FIRST MID ILLINOIS BANCSHARES INC
Form 4
December 17, 2008

FORM 4

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

OMB APPROVAL
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STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

(Print or Type Responses)

1. Name and Address of Reporting Person *
LeFebvre Charles Allen

(Last) (First) (Middle)

RR 1, BOX 301A

(Street)

SULLIVAN, IL 61951

(City) (State) (Zip)

2. Issuer Name **and** Ticker or Trading Symbol
FIRST MID ILLINOIS BANCSHARES INC [FMBH]

3. Date of Earliest Transaction (Month/Day/Year)
12/16/2008

4. If Amendment, Date Original Filed(Month/Day/Year)

5. Relationship of Reporting Person(s) to Issuer
(Check all applicable)
_____ Director _____ 10% Owner
__X__ Officer (give title below) _____ Other (specify below)
EVP-Wealth Management

6. Individual or Joint/Group Filing(Check Applicable Line)
_X_ Form filed by One Reporting Person
___ Form filed by More than One Reporting Person

Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

1.Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)		4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)			5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Indirect Beneficial Ownership (Instr. 4)
			Code	V	Amount	(A) or (D)	Price			

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

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SEC 1474 (9-02)

Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned
(*e.g.*, puts, calls, warrants, options, convertible securities)

1. Title of Derivative Security	2. Conversion or Exercise	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any	4. Transaction Code	5. Number of Derivative Securities	6. Date Exercisable and Expiration Date (Month/Day/Year)	7. Title and Amount of Underlying Securities (Instr. 3 and 4)

(Instr. 3)	Price of Derivative Security	(Month/Day/Year)	(Instr. 8)	Acquired (A) or Disposed of (D) (Instr. 3, 4, and 5)							
			Code	V	(A)	(D)	Date Exercisable	Expiration Date	Title	Amount or Number of Shares
Stock Option	$ 23	12/16/2008		A	2,500		01/01/2010(1)	12/16/2018	Common Stock	2,500

Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
LeFebvre Charles Allen RR 1, BOX 301A SULLIVAN, IL 61951			EVP-Wealth Management	

Signatures

Michael L. Taylor, pursuant to a power of attorney filed 05/07/07.	12/17/2008
**Signature of Reporting Person	Date

Explanation of Responses:

***** If the form is filed by more than one reporting person, *see* Instruction 4(b)(v).

****** Intentional misstatements or omissions of facts constitute Federal Criminal Violations. *See* 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

(1) Options become exercisable in 4 equal annual installments beginning on this date.

(2) N/A

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *see* Instruction 6 for procedure.
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loss or retirement of key executives and research scientists and other specific risks; and

- the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives.

You should review carefully the section entitled “Risk Factors” beginning on page 5 of this prospectus for a discussion of these and other risks that relate to our business and investing in shares of our common stock.

Use Of Proceeds

All shares of our common stock offered by this prospectus are being registered for the accounts of the selling stockholders and we will not receive any proceeds from the sale of these shares.

The shares of common stock offered by this prospectus are issuable upon the exercise of common stock purchase warrants. As such, if a selling stockholder exercises all or any portion of its warrants on a cash basis, we will receive the aggregate exercise price paid by such selling stockholder in connection with any such warrant exercise. The maximum amount of proceeds we would receive upon the exercise of all the warrants on a cash basis would be approximately $747,000.00. However, the selling stockholders may also exercise their warrants through a cashless exercise. In the event a selling stockholder exercises a warrant through a cashless exercise, we will not receive any proceeds from such exercise. We expect to use the proceeds received from the exercise of the warrants, if any, for general working capital purposes.

Market For Our Common Stock And Related Stockholder Matters

Our common stock has been quoted on the OTC Bulletin Board since April 11, 2011 under the symbol NSPR.OB. Prior to that date, there was no active market for our common stock. The following table sets forth the high and low bid prices for our common stock for the periods indicated, as reported by the OTC Bulletin Board. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

Fiscal Year 2011	High	Low
Second Quarter	$2.89	$1.75
Third Quarter	$2.74	$1.80
Fourth Quarter	$2.59	$1.60

Fiscal Year 2012	High	Low
First Quarter	$2.15	$1.10
Second Quarter (through April 24, 2012)	$1.85	$0.87

The last reported sales price of our common stock on the OTC Bulletin Board on April 24, 2012, was $1.02 per share. As of April 25, 2012, there were approximately 233 holders of record of our common stock.

Dividend Policy

In the past, we have not declared or paid cash dividends on our common stock, and we do not intend to pay any cash dividends on our common stock. Rather, we intend to retain future earnings, if any, to fund the operation and expansion of our business and for general corporate purposes.

Selected Financial Data

The following selected consolidated financial data should be read in conjunction with the Consolidated Financial Statements and the Notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Registration Statement on Form S-1. The balance sheet data at December 31, 2011, 2010 and 2009 and the statement of operations data for each of the two years ended December 31, 2011, 2010 and 2009 have been derived from the audited Consolidated Financial Statements for such years, included elsewhere in this Registration Statement on Form S-1. The balance sheet data at December 31, 2008, 2007 and 2006, and the statement of operations data for each of the three years ended December 31, 2008, 2007 and 2006 have been derived from our books and records.

	Statement of Operations Data				
	2011	2010	2009	2008	2007
Revenues	6,004	4,949	3,411	-	-
Cost of Revenues	3,011	2,696	2,291	404	328
Gross Profit (Loss)	2,993	2,253	1,120	(404)	(328)
Gross Margin	50%	46%	33%	0	0
Total Operating Expenses	16,722	5,472	3,837	5,627	5,903
Net Loss	(14,665)	(3,420)	(2,724)	(6,495)	(6,138)
Basic and Diluted loss per common share	(0.24)	(0.07)	(0.06)	(0.14)	(0.14)
Basic and Diluted common shares outstanding	61,439,700	49,234,528	47,658,853	46,364,731	42,647,151

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	Balance Sheet Data				
	2011	2010	2009	2008	2007
Cash, Cash equivalents and short term deposits	5,094	636	376	1,571	2,717
Restricted Cash	91	250	302	30	34
Working Capital	6,389	(53)	(1,289)	589	2,625
Total Assets	10,465	4,355	4,509	4,448	3,923
Shareholder's Equity	6,754	(914)	(1,339)	134	2,949

Selected Quarterly Financial Data

The following selected quarterly consolidated financial data should be read in conjunction with the Consolidated Financial Statements and the Notes thereto and Management’s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Registration Statement on Form S-1. The following table sets forth selected financial information for the dates and periods indicated. Our results for any of these periods are not necessarily indicative of the results to be expected for the year ending December 31, 2012 or for any other future period. Dollar amounts are in thousands, except per share amounts.

		Fiscal Year Ended December 31, 2011			
		First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenues	$	1,686$	1,040$	1,986$	1,292
Cost of Revenues	$	899$	640$	801$	671
Gross Profit (Loss)	$	787$	400$	1,185$	621
Gross Margin		47%	38%	60%	48%
Total Operating Expenses	$	1,957$	2,572$	3,335$	8,858
Net Loss	$	(1,895)$	(2,254)$	(2,283)$	(8,233)
Basic and Diluted loss per common share	$	(0.037)$	(0.04)$	(0.04)$	(0.12)
Basic and Diluted common shares outstanding		50,798,900	63,934,260	64,300,685	66,697,424

		Fiscal Year Ended December 31, 2010			
		First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenues	$	2,097$	908$	1,223$	721
Cost of Revenues	$	1,337$	479$	561$	319
Gross Profit (Loss)	$	760$	429$	662$	402
Gross Margin		36%	47%	54%	56%
Total Operating Expenses	$	1,404$	1,118$	1,379$	1,571
Net Loss	$	(729)$	(663)$	(847)$	(1,181)
Basic and Diluted loss per common share	$	(0.015)$	(0.01)$	(0.02)$	(0.02)
Basic and Diluted common shares outstanding		48,595,241	49,113,463	49,490,460	49,680,214

Management’s Discussion And Analysis Of
Financial Condition And Results Of Operation

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 registration statement on Form S-1.

Overview

We are a medical device company focusing on the development and commercialization of our proprietary stent platform technology, MGuard™. MGuard™ provides embolic protection in stenting procedures by placing a micron mesh sleeve over a stent. Our initial products are marketed for use mainly in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

On March 31, 2011, we completed a series of share exchange transactions pursuant to which we acquired all of the capital stock of InspireMD Ltd., a company formed under the laws of the State of Israel, in exchange for an aggregate of 50,666,663 shares of our common stock. As a result of these share exchange transactions, InspireMD Ltd. became our wholly-owned subsidiary, we discontinued our former business and succeeded to the business of InspireMD Ltd. as our sole line of business.

The share exchange transactions are being accounted for as a recapitalization. InspireMD Ltd. is the acquirer for accounting purposes and we are the acquired company. Accordingly, the historical financial statements presented and the discussion of financial condition and results of operations herein are those of InspireMD Ltd., retroactively restated for, and giving effect to, the number of shares received in the share exchange transactions, and do not include the historical financial results of our former business. The accumulated earnings of InspireMD Ltd. were also carried forward after the share exchange transactions and earnings per share have been retroactively restated to give effect to the recapitalization for all periods presented. Operations reported for periods prior to the share exchange transactions are those of InspireMD Ltd.

