XTENT INC
Form 10-Q
November 12, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2008

or

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

For the transition period from to

Commission File Number 001-33282

XTENT, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**41-2047573**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

125 Constitution Drive

Menlo Park, California 94025-1118

(Address of principal executive offices, including Zip Code)

(650) 475-9400

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act) Yes o No x

As of November 5, 2008, there were 23,282,607 shares of XTENT, Inc. common stock outstanding.

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XTENT, INC.

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PART I: FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

XTENT, INC.

(a development stage company)

CONDENSED BALANCE SHEETS

(unaudited; in thousands, except per share amounts)

	September 30, 2008	December 31, 2007 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,601	$ 13,366
Short-term investments	11,984	44,394
Prepaid expenses and other current assets	801	905
Total current assets	26,386	58,665
Property and equipment, net	4,291	3,601
Other non-current assets	179	149
Total assets	$ 30,856	$ 62,415
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,133	$ 1,960
Accrued liabilities	1,884	2,124
Total current liabilities	3,017	4,084
Commitments and contingencies (note 6)		
Stockholders Equity:		
Common stock: $0.001 par value; 100,000 shares authorized at September 30, 2008 and December 31, 2007; 23,283 and 23,015 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	23	23
Additional paid-in capital	154,779	151,496
Deferred stock-based compensation	(111)	(364)
Accumulated other comprehensive income	16	36
Deficit accumulated during development stage	(126,868)	(92,860)
Total stockholders equity	27,839	58,331
Total liabilities and stockholders equity	$ 30,856	$ 62,415

(1) The condensed balance sheet at December 31, 2007 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in

the United States for complete financial statements.

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

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XTENT, INC.

(a development stage company)

CONDENSED STATEMENTS OF OPERATIONS

(unaudited; in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative Period from June 13, 2002 (Date of Inception) to September 30,
	2008	2007	2008	2007	2008
Operating expenses:					
Research and development (1)	$ 6,679	$ 7,767	$ 25,918	$ 21,694	$ 100,332
General and administrative (1)	2,179	2,632	8,952	7,894	32,495
Total operating expenses	8,858	10,399	34,870	29,588	132,827
Loss from operations	(8,858)	(10,399)	(34,870)	(29,588)	(132,827)
Interest and other income, net	193	860	862	2,658	5,959
Net loss	(8,665)	(9,539)	(34,008)	(26,930)	(126,868)
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock					(13,095)
Net loss attributable to common stockholders	$ (8,665)	$ (9,539)	$ (34,008)	$ (26,930)	$ (139,963)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.37)	$ (0.42)	$ (1.48)	$ (1.35)	
Weighted-average common shares outstanding - basic and diluted	23,211	22,656	23,056	19,999	

(1) Includes the following stock-based compensation charges:

Research and development	$ 369	$ 294	$ 1,150	$ 1,030	$ 4,211
General and administrative	$ 594	$ 490	$ 1,939	$ 1,322	$ 5,093

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

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XTENT, INC.

(a development stage company)

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited; in thousands)

	Nine Months Ended September 30, 2008	2007	Cummulative Period from June 13, 2002 (Date of Inception) to September 30, 2008
Cash flows from operating activities:			
Net loss	$ (34,008)	$ (26,930)	$ (126,868)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	987	821	3,704
Amortization of securities discount	(317)	(1,319)	(2,022)
Gain (loss) on sale of investments	(26)	20	(6)
Loss on disposal of property and equipment	26	9	189
Stock-based compensation expense	3,089	2,352	9,304
Stock issued in exchange for services and patents	150		381
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(257)	(98)	(939)
Accrued interest receivable on securities	361	(142)	(11)
Accounts payable	(827)	926	1,018
Accrued liabilities	(180)	626	1,993
Net cash used in operating activities	(31,002)	(23,735)	(113,257)
Cash flows from investing activities:			
Purchase of investments	(18,360)	(92,073)	(136,598)
Proceeds from maturities of investments	41,130	45,150	112,709
Proceeds from sale of investments	9,963	3,986	13,949
Restricted cash	(30)		(30)
Purchase of property and equipment	(1,705)	(1,808)	(8,181)
Proceeds from sale of property and equipment	2		20
Net cash provided by (used in) investing activities	31,000	(44,745)	(18,131)
Cash flows from financing activities:			
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs			75,592
Proceeds from initial public offering, net of offering costs		69,112	68,237
Principal payments on capital lease obligations			(23)
Proceeds from issuance of common stock and exercise of stock options	237	62	1,183
Net cash provided by financing activities	237	69,174	144,989
Net increase in cash and cash equivalents	235	694	13,601
Cash and cash equivalents at beginning of period	13,366	23,105	
Cash and cash equivalents at end of period	$ 13,601	$ 23,799	$ 13,601

Supplemental disclosure of noncash investing and financing activities:					
Deferred stock-based compensation	$		$		$ 1,272
Reversal of deferred stock-based compensation	$	(65)	$	(22)	$ (160)
Dividend related to beneficial conversion feature of redeemable convertible preferred stock	$		$		$ (13,095)
Equipment acquired under capital leases	$		$		$ (23)
Vesting of restricted common stock from early exercises	$	60	$	78	$ 435
Deferred initial public offering costs	$		$	875	$ 875
Changes in net unrealized gains on investments	$	(20)	$	60	$ 16

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

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XTENT, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(unaudited)

NOTE 1 - Organization and Basis of Presentation

Organization

XTENT, Inc. (the Company), was incorporated in the state of Delaware on June 13, 2002 (inception), and is focused on developing and commercializing innovative drug eluting stent systems for the treatment of coronary artery disease. The Company is in the development stage and since inception has devoted substantially all of its time and efforts to developing products, raising capital and recruiting personnel.

The Company has incurred net operating losses each year since inception. At September 30, 2008, the Company had an accumulated deficit of $126.9 million. The Company has not achieved positive cash flows from operations in any year since inception. In February 2007, the Company completed its initial public offering raising net proceeds of $68.2 million. In order to continue its operations, the Company must achieve profitable operations, obtain additional debt financing or sell additional shares of its equity securities. The Company is exploring options for seeking additional capital through the sale of its equity securities, and has engaged third party consultants to assist in this effort. The deterioration of the worldwide macroeconomic environment coupled with the increased volatility of the financial markets may limit the availability and amount of capital available to the Company. There can be no assurance that the Company will be able to obtain additional financing on terms acceptable to the Company, or at all. As a result, the Board is also considering other alternative strategies.

The failure of the Company to obtain sufficient funds on acceptable terms when needed will require the Company to reduce the scope of, delay, or eliminate some or all of the planned clinical trials, research, development, pursuit of regulatory approvals in certain countries, and commercialization activities, which could have a material adverse effect on the Company s business, results of operations and financial condition.

Management is currently working toward its objective of realizing profitability by obtaining regulatory approval of its products in the United States and Europe. The failure of the Company to obtain approval of its products from regulatory authorities could have a material adverse effect on the Company s business, results of operations, future cash flows and financial condition.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared by the Company in accordance with the accounting principles generally accepted in the United States of America for interim financial information and pursuant to the instructions to Form 10-Q and

Article 10 of Regulation S-X of the Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair statement have been included. The results for the three and nine months ended September 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008, or for any future period. These unaudited condensed financial statements and notes should be read in conjunction with the audited financial statements and the notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2007, filed with the Securities and Exchange Commission on March 17, 2008.

NOTE 2 - Summary of Significant Accounting Policies

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company deposits cash with high credit quality financial institutions. Cash equivalents consist primarily of liquid money market funds.

Investments

Investments with an original maturity of more than three months and less than one year at the date of purchase are considered to be short-term. Investments consist primarily of fixed income securities. The Company classifies its investments as available-for-sale in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* and they are recorded at fair value. The fair value of investments is based on quoted market prices. As of September 30, 2008 all of the Company s investments were short-term in nature.

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Unrealized gains and losses are reported as accumulated other comprehensive income (loss), which is a separate component of stockholders equity, until realized. Premiums (or discounts) on investments are amortized (or accreted) to interest and other income, net over the life of the investment. Realized gains and losses on investments sold are included in interest and other income, net in the Company s statement of operations.

The Company reviews its short-term investments on a regular basis to evaluate whether or not any security has experienced an other-than-temporary decline in fair value. If the Company believes that an other-than-temporary decline exists in one of its marketable securities, it writes down these investments to the fair value and records the write-down within interest and other income, net in the Company s statement of operations.

Restricted Cash

The Company has restricted cash in the amount of $30,000 related to a certificate of deposit held as security against credit cards used by employees in the purchasing department.

Concentration of Credit Risk

The Company s financial instruments that are exposed to concentration of credit risk consist primarily of cash and cash equivalents and short-term investments. Financial instruments are comprised primarily of money market funds, commercial paper and U.S. Government and agency securities rated A1 and P1 or better. The Company s cash is mainly deposited with one major financial institution, which at times exceeds the amount of insurance provided by the Federal Deposit Insurance Corporation on such deposits. The Company mitigates the concentration of credit risk by placing percentage limits on the maximum portion of the investment portfolio which may be invested in any one investment instrument. The Company has not recognized any losses from credit risks on such accounts during any of the periods presented and believes that it is not exposed to any significant risk on these balances.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity from transactions and other events and circumstances other than those resulting from investments by owners and distributions to owners. The Company s unrealized gains (losses) on available-for-sale securities represent the only component of other comprehensive loss that was excluded from the Company s net loss and is reflected as a component of stockholders equity.

Total comprehensive loss during the three and nine months ended September 30, 2008 and 2007 consisted of:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(in thousands)		(in thousands)	
Net loss attributable to common stockholders	$ (8,665)	$ (9,539)	$ (34,008)	$ (26,930)
Change in unrealized gain (loss) on available-for-sale securities	(5)	90	(20)	60
Comprehensive loss	$ (8,670)	$ (9,449)	$ (34,028)	$ (26,870)

Net Loss per Common Share

Basic and diluted net loss per common share is computed using the weighted-average number of shares of common stock outstanding during the period. Potentially dilutive shares consisting of stock options, common stock subject to repurchase, redeemable convertible preferred stock and shares issuable under the Employee Stock Purchase Plan were not included in the diluted net loss per common share calculations for all periods presented because the inclusion of such shares would have had an antidilutive effect.

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A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per common share is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(in thousands, except per share amounts)		(in thousands, except per share amounts)	
Numerator:				
Net loss attributable to common stockholders	$ (8,665)	$ (9,539)	$ (34,008)	$ (26,930)
Denominator:				
Weighted-average common shares outstanding	23,240	22,900	23,132	20,307
Less: Weighted-average unvested common shares subject to repurchase	(29)	(244)	(76)	(308)
Weighted-average common shares outstanding used in computing basic and diluted net loss per common share	23,211	22,656	23,056	19,999
Net loss per share attributable to common stockholders - basic and diluted	$ (0.37)	$ (0.42)	$ (1.48)	$ (1.35)

The following potentially dilutive shares were excluded from the computation of diluted net loss per common share for the periods presented because including them would have an antidilutive effect:

	Periods Ended September 30,	
	2008	2007
	(in thousands)	
Options to purchase common stock	2,632	1,977
Common stock subject to repurchase	15	222
Shares issuable under Employee Stock Purchase Plan	47	50

Recent and Adopted Accounting Pronouncements

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (the GAAP hierarchy). SFAS No. 162 will become effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The Company does not expect the adoption of SFAS No. 162 to have a material effect on the Company s financial position, operating results or cash flows.

