludes $1.5 million in non-cash financial expenses and $1.3 million in share-based compensation expenses. See "Use of Non-GAAP Financial Measures" and "Reconciliation of Non-GAAP Net Loss" below.

Cash and Cash Equivalents

As of March 31, 2014, cash and cash equivalents were $13.7 million, compared to $17.5 million as of December 31, 2013.

Investor Conference Call

The Company will host a conference call at 4:30 p.m. ET on Wednesday, May 7 th to review its financial results and business outlook. Participants should call (877) 407-0784 (United States) or (201) 689-8560 (International) and request the InspireMD call or provide confirmation code: 13581583. A live webcast of the call will also 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.

An archive of the webcast will be available approximately one hour after completion of the live event and will be accessible on the Investor Relations section of the Company's website at www.inspire-md.com/site_en/for-investors for a limited time. A dial-in replay of the call will also be available to those interested until May 21 st . To access the replay, dial (877) 870-5176 (United States) or (858) 384-5517 (International) and enter code: 13581583.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MGuard(TM) with MicroNet(TM) technology to make its products the industry standard for embolic protection 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 MicroNet technology in coronary, carotid (CGuard(TM)) and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

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, the Company believes 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 amortization. Non-cash financial expenses are items that are related to the amortization of discount on convertible debt and related issuance costs, the revaluation of warrants and expenses related to the anti-dilution rights of our March 2011 investors.

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) product malfunctions, (vii) the Company's limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for the Company's products, (ix) the Company's efforts to successfully obtain and maintain intellectual property protection covering its products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) the Company's reliance on single suppliers for certain product components, (xii) 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 Transition Report on Form 10-KT 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.

Investor Contacts:
Todd Fromer / Garth Russell
KCSA Strategic Communications
Phone: 212-896-1215 / 212-896-1250
Email: tfromer@kcsa.com / grussell@kcsa.com

Media Contacts:
Lewis Goldberg / Samantha Wolf
KCSA Strategic Communications
Phone: 212-896-1216 / 212-896-1220
Email: lgoldberg@kcsa.com / swolf@kcsa.com

######

CONSOLIDATED STATEMENTS OF OPERATIONS [1]
(U.S. dollars in thousands, except per share data)

	Three months ended March 31,	
	2014	**2013**
Revenues	$ 1,482	$ 1,514
Cost of revenues	625	674
Gross Profit	857	840
Operating Expenses:		
Research and development	2,577	907
Selling and marketing	1,276	804
General and administrative	2,539	2,340
Total operating expenses	6,392	4,051
Loss from operations	(5,535)	(3,211)
Financial expenses	413	1,692
Loss before tax expenses	(5,948)	(4,903)
Tax expenses (Income)	20	(18)
Net Loss	$ (5,968)	$ (4,885)
Net loss per share – basic and diluted	$ (0.18)	$ (0.27)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	34,051,703	18,196,083

RECONCILIATION OF NON-GAAP NET LOSS [2]
(U.S. dollars in thousands, except per share data)

	Three months ended March 31,	
	2014	**2013**
GAAP Net Loss	$ (5,968)	$ (4,885)
Non-GAAP Adjustments:		
Non-cash financial expenses (income) [3]	(6)	1,458
Share-based compensation expenses	1,019	1,299
Royalties buyout expenses and amortization	15	0
Total Non-GAAP Adjustments	1,028	2,757
Non-GAAP Net Loss	$ (4,940)	$ (2,128)
Non-GAAP net loss per share – basic and diluted	$ (0.15)	$ (0.12)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	34,051,703	18,196,083

CONSOLIDATED BALANCE SHEETS [4]

(U.S. dollars in thousands)

ASSETS	March 31, 2014	December 31, 2013
Current Assets:		
Cash and cash equivalents	$ 13,706	$ 17,535
Restricted cash	93	93
Accounts receivable:		
Trade	1,494	1,855
Other	465	387
Prepaid expenses	110	141
Inventory	1,343	1,593
Total current assets	17,211	21,604
Property, plant and equipment, net	624	652
Non-current assets:		
Deferred issuance costs	293	310
Funds in respect of employee rights upon retirement	455	434
Long term prepaid expenses	85	114
Royalties buyout	837	852
Total non-current assets	1,670	1,710
Total assets	$ 19,505	$ 23,966

LIABILITIES AND EQUITY	March 31, 2014	December 31, 2013
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 1,405	$ 1,623
Other	3,814	3,141
Advanced payment from customers	190	179
Current maturity of loan	2,099	1,181
Total current liabilities	7,508	6,124
Long-term liabilities:		
Liability for employees rights upon retirement	636	610
Long term loan	7,748	8,593
Total long-term liabilities	8,384	9,203
Total liabilities	15,892	15,327
Equity:		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 34,054,060 and 33,983,346 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	3	3
Additional paid-in capital	91,894	90,952
Accumulated deficit	(88,284)	(82,316)
Total equity	3,613	8,639
Total liabilities and equity	$ 19,505	$ 23,966

(1) All 2014 financial information is derived from the Company's 2014 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission, and all 2013 financial information is derived from the Company's 2013 financial statements, as disclosed in the Company's Transition Report on Form 10-KT, filed with the Securities and Exchange Commission.