Recent Events

On April 5, 2012, we issued senior secured convertible debentures due April 5, 2014 in the original aggregate principal amount of $11,702,128 and five-year warrants to purchase an aggregate of 3,343,465 shares of our common stock at an exercise price of $1.80 per share in exchange for aggregate gross proceeds of $11,000,000. The convertible debentures were issued with a 6% original issuance discount, bear interest at an annual rate of 8% and are convertible at any time into shares of common stock at an initial conversion price of $1.75 per share. In converting the convertible debentures, investors shall receive a conversion premium equal to 8%, per annum, of the principal amount being converted. In addition, the investors may require us to redeem the convertible debentures after 18 months for 112% of the then outstanding principal amount, plus all accrued interest, and we may prepay the convertible debentures after six months for 112% of the then outstanding principal amount, plus all accrued interest. In connection with this financing, we paid placement agent fees of $848,750 and issued placement agents warrants to purchase 312,310 shares of common stock, with terms identical to the warrants issued to the investors.

On October 31, 2011, our stockholders authorized our board of directors to amend our amended and restated certificate of incorporation to effect a reverse stock split of our common stock at a ratio of one-for-two to one-for-four, at any time prior to our 2012 annual stockholders' meeting, the exact ratio of the reverse stock split to be determined by the board. As of the date of this prospectus, we have not effected the reverse stock split and, as such, the information with respect to our common stock in this prospectus and the accompanying financial statements and related notes does not give effect to any reverse stock split. In addition, pursuant to the securities purchase agreement under which the convertible debentures that we issued on April 5, 2012 were sold, until April 5, 2013, we are not premitted to effectuate any reverse stock splits without the prior written consent of the holders of at least 60% of the outstanding principal amount of the convertible debentures other than for purposes of qualifying for initial listing on a national securities exchange or meeting the continued listing requirements of such exchange.

On October 4, 2011, InspireMD Ltd., our wholly-owned subsidiary, entered into a clinical trial services agreement with Harvard Clinical Research Institute, Inc., pursuant to which Harvard Clinical Research Institute, Inc. will conduct a study entitled "MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction" on our behalf. We will pay Harvard Clinical Research Institute, Inc. an estimated fee of approximately $10 million for conducting the study, subject to adjustment dependent upon changes in the scope and nature of the study, as well as other costs to be determined by the parties.

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Explanation of Responses:

Critical Accounting Policies

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates using assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting periods. Actual results could differ from those estimates.

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to revenue recognition including provision for returns, legal contingencies and estimation of the fair value of share-based compensation and convertible debt.

Functional currency

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

The dollar figures are determined as follows: transactions and balances originally denominated in dollars are presented in their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. The resulting translation gains or losses are recorded as financial income or expense, as appropriate. For transactions reflected in the statements of operations in foreign currencies, the exchange rates at transaction dates are used. Depreciation and changes in inventories and other changes deriving from non-monetary items are based on historical exchange rates.

Fair value measurement

Fair value is defined as 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.

In determining fair value, we use various valuation approaches, including market, income and/or cost approaches. Hierarchy for inputs is used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. The hierarchy is broken down into three levels based on the reliability of inputs.

Concentration of credit risk and allowance for doubtful accounts

Financial instruments that may potentially subject us to a concentration of credit risk consist of cash, cash equivalents and restricted cash, which are deposited in major financial institutions in the U.S., Israel and Germany, and trade accounts receivable. Our trade accounts receivable are derived from revenues earned from customers from various countries. We perform ongoing credit evaluations of our customers' financial condition and, generally, require no collateral from our customers. We also have a credit insurance policy for some of our customers. We maintain an allowance for doubtful accounts receivable based upon the expected ability to collect the accounts receivable. We review our allowance for doubtful accounts quarterly by assessing individual accounts receivable and all other

balances based on historical collection experience and an economic risk assessment. If we determine that a specific customer is unable to meet its financial obligations to us, we provide an allowance for credit losses to reduce the receivable to the amount our management reasonably believes will be collected. To mitigate risks, we deposit cash and cash equivalents with high credit quality financial institutions. Provisions for doubtful debts are netted against "Accounts receivable-trade."

Inventory

Inventories include finished goods, work in process and raw materials. Inventories are stated at the lower of cost (cost is determined on a “first-in, first-out” basis) or market value. Our inventories generally have a limited shelf life and are subject to impairment as they approach their expiration dates. We regularly evaluate the carrying value of our inventories and when, in our opinion, factors indicate that impairment has occurred, we establish a reserve against the inventories’ carrying value. Our determination that a valuation reserve might be required, in addition to the quantification of such reserve, requires us to utilize significant judgment. Although we make every effort to ensure the accuracy of forecasts of future product demand, any significant unanticipated decreases in demand could have a material impact on the carrying value of our inventories and reported operating results. To date, inventory adjustments have not been material. With respect to inventory on consignment, see “Revenue recognition” below.

Revenue recognition

Revenue is recognized when delivery has occurred, evidence of an arrangement exists, title and risks and rewards for the products are transferred to the customer, collection is reasonably assured and when product returns can be reliably estimated. When product returns can be reliably estimated a provision is recorded, based on historical experience, and deducted from revenues. The provision for sales returns and related costs are included in “Accounts payable and accruals - Other” under “current liabilities” and “Inventory on consignment,” respectively.

When returns cannot be reliably estimated, both related revenues and costs are deferred, and presented under "Deferred revenues" and "Inventory on consignment," respectively.

As of December 31, 2011, there was no deferred revenue in the balance sheet since, as of such date, the rate of returns could be reliably estimated.

Our revenue arrangements may contain delivery of free products upon the achievement of sales targets. Each period, we estimate the amount of free products to which these distributors will be entitled based upon the expected achievement of sales targets and defer a portion of revenues accordingly.

We recognize revenue net of value added tax.

Research and development costs

Research and development costs are charged to the statement of operations as incurred.

Share-based compensation

Employee option awards are classified as equity awards and accounted for using the grant-date fair value method. The fair value of share-based awards is estimated using the Black-Scholes valuation model, which is expensed over the requisite service period, net of estimated forfeitures. We estimate forfeitures based on historical experience and anticipated future conditions.

We elected to recognize compensation expenses for awards with only service conditions that have graded vesting schedules using the accelerated multiple option approach.

We account for equity instruments issued to third party service providers (non-employees) by recording the fair value of the options granted using an option pricing model, at each reporting period, until rewards are vested in full. The

expense is recognized over the vesting period using the accelerated multiple option approach. The expense relates to options granted to third party service providers with respect to successful investor introductions that are recorded at their fair value in equity, as issuance costs.

In addition, certain of our share-based awards are performance based, i.e., the vesting of these awards depends upon achieving certain goals. We estimate the expected pre-vesting award probability, i.e., the expected likelihood that the performance conditions will be achieved, and only recognize expense for those shares expected to vest.

Uncertain tax and value added tax positions

We follow a two-step approach to recognizing and measuring uncertain tax and value added tax positions. The first step is to evaluate the tax and value added tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit. The second step is to measure the tax and value added tax benefit as the largest amount that is more than 50% and 75%, respectively, likely of being realized upon ultimate settlement. Such liabilities are classified as long-term, unless the liability is expected to be resolved within twelve months from the balance sheet date. Our policy is to include interest and penalties related to unrecognized tax benefits within financial expenses.

Results of Operations

Twelve months ended December 31, 2011 compared to twelve months ended December 31, 2010

Revenues. For the twelve months ended December 31, 2011, total revenue increased approximately $1.1 million, or 21.3%, to approximately $6.0 million from approximately $4.9 million during the same period in 2010. The $1.1 million increase was attributable primarily to an increase in volume, as described more fully below. The following is an explanation of the approximately $1.1 million increase in revenue broken down by its main two components, an increase in gross revenues of approximately $2.5 million offset by a net decrease in deferred revenues of approximately $1.4 million.

For the twelve months ended December 31, 2011, total gross revenue increased by approximately $2.5 million, or 77.6%, to approximately $5.7 million from approximately $3.2 million during the same period in 2010. This increase in total gross revenue was predominantly volume based, with increased volume accounting for approximately $2.3 million, or approximately 72.5%, and price increases accounting for the remaining approximately $0.2 million, or approximately 5.1%. In general, we focused on opening new markets, such as India, and also increasing sales in existing markets by presenting clinical data at conferences and individual presentations to doctors about the merits of MGuardTM. With respect to individual markets, this increase in gross revenue was mainly attributable to the first time shipment of approximately $1.2 million to our distributor in India during the twelve months ended December 31, 2011, an increase of approximately $0.4 million of gross revenue from our new distributor in Russia, an increase of approximately $0.4 million of gross revenue from our distributor in Israel, an increase of approximately $0.3 million of gross revenue from our distributor in Brazil, an increase of approximately $0.2 million of gross revenue from our distributor in Spain, an increase of approximately $0.2 million of gross revenue from our distributor in Argentina, an increase of approximately $0.1 million of gross revenue from our distributor in South Africa, an increase of approximately $0.1 million of gross revenue from our new distributor for sales in Ukraine, an increase of approximately $0.1 million of gross revenue from our new distributor in the Netherlands and an increase of approximately $0.1 million of gross revenue from our distributor in Mexico. This increase was partially offset by a decrease of approximately $0.2 million in gross revenue from our distributor in Germany, a decrease of approximately $0.2 million in gross revenue from our distributor in Pakistan, a decrease of approximately $0.2 million from our distributor in Poland, a decrease of approximately $0.1 million in gross revenue from our distributor in Italy, and a decrease of approximately $0.1 million in gross revenue to our distributor in France, all due to lower sales volume to these suppliers. We also shipped and recognized gross revenue for approximately $0.2 million more from our remaining distributors during the twelve months ended December 31, 2011, as compared to the same period in 2010.