On January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements*, (SFAS 157) as it relates to financial assets and financial liabilities. In February 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) No. FAS 157-2, *Effective Date of FASB Statement No. 157,* which delayed the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except

those that are recognized or disclosed at fair value in the financial statements on at least an annual basis, until January 1, 2009 for calendar year-end entities. Also in February 2008, the FASB issued FSP No. FAS 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13,* which states that SFAS No. 13, *Accounting for Leases,* (SFAS 13) and other accounting pronouncements that address fair value measurements for purposes of lease classification or measurement under SFAS 13 are excluded from the provisions of SFAS 157, except for assets and liabilities related to leases assumed in a business combination that are required to be measured at fair value under SFAS No. 141, *Business Combinations,* (SFAS 141) or SFAS No. 141 (revised 2007) *Business Combinations,* (SFAS 141(R)). SFAS 157 defines fair value, establishes a

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framework for measuring fair value in accounting principles generally accepted in the United States of America, and expands disclosures about fair value measurements. The provisions of this standard apply to other accounting pronouncements that require or permit fair value measurements and are to be applied prospectively with limited exceptions. The adoption of SFAS 157 did not have a material impact on the Company s financial position, operating results or cash flows. The Company has not yet determined the impact on its financial statements from the adoption of SFAS No. 157 as it pertains to non-financial assets and non-financial liabilities.

NOTE 3 - Investments

Short-term investments, which are classified as available-for-sale, had maturities of less than one year and consisted of the following:

As of September 30, 2008	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(in thousands)		
US government and agency securities	$ 9,976	$ 12	$	$ 9,988
Commercial paper	1,992	4		1,996
Total	$ 11,968	$ 16	$	$ 11,984

As of December 31, 2007	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(in thousands)		
Commercial paper	$ 4,685	$ 21	$	$ 4,706
US government and agency securities	33,694	21	(9)	33,706
Corporate bonds	5,979	3		5,982
Total	$ 44,358	$ 45	$ (9)	$ 44,394

Fair Value Measurements

In the first quarter of 2008, we adopted SFAS No. 157, *Fair Value Measurements* for financial assets and liabilities. This standard defines fair value as the price that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). SFAS No. 157 classifies the inputs used to measure fair value into the following hierarchy:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

- Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

- Level 3: Unobservable inputs that reflect the reporting entity s own assumptions.

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The Company s cash equivalents and short-term investments are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The fair value hierarchy of the Company s marketable securities at fair value in connection with the adoption of SFAS No. 157 consisted of the following as of September 30, 2008:

	Balance as of September 30, 2008	Significant Other Observable Inputs (Level 1) (in thousands)	Significant Other Observable Inputs (Level 2)
Money market funds (1)	$ 12,349	$ 12,349	$
US government and agency securities	9,988		9,988
Commercial paper	1,996		1,996
Total	$ 24,333	$ 12,349	$ 11,984

(1) Money market funds are classified as part of cash equivalents on the condensed balance sheet.

NOTE 4 - Common Stock

On February 1, 2007, the Company sold 4,700,000 shares of its common stock at a public offering price of $16.00 per share. Net cash proceeds from the Initial Public Offering were approximately $68.2 million, after deducting underwriting discounts and commissions and other offering costs.

Each share of common stock has the right to one vote. The holders of common stock are entitled to dividends when funds are legally available and when declared by the Board of Directors.

Restricted common stock

Certain common stock option holders have the right to exercise unvested options, subject to a repurchase right held by the Company to repurchase the stock, at the original exercise price, in the event of voluntary or involuntary termination of employment of the stockholder. In accordance with Emerging Issues Task Force Issue No. 00-23, *Issues Related to the Accounting for Stock Compensation* under APB 25 and FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, the Company accounts for the cash received in consideration for the early exercised options as a liability. As of September 30, 2008 and December 31, 2007, there were approximately 15,000 and 164,000 shares of common stock, respectively, subject to repurchase, and a related liability of $6,000 and $66,000, respectively.

NOTE 5 - Stock Option Plans

Stock-based compensation and valuation assumptions

The Company calculates the fair value of each option award on the date of grant using the Black-Scholes option pricing model. The following assumptions were used for each respective period:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	**2007**	**2008**	**2007**
Stock Options:				
Expected volatility	63%	51%	60% - 63%	51% - 54%
Risk free rate	3.21% - 3.25%	4.03% - 5.10%	2.45% - 3.25%	4.03% - 5.10%
Dividend yield	0%	0%	0%	0%
Expected term (in years)	4.65	4.65	4.65	4.65
ESPP:				
Expected volatility	100%	42% - 50%	42% - 100%	42% - 50%
Risk free rate	1.90%	4.91% - 5.13%	1.9% - 3.56%	4.91% - 5.13%
Dividend yield	0%	0%	0%	0%
Expected term (in years)	0.5	0.50 to 0.79	0.5	0.50 to 0.79

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The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding and is based on the option vesting term, contractual terms and industry peers as the Company did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. ESPP terms are for the purchase periods starting February 1, 2007 (Initial Public Offering) and May 15, 2007, both of which ended on November 15, 2007, the purchase period that began on November 15, 2007 and ended on May 15, 2008, and the purchase period that began on May 15, 2008 and will end on November 15, 2008.

The expected stock price volatility assumptions for the Company s stock options and ESPP for the three and nine months ended September 30, 2008 and 2007 were determined by examining the historical volatilities for industry peers in combination with the historical volatility of the Company since its Initial Public Offering on February 1, 2007. The Company will continue to analyze its historical stock price volatility and expected term assumptions as more historical data for the Company s common stock becomes available.

The risk-free interest rate assumption at the date of grant is based on the interest rate on U.S Treasury instruments whose term was consistent with the expected term of the Company s stock options and ESPP.

The expected dividend assumption is based on the Company s history and expectation of dividend payouts. In addition, SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. Prior to the adoption of SFAS 123(R), the Company accounted for forfeitures as they occurred.

Stock option activity for the nine months ended September 30, 2008 was as follows:

		Options Outstanding	
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price
	(in thousands, except weighted average exercise price)		
Balance as of December 31, 2007	67	2,167	$ 5.12
Additional shares reserved	1,821		
Options granted	(1,073)	1,073	6.07
Options exercised		(175)	0.61
Options canceled	433	(433)	6.99
Balance as of September 30, 2008	1,248	2,632	$ 5.50

Non-Employee Stock-based Compensation

The Company accounts for equity instruments to or held by non-employees at their fair value on the measurement date in accordance with EITF 96-18. Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. The

Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services rendered.

The fair value of the stock options granted to non-employees is calculated at each reporting date using the Black Scholes options pricing model using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Expected volatility	60%	56%	56% - 60%	56% - 57%
Risk free rate	2.99% to 3.47%	4.32% to 4.48%	2.71% to 4.25%	4.32% to 5.0%
Dividend yield	0%	0%	0%	0%
Contractual remaining term (in years)	6 to 10	7 to 10	6 to 10	7 to 10

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Stock-based compensation expense will fluctuate as the fair value of the common stock fluctuates. In connection with the grant of stock and stock options to non-employees, the Company recorded stock-based compensation charges of approximately $0.8 million for the period from June 13, 2002 (inception) to September 30, 2008. For the nine months ended September 30, 2008 and 2007, the Company recorded stock-based compensation charges for non-employees of approximately $21,000 and $136,000, respectively.

NOTE 6 - Commitments and Contingencies

Operating Lease

In May 2007, the Company entered into an amendment to the lease agreement pursuant to which it leases its offices and manufacturing facilities. The lease amendment extends the term of the lease through May 31, 2012. The Company may terminate the lease for any reason on or after May 1, 2009 with 180 days of notice, and the landlord may terminate the lease with 180 days of notice on or after that date provided it has obtained certain redevelopment rights with respect to the leased premises. In September 2008, the Company entered into another amendment to the lease agreement which extended the lease termination option to May 1, 2010.

As of September 30, 2008, future minimum lease payments under non-cancelable operating leases are as follows:

	Total	Remainder of 2008	2009	2010	2011	2012
			(in thousands)			
Minimum lease commitments	$ 1,811	$ 117	$ 479	$ 493	$ 508	$ 214

Royalty and Milestone Obligations

The Company has entered into royalty agreements with Biosensors and SurModics for proprietary materials that are critical to the success of the Company s products. The terms of the agreements call for milestone payments prior to achieving sales, and quarterly royalty payments based on the greater of specified minimums or a percentage of net sales. As of December 31, 2007 and September 30, 2008, future minimum royalty payments for these suppliers were approximately $2.1 and $2.0 million, respectively. During the year ended December 31, 2007 and nine months ended September 30, 2008, the Company made minimum royalty payments of $40,000 and $60,000, respectively, for each of the periods.

License Agreements

On July 24, 2008, the Company entered into an assignment agreement with Millimed, A/S assigning to the Company the entire and exclusive right, title and interest in certain intellectual property that the Company previously licensed from Millimed pursuant to a license agreement dated July 10, 2006. In consideration of this assignment the Company issued 50,000 shares of unregistered common stock to a third party at $3.00 per share. Pursuant to the terms of the assignment agreement, the third party paid $150,000 directly to Millimed. The $200,000 milestone payment that was required under the original license agreement is no longer required.

The Company also has contingent milestone payments of $20,000 that are payable to another licensor upon achievement of milestones. No milestone payments were made on this license agreement during the year ended December 31, 2007 and the nine months ended September 30, 2008.

Purchase Commitments

In April 2007, the Company entered into a supply agreement with Fortimedix B.V., under which Fortimedix B.V. agreed to manufacture and deliver stents for use in the Company s products. The terms of the agreement require minimum purchases over two years at contractual prices set in Euros. As of September 30, 2008, there were no outstanding purchase order commitments for stents. Under the terms of the supply agreement, any further annual purchase commitments have been delayed until the Company receives approval from the FDA to begin clinical trials in the United States.

In December 2007, the Company entered into the Amended and Restated License Agreement with Biosensors International Group, Ltd., under which the Company purchases the drug and polymer components used on its stents under purchase commitments which totaled approximately $171,000 as of September 30, 2008. In addition, the Company will also pay royalties to Biosensors under the license agreement when revenues are generated from product sales.

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On October 17, 2007, the Company entered into a Contract Research Organization Agreement with Bailer Research, Inc., under which Bailer will provide certain monitoring services with respect to the Company s United States clinical trial when approval is received from the FDA to begin the clinical trial. The commitment under this contract is estimated to be between $11 to $13 million over a period of 79 months. Payments will be made in installments based on trial related milestones.

On January 28, 2008, the Company entered into a contract with Cardiovascular Research Foundation (CRF) under which CRF will perform certain data coordination and analysis services in connection with the Company s clinical trial in the United States. The Company estimates that a total of $6.9 to $7.7 million will be paid to CRF over a period of approximately 75 months. Payments will be made in installments based on related trial milestones.

On April 7, 2008, the Company entered into an agreement with Vascotube GMBH under which the Company has committed to purchase minimum quantities of material over the subsequent twelve month period. As of September 30, 2008, the Company has a remaining commitment in the amount of approximately $459,000 remaining under this agreement.

Contingencies

The Company is not currently subject to any material legal proceedings. The Company may from time to time, however, become a party to various legal proceedings arising in the ordinary course of business.

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with the Company s amended and restated certificate of incorporation and bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company s request in such capacity. The Company also has entered into indemnification agreements with its directors and officers, pursuant to which it has indemnification obligations to them. There have been no claims to date and the Company has a director and officer insurance policy that may enable it to recover a portion of any amounts paid for future claims.

NOTE 7 - Income Taxes

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes: An Interpretation of FASB Statement No. 109* (FIN No. 48). As of September 30, 2008, the Company has no unrecognized tax benefit.

The Company s practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties at September 30, 2008 or December 31, 2007.

The Company files U.S. Federal and California state tax returns. The Company is currently not subject to income tax examinations and, in general, all tax years remain open due to net operating losses.