(2) Our non-GAAP net loss is presented as management uses this supplemental non-GAAP financial measure to evaluate performance period over period, analyze the underlying trends in our business, and establish operational goals and forecasts that are used in allocating resources. We believe by presenting this additional measurement, we are providing investors with greater transparency to the information used by our management for our financial and operational decision-making, as well as allowing investors to see our results "through the eyes" of management. We further believe that providing this information assists our investors in understanding our operating performance and the methodology used by management to evaluate and measure such performance.

(3) Non-cash financial expenses (income) are items related to the amortization of the discount on the convertible loan and its related issuance costs, the issuance of shares as a result of the anti-dilution rights of our March 2011 investors and the revaluation of warrants.

(4) All March 31, 2014 financial information is derived from the Company's 2014 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission and all December 31, 2013 financial information is derived from the Company's 2013 audited financial statements, as disclosed in the Company's Transition Report on Form 10-KT, filed with the Securities and Exchange Commission.

InspireMD Announces Positive Results from iMOS Prime Registry for the MGuard Prime EPS

- - -

Study of 97 patients resulted in zero mortalities in STEMI patients as of 30-day follow up

- - -

Results to be presented at EuroPCR meeting in Paris on Thursday, May 22 nd at 4:50 p.m. CEST

BOSTON, Ma – May 7, 2014 – InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), a leader in embolic protection stents (EPS), today announced new results from the iMOS (**I** nternational **M** Guard **O** bservational **S** tudy) Prime Registry demonstrating that use of the MGuard ™ Prime in cases of acute ST-segment elevation myocardial infarction (STEMI) patients undergoing percutaneous coronary intervention (PCI) resulted in complete ST-resolution in approximately 75% of cases, and a 2.2% rate of Major Adverse Cardiac Events (MACE) at 30 days, including zero cases of mortality.

The iMOS Prime Registry evaluated the 'Real World' Clinical Performance of the MGuard Prime Coronary Stent System in patients with acute STEMI undergoing PCI. Between December 13, 2012 and March 19, 2014, there were 97 patients with STEMI enrolled at two sites in the Netherlands.

"I have treated many patients with coronary disease requiring a thrombus management solution over the years and I am excited to share results from the recently completed iMOS Prime registry in a real world setting which looked at the MGuard Prime EPS performance," stated Dr. Giovanni Amoroso, Interventional Cardiologist at OLVG Hospital in the Netherlands. "This iMOS registry is the first study done exclusively with the lower profile MGuard Prime embolic protection system. I am happy to report that device success was achieved in 100% of all cases. In addition, TIMI 3 flow was achieved 92% of the time, complete ST-resolution was achieved in approximately 75% of the cases, and finally, 30 day all-cause mortality was 0%. We plan to continue to follow the patients out to 12 months."

The iMOS Prime Registry achieved a 2.2% rate of Major Adverse Cardiac Events rate (MACE) at 30 days, the primary endpoint for the study. MACE is defined as the composite of cardiac death, myocardial infarction (Q wave and non-Q wave) or target lesion revascularization (PTCA or CABG).

"The MGuard Prime's performance in the iMOS Prime Registry is consistent with our previous STEMI studies, reinforcing our belief that the MGuard Prime may offer superior mortality benefits compared to other stents on the market," stated Alan Milinazzo, President and Chief Executive Officer of InspireMD. "Further, during this study, there was a 100% success rate reported in the delivery and deployment of the MGuard Prime."

The MGuard Prime utilizes the Company's proprietary MicroNet™ technology, which is a circular knitted mesh that wraps around a cobalt chromium stent to protect patients from plaque debris flowing downstream upon deployment. This advanced technology allows the MGuard Prime to specifically address the unmet need for STEMI patients, and save the life of those who suffer from heart attacks.

About Stenting and MGuard™ Prime 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 Prime EPS is integrated with a precisely engineered micro net mesh that is designed to prevent 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 Prime 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.

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 our 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 our products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xiii) the fact that we conduct business in multiple foreign jurisdictions, exposing us 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 Transition Report on Form 10-KT 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.

Investor Contacts:
Todd Fromer / Garth Russell
KCSA Strategic Communications
Phone: 212-896-1215 / 212-896-1250
Email: tfromer@kcsa.com / grussell@kcsa.com

Media Contacts:
Lewis Goldberg / Samantha Wolf
KCSA Strategic Communications
Phone: 212-896-1216 / 212-896-1220
Email: lgoldberg@kcsa.com / swolf@kcsa.com