For the twelve months ended December 31, 2011, net deferred revenue recognized decreased by approximately $1.4 million, or 83.8%, to approximately $0.3 million from approximately $1.7 million during the same period in 2010. The key driver of this decrease was a decrease in the volume of revenue deferred to 2011 compared to the volume of revenue deferred to 2010, accounting for approximately $1.3 million, or approximately 74.5%, with the remaining approximately $0.1 million, or 9.3%, being driven by price decreases in the revenue deferred to 2011 compared to the

revenue deferred to 2010. Revenue recognition out of deferred income had less of an impact in 2011 as compared to 2010 due to the fact that we deferred mainly shipments in 2008 and 2009 that were recognized in 2010. In 2010, only a small set of customers had a large portion of their revenues deferred until 2011.

For the twelve months ended December 31, 2011, our net deferred revenue recognized consisted of approximately $0.2 million attributable to our distributor in Israel, approximately $0.1 million to our distributor in Brazil, and approximately $0.1 million to our distributor in Poland, offset by approximately $0.1 million deferred for a shipment to our distributor in India. Our distributor in Israel had a contractual right to return all purchases to us within 18 months of the purchase date. Due to our inability to accurately estimate the amount of future returns, all sales to this distributor were deferred until this 18 month return period elapsed. On May 9, 2011, our distributor in Israel agreed to revoke its previous rights to return purchases, resulting in all future sales being final. The deferred revenue of approximately $0.2 million recognized during the twelve months period ended December 31, 2011 accounted for all previous purchases by the distributor that the distributor no longer had a contractual right to return and were not yet recognized as revenues. Our distributor in Brazil has a contractual right to return all purchases for up to six months from the delivery date. Due to our inability to accurately estimate the amount of future returns by our distributor in Brazil, all sales made to it were also deferred until the six month return period elapsed. The deferred revenue of approximately $0.1 million recognized during the twelve months period ended December 31, 2011 accounted for purchases made in December 2010 that were not returned by the Brazilian distributor and were not yet recognized as revenues. In 2011, it was decided that due to lack of actual returns from the Brazilian distributor, despite the clause in their contract, we will no longer defer revenue pertaining to current shipments. Our distributor in India made their first purchase in 2011. Because of our inexperience with this distributor, management decided to defer a portion of the shipment until 2012, when it could better determine if a portion of it would be returned.

For the twelve months ended December 31, 2010, net deferred revenue recognized of approximately $1.7 million was comprised mainly of shipments from 2008 and 2009 to our distributor in Poland of approximately $1.3 million, to our distributor in Brazil of approximately $0.4 million. For the twelve months ended December 31, 2010, our distributor in Poland, subject to our sole discretion, had the right to return our products. Because we were unable to develop estimates for the level of returns, the $1.3 million worth of shipments made to the distributor in Poland that we recorded as deferred revenues was only recognized during the twelve months ended December 31, 2010 as revenues. As noted above, our distributor in Brazil has a contractual right to return all purchases for up to six months from the delivery date. As also noted above, due to our inability to accurately estimate the rate of return by this distributor, all sales made to it were also deferred until the six month return period elapsed. The deferred revenue of approximately $0.4 million recognized during the twelve months period ended December 31, 2010 accounted for purchases made in December 2009 that were not returned and were not yet recognized as revenues.

Gross Profit. For the twelve months ended December 31, 2011, gross profit (revenue less cost of revenues) increased 32.8%, or approximately $0.7 million, to approximately $3.0 million from approximately $2.3 million during the same period in 2010. Gross margin increased from 45.5% in the twelve months ended December 31, 2010 to 49.9% in the twelve months ended December 31, 2011. In addition to an increase in sales, we were able to improve our gross profit because of reduced production cost per stent driven by a reduction in price per unit from our subcontractor and economies of scale. For the twelve months ended December 31, 2011, our average selling price per stent recognized in revenue was $571, and we recognized the sale of 10,523 stents, compared to an average price of $606 per stent and 8,171 stents recognized in revenue for the same period in 2010. Our cost of goods sold per stent decreased from an average of $330 per stent recognized in revenue for the twelve months ended December 31, 2010 to an average of $286 per stent for the same period in 2011. The higher price per stent for the twelve months ended December 31, 2010 was affected by the price of stents sold in 2008 and 2009 to one of our European distributors in Euros when the Euro was much stronger than the U.S. dollar, at an average price of $997 when translated to U.S. dollars.

Research and Development Expense. For the twelve months ended December 31, 2011, research and development expense increased 84.9%, or approximately $1.2 million, to approximately $2.5 million from approximately $1.3 million during the same period in 2010. The increase in cost resulted primarily from higher clinical trial expenses of approximately $1.2 million, attributable mainly to the U.S. Food and Drug Administration clinical trial (approximately $0.9 million) and the MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial)

(approximately $0.3 million), and an increase of approximately $0.3 million in salaries, offset by approximately $0.2 million reduction in miscellaneous expenses and approximately $0.1 million reduction in share based compensation. Research and development expense as a percentage of revenue increased to 41.2% in 2011 from 27.0% in 2010.

Selling and Marketing Expense. For the twelve months ended December 31, 2011, selling and marketing expense increased 59.6%, or approximately $0.7 million, to approximately $2.0 million from approximately $1.3 million during the same period in 2010. The increase in selling and marketing expense resulted primarily from approximately $0.3 million of additional salaries and approximately $0.4 million of share based compensation of predominately newly hired sales personnel as we expanded our sales activities worldwide, and approximately $0.1 million of commissions pertaining mainly to our first time shipment of approximately $1.2 million to our distributor in India. This increase was partially offset by a decrease of approximately $0.1 million in advertising expenses. Selling and marketing expense as a percentage of revenue increased to 32.9% in 2011 from 25.0% in 2010.

General and Administrative Expense. For the twelve months ended December 31, 2011, general and administrative expense increased 323.6%, or approximately $9.4 million, to approximately $12.3 million from $2.9 million during the same period in 2010. The increase resulted primarily from an increase in share based compensation of $7.5 million (which predominately pertains to directors' compensation), an increase of approximately $0.5 million in salary expenses (due to an increase in employee infrastructure to accommodate and comply with Securities and Exchange Commission standards and reporting), an increase in investor related activities of approximately $0.5 million (due to us having been a publicly reporting company during the twelve months ended December 31, 2011, but not during the same period in 2010), an increase of approximately $0.5 million in litigation expenses (primarily due to a provision for our potential loss related to a threatened lawsuit from a finder claiming a future success fee and commissions for assistance in finding our distributor in Brazil), approximately $0.3 million in legal fees (also related primarily to compliance with Securities and Exchange Commission standards), and approximately $0.2 million in audit fees to accommodate and comply with Securities and Exchange Commission standards and reporting. This increase was partially offset by a decrease of approximately $0.1 million in miscellaneous expenses. General and administrative expense as a percentage of revenue increased to 204.4% in 2011 from 58.6% in 2010.

Financial Expenses. For the twelve months ended December 31, 2011, financial expense increased 506.5%, or approximately $0.8 million, to approximately $1.0 million from $0.2 million during the same period in 2010. The increase in expense resulted primarily from a one-time financial expense recording of approximately $0.6 million in the first quarter of 2011 pertaining to the revaluation of an outstanding convertible loan at fair value prior to redemption and approximately $0.2 million for the favorable impact of exchange rate differences for the twelve months ended December 31, 2010 that did not occur during the twelve months ended December 31, 2011. Financial expense as a percentage of revenue increased from 3.1% in 2010 to 15.6% in 2011.

Tax Expenses. Tax expense remained relatively flat at $2,000 for the twelve months ended December 31, 2011, as compared to $47,000 during the same period in 2010. Our expenses for income taxes reflect primarily the tax liability due to potential tax exposure.

Net Loss. Our net loss increased by approximately $11.3 million, or 328.8%, to $14.7 million for the twelve months ended December 31, 2011 from $3.4 million during the same period in 2010. The increase in net loss resulted primarily from an increase in operating expenses of approximately $11.2 million (see above for explanation) and an increase of approximately $0.8 million in financial expenses (see above for explanation). This increase was partially offset by an increase in gross profit of approximately $0.7 million (see above for explanation).

Twelve months ended December 31, 2010 compared to twelve months ended December 31, 2009

Revenues. For the twelve months ended December 31, 2010, total revenue increased approximately $1.5 million, or 45.1%, to approximately $4.9 million from approximately $3.4 million in 2009. The $1.5 million increase in revenue was primarily attributable to an increase in the amount of net deferred revenues recognized during 2010.

For a description of the revenue deferred to 2010, see "Twelve months ended December 31, 2011 compared to twelve months ended December 31, 2010" above.