NOTE 8 Reduction in Force

On July 10, 2008 the Company announced an initiative to reduce employee headcount by eliminating 46 regular jobs and 26 temporary positions. This reduction represented approximately 34% of the total workforce and was completed in July 2008. The total cash payments and expenses incurred in connection with this reduction in workforce was approximately $210,000, including approximately $7,000 of non-cash expenses. All expenses were paid during the quarter ended September 30, 2008.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

INTRODUCTION

The following discussion should be read in conjunction with the financial statements and the related notes included in this Form 10-Q, in our Form 10-K for the year ended December 31, 2007 and in our other filings with the Securities and Exchange Commission, or SEC. This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws. These statements include, but are not limited to, those concerning the following: future events, our future financial performance, business strategy, product introductions and plans and objectives of management for future operations, regulatory approvals and clinical timelines. Forward-looking statements are subject to risks and uncertainties that could cause actual results and events to differ materially. For a detailed discussion of these risks and uncertainties, see Part II, Item 1A Risk Factors below. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-Q.

BUSINESS OVERVIEW

We are a development stage medical device company focused on developing and commercializing our proprietary Custom NX drug eluting stent, or DES, systems to treat coronary artery disease, or CAD. Since inception we have devoted substantially all of our resources to start-up activities, raising capital and performing research and development, including product design, testing, manufacturing and clinical trials. We have focused our development efforts on creating our Custom NX DES Systems, which allow a physician to deploy single or multiple stents of customizable length with a single device. We have not yet received any government regulatory approvals necessary to commercialize any of our products.

We are conducting clinical trials to evaluate our Custom NX stent and stent delivery systems. In October 2008, the one year data from our CUSTOM III clinical trial, the two year data from our CUSTOM II clinical trial and the three year data from our CUSTOM I clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. We believe the data from these clinical trials provides preliminary evidence of safety and efficacy and supports further development of our in-situ customization approach.

CUSTOM I. Our CUSTOM I clinical trial was designed to evaluate the preliminary safety and efficacy of in-situ customization using our proprietary stent technology and drug coating, consisting of a 36mm stent to treat diseased coronary artery lesions in 2.6mm to 3.1mm diameter arteries. Enrollment of 30 patients was completed in July 2005 at three cardiology centers in Europe. Patients were reassessed at 30 days, four months, eight months and 12 months.

CUSTOM II. Our CUSTOM II clinical trial is designed to evaluate the safety of in-situ customization for long lesions and multiple lesions using our Custom NX 60 DES Catheter System. The Custom NX60 was used to treat patients with long lesions or lesions in multiple diseased coronary arteries ranging from 2.5 to 3.0mm in diameter and up to two lesions. Enrollment of 100 patients was completed in October 2006 at ten cardiology centers in Europe. Of the 100 patients enrolled in CUSTOM II, 69 patients were enrolled in the long lesion cohort which consisted of patients with lesions greater than 20mm in length. The remaining 31 patients were enrolled in the two-lesion cohort. Patients were reassessed at 30 days, six months and 12 months. Follow up is scheduled to occur annually for five years.

CUSTOM III. Our CUSTOM III clinical trial was designed to evaluate in-situ customization for long lesions and multiple lesions using an enhanced version of our Custom NX DES Systems. The enhanced version included a number of changes to the handle improving ease-of-use for physician. The primary endpoint of the study was safety with secondary endpoints. The enrollment in the CUSTOM III trial began in September 2006, but was delayed in November 2006 following a sterilization validation problem with the devices to be used in the trial. Enrollment was reinitiated on April 2, 2007 and was completed in August 2007.

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The table below provides a summary of the results to date for our CUSTOM I, CUSTOM II and CUSTOM III clinical trials. The results from our CUSTOM I, II and III clinical trials do not necessarily predict the outcome of a large-scale clinical trial, which will be required for obtaining FDA approval for our products in the United States.

CUSTOM I, II and III Summary of Clinical Trial Results

Clinical Outcomes	**CI + CII + CIII**	**CI + CII + CIII**	**CI + CII**	**C-I**
	N = 220	N = 220	N = 130	N=30
	6M	12M	24M	36M
Cardiac Death [n]	1	1	1	1
MI [n]	8	8	10	2
Q-Wave	2	2	3	
Non Q-Wave	6	6	6	2
TLR [n]	10	13	7	1
Total MACE [%]	8.6%	10%	14.6%	13.3%
Early Stent Thrombosis (30 days or less)	2	2	2	0
Late Stent Thrombosis (more than 30 days)	0	0	1	0

As used in the table above, the term TLR, or Target Lesion Revascularization, means the number of patients at follow-up who required another coronary intervention, such as balloon angioplasty or bypass surgery to treat the same lesion in the artery, within the stent or within 5mm of either side of the stent. The term MI means Myocardial Infarction. The term MACE means Major Adverse Cardiac Event.

We will need CE Mark in the European Union in order to commercialize our products in the European Union and certain other countries that recognize CE Mark. In December 2007, we submitted an application for CE Mark to our European Notified Body using the data from our CUSTOM I, II and III clinical trials. In July 2008, our Notified Body forwarded to us a response from the Medicines Evaluation Board, or MEB, which reviews the drug portion of our CE Mark application. The response indicates that the MEB may require additional clinical data, including a randomized trial, before providing us with CE Mark. In September 2008, we met with staff from the MEB to obtain clarification regarding their response to our CE Mark application. We are currently preparing our response to the MEB s questions which we expect to file by the end of 2008.

We will need premarket approval, or PMA, from the U.S. Food and Drug Administration, or FDA, before we can market our products in the United States, which we expect will require data from large clinical trials with up to 2,000 patients implanted with our products. To initiate our CUSTOM IV trial in the United States, we must first obtain clearance for an investigational device exemption, or IDE, from the FDA. In September 2007, we applied for our IDE and in October 2007 we received questions back from the FDA regarding our IDE application. Since then, we have established an agreed upon timeline of deliverables, and we now expect to commence our pivotal trial in the U.S. in 2009.

In July 2008 we completed an initiative to reduce employee headcount by 46 regular jobs and 26 temporary positions. This reduction represented 34% of the total workforce. The total expense incurred in connection with this reduction in workforce was approximately $210,000, including approximately $7,000 of non-cash expenses. We anticipate that this workforce reduction initiative combined with other cost saving initiatives will result in average monthly expense reductions of approximately $1.3 million.

To date, we have not generated any revenue from our development activities and will not be able to generate revenue until one of our products is approved, if ever. We have incurred net losses in each year since our inception in June 2002. Through September 30, 2008, we had an accumulated deficit of $126.9 million. We expect our losses to continue to increase as we expand our clinical trial activities and initiate commercialization activities. Since inception we have financed our operations primarily through the sale of our equity securities. On February 1, 2007 we completed the initial public offering of our common stock which raised net proceeds of $68.2 million. We are exploring options for seeking additional capital through the sale of our equity securities, and have engaged third party consultants to assist us in this effort. The deterioration of the worldwide macroeconomic environment coupled with the increased volatility of the financial markets may limit the availability and amount of capital available to us. There can be no assurance that we will be able to obtain additional financing on terms acceptable to us, or at all. As a result, our Board is also considering other strategic alternatives. We believe our cash balance of $25.6 million as of the end of the third quarter is sufficient to fund our current scope of activities at least through the second quarter of 2009.

In May 2004, we entered into a license agreement with Biosensors. Pursuant to the agreement, we obtained worldwide non-exclusive rights to use Biosensors drug coating on our products, and agreed to pay specified minimum royalties and royalties based on net sales of our products. In December 2007, we entered into an amended and restated license agreement with Biosensors. Pursuant to the original agreement, Biosensors formulated the drug coating and we purchased the drug coating from them. Under the restated agreement, we have the right to purchase the drug and polymer components separately and formulate the coating ourselves. We have completed the work necessary to perform the formulation ourselves but we will continue to purchase the drug coating formulated by Biosensors until we obtain certain regulatory approvals necessary in order to perform our own formulation for commercial use outside the United States.

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CRITICAL ACCOUNTING POLICIES AND ESTIMATES

We base the discussion and analysis of our financial condition, results of operations and liquidity and capital resources upon our unaudited condensed financial statements, which we prepare in accordance with U.S. generally accepted accounting principles. In preparing these financial statements, we must make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses. We evaluate our estimates based on historical experience and various other assumptions we believe are reasonable under the circumstances. Our actual results could differ materially from these estimates under different assumptions or conditions.

FINANCIAL OPERATIONS

Revenue

To date, we have not generated any revenue from the sale of our stent systems.

Research and Development

Since inception, we have devoted a significant amount of resources to develop our Custom NX DES Systems. We expect our research and development expenditures to increase as we continue to devote significant resources to developing our products, in particular, completing the clinical trials necessary to support regulatory approval. From our inception through September 30, 2008, we incurred $100.3 million in research and development expenses.

General and Administrative

General and administrative expenses consist primarily of compensation for executive, finance, marketing and administrative personnel including stock-based compensation. Other significant expenses include professional fees for accounting and legal services associated with our efforts to obtain and maintain protection for intellectual property related to our Custom NX DES Systems. From our inception through September 30, 2008, we incurred $32.5 million in general and administrative expenses.

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RESULTS OF OPERATIONS

COMPARISON OF THREE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

Revenue

We did not generate any revenue during the three months ended September 30, 2008 or 2007.

Research and Development

	Three Months Ended September 30,		Dollar Change
	2008	2007	
	(in thousands)		
Research and development expenses	$ 6,679	$ 7,767	$ (1,088)

The $1.1 million decrease in research and development expenses for the three months ended September 30, 2008, compared to the three months ended September 30, 2007, was primarily attributable to:

- A decrease of $1.2 million for prototype parts, supplies, and outside services related to product development for our Custom NX DES systems;

- A decrease of $0.2 million in expenses related to the support of our clinical research studies in 2008 as compared to the higher expense related to support of our CUSTOM III clinical trial in the third quarter of 2007;

- A decrease of $0.2 million in personnel costs offset by a $0.2 million increase related to the reduction in force completed in July 2008; partially offset by

- An increase of $0.2 million related to the license agreement with Millimed; and

- An increase of $0.1 million in stock-based compensation expense.

We expect our research and development expenses to increase significantly as we continue the development of our Custom NX DES Systems and conduct additional clinical trials.

General and Administrative

	Three Months Ended September 30,		
	2008	2007	Dollar Change
	(in thousands)		
General and administrative expenses	$ 2,179	$ 2,632	$ (453)

The $0.5 million decrease in general and administrative expenses for the three months ended September 30, 2008, compared to the three months ended September 30, 2007, was primarily attributable to:

- A decrease of $0.3 million in consulting and other administrative services as we implement cost saving measures associated with the reduction in force in July 2008;

- A decrease of $0.1 million in legal and accounting spending;

- A decrease of $0.1 million in personnel costs offset by an increase of approximately $37,000 related to the reduction in force in July 2008;

- A decrease of $0.1 million due to spending for trade shows, travel and marketing materials; partially offset by

- An increase of $0.1 million in employee stock-based compensation expense.

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We expect our general and administrative expenses to increase significantly due to the costs associated with the commercialization of our products.

Interest and Other Income, Net

	Three Months Ended September 30,		Dollar Change
	2008	2007	
	(in thousands)		
Interest and other income, net	$ 193	$ 860	$ (667)

The $0.7 million decrease in interest and other income, net, for the three months ended September 30, 2008, compared to the three months ended September 30, 2007, was primarily attributable to a decrease in the levels of cash, cash equivalents and short-term investments, as well as lower average interest rates.

COMPARISON OF NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

Revenue

We did not generate any revenue during the nine months ended September 30, 2008 or 2007.

Research and Development

	Nine Months Ended September 30,		Dollar Change
	2008	2007	
	(in thousands)		
Research and development expenses	$ 25,918	$ 21,694	$ 4,224

The $4.2 million increase in research and development expenses for the nine months ended September 30, 2008, compared to the nine months ended September 30, 2007, was primarily attributable to:

- An increase of $2.5 million in personnel costs related to the hiring of additional employees in our research and development and manufacturing departments;

- An increase of $0.8 million for prototype parts, supplies, and outside services related to product development for our Custom NX DES systems;

- A increase of $0.7 million in rent, depreciation on equipment and facilities costs as we expanded our manufacturing capacity;

- An increase of $0.3 million in stock-based compensation expense related to headcount increases earlier in the year;

- An increase of $0.2 million related to the license agreement with Millimed; partially offset by

- A decrease of $0.3 million in expenses related to the support of our clinical research studies in 2008 as compared to the higher expense related to support of our CUSTOM III clinical trial during 2007.

General and Administrative

	Nine Months Ended September 30,		Dollar Change
	2008	2007	
	(in thousands)		
General and administrative expenses	$ 8,952	$ 7,894	$ 1,058

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The $1.1 million increase in general and administrative expenses for the nine months ended September 30, 2008, compared to the nine months ended September 30, 2007, was primarily attributable to:

- An increase of $0.9 million in personnel costs related to the hiring of additional employees in our administration departments including approximately $37,000 related to the reduction in force completed in July 2008;

- An increase of $0.2 million in insurance, legal, accounting and other administrative expenses;

- An increase of $0.3 million in rent, depreciation on equipment and facilities costs as we expand our manufacturing capacity; partially offset by

- A decrease of $0.3 million in consulting and other administrative services as we implement cost saving measures associated with the reduction in force in July 2008.

Interest and Other Income, Net

	Nine Months Ended September30,		Dollar Change
	2008	2007	
	(in thousands)		
Interest and other income, net	$ 862	$ 2,658	$ (1,796)

The $1.8 million decrease in interest and other income, net, for the nine months ended September 30, 2008, compared to the nine months ended September 30, 2007, was primarily attributable to a decrease in the levels of cash, cash equivalents and short-term investments, as well as lower average interest rates.

LIQUIDITY AND CAPITAL RESOURCES

Our cash and cash equivalents, and short-term investments balances as of September 30, 2008 and December 31, 2007 are summarized as follows:

	As of September 30, 2008	As of December 31, 2007
	(in thousands)	
Cash and cash equivalents	$ 13,601	$ 13,366
Short-term investments	11,984	44,394
Total cash and cash equivalents and short-term investments	$ 25,585	$ 57,760

Sources of Liquidity

We are in the development stage and have incurred losses since our inception in June 2002. As of September 30, 2008, we had an accumulated deficit of $126.9 million. Prior to our Initial Public Offering, we funded our operations from the private placements of our convertible preferred stock resulting in aggregate net proceeds of $75.6 million through December 31, 2006. On February 1, 2007, we completed our Initial Public Offering, raising $68.2 million in net proceeds. We are exploring options for seeking additional capital through the sale of our equity securities, and have engaged third party consultants to assist us in this effort. The deterioration of the worldwide macroeconomic environment coupled with the increased volatility of the financial markets may limit the availability and amount of capital available to us. There can be no assurance that we will be able to obtain additional financing on terms acceptable to us, or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could require the Company to reduce the scope of, delay, or eliminate some or all of the planned clinical trials, research and development, pursuit of regulatory approvals in certain countries, and commercialization activities, which could have a material adverse effect on the Company s business, results of operations and financial condition.

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The process of developing our products will continue to require significant research and development, clinical trials and regulatory approvals. These activities, together with increases in selling, general and administrative expenses, as we prepare for a commercial launch of our products in Europe, are expected to result in substantial operating losses for the next several years.

As of September 30, 2008, we did not have any outstanding or available debt financing arrangements, we had working capital of $23.4 million, and our primary source of liquidity was $25.6 million in cash and cash equivalents and short-term investments.

Cash Flows

Our operating, investing and financing activities for the nine months ended September 30, 2008 and September 30, 2007 are summarized as follows:

	Nine Months Ended September 30,	
	2008	**2007**
	(in thousands)	
Net cash used in operating activities	$ (31,002)	$ (23,735)
Net cash provided by (used in) investing activities	31,000	(44,745)
Net cash provided by financing activities	237	69,174
Net increase in cash and cash equivalents	$ 235	$ 694

Operating Activities

Net cash used in operating activities was $31.0 million for the nine months ended September 30, 2008, compared to $23.7 million for the nine months ended September 30, 2007. The net cash used in operating activities for the nine months ended September 30, 2008 and 2007 primarily reflects expenses related to product development and clinical trials. These expenses were partially offset by depreciation and amortization, amortization of securities discounts, gain on sale of investments, non-cash stock-based compensation and non-cash changes in operating assets and liabilities.

Investing Activities

Net cash provided by investing activities was $31.0 million for the nine months ended September 30, 2008, compared to net cash used in investing activities of $44.7 million for the nine months ended September 30, 2007. Net cash provided by investing activities for the nine months ended September 30, 2008 was attributable to the proceeds from the sales of investments of $10.0 million and the proceeds from the maturities of investments of $41.1 million, which were partially offset by the purchase of short-term investments of $18.4 million and the purchase of property and equipment of $1.7 million. Net cash used in investing activities for the nine months ended September 30, 2007 was primarily attributable to the purchase of short-term investments of $92.1 million and the purchase of property and equipment of $1.8 million, which was

partially offset by the maturities and sale of short-term investments of $45.2 million and $4.0 million, respectively.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2008 was $237,000, compared to $69.2 million for the nine months ended September 30, 2007. Net cash provided by financing activities for the nine months ended September 30, 2008 was attributable to the proceeds from the exercise of stock options and the purchase of stock through the Employee Stock Purchase Plan. Net cash provided by financing activities for the nine months ended September 30, 2007 was primarily attributable to our Initial Public Offering in February 2007.

Operating Capital and Capital Expenditure Requirements

To date, we have not commercialized any products. We do not anticipate generating any revenue unless and until we successfully obtain CE Mark or FDA marketing approval for, and begin selling, our Custom NX DES Systems. We anticipate that we will continue to incur substantial net losses for the next several years as we develop our products, conduct and complete clinical trials, pursue additional applications for our technology platform, expand our clinical development team and corporate infrastructure, and prepare for the potential commercial launch of our products.

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We believe our cash balance of $25 million as of the end of the third quarter is sufficient to fund our current scope of activities at least through the second quarter of 2009. We are exploring options for seeking additional capital through the sale of our equity securities, and have engaged third party consultants to assist in this effort. The deterioration of the worldwide macroeconomic environment coupled with the increased volatility of the financial markets may limit the availability and amount of capital. There can be no assurance that we will be able to obtain additional financing on terms acceptable to us, or at all. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We will also require additional capital beyond our current cash balance. For example, we will need to raise additional funds in order to build our sales force and commercialize our products. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned clinical trials, research, development and commercialization activities, which could materially harm our business. We anticipate spending approximately $45.0 million to complete our CUSTOM IV and V clinical trials. In addition, we will spend additional funds for regulatory approvals and for activities to commercialize our Custom NX DES Systems, if approved. The development of any new applications of our custom length stent technology and new products will also require the expenditure of significant financial resources and take several years to complete.

Our forecasts for the period of time through which our financial resources will be adequate to support our operations and the costs to complete development of products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the Risk Factors contained in Item 1A of Part II of this report. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the development of medical devices, such as our Custom NX DES Systems, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to complete ongoing clinical trials and successfully deliver a commercial product to market. Our future funding requirements will depend on many factors, including but not limited to:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;

- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;

- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;

- the terms and timing of any collaborative, licensing and other arrangements that we may establish;

- the cost and timing of regulatory approvals;

- the cost and timing of establishing sales, marketing and distribution capabilities;

- the cost of establishing clinical and commercial supplies of our products and any products that we may develop;

- the effect of competing technological and market developments; and

- licensing technologies for future development.

Future capital requirements will also depend on the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Contractual Obligations

Our principal commitments as of September 30, 2008 consist of obligations under operating leases and purchase obligations that we enter into through the normal course of business. See Note 6 of our Notes to Condensed Financial Statements for more detailed information.

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Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet activities as defined in Regulation S-K Item 303(a)(4).

Recent and Adopted Accounting Pronouncements

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (the GAAP hierarchy). SFAS No. 162 will become effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. We do not expect the adoption of SFAS No. 162 to have a material effect on our financial position, operating results or cash flows.

On January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements*, (SFAS 157) as it relates to financial assets and financial liabilities. In February 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position (FSP) No. FAS 157-2, *Effective Date of FASB Statement No. 157,* which delayed the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on at least an annual basis, until January 1, 2009 for calendar year-end entities. Also in February 2008, the FASB issued FSP No. FAS 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13,* which states that SFAS No. 13, *Accounting for Leases,* (SFAS 13) and other accounting pronouncements that address fair value measurements for purposes of lease classification or measurement under SFAS 13 are excluded from the provisions of SFAS 157, except for assets and liabilities related to leases assumed in a business combination that are required to be measured at fair value under SFAS No. 141, *Business Combinations,* (SFAS 141) or SFAS No. 141 (revised 2007), *Business Combinations,* (SFAS 141(R)). SFAS 157 defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States of America, and expands disclosures about fair value measurements. The provisions of this standard apply to other accounting pronouncements that require or permit fair value measurements and are to be applied prospectively with limited exceptions. The adoption of SFAS 157 did not have a material impact on our financial position, operating results or cash flows. We have not yet determined the impact on our financial statements from the adoption of SFAS No. 157 as it pertains to non-financial assets and non-financial liabilities.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest rate risk

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and investments in a variety of marketable securities, including commercial paper, money market funds and U.S. government and agency securities. Our cash and cash equivalents as of September 30, 2008 consist primarily of liquid money market funds. Our short-term investments as of September 30, 2008 consist of U.S. government and agency securities and commercial paper. Due to the short-term nature of our investments, we believe that there is no material exposure to interest rate risk.

Exchange rate risk

Under our Supply Agreement with Fortimedix B.V., we have market risk exposure to adverse changes in foreign exchange rates. The cost of the stents we purchase from Fortimedix requires payment in euros. Fluctuations in the euro to U.S. dollar exchange rate therefore impacts the cost of our product. To date, we have not experienced any significant negative foreign exchange transaction losses. We expect higher product costs if there is a decline in the exchange rate between the U.S. dollar and the euro. Based upon the supply agreement, any further annual purchase commitments have been delayed until we receive approval from the FDA to begin clinical trials in the United States. As a policy, we do not engage in speculative or leveraged transactions, nor do we hold financial instruments for trading purposes.

If we expand our overseas operations, our operating results may become subject to more significant fluctuations based on changes in exchange rates of foreign currencies in relation to the U.S. dollar. We will periodically analyze our exposure to currency fluctuations and may adjust our policies to address any future potential exchange rate risk.

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ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2008.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None

ITEM 1A. RISK FACTORS

Risks Related to Our Business

We are a development stage company with a history of losses, and we expect to incur net losses for the foreseeable future.

We have incurred net losses since our inception in June 2002. For the years ended December 31, 2007, 2006, and 2005, we had net losses of $38.8 million, $25.0 million and $14.0 million, respectively. As of September 30, 2008, we had an accumulated deficit of $126.9 million. To date, we have financed our operations primarily through private placements of our equity securities and our Initial Public Offering, completed on February 1, 2007, and have devoted substantially all of our resources to research and development and clinical studies related to our Custom NX DES Systems, which consist of the Custom NX 36 and the Custom NX 60. Since we have not received CE Mark or approval from the U.S. Food and Drug Administration, or FDA, or any other regulatory authority for our products, we are unable to market our current products and have not generated any revenue since our inception. We expect our research and development expenses to increase significantly in connection with our clinical trials and other product development activities. If we receive CE Mark or FDA approval of our Custom NX DES Systems, we expect to incur significant sales and marketing expenses and manufacturing expenses as we commercialize our products. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses will continue to have an adverse effect on our stockholders equity.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We are exploring options for seeking additional capital through the sale of our equity securities, and have engaged third party consultants to assist in this effort. The deterioration of the worldwide macroeconomic environment coupled with the increased volatility of the financial markets may limit the availability and amount of capital available to us. There can be no assurance that we will be able to obtain additional financing on terms acceptable to us, or at all. As a result, our Board is also considering other alternative strategies. We will need to raise substantial additional capital to:

- fund our operations and clinical trials;

- continue our research and development;

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- scale-up our manufacturing operations;

- defend, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;

- commercialize our products, if any such products receive regulatory approval for commercial sale; and

- acquire or in-license companies, products or intellectual property.