For the twelve months ended December 31, 2009, net deferred revenue of approximately $0.1 million was comprised mainly of shipments made in 2009 but deferred and recognized in 2010 to our distributor in Brazil in the amount of approximately $0.4 million, to our distributor in Poland in the amount of $0.2 million and to our distributor in Israel in the amount of $0.2 million, offset by shipments made in 2008 but deferred and recognized in revenue in 2009 from our distributor in Italy in the amount of $0.5 million, and from our distributor in Cyprus in the amount of $0.2 million. See "Twelve months ended December 31, 2011 compared to twelve months ended December 31, 2010" above for the reasons why such revenue was deferred and/or recognized for each of the distributors listed above.

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Total gross revenue for the twelve months ended December 31, 2010 remained relatively flat in comparison to the twelve months ended December 31, 2009, increasing by approximately $46,000. This increase was predominantly volume based, with increased volume accounting for approximately $263,000, offset by price decreases in the amount of $217,000. The increase in volume was evenly distributed among our distributors. The decrease in prices were due to our penetration of newly opened markets, namely Brazil, Slovakia and Cypress, in 2010, which required reduced prices as compared to 2009.

Gross Profit. For the twelve months ended December 31, 2010, gross profit (revenue less cost of revenues) increased 101.2%, or approximately $1.1 million, to approximately $2.2 million from approximately $1.1 million during the same period in 2010. Our gross margin percentage for the twelve months ended December 31, 2010 increased to 45.5% of revenues, compared to 32.8% during the same period in 2009. In addition to an increase in sales, we were able to improve our gross profit because of reduced production cost per stent driven by reduction in price per unit from our subcontractor and economies of scale. For the twelve months ended December 31, 2010, our average selling price per stent recognized in revenue was $606, and we recognized the sale of 8,171 stents, compared to an average price of $577 per stent and 5,910 stents recognized in revenue for the same period in 2009. Our cost of goods sold per stent decreased from an average of $380 per stent recognized in revenue for the twelve months ended December 31, 2009 to an average of $330 per stent for the same period in 2010. The higher price per stent for the twelve months ended December 31, 2010 was affected by the price of stents sold in 2008 and 2009 to one of our Europeans distributors in Euros when the Euro was much stronger than the U.S. dollar, at an average price of $997 when translated to U.S. dollars.

Research and Development Expense. For the twelve months ended December 31, 2010, research and development expense remained relatively flat at approximately $1.3 million as compared to the same period in 2009. Research and development expense as a percentage of revenue decreased to 27.0% in 2010 from 39.0% in 2009.

Selling and Marketing Expense. For the twelve months ended December 31, 2010, selling and marketing expense increased approximately $0.2 million, or 18.8%, to approximately $1.2 million from approximately $1.0 million during the same period in 2009. The increase in cost resulted primarily from an increase of approximately $0.2 million in advertising expenses. Selling and marketing expense as a percentage of revenue decreased to 25.0% in 2010 from 30.5% in 2009.

General and Administrative Expense. For the twelve months ended December 31, 2010, general and administrative expense increased approximately $1.4 million, or 97.5% to approximately $2.9 million from approximately $1.5 million during the same period in 2009. The increase resulted primarily from an increase in share based compensation of approximately $0.7 million (of which approximately $0.5 million related to employees and $0.2 million related to directors), an increase of approximately $0.2 million in audit fees (as we prepared for the transition from Israel GAAP to U.S. GAAP), an increase of $0.1 million in salary expenses, and an increase of approximately $0.4 million in other expenses (due to our overall expansion). General and administrative expense as a percentage of revenue increased to 58.6% in 2010 from 43.0% in 2009.

Financial Expenses (Income). For the twelve months ended December 31, 2010, financial expense increased to approximately $0.2 million from income of $4,000 for the same period in 2009. The increase in expense resulted primarily from a one time financial income recording of $0.3 million in 2009 pertaining to the cancellation of the conversion feature of a convertible loan that was repaid in the same year. Financial expense as a percentage of revenue increased to 3.1% in 2010, compared to financial income as a percent of revenue of 1.2% in 2009.

Tax Expenses. Tax expense remained flat at $47,000 for the twelve months ended December 31, 2010 and 2009. Our expenses for income taxes reflect primarily the tax liability due to potential tax exposure.

Net Loss. Our net loss increased by approximately $0.7 million, or 25.6%, to approximately $3.4 million in 2010 from approximately $2.7 million during the same period in 2009. The increase in net loss resulted primarily from an increase in operating expenses of approximately $1.6 million (see above for explanation) and an increase of approximately $0.2 million in financial expenses (see above for explanation). This increase was partially offset by an increase in gross profit of approximately $1.1 million (see above for explanation).

Liquidity and Capital Resources

Twelve months ended December 31, 2011 compared to twelve months ended December 31, 2010

General. At December 31, 2011, we had cash and cash equivalents of approximately $5.1 million, as compared to $0.6 million at December 31, 2010. The increase is attributable primarily to the private placement conducted in conjunction with the share exchange transactions on March 31, 2011 and other private equity issuances prior to and after the share exchange transactions. We have historically met our cash needs through a combination of issuance of new shares, borrowing activities and sales. Our cash requirements are generally for product development, clinical trials, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was approximately $6.0 million for the twelve months ended December 31, 2011, and approximately $2.7 million for the same period in 2010. The principal reasons for the usage of cash in our operating activities for the twelve months ended December 31, 2011 included a net loss of approximately $14.7 million and a decrease in working capital of approximately $2.0 million, offset by approximately $9.6 million in non-cash share based compensation, an approximately $0.9 million in non-cash financial expenses related to the revaluation of a convertible loan and approximately $0.2 million of all other.

Cash provided by our investing activities was approximately $13,000 during the twelve months ended December 31, 2011, compared to approximately $46,000 of cash used by investing activities during the same period in 2010. The principal reason for the decrease in cash flow from investing activities during 2011 was a decrease in restricted cash of approximately $160,000 offset by the purchase of approximately $140,000 of new manufacturing equipment.

Cash flow generated from financing activities was approximately $10.7 million for the twelve months ended December 31, 2011, and $3.0 million for the same period in 2010. The principal reason for the increase in cash flow from financing activities during 2011 was the private placement conducted in conjunction with the share exchange transactions on March 31, 2011 and other private equity issuances and exercise of options prior to and after the share exchange transactions in the aggregate amount of approximately $12.1 million, offset by the repayment of the non-converted portion of a convertible loan in the amount of approximately $1.0 million and the partial repayment of a long-term loan in the amount of approximately $0.4 million.

As of December 31, 2011, our current assets exceeded current liabilities by a multiple of 2.8. Current assets increased approximately $5.9 million during 2011, mainly due to cash raised from the private placements in 2011, while current liabilities decreased approximately $0.5 million during the same period. As a result, our working capital surplus increased by approximately $6.4 million to approximately $6.3 million during the twelve months ended December 31, 2011.

Credit Facilities. As of December 31, 2011, we had a long term loan in the amount of approximately $0.1 million bearing interest at the three month U.S. Dollar LIBOR rate plus 4% per annum. The loan is payable in eight quarterly installments during a period of three years that began in April 2010 and ends in January 2012. According to the loan agreement, in case of an “exit transaction,” we will be required to pay to the bank an additional $0.25 million if the sum received in a “liquidity event” or the value of the company in an “IPO” is higher than $100 million.

Convertible Loans. Prior to December 31, 2011, we had a convertible loan with an aggregate principal amount outstanding of approximately $1.58 million that bore 8% interest. Following the share exchange transactions on March 31, 2011, $580,000 plus accrued interest converted into shares of our common stock. The remaining principle in the amount of $1.0 million was repaid on May 15, 2011.

Sales of Stock. For the twelve months ended December 31, 2011, we issued an aggregate of 12,315,145 shares of common stock and warrants to purchase 6,709,073 shares of common stock for gross proceeds of approximately $13.7 million and corresponding net proceeds of approximately $12.1 million.

Twelve months ended December 31, 2010 compared to twelve months ended December 31, 2009

General. At December 31, 2010, we had cash and cash equivalents of approximately $0.6 million, as compared to $0.4 million at December 31, 2009.

Cash used in our operating activities was approximately $2.7 million for the twelve months ended December 31, 2010, and approximately $1.5 million for the same period in 2009. The principal reasons for the increase in cash used in operations in 2010 included a net loss of approximately $3.4 million, a decrease of approximately $1.6 million in deferred revenues offset by approximately $1.6 million of non cash share based compensation expense, an increase of approximately $0.4 million in other working capital and $0.3 million of other non cash adjustments.

Cash used in investing activities was approximately $46 thousand for the twelve months ended December 31 2010 and approximately $0.3 million for the same period in 2009. The principal reasons for the decrease in cash flow from investing activities included approximately $81 thousand for plant and equipment purchases offset by a decrease of approximately $52 thousand in restricted cash.

Cash flow generated from financing activities was approximately $3.0 million for the twelve months ended December 31, 2010, and approximately $0.7 million for the same period in 2009. The principal reasons for the increase in cash flow from financing activities during 2010 were the issuance of approximately $1.8 million in new shares and the issuance of a convertible loan of approximately $1.5 million, offset by the repayment of a long term loan in the amount of approximately $0.3 million.