We believe our cash balance of $25.6 million as of the end of the third quarter is sufficient to fund the current scope of activities at least through the second quarter of 2009. However, our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;

- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;

- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;

- the terms and timing of any collaborative, licensing and other arrangements that we may establish;

- the cost and timing of regulatory approvals;

- the cost and timing of establishing sales, marketing and distribution capabilities;

- the cost of establishing clinical and commercial supplies of our products and any products that we may develop;

• the effect of competing technological and market developments;

• licensing technologies for future development; and

• the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Any required additional capital may not be available on reasonable terms, if at all. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. To raise capital, we may decide to sell unregistered stock at a discount to market with or without the issuance of warrants. The sale of securities at a discount or the issuance of warrants may result in additional dilution to our existing stockholders. In connection with this type of financing, we would likely be obligated to register such shares for resale at a later date. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs.

We will require additional capital beyond our current cash balance. For example, we will need to raise additional funds in order to build our sales force and commercialize our products. Any such required additional capital may not be available on reasonable terms, if at all. We anticipate spending approximately $45.0 million to complete our CUSTOM IV and V clinical trials. In addition, we will spend additional funds for regulatory approvals and for activities to commercialize our Custom NX DES systems, if approved. The development of any new applications of our custom length stent technology and new products will also require the expenditure of significant financial resources and take several years to complete.

If adequate funds are not available, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products. Any of these factors could harm our financial condition.

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We are wholly dependent on a third party for the development of the drug coating placed on our drug eluting stents and any delay or failure by such third party to successfully develop the drug coating or to submit acceptable Drug Master Files, or MAFs, to regulatory authorities could delay our clinical trials or prevent or delay commercialization of our Custom NX DES Systems.

In May 2004, we entered into a license agreement with Biosensors. In December 2007, we entered into an amended and restated license agreement with Biosensors which superseded the prior agreement. Pursuant to the agreement, we obtained non-exclusive rights to use Biosensors drug coating on our stent platform. The drug coating consists of Biolimus A9® , an anti-inflammatory drug that is a derivative of rapamycin, and PolyLactic Acid, orPLA, a biodegradable polymer used to release the drug over time. In January 2008, Biosensors announced that it had received CE Mark approval for its BioMatrix drug eluting stent which uses the Biolimus A9 and PLA drug coating. The drug coating has not been approved for any use in the United States or any other jurisdiction.

To date, Biosensors has made only limited public disclosures regarding filings it has made with the FDA in connection with the Drug Master File, or MAF, for its BioMatrix drug eluting stent. In order to obtain CE Mark and IDE approval for our Custom NX DES Systems, we require Biosensors, acting on our behalf, to submit MAFs related to our drug coating to our Notified Body and the FDA. Although Biosensors received CE Mark for its Biomatrix stent, there can be no guarantee that any MAF that Biosensors submits to a regulatory authority on our behalf will be acceptable.

We submitted our application for CE Mark of our Custom NX DES systems in December 2007. In July 2008, our Notified Body forwarded to us a response from the Medicines Evaluation Board, or MEB, which reviews the drug portion of our CE Mark application. The response indicates that the MEB may require additional clinical data, including a randomized trial before providing us with CE Mark. In September 2008, we met with staff from the MEB to obtain clarification regarding their response to our CE Mark application. We are currently preparing our response to the MEB s questions which we expect to file by the end of 2008. As part of our application for CE Mark, Biosensors submitted a MAF related to our drug coating to the designated Notified Body who reviews our CE Mark application. We will have to obtain a favorable opinion on this MAF from the MEB in the Netherlands before our designated Notified Body can provide us with CE Mark.

In July 2008, Biosensors received questions from the MEB regarding the MAF. Any delays Biosensors experiences or problems it has in responding to these questions may substantially delay the commercialization of our Custom NX DES systems in Europe as well as certain non-European countries that recognize the European Union s CE Mark.

In order to obtain IDE approval from the FDA allowing us to initiate our CUSTOM IV clinical trial in the United States and in order to obtain the PMA allowing us to commercialize our Custom NX DES Systems in the United States, we need Biosensors to submit acceptable MAFs related to our drug coating to the FDA on our behalf. Any delays Biosensors experiences or problems it has in developing these acceptable MAFs or responding to questions the FDA may have concerning the MAFs may substantially delay our currently planned clinical trials and the development of our products and we may be required to restart clinical programs with an alternative drug coating.

In the event we experience these delays or need to restart clinical programs, our regulatory and commercialization timelines will need to be extended and we may experience a significant decline in our stock price.

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We currently do not have, and may never have, any products available for sale and our efforts to obtain product approvals and commercialize our products may not succeed or may result in delays for many reasons.

We are a development stage medical device company with a limited history of operations and we currently do not have any products available for sale or other sources of revenue. Our ability to generate revenue depends entirely upon the successful clinical development, regulatory approval and commercialization of our Custom NX DES Systems. Our products under development and any other products that we develop will require extensive additional clinical testing, regulatory approval and significant marketing efforts before they can be sold and generate any revenue. Our efforts to commercialize our products may not succeed for a number of reasons including:

- our products may not demonstrate safety and efficacy in our clinical trials;

- we are wholly dependent on the efforts undertaken by the supplier of the drug coating for our products, and may be significantly impacted by any regulatory delays or barriers that our supplier may encounter in submitting an adequate or acceptable MAF for the drug coating to the regulatory authorities on our behalf;

- we may not be able to obtain regulatory approvals for our products, or the approved indications for our products may be narrower than we seek;

- we may experience delays in our development program, including initiation and completion of our clinical trials;

- any products that are approved may not be accepted in the marketplace by physicians and patients;

- physicians may not receive adequate coverage and reimbursement for procedures using our products;

- any rapid technological change may make our technology and products obsolete;

- we may not be able to manufacture our Custom NX DES Systems in commercial quantities or at an acceptable cost;

• we may not have adequate financial or other resources to complete the development and commercialization of our Custom NX DES Systems; and

• we may be sued for infringement of intellectual property rights and could be enjoined from manufacturing or selling our products.

We cannot market our products in the European Union until we receive CE Mark or in the United States until we receive PMA. If we are not successful in the initiation and completion of clinical trials for the development, approval and commercialization of our Custom NX DES Systems for the treatment of coronary artery disease, or CAD, we may never generate any revenue and may be forced to cease operations.

We have not received, and may never receive, FDA or other regulatory approvals to market our Custom NX DES Systems.

Our Custom NX DES Systems are combination products, incorporating both a drug element and a medical device, and the combination device will be regulated as a Class III medical device in the United States. Information regarding the drug coating for our stents will be reviewed by the FDA s Center for Drug Evaluation and Research, or CDER, based on the MAF submitted by Biosensors on our behalf, and the device will be reviewed by the FDA s Center for Devices and Radiological Health, or CDRH, with the overall product subject to approval by CDRH as a medical device. We believe that no separate approval for the drug independent of the device is required.

We do not currently have the necessary regulatory approvals to market our Custom NX DES Systems or any other products in the United States or in any foreign market, including the European Union. If we obtain the necessary regulatory approvals, we plan initially to launch our products in the European Union and later in the United States. Regulatory approval in the European Union for our products will require us to successfully obtain CE Mark from our designated Notified Body. In March 2007, the European Medicines Agency proposed new guidelines for the approval of drug eluting stents. These new guidelines, which are more rigorous than the previous standards, were finalized in May 2008 and will become effective in December 2008.

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The regulatory approval process in the United States for our products involves, among other things, successfully receiving authorization from the FDA to conduct clinical trials under an investigational device exemption, or IDE, completing pre-clinical and clinical trials, and applying for and obtaining PMA from the FDA. The PMA process requires us to demonstrate the safety and efficacy of our products to the FDA s satisfaction. This process is expensive and uncertain and requires detailed and comprehensive scientific and human clinical data. While the FDA review process generally takes one to three years after filing the PMA application, our PMA application review could take much longer and may never result in the FDA granting PMA. The FDA could delay, limit or deny approval of our PMA application for many reasons, including:

• our stent systems may not be safe or effective or may not otherwise meet the FDA s requirements;

• the data from our pre-clinical studies and clinical trials may be insufficient to support approval;

• the manufacturing process or facilities we or our suppliers use may not meet stringent regulatory requirements;

• the information provided by the supplier of the drug coating in the MAF it submits to the FDA on our behalf may be inadequate; and

• changes in FDA approval policies or adoption of new regulations may require us to provide additional data.

We will also have to obtain similar, and in some cases more stringent, foreign regulatory approval in order to commercialize our products outside of the United States. Even if approved, our Custom NX DES Systems may not be approved for the indications that are necessary or desirable for successful commercialization. We may not obtain the necessary regulatory approvals to market our products in the European Union, United States or in other markets. Any delay in, or failure to receive or maintain, approval for our products could prevent us from generating revenue or achieving profitability.

Preliminary third-party data has raised concerns that drug eluting stents may cause an increase in late-stent thrombosis. In response to these concerns, regulatory authorities in the United States and Europe have issued statements and developed enhanced guidelines for the approval of drug eluting stents. As a result of these enhanced guidelines we may experience further delays in obtaining regulatory clearances for our products and, even if approved, the preliminary third-party data concerning late-stent thrombosis may significantly impair market acceptance of our products.

On September 14, 2006, the FDA issued a *Statement on Coronary Drug-Eluting Stents* , which discusses clinical data presented at the March 2006 American College of Cardiology Scientific Sessions in Atlanta, Georgia and at the September 2006 European Society of Cardiology Annual Meeting/World Congress of Cardiology Meeting in Barcelona, Spain. This data suggested a small but significant increase in the rate of death and myocardial infarction, or heart attack, potentially due to late-stent thrombosis, in patients treated with drug eluting stents at 18 months to three years after stent implantation. The FDA stated that, while these studies have raised important questions regarding the safety and efficacy of drug eluting stents, it is not possible to fully characterize the mechanisms, risks and incidence rates of late-stent thrombosis following

implantation of drug eluting stents based on currently available data. The FDA has not issued any new position to date regarding the safety of drug eluting stents. Although more recent studies have suggested that the safety of drug eluting stents is comparable to that of bare metal stents, the FDA and the European regulatory agencies have issued new guidelines for the approval of drug eluting stents which require additional clinical data and may prolong the process for obtaining regulatory approval.

In March 2007, the European Medicines Agency proposed new guidelines for the approval of drug eluting stents. These new guidelines, which are more rigorous than the previous standards, were finalized in May 2008 and will become effective in December 2008.

In March 2008, the FDA published draft guidance regarding non-clinical and clinical studies for drug eluting stents. The draft guidance includes recommendations regarding the following areas:

- Engineering testing,

- Biocompatibility testing,

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- Animal studies,

- Chemistry and manufacturing controls,

- Clinical pharmacology and drug release,

- Drug pharmacology, toxicology and safety data,

- Clinical studies, and

- Post approval studies.

In April 2008, the FDA also conducted a public workshop on the draft guidance documents and provided clarification on the above matters. Although the draft guidelines are currently considered non-binding recommendations, they have been published for public comment and it is expected that the FDA will conduct any application review for new drug eluting stent catheter systems following the general principles highlighted in the guidance.

Complying with the new and more rigorous standards in the United States and Europe may require us to obtain additional data or conduct further studies. This may delay regulatory approval of our products. In addition, if in the future, new studies raise questions concerning the safety of drug eluting stents, the DES market in general may shrink and market acceptance of our products may be significantly impaired.

If Biosensors fails to supply us with sufficient quantities of our drug coating, development and commercialization of our Custom NX DES Systems may be prevented or delayed as a result.

We obtain our entire supply of the drug coating, PLA and BA9 for our stents from Biosensors and we are unaware of any alternative source for this drug coating. Under the amended and restated license agreement which we entered into with Biosensors in December 2007, we have the right to purchase the components of the drug coating, which are the drug and the PLA, from Biosensors in order to perform the coating formulation ourselves. We have completed the work necessary to perform the formulation ourselves, but we will continue to purchase the formulated drug coating from Biosensors until we obtain certain regulatory approvals necessary in order to perform our own formulation for commercial use outside the United States. We do not have the right to use alternate suppliers for this drug coating that we obtain from Biosensors, or the components of the drug coating which we plan to purchase from them in the future. In addition, there is no other source for the drug coating or components and we are contractually restricted from obtaining Biolimus A9 from any other source and we have not in-licensed an alternative drug for use in the event we are unable to obtain a sufficient supply of Biolimus A9. Currently, Biosensors relies on a

sole-source, Nippon Kayaku, a third-party Japanese pharmaceutical company, to manufacture and supply them with Biolimus A9, which Biosensors mixes with the PLA. We have no relationship with, control over, or contact with this pharmaceutical company and cannot contract directly with it to obtain Biolimus A9 if we are unable to obtain Biolimus A9 from Biosensors. In addition, the pharmaceutical company is subject to significant legal and regulatory requirements with regard to the production of Biolimus A9, including onerous current Good Manufacturing Practices regulations, or GMP, which are strictly enforced by the FDA, and the Ministry of Health, Labor, and Welfare in Japan and any failure on the part of the pharmaceutical company to comply with these requirements may interrupt Biosensors supply of Biolimus A9 and ultimately, our supply of the drug coating. Biosensors has also entered into, and may continue to enter into, agreements to supply the drug coating to other licensees. Our clinical trials and the development and commercialization of our Custom NX DES Systems could be prevented or delayed if:

• the supplier of our drug coating is unable or refuses to meet our demand;

• our license agreement with Biosensors terminates for any reason, including insolvency or our failure to obtain CE Mark or commercialize within one year of the date upon which the MAF that Biosensors submits in connection with our CE Mark application is approved by the MEB; or

• the supplier of our drug coating does not meet regulatory quality requirements and other specifications, certain regulatory approvals need to be obtained.

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To date, our drug coating requirements have been limited to small quantities that we need to conduct our development and pre-clinical and clinical trials. If we obtain market approval for our products, we anticipate that we will require substantially larger quantities of the drug coating or the components of the drug coating. Biosensors may not provide us with sufficient quantities of the drug coating or components and such supply may not meet our quality requirements or other specifications. For example, we have, in the past, experienced interruptions in the supply of adequate quantities of acceptable drug coating. In addition, Biosensors has informed us that it plans to close its Newport Beach, California facility where the drug coating that it currently supplies to us is formulated. In order to use drug coating formulation prepared at another Biosensors facility, or at our own facility, for the manufacture of devices intended for commercial use outside the United States, certain regulatory approvals need to be obtained. If such regulatory approvals are not acquired before the closure of the Newport Beach facility, we may experience an interruption in the supply of drug coating suitable for commercial use outside the United States. In the event we do not receive adequate supplies of acceptable drug coating or components, we will likely be unable to locate an alternative supplier, or any alternative drug, in a timely manner or on commercially reasonable terms, if at all. Any additional new source for Biolimus A9, the PLA or the drug coating will require the consent of Biosensors and prior FDA approval, which will require significant time and effort to obtain and there can be no assurance that we will obtain such regulatory approval. The inability to obtain sufficient quantities of the drug coating or components, or any delay in obtaining such supply could delay our clinical trials or affect the commercialization of our Custom NX DES Systems, which could have a significant adverse affect on our future operations.

We rely on third parties to test the drug coating for our stents, and these third parties may use test methods that others may claim as their own. If we must obtain a license to use these methods or develop new testing methods, we may experience delays in our ability to initiate clinical trials or to obtain regulatory approvals for our products as a result.

Certain tests related to the drug coating on our stents must be performed before the stents can be used in clinical trials or approved for commercial sale. We have agreed with Biosensors that we will be responsible for performing some of these tests. We have not developed the technology or methods to perform all this testing in-house, and plan to rely on third parties to conduct some of the testing. We have identified certain third parties who we believe have the capability to conduct this testing using methods that do not violate the proprietary rights of others. We can provide no assurance, however, that these testing methods will not violate such rights. If others assert rights to these testing methods, we may need to obtain a license giving us the right to use the testing methods or identify or develop other methods for performing the required testing. We cannot assure you that a license will be available to us or that it will be available on terms that are agreeable to us. If we are unable to obtain a license, we cannot assure you that we will be able to identify or develop alternate testing methods that meet our needs without delaying our regulatory submissions or approvals. This may result in a delay in the release of, or an inability to release, our stents for use in U.S. clinical trials or commercial products and our ability to generate revenue would be adversely affected as a result.

We do not have long-term data regarding the safety and efficacy of our Custom NX DES Systems. Any long-term data that is generated may not be consistent with our limited short-term data, which could affect the regulatory approval of our products or the rate at which our products are adopted.

An important factor in our clinical trials, upon which the safety and efficacy of our Custom NX DES Systems may be measured, is the rate of restenosis, or the renarrowing of the treated artery over time, and the rate of reintervention, or retreatment following the procedures using the Custom NX DES Systems. We believe that physicians and regulators will compare the rates of long-term restenosis and reintervention for our Custom NX DES Systems against other drug eluting or bare metal stent procedures and other alternative procedures.

If, in our planned large-scale comparative pivotal clinical trial, we fail to demonstrate restenosis and reintervention rates, as well as other clinical trial end-points and performance, comparable to other drug eluting and bare metal stents that have been approved by the FDA, our ability to successfully market our Custom NX DES Systems may be significantly limited. If the long-term rates of restenosis and reintervention do not meet regulators or physicians expectations, our Custom NX DES Systems may not receive regulatory approval or, if approved, may not become

widely adopted and physicians may recommend that patients receive alternative drug eluting stents, such as the Cypher ® stent, the Taxus ® Express2 stent, the Taxus Liberte stent, the Endeavor® stent, the Xience™ V stent and the Promus™ stent, the six drug eluting stents currently marketed in the United States. Another important factor upon which the safety and efficacy of our Custom NX DES Systems will be measured is the incidence of late-stent thrombosis following procedures using our drug eluting stents. Some clinical data suggests a small but significant increase in the rate of death and heart attack associated with drug eluting stents when compared to bare metal stents, possibly due to late-stent thrombosis. The FDA convened a public meeting of its Circulatory System Devices Advisory Panel on December 7 and 8, 2006 with the intention of obtaining additional information on the risks, timing and incidence rates of late-stent thrombosis. In March 2008, the FDA published draft guidance regarding non-

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clinical and clinical studies for drug eluting stents See Preliminary third-party data has raised concerns that drug eluting stents may cause an increase in late-stent thrombosis. We cannot assure you that our long-term data, once obtained, will be different than that suggested in the recent studies regarding late-stent thrombosis.

Additionally, other efficacy factors may influence a physician s decision over what stents to deploy. Our Custom NX DES Systems stent segments may separate excessively at the time of deployment in the artery or over time. Any such separation may lead to restenosis occurring between the segments or other adverse events. If the results obtained from our clinical trials indicate that our products are not as safe or effective as other treatment options or as current short-term data would suggest, our products may not be approved, adoption of our products may suffer and our business would be harmed.

If our pre-clinical studies or clinical trials do not meet safety or efficacy endpoints, or if we experience significant delays in completing these studies or trials, our ability to commercialize our Custom NX DES Systems or other products and our financial position will be impaired.

Before marketing and selling our Custom NX DES Systems or any other products, we must successfully complete pre-clinical studies and clinical trials that demonstrate that our products are safe and effective. We currently have a very limited amount of clinical data regarding the safety and efficacy of our Custom NX DES Systems, and no published data beyond two years. The results from our limited short-term clinical experience for our Custom NX DES Systems do not necessarily predict long-term clinical benefit and may not be replicated in subsequent clinical trials. Furthermore, all of our existing data has been produced in studies that involve relatively small patient groups, and the data may not be reproduced in wider patient populations. We plan to conduct additional large-scale clinical trials to determine whether our products are safe and effective and to support our applications for regulatory approval in the United States. We expect that one or more of these additional clinical studies will be a comparative study comparing the safety and efficacy of our stents to the Xience stent, the Promus stent, the Cypher stent, the Taxus Express2 stent, the Taxus Liberte stent or the Endeavor ® stent, the six drug eluting stents marketed in the United States, or to other stents that may become approved for marketing in the United States, and that these studies will involve large patient populations of approximately 2,000 patients implanted with our device.

The commencement or completion of any of our clinical trials may be delayed or halted for numerous reasons, including, but not limited to, the following:

• Biosensors fails to submit on our behalf and in a timely fashion, if at all, a MAF for the drug coating with the FDA, or such filing fails to meet regulatory requirements;

• Biosensors fails to respond in a timely manner, if at all, to questions that the FDA may have concerning a MAF Biosensors submits to the FDA on our behalf, in connection with our IDE submission;

• the FDA or other regulatory authorities do not approve our clinical trial protocols or our clinical trials, or suspend or place a clinical trial on hold;

• patients do not enroll in clinical trials at the rate we expect;

• third-party clinical investigators do not conduct follow-up visits with patients or patients drop out of the clinical trial at rates we do not expect;

• patients experience adverse events, which may or may not be related to our products;

• patients die during a clinical trial for a variety of reasons, including the advanced stage of their disease and medical problems, which may or may not be related to our products;

• third-party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other regulatory requirements, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;

• regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials if investigators find us or our suppliers not in compliance with regulatory requirements;

• changes in governmental regulations or administrative actions;

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- the interim results of our clinical trials are inconclusive or negative; or

- our clinical trial designs, although approved, are inadequate to demonstrate safety and/or efficacy.

Before we can commence our planned pivotal clinical trial in the United States for our Custom NX DES Systems, we must receive the FDA s approval of our IDE application. In September 2007, we applied for our IDE and in October 2007 we received questions back from the FDA regarding our IDE application. Since then, we have established an agreed upon timeline of deliverables and we now expect to commence our pivotal trial in the U.S. in 2009.

Product development, including pre-clinical studies and clinical testing, is a long, expensive and uncertain process and is subject to delays. It may take us several years to complete our testing, if we complete it at all, and a clinical trial may fail at any stage. Furthermore, data obtained from any clinical trial may be inadequate to support a PMA application or any foreign regulatory applications. Additionally, pre-clinical and clinical data can also be interpreted in different ways, which could delay, limit or prevent regulatory approval for our products.

Clinical trials necessary to support a PMA application will be expensive and will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

Clinical trials necessary to support a PMA application for our Custom NX DES Systems will be expensive and will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. The clinical trials supporting the PMA applications for the Cypher stent, the Taxus Express2 stent and the Endeavor stent, which are approved by the FDA and currently marketed, involved patient populations of approximately 1,000, 1,300 and 1,100 respectively. We expect that we will provide the FDA with data on approximately 2,000 patients implanted with our device, with 12-month follow-up to support our PMA application. The FDA may require us to submit data on a greater number of patients or a longer follow-up period. For example, at an FDA workshop held in April 2008, the FDA recommended 18 month follow-up on at least 50% of patients. Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of our products, or they may be persuaded to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays or result in the failure of the clinical trial.