As of December 31, 2010, current assets were approximately equal with our current liabilities. Current assets decreased approximately $0.2 million during the twelve months ended December 31, 2010 while current liabilities decreased by approximately $1.5 million during the same period. As a result, our working capital deficiency decreased by approximately $1.2 million to approximately $53,000 during the twelve months ended December 31, 2010.

We believe that funds available at April 25, 2012, together with our anticipated revenues, are expected to fund our operations until at least the first quarter of 2013, assuming our MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial) is successful and we, accordingly, invest significantly in sales and marketing. However, if our MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial) is not as successful as anticipated and we scale back expansion plans and general overhead, funds available at April 25, 2012, together with our anticipated revenues, are expected to fund our operations through the end of 2013. Thereafter, or before then to expand the breadth of our present business, we will need to raise further capital, through the sale of additional equity securities or otherwise. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our MGuardTM 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 our product offerings. However, we may be unable to raise sufficient additional capital when we need it or raise capital on favorable terms. The terms of any securities issued by us 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 our securities then outstanding. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly, possibly postpone or halt our U.S. Food and Drug Administration clinical trial or obtain funds by entering into financing agreements on unattractive terms.

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 October 2009, the Financial Accounting Standards Board issued amendments to the accounting and disclosure for revenue recognition. These amendments, effective for fiscal years beginning on or after June 15, 2010 (early adoption is permitted), modify the criteria for recognizing revenue in multiple element arrangements and require companies to develop a best estimate of the selling price to separate deliverables and allocate arrangement consideration using the relative selling price method. Additionally, the amendments eliminate the residual method for allocating arrangement considerations. We do not expect the standard to have material effect on its consolidated financial statements.

In January 2010, the Financial Accounting Standards Board updated the “Fair Value Measurements Disclosures”. More specifically, this update will require (a) an entity to disclose separately the amounts of significant transfers in and out of Levels 1 and 2 fair value measurements and to describe the reasons for the transfers; and (b) information about purchases, sales, issuances and settlements to be presented separately (i.e. present the activity on a gross basis rather than net) in the reconciliation for fair value measurements using significant unobservable inputs (Level 3 inputs). This update clarifies existing disclosure requirements for the level of disaggregation used for classes of assets and liabilities measured at fair value, and requires disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements using Level 2 and Level 3 inputs. This update will become effective as of the first interim or annual reporting period beginning after December 15, 2009, except for the gross presentation of the Level 3 roll forward information, which is required for annual reporting periods beginning after December 15, 2010 and for interim reporting periods within those years. The adoption of the new guidance did not have a material impact on our consolidated financial statements.

In May 2011, the Financial Accounting Standards Board issued amended guidance and disclosure requirements for fair value measurements. These changes will be effective January 1, 2012 on a prospective basis. Early application is not permitted. These amendments are not expected to have a material impact to the consolidated financial results.

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the New Israeli Shekel, or NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products.

Tabular Disclosure of Contractual Obligations

The following table summarizes our outstanding contractual obligations as of December 31, 2011:

	Payments due by period (amounts in thousands)				
Contractual Obligations	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Long-term loan (1)	$ 94	$ 94	$ 0	$ 0	$ 0
Operating lease obligations (2)	858	304	554	0	0
Accounts Payable	1,670	1,670	0	0	0
Total	$ 2,622	$ 2,068	$ 554	$ 0	$ 0

(1) Our long-term loan obligations as of December 31, 2011 consisted of a loan with Mizrahi Tefahot Bank. According to our agreement with Mizrahi Tefahot Bank, we received a loan amounting to $750,000, bearing annual interest (quarterly paid) equal to LIBOR + 4%. The loan is payable in eight quarterly installments during a period of 3 years beginning April 2010. As of December 31, 2011, the remaining balance outstanding of this loan was $94,000.

(2) Our operating lease obligations consist of the lease for our offices and manufacturing facilities in Tel Aviv, Israel and the leases for the majority of our company cars.

Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to fluctuations in interest rates and in foreign currency exchange rates.

Interest Rate Exposure

Our exposure to market risk relates primarily to short-term investments, including funds classified as cash equivalents. As of December 31, 2011, all excess funds were invested in time deposits and other highly liquid investments, therefore our interest rate exposure is not considered to be material.

Foreign Currency Exchange Rate Exposure

Our foreign currency exchange rate exposure continues to evolve as we grow internationally. Our exposure to foreign currency transaction gains and losses is the result of certain revenues and expenses being denominated in currencies other than the U.S. dollar, primarily the Euro and the New Israeli Shekel. We do not currently engage in hedging or similar transactions to reduce these risks. Fluctuations in currency exchange rates could impact our results of operations, financial position, and cash flows.

Business

History

We were organized in the State of Delaware on February 29, 2008 as Saguaro Resources, Inc. to engage in the acquisition, exploration and development of natural resource properties. On March 28, 2011, we changed our name from “Saguaro Resources, Inc.” to “InspireMD, Inc.”

On March 31, 2011, we completed a series of share exchange transactions pursuant to which we issued the shareholders of InspireMD Ltd. 50,666,663 shares of common stock in exchange for all of InspireMD Ltd.’s issued and outstanding ordinary shares, resulting in the former shareholders of InspireMD Ltd. holding a controlling interest in us and InspireMD Ltd. becoming our wholly-owned subsidiary.

Immediately following the share exchange transactions, we transferred all of our pre-share exchange operating assets and liabilities to our wholly-owned subsidiary, Saguaro Holdings, Inc., a Delaware corporation, and transferred all of Saguaro Holdings, Inc.’s outstanding capital stock to Lynn Briggs, our then-majority stockholder and our former president, chief executive officer, chief financial officer, secretary-treasurer and sole director, in exchange for the cancellation of 7,500,000 shares of our common stock held by Ms. Briggs.

After the share exchange transactions and the divestiture of our pre-share exchange operating assets and liabilities, we succeeded to the business of InspireMD Ltd. as our sole line of business, and all of our then-current officers and directors resigned and were replaced by some of the officers and directors of InspireMD Ltd.

Overview

We are an innovative medical device company focusing on the development and commercialization of our proprietary stent platform technology, MGuard™. MGuard™ provides embolic protection in stenting procedures by placing a micron

mesh sleeve over a stent (see photograph below of an MGuard™ Stent). Our initial products are marketed for use mainly in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). According to the TYPHOON STEMI trial (New England Journal of Medicine, 2006) and the SOS SVG Trial (Journal of the American College of Cardiology, 2009), of patients with acute myocardial infarction and saphenous vein graft coronary interventions, 7.5% to 44% experience major adverse cardiac events, including cardiac death, heart attack, and restenting of the artery. When performing stenting procedures in patients with acute coronary symptoms, interventional cardiologists face a difficult dilemma in choosing between bare-metal stents, which have a high rate of restenosis (formation of new blockages), and drug-eluting (drug-coated) stents, which have a high rate of late thrombosis (formation of clots months or years after implantation), require administration of anti-platelet drugs for at least one year post procedure, are more costly than bare-metal stents and have additional side effects. We believe that MGuard™ is a simple, seamless and complete solution for these patients.

MGuardTM Sleeve – Microscopic View

We intend to use our MGuard™ technology in a broad range of coronary related situations in which complex lesions are required and make it an industry standard for treatment of acute coronary syndromes. We believe that patients will benefit from a cost-effective alternative with a greater clinical efficacy and safety profile than other stent technologies. We believe that with our MGuard™ technology, we are well positioned to emerge as a key player in the global stent market.

We also intend to apply our technology to develop additional products used for other vascular procedures, specifically carotid (the arteries that supply blood to the brain) and peripheral (other arteries) procedures.

In October 2007, our first generation product, the MGuard™ Coronary, received CE Mark approval for treatment of coronary arterial disease in the European Union. CE Mark is a mandatory conformance mark on many products marketed in the European Economic Area and certifies that a product has met European Union consumer safety, health or environmental requirements. We began shipping our product to customers in Europe in January 2008 and have since expanded our global distribution network to Canada, Southeast Asia, India and Latin America.

Our initial MGuard™ products incorporated a stainless steel stent. We replaced this stainless steel platform with a more advanced cobalt-chromium based platform, which we refer to as MGuard Prime™. We believe the new platform will be superior because cobalt-chromium stents are generally known in the industry to provide better outcomes and possibly even a reduction in major adverse cardiac events. We believe we can use and leverage the MGuard™ clinical trial results to market MGuard Prime™. MGuard Prime™ received CE Mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. MGuard™ refers to both our initial products and MGuard Prime™, as applicable.

Business Segment and Geographic Areas

For financial information about our one operating and reportable segment and geographic areas, refer to “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Note 13. “Entity Wide Disclosures” to our Consolidated Financial Statements.

Our Industry

According to Fact Sheet No. 310/June 2011 of the World Health Organization, approximately 7.3 million people worldwide died of coronary heart disease in 2008. Physicians and patients may select from among a variety of treatments to address coronary artery disease, including pharmaceutical therapy, balloon angioplasty, stenting with bare metal or drug-eluting stents, and coronary artery bypass graft procedures, with the selection often depending upon the stage of the disease. A stent is an expandable “scaffold-like” device, usually constructed of a stainless steel material, that is inserted into an artery to expand the inside passage and improve blood flow.