Physicians may not widely adopt our Custom NX DES Systems unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our Custom NX DES System provides a safe and effective alternative to other existing treatments for coronary artery disease, and meets other physician expectations.

Physicians tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party coverages and reimbursement. We believe that physicians will not widely adopt our Custom NX DES Systems unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our Custom NX DES Systems provides a safe and effective alternative to other existing treatments for coronary artery disease, including coronary artery bypass

grafting, or CABG, balloon angioplasty, bare metal stents and other drug eluting stents, such as Johnson & Johnson s Cypher stent and Boston Scientific s Taxus Express2 stent. In particular, the use of bare metal stents has reportedly increased, and the use of drug eluting stents has reportedly decreased, at certain hospitals in the United States and elsewhere as a result of recent clinical data indicating a higher incidence rate of late stent thrombosis. We cannot predict the effect that this or other data questioning the safety of drug eluting stents will have on the drug eluting stent market.

We cannot provide any assurance that the data collected from our current and planned clinical trials will be sufficient to demonstrate that our Custom NX DES Systems are an attractive alternative to other drug eluting stent procedures. If we fail to demonstrate safety and efficacy that is at least comparable to other drug eluting or bare metal stents that have received regulatory approval and that are available on the market, our ability to successfully market our Custom NX DES Systems will be significantly limited. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician s actual experience with our Custom NX DES Systems will vary. Clinical trials conducted with our Custom NX DES Systems have involved procedures performed by physicians who are technically proficient and are high-volume users of drug eluting stents. Consequently, both short- and long-term results reported in these clinical trials may be significantly more

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favorable than typical results of practicing physicians, which could negatively impact rates of adoption of our products. In addition to safety and efficacy, we believe that product characteristics such as ease of use and consistency of performance are also important. If we are not able to meet physician expectations with respect to these characteristics, market acceptance and adoption of our products may be impacted. We also believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our Custom NX DES Systems will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published.

Problems with the stent to be used in the control group during our planned U.S. pivotal clinical trial could adversely affect its outcome.

We expect our pivotal clinical trial in the United States to compare the performance, including safety and efficacy, of our products against that of a currently marketed drug eluting stent, or a drug eluting stent that becomes approved for marketing in the near future. Our planned pivotal clinical trial could be significantly delayed or harmed if the stent we use for the control group experiences problems. We may use one of the six currently marketed drug eluting stents, the Xience V stent, the Promus stent, the Cypher stent, the Taxus Express2 stent, the Taxus Liberte stent or the Endeavor stent, or a drug eluting stent that becomes approved for marketing in the near future, as the control stent in our planned pivotal clinical trial. In July 2004, Boston Scientific announced the recall of approximately 85,000 Taxus stent systems and approximately 11,000 Express2 stent systems due to characteristics in the delivery catheters that had the potential to impede balloon deflation during a balloon angioplasty procedure. In August 2004, Boston Scientific announced that it would recall an additional 3,000 Taxus stents. If prior to or during the enrollment and treatment period for our planned pivotal clinical trial, there is a recall of the control stent or the control stent is removed from the market, our trial would likely be substantially delayed. The FDA could also require us to redesign the clinical trial based on an alternative control stent. Any significant delay or redesign could impair our ability to commercialize our Custom NX DES Systems.

Our products are based on a new technology, and we have only limited experience in regulatory affairs, which may affect our ability or the time required to obtain necessary regulatory approvals, if at all.

Drug eluting stents were introduced in the United States in 2003. To date, the FDA has approved only the Taxus Express2, the Taxus Liberte, the Cypher, the Endeavor, the Xience V and the Promus drug eluting stents for commercial sale. Because drug eluting stents are relatively new and long-term success measures have not been completely validated, regulatory agencies, including the FDA, may take significantly more time in evaluating product approval applications for those types of products. For example, there are currently several methods of measuring restenosis and we do not know which of these metrics, or combination of these metrics, will be considered appropriate by the FDA for evaluating the clinical efficacy of stents. Treatments may exhibit a favorable measure using one of these metrics and an unfavorable measure using another metric. Any change in the accepted metrics may result in reconfiguration of, and delays in, our clinical trials. Furthermore, the result of recent studies suggesting a correlation between drug eluting stents and incidents of late-stent thrombosis may further delay and complicate the regulatory pathway for our products. Additionally, we have limited experience in filing and prosecuting the applications necessary to gain regulatory approvals, and we have limited personnel and resources to dedicate to the filing and prosecution of these applications. As a result, we may experience a long regulatory process in connection with obtaining regulatory approvals for our products.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

We do not have the ability to independently conduct clinical trials for our products, and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. In addition, we rely on third parties to assist with the pre-clinical development of our products. If these third parties do not successfully carry out their contractual duties or

regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our products on a timely basis, if at all. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

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Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. In particular we and our suppliers are required to comply with the Quality System Regulation, or QSR, for the manufacture of our Custom NX DES Systems and GMP for the manufacture of our drug coating and other regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing approval. The FDA enforces the GMP and QSR through unannounced inspections. We and our third-party manufacturers and suppliers have not yet been inspected by the FDA and will have to successfully complete such inspections before we receive regulatory approvals for our products. Failure by us or one of our suppliers, including the supplier of our drug coating, to comply with statutes and regulations administered by the FDA and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following enforcement actions:

- warning letters or untitled letters;
- fines and civil penalties;
- unanticipated expenditures;
- delays in approving, or refusal to approve, our products;
- withdrawal or suspension of approval by the FDA or other regulatory bodies;
- product recall or seizure;
- orders for physician notification or device repair, replacement or refund;
- interruption of production;
- operating restrictions;

- injunctions; and

- criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed. If the FDA determines that our promotional materials, training or other activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Moreover, any modification to a device that has received FDA approval that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new approval from the FDA. If the FDA disagrees with any determination by us that new approval is not required, we may be required to cease marketing or to recall the modified product until we obtain approval. In addition, we could also be subject to significant regulatory fines or penalties.

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In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or efficacy of our products, and we will be required to report adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR or GMP, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties. For example, Boston Scientific has initiated significant recalls of its stent products due to manufacturing and other quality issues associated with the products.

Further, healthcare laws and regulations may change significantly in the future. Any new healthcare laws or regulations may adversely affect our business. A review of our business by courts or regulatory authorities may result in a determination that could adversely affect our operations. Also, the healthcare regulatory environment may change in a way that restricts our operations.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

We intend to market our products in international markets. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals, and may need to conduct additional clinical trials. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Risks Related to Our Intellectual Property

Third parties hold a large number of patents related to stents and we do not have rights to many of these patents.

Intellectual property rights, including in particular patent rights, play a critical role in the medical device industry, and therefore in our business. We face significant risks relating to patents, both as to our own patent position as well as to patents held by third parties. If any third-party intellectual property claim against us is successful, we could be prevented from commercializing our Custom NX DES Systems or other products.

There are numerous U.S. and foreign issued patents and pending patent applications owned by third parties with patent claims in areas that are the focus of our product development efforts. We are aware of patents owned by third parties, to which we do not have licenses, that relate to, among other things:

- use of rapamycin or its analogs to treat restenosis;

- stent structures and materials;

- catheters used to deliver stents; and

- stent manufacturing and coating processes.

Cordis, a subsidiary of Johnson & Johnson, is the owner of a number of patents and patent applications directed to the use and delivery of rapamycin or its analogs mixed in a polymer coating on a drug eluting stent for the treatment of restenosis. These include, without limitation, the Wright family of patents and the Falotico family of patents. Wyeth owns, and has licensed to Cordis, the Morris family of patents which are directed to the use of rapamycin for the treatment of restenosis, including the delivery of rapamycin from a stent impregnated with the drug.

Boston Scientific holds rights to the Grainger family of patents directed to methods of inhibiting smooth muscle cell proliferation, or growth, using certain compounds and to the Kunz family of patents directed to methods for maintaining vessel luminal area with a stent that includes a cytostatic, or cell division inhibiting, agent.

Various patents owned by third parties are directed to stent structures and materials. These patents include a group of Lau patents that were owned by Guidant Corporation, a newly acquired subsidiary of Boston Scientific whose stent technology has been acquired by Abbott Vascular subject to certain rights retained by Boston Scientific, which are directed to flexible stent structures. The Boneau family of patents, owned by Medtronic, are directed to stents comprising multiple

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closed-loop elements. The Fariabi family of patents, formerly owned by Guidant, are directed to stents comprising cobalt- chromium alloys. The Israel and Pinchasik families of patents, owned by Medinol, are directed to stents with meandering strut patterns. A patent owned by Wall is directed to a radially collapsible mesh sleeve.

Other third-party patents are directed to stent delivery catheter technology. There are also a number of patents that were held by Guidant Corporation directed to rapid exchange catheters for angioplasty and stent delivery. These include, without limitation, the Yock and Horzewski families of patents, directed to rapid exchange angioplasty catheters, and the Lau family of patents directed to rapid exchange stent catheters. Boston Scientific owns other patents directed to rapid exchange angioplasty catheters, including, the Bonzel family of patents. Medtronic owns certain patents directed to guidewire handling technology in stent delivery catheters, including certain patents issued to Crittenden and Kramer. A patent issued to Fischell is directed to a sheathed stent delivery catheter. Guidant Corporation also held a patent issued to Cox, directed to a stent delivery catheter having an adjustable-length balloon. Certain patents owned by Boston Scientific or its subsidiaries are also directed to stent delivery catheters having adjustable-length balloons. Certain patents owned by third parties relate to methods for coating stents. For example, the Hossainy family of patents that were held by Guidant Corporation are directed to methods of coating stents with a primer layer and a reservoir layer.

While one of the Yock patents directed to rapid exchange angioplasty catheters was due to expire in October 2008, Abbott has filed an application for patent extension under the Hatch-Waxman Act and was recently granted an interim extension of the patent term for a period of one year by the US Patent and Trademark Office. Before October, 2009, the US Patent and Trademark Office will determine the total length of the extension to which Abbott may be entitled under the Hatch-Waxman Act. This could result in an extension of the term of this patent even beyond October 2009.

The patents described above could be found to cover our technology and may materially and adversely affect our business. In addition, these patents are given only as examples and there may be other patents in addition to those described above that may materially and adversely affect our business. Moreover, because patent applications can take many years to issue and remain confidential for the first 18 months after filing, there may be currently pending applications, unknown to us, which may later result in issued patents that pose a material risk to us.

Many of our competitors are much larger than we are, with significant resources and incentives to initiate litigation against us.

Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our Custom NX DES Systems based on one or more of these patents. It is also possible that a lawsuit asserting patent infringement and related claims will be filed against us and it is possible that a lawsuit may have already been filed against us of which we are not aware. A number of these patents are owned by very large and well-capitalized companies that are active participants in the stent market. As the number of competitors in the drug eluting stent market grows, the possibility of inadvertent patent infringement by us or a patent infringement claim against us increases.

These companies have maintained their position in the market by, among other things, establishing intellectual property rights relating to their products and enforcing these rights aggressively against their competitors and new entrants into the market. All of the major companies in the stent and related markets, including Abbott Vascular (which acquired Guidant s stent technology), Boston Scientific, Johnson & Johnson and Medtronic, have been repeatedly involved in patent litigation relating to stents since at least 1997. For example, in the past year Boston Scientific, Medtronic, and Abbott Vascular have each been sued by Johnson & Johnson and/or Wyeth for infringement of the Morris, Wright,

and/or Falotico patents. The stent and related markets have experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay the introduction of new products and technologies. We may pose a competitive threat to many of the companies in the stent and related markets. Accordingly, many of these companies will have a strong incentive to take steps, through patent litigation or otherwise, to prevent us from commercializing our products.