According to the January 3, 2011 2011 MEDTECH OUTLOOK produced by the Bank of Montreal Investment Banking Group, known as BMO Capital Markets, after registering a compounded annual growth rate from 2002 to 2009 of approximately 13%, the revenues from global coronary stents market is predicted to remain relatively constant, although in volume of stents the market is predicted to continue to grow. The growth in volume is due to the appeal for less invasive percutaneous coronary intervention procedures and advances in technology coupled with the increase in the elderly population, obesity rates and advances in technology.

Coronary artery disease is one of the leading causes of death worldwide. The treatment of coronary artery disease includes alternative treatment methodologies, that is, coronary artery bypass grafting or angioplasty (percutaneous coronary intervention) with or without stenting. According to the January 3, 2011 2011 MEDTECH OUTLOOK produced by the BMO (Bank of Montreal) Investment Banking Group, the percutaneous coronary intervention procedures involving stents are increasingly being used to treat coronary artery diseases with an 88.3% penetration rate in 2009.

Our Products

The MGuard™ stent is an embolic protection device based on a protective sleeve, which is constructed out of an ultra-thin polymer mesh and wrapped around the stent. The protective sleeve is comprised of a micron level fiber-knitted mesh, engineered in an optimal geometric configuration and designed for utmost flexibility while retaining strength characteristics of the fiber material (see illustration below). The sleeve expands seamlessly when the stent is deployed, without affecting the structural integrity of the stent, and can be securely mounted on any type of stent.

MGuardTM Deployed in Artery

The protective sleeve is designed to provide several clinical benefits:

- the mesh diffuses the pressure and the impact of deployment exerted by the stent on the arterial wall and reduces the injury to the vessel;
- it reduces plaque dislodgement and blocks debris from entering the bloodstream during and post procedure (called embolic showers);
- in future products, when drug coated, the mesh is expected to deliver better coverage and uniform drug distribution on the arterial wall and therefore potentially reduce the dosage of the active ingredient when compared to approved drug-eluting stents on the market; and
- it maintains the standards of a conventional stent and therefore should require little to no additional training by physicians.

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Explanation of Responses: 32

MGuardTM – Coronary Applications

Our MGuardTM Coronary with a bio-stable mesh and our MGuardTM Coronary with a drug-eluting mesh are aimed at the treatment of coronary arterial disease.

MGuardTM Coronary and MGuard Prime™ with a bio-stable mesh Our first MGuardTM product, the MGuardTM Coronary with a bio-stable mesh, is comprised of our mesh sleeve wrapped around a bare-metal stent. It received CE Mark approval in October 2007 and, in January 2008, we started shipping this product to customers and distributors in Europe. MGuard Prime™ with a bio-stable mesh is comprised of our mesh sleeve wrapped around a cobalt-chromium stent. In comparison to a conventional bare-metal stent, we believe the MGuardTM Coronary and MGuard Prime™ with a bio-stable mesh provide protection from embolic showers. Results of clinical trials on the MGuardTM Coronary stent, including the MAGICAL, PISCIONE and MGuard international registry (iMOS) clinical trials described below (see "Business – Product Development and Critical Milestones - Comparison of Clinical Trial Results to Date with Results Achieved Using Bare Metal or Drug-Eluting Stents in the STEMI population" below), indicate positive outcomes and safety measures, as explained below (see "Business – Product Development and Critical Milestones - Comparison of Clinical Trial Results to Date with Results Achieved Using Bare Metal or Drug-Eluting Stents in the STEMI population" below). The results of these clinical trials for the MGuardTM Coronary stent suggest higher levels of myocardial blush grade 3 (occurrence in 73% of patients in the MAGICAL study and 90% of patients in the PISCIONE study, for the MGuardTM Coronary stent) and lower rates of 30 day and 1 year major adverse cardiac event rates, (2.4% and 5.9%, respectively, for the MGuardTM Coronary stent), as compared to the levels and rates of other bare-metal and drug-eluting stents, as reported by Svilaas, et. al. ("Thrombus Aspiration during Primary Percutaneous Coronary Intervention," New England Journal of Medicine, Volume 358, 2008). As reported in the study by Svilaas, et. al., myocardial blush grade 3 occurred in 32.2% of patients with a bare-metal stent and 45.7% of patients with a bare-metal stent preceded by an aspiration procedure, and the 30 day and 1 year major adverse cardiac event rates were 9.4% and 20.3%, respectively, for patients with a bare-metal stent and 6.8% and 16.6%, respectively, for patients with a bare-metal stent preceded by an aspiration procedure. Furthermore, results from a recent HORIZONS-AMI trial demonstrated that 1 year major adverse cardiac event rates were 10.9% for patients with drug eluting stents. Myocardial blush grade refers to a 0-3 grade scale given to the adequacy of perfusion and blood flow through an area served by a coronary artery; the longer the blush persists, the poorer the blood flow and the lower the myocardial blush grade. Ndrepepa, et. al. ("5-Year Prognostic Value of No-Reflow Phenomenon After Percutaneous Coronary Intervention in Patients With Acute Myocardial Infarction," Journal of the American College of Cardiology, Volume 55, Issue 21, 2010) reported that high myocardial blush grades correlate with higher survival rates among affected patients. Sustained performance by the MGuardTM Coronary stent with respect to contributing to higher levels of myocardial blush grade 3 and lower rates of 30 day and 1 year major adverse cardiac event rates would differentiate the MGuardTM Coronary stent from other bare-metal and drug-eluting stents that do not offer such benefits.

MGuardTM Coronary with a drug eluting bio-absorbable mesh. Based upon the clinical profile of MGuardTM Coronary, we anticipate that the MGuardTM Coronary with a drug-eluting bio-absorbable mesh will offer both the comparable myocardial blush grade 3 levels and 30-day and 1-year major adverse cardiac event rates as the MGuardTM Coronary with a bio-stable mesh, as described above, and a comparative restenosis rate, which is the rate at which patients experience formation of new blockages in their arteries, when compared to existing drug-eluting stents. The bio-absorbability of MGuardTM Coronary with a drug eluting bio-absorbable mesh is intended to improve upon the bio-absorbability of other drug-eluting stents, in light of the large surface area of the mesh and the small diameter of the fiber. We intend for the protective sleeve on the MGuardTM Coronary with a drug-eluting bio-absorbable mesh to improve uniform distribution of the applied drug to the vessel wall for improved drug therapy management compared to other drug-eluting stents, where the drug is distributed on the struts only. If this intended result is achieved with respect to the improved and uniform distribution of the applied drug to the vessel wall, the total

dosage of the medication potentially could be reduced while increasing its efficacy. MGuardTM Coronary with a drug-eluting bio-absorbable mesh is expected to promote smooth and stable endothelial cell growth and subsequent attachment to the lumen of the vessel wall, which is essential for rapid healing and recovery. In addition, we believe bio-absorbable drug-eluting mesh may enable the use of more effective drug therapies that presently cannot be effectively coated on a metal-based stent due to their poor diffusion capabilities. Because the drug-eluting bio-absorbable mesh will be bio-absorbable, we anticipate that the mesh will completely dissolve after four months, which we expect will result in fewer of the chronic long term side effects that are associated with the presence of the drug.

MGuardTM – Carotid Applications

We intend to market our mesh sleeve coupled with a self-expandable stent (a stent that expands without balloon dilation pressure or need of an inflation balloon) for use in carotid-applications. We believe that our MGuardTM design will provide substantial advantages over existing therapies in treating carotid artery stenosis (blockage or narrowing of the carotid arteries), like conventional carotid stenting and endarterectomy (surgery to remove blockage), given the superior embolic protection characteristics witnessed in coronary arterial disease applications. We intend that the embolic protection will result from the mesh sleeve, as it traps emboli at their source. In addition, we believe that MGuardTM Carotid will provide post-procedure protection against embolic dislodgement, which can occur immediately after a carotid stenting procedure and is often a source of post-procedural strokes. Schofer, et. al. ("Late cerebral embolization after emboli-protected carotid artery stenting assessed by sequential diffusion-weighted magnetic resonance imaging," Journal of American College of Cardiology Cardiovascular Interventions, Volume 1, 2008) have also shown that the majority of the incidents of embolic showers associated with carotid stenting occur immediately post-procedure.

MGuardTM – Peripheral Applications

We intend to market our mesh sleeve coupled with a self-expandable stent (a stent that expands without balloon dilation pressure or need of an inflation balloon) for use in peripheral applications. Peripheral Artery Disease, also known as peripheral vascular disease, is usually characterized by the accumulation of plaque in arteries in the legs, need for amputation of affected joints or even death, when untreated. Peripheral Artery Disease is treated either by trying to clear the artery of the blockage, or by implanting a stent in the affected area to push the blockage out of the way of normal blood flow.

The Peripheral Artery Disease market consists of three segments: Aortic Aneurysm, Renal, Iliac and Bilary and Femoral-Popliteal procedures. Aortic Aneurysm is a condition in which the aorta, the artery that leads away from the heart, develops a bulge and is likely to burst. This condition often occurs below the kidneys, in the abdomen. Renal, Iliac and Bilary procedures refer to stenting in the kidney, iliac arteries (which supply blood to the legs) and liver, respectively. Femoral-Popliteal procedures involve stenting in vessels in the legs.

As in carotid procedures, peripheral procedures are characterized by the necessity of controlling embolic showers both during and post-procedure. Controlling embolic showers is so important in these indications that physicians often use covered stents, at the risk of blocking branching vessels, to ensure that emboli does not fall into the bloodstream. We believe that our MGuardTM design will provide substantial advantages over existing therapies in treating peripheral artery stenosis (blockage or narrowing of the peripheral arteries).

Product Development and Critical Milestones

Below is a list of the products described above and our projected critical milestones with respect to each. As used below, "Q" stands for our fiscal quarter. While we currently anticipate seeking approval from the U.S. Food and Drug Administration for all of our products in the future, we have only outlined a timetable to seek U.S. Food and Drug Administration approval for our MGuardTM Coronary plus with bio-stable mesh product in our current business plan. The use of the term "to be determined" in the table below with regard to certain U.S. Food and Drug Administration trial milestones indicates that the achievements of such milestones is unable to be accurately predicted as such milestones are too far in the future.

Product	Indication	Start Development	CE Mark	European Union	FDA Approval	U.S. Sales

				Sales		
MGuard™ Coronary Plus Bio-Stable Mesh	Bypass/ Coronary	2005	Oct. 2007	Q1-2008	Q3-2015-Q4-2015	2015
MGuard™ Peripheral Plus Bio-Stable Mesh	Peripheral Arteries	Q1-2011	Q4-2012	To be determined	To be determined	To be determined
MGuard™ Carotid Plus Bio-Stable Mesh	Carotid Arteries	Q1-2011	Q4-2012	To be determined	To be determined	To be determined
MGuard™ Coronary Plus Bio-Absorbable Drug-Eluting Mesh	Bypass/ Coronary	Q1-2013	Q3-2016	Q4-2016	To be determined	To be determined

With respect to the timetable for MGuard™ Coronary Plus Bio-Stable Mesh, the expected timing for the U.S. Food and Drug Administration approval and U.S. sales has been changed due to unanticipated delays in the U.S. Food and Drug Administration approval process. With respect to the timetable for MGuard™ Peripheral Plus Bio-Stable Mesh, the expected commencement of sales in the European Union has been delayed on account of our desire to provide extra time after obtaining CE Mark approval to promote our product and develop a proper launching program for it. With respect to MGuard™ Carotid Plus Bio-Stable Mesh, we have determined that the expected commencement of sales in the European Union can no longer be accurately predicted because we have delayed the further development of this product subject to obtaining additional funding for its development.

We anticipate that our MGuardTM Coronary plus with bio-stable mesh product will be classified as a Class III medical device by the U.S. Food and Drug Administration.

Pre-Clinical Studies

We performed laboratory and animal testing prior to submitting an application for CE Mark approval for our MGuardTM Coronary with bio-stable mesh. We also performed all CE Mark required mechanical testing of the stent. We conducted pre-clinical animal trials at Harvard and MIT Biomedical Engineering Center BSET lab in July 2006 and August 2007. In these animal trials, on average, the performance of the MGuardTM Coronary with bio-stable mesh was comparable with the performance of control bare-metal stents. Analysis also indicated that in these animal trials the mesh produced levels of inflammation comparable with those levels produced by standard bare-metal stents. No human trials were conducted as part of these pre-clinical trials.

The table below describes our completed and planned pre-clinical trials. The use of the term “To be determined” in the table below with regard to milestone dates in our pre-clinical studies indicates that we have not yet decided when to schedule such milestones.

Product	Stent Platform	Approval Requirement	Start of Study	End of Study
MGuardTM Coronary	Bare-Metal Stent Plus Bio-Stable Mesh	CE Mark (European Union + Rest of World)	Q4-2006	Q3-2007
	Drug-Eluting Mesh (Bare-Metal Stent Plus	CE Mark (European Union + Rest of World)	To be determined	To be determined
	Drug-Eluting Mesh)	FDA (U.S.)	To be determined	To be determined
	Cobalt-Chromium Stent Plus Bio-Stable Mesh	FDA	Q3-2012	Q3-2015 - Q4-2015
MGuardTM Peripheral/Carotid	Self Expending System Plus Mesh	CE Mark (European Union + Rest of World)	To be determined	To be determined
MGuardTM Carotid		FDA (U.S.)		

Self Expending System Plus Mesh	Peripheral information on animals can be used

With respect to the preclinical studies for MGuardTM Coronary, the drug-eluting mesh trials have been indefinitely suspended due to our determination to focus our time and resources on other trials at this time and the start of the cobalt-chromium stent plus bio-stable mesh trial was delayed from our previously announced target due to the delay of the U.S. Food and Drug Administration approval process for MGuard™ Coronary Plus Bio-Stable Mesh.

With respect to the preclinical studies for MGuard Peripheral/Carotid, the start of study of the Self Expending System Plus Mesh trial has been delayed from our previously announced target due to a delay in our receipt of anticipated funding.

Clinical Trials

The table below describes our completed and planned clinical trials. The use of the term "To be determined" in the table below with regard to milestone dates in our clinical trials indicates that we have not yet decided when to schedule such milestones. All milestone dates set forth in the table below are our best estimates based upon the current status of each clinical trial.

						Study Status		
Product	Stent Platform	Clinical Trial Sites	Follow-up Requirement	Objective	No. of Patients	Start	End Enrollment	End of Study
MGuardTM Coronary	Bare-Metal Stent Plus	Germany – two sites	12 months	Study to evaluate safety and performance of MGuardTM system	41	Q4-2006	Q4- 2007	Q2-2008
	Bio-Stable Mesh	Brazil – one site	12 months		30	Q4-2007	Q1-2008	Q2-2009
		Poland – four sites	6 months		60	Q2-2008	Q3-2008	Q2-2009
		International MGuardTM Observational Study - worldwide - 50 sites	12 months		1,000	Q1-2008	Q4-2013	Q4-2013
		Israeli MGuardTM Observational Study - Israel - 8 sites	6 months		100	Q2-2008	Q3-2011	Q3-2012
		Master randomized control trial - 7 countries, 50 centers in South America, Europe and Israel	12 months		430	Q2-2011	Q2-2012	Q2-2013
		Brazil – 25 sites	12 months		500	Q3-2010	To be determined	To be determined
		FDA Study - 40 sites, U.S. and out of U.S.	12 months	Pilot study to evaluate safety and performance of	800	Q1-2012 - Q2-2012	Q3-2013 – Q1-2014	Q4-2014 - Q2-2015

			MGuardTM system for FDA approval				
	South America and Europe – 10 sites	8-12 months	Pilot study to evaluate safety and	500	To be determined	To be determined	To be determined
Drug-Eluting Stent (Bare-Metal Stent + Drug Eluting Mesh)	U.S. – 50 sites	12 months	performance of MGuardTM system for FDA and CE Mark approval	2,000	To be determined	To be determined	To be determined
	Rest of World as a registry study	8-12 months	Evaluation of safety and efficacy for specific indications	400	To be determined	To be determined	To be determined

						Study Status		
Product	Stent Platform	Clinical Trial Sites	Follow-up Requirement	Objective	No. of Patients	Start	End Enrollment	End of Study
MGuardTM Peripheral	Self Expanding System + Mesh	South America and Europe – four sites	12 months	Pilot study to evaluate safety and performance of MGuardTM system for CE Mark approval	50	To be determined	To be determined	To be determined
		South America and Europe – six sites	6 months		150	To be determined	To be determined	To be determined
MGuardTM Carotid	Self Expanding System + Mesh	Rest of World as a registry study	6 months	Evaluation of safety and efficacy for specific indications post-marketing	100	To be determined	To be determined	To be determined

Each of the patient numbers and study dates set forth in the tables above are management's best estimate of the timing and scope of each referenced trial. Actual dates and patient numbers may vary depending on a number of factors, including, without limitation, feedback from reviewing regulatory authorities, unanticipated delays by us, regulatory authorities or third party contractors, actual funding for the trials at the time of trial initiation and initial trial results.

With respect to the MGuardTM Coronary clinical trial for the Master randomized control trial, the start and end enrollment dates have been delayed from our previously announced target by a fiscal quarter and the end of study date has been delayed from our previously announced target by two fiscal quarters due to delays in the necessary approvals of the trial by local ethical committees in certain of the participant countries.

The MGuardTM Coronary clinical trials for the drug-eluting stent have been delayed from our previously announced target due to a delay in our receipt of anticipated funding.

With respect to the MGuardTM Peripheral clinical trial for the self expanding system + mesh, the start date has been delayed from our previously announced start date due to a delay in our receipt of anticipated funding.

With respect to the MGuardTM Carotid clinical trial for the self expanding system + mesh, the number of patients has been decreased due to feedback from the clinical trial leaders that a smaller patient population would be sufficient for this clinical trial.

Completed Clinical Trials for MGuardTM Coronary Bare-Metal Stent Plus Bio-Stable Mesh

As shown in the table above, we have completed five clinical trials with respect to our MGuardTM Coronary with bio-stable mesh. Our first study, conducted at two centers in Germany, included 41 patients with either saphenous vein graft coronary interventions or native coronary lesions treatable by a stenting procedure (blockages where no bypass procedure was performed). The MGuardTM Coronary rate of device success, meaning the stent was successfully deployed in the target lesion, was 100% and the rate of procedural success, meaning there were no major adverse cardiac events prior to hospital discharge, was 95.1%. At six months, only one patient (2.5% of participants) had major myocardial infarction (QWMI) and 19.5% of participants had target vessel revascularization (an invasive procedure required due to a stenosis in the same vessel treated in the study). This data supports MGuardTM's safety in the treatment of vein grafts and native coronary legions.

Our 2007 study in Brazil included 30 patients who were candidates for a percutaneous coronary intervention (angioplasty) due to narrowing of a native coronary artery or a bypass graft. In all patients, the stent was successfully deployed with perfect blood flow parameters (the blood flow parameter is a measurement of how fast the blood flows in the arteries and the micro circulation system in the heart). There were no major cardiac events at the time of the follow-up 30 days after the deployment of the stents.

The study in Poland included 60 patients with acute ST-segment elevation myocardial infarction (the most severe form of a heart attack, referred to as "STEMI"). The purpose of the study was to confirm the clinical performance of MGuardTM Coronary with bio-stable mesh when used in STEMI patients where percutaneous coronary intervention is the primary line of therapy. Perfect blood flow in the artery was achieved in 90% of patients, perfect blood flow into the heart muscle was achieved in 73% of patients and complete restoration of electrocardiogram normality was achieved in 61% of patients. The total major adverse cardiac events rate during the six-month period following the deployment of the stents was 0%.

Ongoing Clinical Trials for MGuardTM Coronary Bare-Metal Stent Plus Bio-Stable Mesh

Our ongoing observation study in Europe is an open registry launched in the first fiscal quarter of 2009. This registry is expected to enroll up to 1,000 patients and is aimed at establishing the performance of MGuardTM Coronary with bio-stable mesh in a "real world" population. To date, the primary countries to join are Austria, Czech Republic and Hungary. The primary endpoint that this registry will evaluate is the occurrence of major adverse cardiac events at six months following deployment of the stent, and the clinical follow-up will continue for a period of up to one year per patient. As of April 25, 2012, 541 patients of the prospective 1,000 have been enrolled in 28 sites.

Our ongoing observational study in Israel is an open registry launched in the fourth fiscal quarter of 2009. This registry is expected to enroll up to 100 patients. The purpose of this study is to support local Israeli regulatory approval. The primary endpoint that this registry will evaluate is the occurrence of major adverse cardiac events at 30 days following deployment of the stent, and the clinical follow-up will be conducted at six months following deployment of the stent. As April 25, 2012, 86 patients of the prospective 100 have been enrolled.

In the third fiscal quarter of 2010, we launched a Brazilian registry to run in 25 Brazilian sites and enroll 500 patients. The primary endpoint that this registry will evaluate is the occurrence of major adverse cardiac events at six months following the deployment of the stent, and the clinical follow-up will continue for a period of up to one year per patient. As of April 25, 2012, 19 patients of the prospective 500 have been enrolled.

Comparison of Clinical Trial Results to Date with Results Achieved Using Bare Metal or Drug-Eluting Stents in the STEMI population

We conducted a meta-analysis of data from four clinical trials in which MGuardTM was used:

- The MAGICAL study, a single arm study in which 60 acute ST-segment elevation myocardial infarction (the most severe form of a heart attack, referred to as STEMI) patients with less than 12 hours symptom onset were enrolled, as reported in "Mesh Covered Stent in ST-segment Elevation Myocardial Infarction" in EuroIntervention, 2010;

- the PISCIONE study, a single arm study in which 100 STEMI patients were enrolled, as reported in "Multicentre Experience with MGuard Net Protective Stent in ST-elevation Myocardial Infarction: Safety, Feasibility, and Impact on Myocardial Reperfusion" in Catheter Cardiovasc Interv, 2009;

- the iMOS study, a Registry on MGuard use in the "real-world" population, from a study whose data was not published; and

- the Jain study, which looks at a small group of 51 STEMI patients, as reported in "Prevention of Thrombus Embolization during Primary Percutaneous Intervention Using a Novel Mesh Covered Stent" in Catheter Cardiovasc Interv, 2009.

Our meta-analysis included data from the following trials:

- The CADILLAC (Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications) study, which found that primary stent implantation is a preferred strategy for the treatment of acute myocardial infarction, as reported in "A Prospective, Multicenter, International Randomized Trial Comparing Four Reperfusion Strategies in Acute Myocardial Infarction: Principal Report of the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications (CADILLAC)" Trial in Journal of American College of Cardiology, 2001;

- The EXPORT trial which was a randomized open-label study whose primary endpoint was to evaluate flow improvement in AMI patients using either conventional stenting or aspiration followed by stenting, as reported in "Systematic Primary Aspiration in Acute Myocardial Percutaneous Intervention: A Multicentre Randomised Controlled Trial of the Export Aspiration Catheter" in EuroIntervention, 2008;

- The EXPIRA trial which was a single-center study aimed to explore pre-treatment with manual thrombectomy as compared to conventional stenting, as reported in "Thrombus Aspiration During Primary Percutaneous Coronary Intervention Improves Myocardial Reperfusion and Reduces Infarct Size: The EXPIRA (Thrombectomy with Export Catheter in Infarct-related Artery During Primary Percutaneous Coronary Intervention) Prospective, Randomized Trial" in Journal of American College of Cardiology, 2009;

- The REMEDIA trial, whose objective was to assess the safety and efficacy of the EXPORT catheter for thrombus aspiration in STEMI patients, as reported in "Manual Thrombus-Aspiration Improves Myocardial Reperfusion: The Randomized Evaluation of the Effect of Mechanical Reduction of Distal Embolization by Thrombus-Aspiration in Primary and Rescue Angioplasty (REMEDIA) Trial" in Journal of American College of Cardiology, 2005;

- The Horizons-AMI (Harmonizing Outcomes with RevascularIZatiON and Stents in Acute MI), which is the largest randomized trial which compared DES to BMS in MI patients, as reported in "Paclitaxel-Eluting Stents Versus Bare-Metal Stents in Acute Myocardial Infarction" in New England Journal of Medicine, 2009; and

- The TAPAS Trial which showed that thrombus aspiration before stenting benefits MI patients, as reported in "Thrombus Aspiration During Primary Percutaneous Coronary Intervention" in New England Journal of Medicine, 2009.

The meta analysis of MGuardTM outcomes in STEMI population show comparable rates of thrombolysis in myocardial infarction (TIMI) 3 flow with no significant difference of the historical control as compared to MGuardTM(88.5% and 91.7%, respectively), while the rates of myocardial blush grade score 3 (37.3% for the historical control and 81.6% for MGuardTM) and ST segment resolution>70% (53.6% for the historical control and 79.1% for MGuardTM) are statistically significantly better with the MGuardTM. MGuardTM also appears consistently superior at the 30 days major adverse cardiac event (8.4% for the historical control and 2.4% for MGuardTM) and 1 year major adverse cardiac event (13.3% for the historical control and 5.9% for MGuardTM) endpoints. The data appears in the following tables.

	NAME OF STUDY				
	MAGICAL	PISCIONE	iMOS	Jain	Average
Number of Patients	60	100	203	51	414 (Total)
Thrombolysis in myocardial infarction 0-1,%	0	0	1.2	0	0.6
Thrombolysis in myocardial infarction 3,%	90	85	93.5	100	91.7
Myocardial blush grade 0-1,%	3.3	0	--	--	1.2
Myocardial blush grade 3,%	73	90	80	--	81.6
ST segment resolution>70%,%	61	90	--	--	79.1
ST segment resolution>50%,%	88	--	85.4	96	87.6
30 day major adverse cardiac event,%	0	2.2	3.2	--	2.4
6 month major adverse cardiac events,%	0	4.5	6.0	--	4.6
1 year major adverse cardiac events,%	--	5.6	6.0	6.0	5.9
1 year target vessel revascularization		2.3	2.3	6.0	2.8
Acute Binary Resteonosis 6M,%	--	--	19.0*	--	19.0

Trial	CADILLAC	Horizons-AMI	Horizons-AMI	TAPAS	TAPAS	EXPORT	EXPORT	EXPIRA	EXPIRA	REM
Group	Stent + Abciximab	BMS	DES	Thrombus aspiration	control	control	TA	control	Thrombus aspiration	Thro aspir
Number of Patients	524	749	2257	535	536	129	120	87	88	5
Thrombolysis in myocardial infarction 0-1,%	--	--	--	--	--	3.9	2.4	1.1	0	-
Thrombolysis in myocardial infarction 3,%	96.9	87.6	89.8	86	82.5	76.9	82	--	--	-
Myocardial blush grade 0-1,%	48.7	--	--	17.1	26.3	31.6	27.6	40.2	11.4	3
Myocardial blush grade 3,%	17.4	--	--	45.7	32.2	25.4	35.8	--	--	-
	62	--	--	56.6	44.2	--	--	39.1	63.6	5

ST segment resolution>70%,%										
ST segment resolution>50%,%	--	--	--	--	--	71.9	85	--	--	-
30 day major adverse cardiac event,%	4.4	--	--	6.8	9.4	--	--	--	--	1
6 month major adverse cardiac events,%	10.2	--	--	--	--	--	--	--	--	-
1 year major adverse cardiac events,%	--	13.1	10.9	16.6	20.3	--	--	--	--	-
Acute Binary Resteonosis 6 month,%	20.8	--	--	--	--	--	--	--	--	-
1 year target vessel revascularization		7.4	4.6	12.9	11.2					
Acute Binary Resteonosis 1 year,%	--	21	8.3	--	--					