Any lawsuit, whether initiated by us to enforce our intellectual property rights or by a third party against us alleging infringement, may cause us to expend significant financial and other resources, and may divert our attention from our business.

In any infringement lawsuit, a third party could seek to enjoin, or prevent, us from commercializing our Custom NX DES Systems or any future products, may seek damages from us and any such lawsuit would likely be expensive for us to defend against. Our involvement in intellectual property litigation could result in significant expense. Some of our competitors, such as Boston Scientific, Johnson & Johnson, Abbott Vascular and Medtronic, have considerable resources

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available to them and a strong economic incentive to undertake substantial efforts to stop or delay us from bringing our Custom NX DES Systems to market and achieving market acceptance. We, on the other hand, are a development stage company with comparatively few resources available to us to engage in costly and protracted litigation. A court may determine that patents held by third parties are valid and infringed by us and we may be required to:

• pay damages, including up to treble damages and the other party s attorneys fees, which may be substantial;

• cease the development, manufacture, use and sale of products that infringe the patent rights of others, including our Custom NX DES Systems, through a court-imposed sanction called an injunction;

• expend significant resources to redesign our technology so that it does not infringe others patent rights, or to develop or acquire non-infringing intellectual property, which may not be possible;

• discontinue manufacturing or other processes incorporating infringing technology; or

• obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

Any development or acquisition of non-infringing products or technology or licenses could require the expenditure of substantial time and other resources and could have a material adverse effect on our business and financial results. If we are required to, but cannot, obtain a license to valid patent rights held by a third party, we would likely be prevented from commercializing the relevant product. We believe that it is unlikely that we would be able to obtain a license to any necessary patent rights controlled by companies against which we would compete directly. If we need to redesign products to avoid third-party patents, we may suffer significant regulatory delays associated with conducting additional studies or submitting technical, manufacturing or other information related to the redesigned product and, ultimately, in obtaining regulatory approval.

While our products are in clinical trials, and prior to commercialization, we believe our activities in the United States related to the submission of data to the FDA could fall within the scope of the statutory infringement exemption that covers activities related to developing information for submission to the FDA. However, this statutory exemption would not cover our stent manufacturing or other activities in the United States that support overseas clinical trials or commercial sales if those activities are not also reasonably related to developing information for submission to the FDA. Currently available drug eluting stents are manufactured outside of the United States, which may insulate manufacturers from adverse rulings on U.S. patent infringement claims. In an adverse ruling, a court may order an injunction requiring a company to stop its U.S. domestic manufacturing operations. We currently do not have any plans to manufacture our stents outside of the United States and any finding of patent infringement against us in the United States could result in our being enjoined from manufacturing our products in the United States and could affect our ability to sell our products in the European Union. In any event, the fact that no third party has asserted a patent infringement claim against us to date should not be taken as an indication, or provide any level of comfort, that a patent infringement claim will not be asserted against us prior to or upon commercialization.

In addition, some of our agreements, including our agreement with Biosensors for the supply of the drug coating and our agreement with SurModics for the supply of the lubricious coating on our catheter require us to indemnify the other party in certain circumstances where our products have been found to infringe a patent or other proprietary rights of others. An indemnification claim against us may require us to pay substantial sums to our licensor or supplier, including its attorneys fees.

If we are unable to obtain and maintain intellectual property protection covering our products, others may be able to make, use or sell our products, which would adversely affect our revenue.

Our ability to protect our products from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. As of September 30, 2008 we had seven issued U.S. patents, one of which is under exclusive license, covering certain aspects of the technology that we intend to commercialize and a number of other issued patents and pending patent applications in the United States and abroad. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering medical devices and pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any of our issued patents may not provide us with commercially meaningful protection for our products or afford us a commercial advantage against our competitors or their competitive products or processes. In addition, patents may not issue from any pending or future patent applications owned by or licensed

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to us, and moreover, patents that have issued to us or may issue in the future may not be valid or enforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing products like ours, despite our patent rights.

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the validity of our issued patents or the patentability of our pending patent applications. For example, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the United States Patent and Trademark Office, or USPTO, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO to determine priority of invention in the United States. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the United States. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

We may initiate litigation to enforce our patent rights, which may prompt our adversaries in such litigation to challenge the validity, scope or enforceability of our patents. If a court decides that our patents are not valid, not enforceable or of a limited scope, we will not have the right to stop others from using our technology.

We also rely on trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. In addition, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition against us.

We are aware that another medical business that holds patents to certain stent designs has used the name XTENT for limited purposes in the past. If it turns out that the other business has superior trademark rights in the name, and if the other business were to challenge our use of the XTENT name, we would then need to convince a court that there is no likelihood of consumer confusion. If we were unsuccessful in court, then we could be held liable for trademark infringement and we might then have to change our name as well as pay monetary damages. If we were forced to change our name, we may suffer from a loss of brand recognition, we may be required to retrieve product and interrupt supply, and may have to devote substantial resources advertising and marketing our products under a new brand name.

Risks Related to Commercialization

The medical device industry is highly competitive and subject to rapid technological change. If our competitors are better able to develop and market products that are safer, more effective, less costly or otherwise more attractive than any products that we may develop, our commercial opportunity will be reduced or eliminated.

The medical device industry is highly competitive and subject to rapid and profound technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products for use in the treatment of CAD.

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions in the United States and abroad. Most of the companies developing or marketing competing products are publicly traded or divisions of publicly-traded companies, and these companies enjoy several competitive advantages, including:

- greater financial and human resources for product development, sales and marketing, and patent litigation;

- significantly greater name recognition;

- established relations with healthcare professionals, customers and third-party payors;

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• additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;

• established distribution networks; and

• greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products and marketing approved products.

For example, Johnson & Johnson, Boston Scientific, Medtronic and Abbott Laboratories, four companies with far greater financial and marketing resources than we possess, have each developed, and are actively marketing, drug eluting stents that have been approved by the FDA. We may be unable to demonstrate that our Custom NX DES Systems offer any advantages over Johnson & Johnson s Cypher stent, Boston Scientific s Taxus Express2, Taxus Liberte or Promus stents, Abbott Laboratories Xience V stent or Medtronic s Endeavor stent. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with, or mergers with or acquisitions by, large and established companies or through the development of novel products and technologies.

The industry in which we operate has undergone, and is expected to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technical advances are made. Our competitors may develop and patent processes or products earlier than us, obtain regulatory approvals for competing products more rapidly than us, and develop more effective or less expensive products or technologies that render our technology or products obsolete or non-competitive. For example, we are aware of companies that are developing various other less-invasive technologies for treating CAD, which could make our stent platform obsolete. We also compete with our competitors in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business. If our competitors are more successful than us in these matters, our business may be harmed.

If we are unable to establish sales and marketing capabilities or enter into and maintain arrangements with third parties to sell and market our Custom NX DES Systems, our business may be harmed.

We do not have a sales organization and have no experience as a company in the sales, marketing and distribution of stent systems or other medical devices. To be successful in commercializing our products we must either develop a sales and marketing infrastructure or enter into distribution arrangements with others to market and sell our products. We have not yet hired any European sales people or entered into any third-party distribution agreements.

After establishing our European sales channels, if our Custom NX DES Systems are approved for commercial sale in the United States, we currently plan to establish our own direct U.S. sales force. If we develop our own marketing and sales capabilities, our sales force will be competing with the experienced and well-funded marketing and sales operations of our more established competitors. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. We may not be able to develop this capacity on a timely basis or at all. If we are unable to establish sales and marketing capabilities, we will need to contract with third parties to market and sell our products in the United States. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services in the United States or internationally, our product revenue could be lower than if we directly marketed and sold our products, or any

other stent system or related device that we may develop. Furthermore, to the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. Some of our future distributors may market their own products or distribute other companies products that compete with ours, and they may have an incentive not to devote sufficient efforts to marketing our products. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

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We have limited device manufacturing and drug coating capabilities and manufacturing personnel, and if our device manufacturing and drug coating facilities or our suppliers are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We currently have limited resources, facilities and experience to commercially manufacture the device component of our products and apply the drug coating to the stents. In addition, pursuant to the terms of the restated license agreement with Biosensors, we plan to perform our own drug coating formulation.. In order to produce our Custom NX DES Systems in the quantities that we anticipate will be required to meet anticipated market demand, we will need to increase, or scale-up, the production process by a significant factor over our current level of production. There are technical challenges to scaling-up manufacturing capacity and developing commercial-scale manufacturing facilities that will require the investment of substantial additional funds and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required scale-up in a timely manner or at all. If we are unable to do so, we may not be able to produce products in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, if at all. If we develop and obtain regulatory approval for our products and are unable to manufacture a sufficient supply of our products, our revenue, business and financial prospects would be adversely affected. In addition, if the scaled-up production process is not efficient or produces stents that do not meet quality and other standards, our future gross margins may decline.

We currently assemble our Custom NX DES Systems and apply the drug coating at our facilities in Menlo Park, California. Under the terms of our lease agreement for these facilities, our landlord may terminate our lease at any time on or after May 1, 2010 by giving us 180 days notice, if it has obtained certain redevelopment rights with respect to the leased premises. Prior to the commercial launch of our product, our leased premises will have to be inspected and approved by the FDA, and will likely require additional certifications by the State of California Department of Health Services, or CDHS. Our facility and quality systems are also required to pass annual audits for purposes of International Standardisation Organization, or ISO, compliance. If audits and inspections of our facilities determine that our facility does not meet applicable standards, or if there is a disruption to our existing manufacturing facility, or if our landlord elects to terminate our lease on or after May 1, 2010, we will have no other means of manufacturing our products until we are able to restore the manufacturing capability at our facility or lease alternative manufacturing facilities and obtain regulatory approval for these facilities. Because our Menlo Park facilities are located in a seismic zone, we face the risk that an earthquake may damage our facilities and disrupt our operations. If we are unable to produce sufficient quantities of our products for use in our current and planned clinical trials, if we obtain regulatory approval of our products and are unable to produce sufficient quantities of our products to support our planned commercial activities or if our manufacturing process yields substandard products, our development and commercialization efforts would be delayed.

If the cost of our drug coating or other components of our stent systems increase significantly, our business and our results of operations may be harmed.

Under the terms of our license agreement with Biosensors, the price we pay for our drug coating or the components thereof once we begin performing the formulation of the coating ourselves, may increase as Biosensors cost of manufacturing and supplying the drug coating or components increases. We have experienced one price increase in the past and we may experience additional increases in the future. If we experience significant increases in the cost of our drug coating or other key components of our stent systems, our business and our results of operations may be harmed.

Our manufacturing facilities and the manufacturing facilities of our suppliers must comply with strictly enforced regulatory requirements. If we fail to achieve regulatory approval for these manufacturing facilities, our business and our results of operations would be harmed.

Completion of our clinical trials and commercialization of our products require access to, or the development of, manufacturing facilities that comply with QSR and GMP. We may establish a manufacturing facility outside of the United States and can provide no assurance that our manufacturing facility would meet applicable foreign regulatory requirements or standards at acceptable cost, on a timely basis, or at all. In addition, the FDA must approve facilities that manufacture our products for domestic commercial purposes, as well as the manufacturing processes and specifications for the product. Biosensors and suppliers of components of, and products used to manufacture, our products must also comply with FDA and foreign regulatory requirements, which often require significant time, money and record-keeping and quality assurance efforts and subject us and our suppliers to potential regulatory inspections and stoppages. We, Biosensors, or our other suppliers may not satisfy these regulatory requirements. If we or our suppliers do not achieve required regulatory approval for our manufacturing operations, our commercialization efforts could be delayed, which would harm our business and our results of operations.

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We depend on single-source suppliers for some of the components in our Custom NX DES Systems. The loss of these suppliers could delay our clinical trials or prevent or delay commercialization of our Custom NX DES Systems.

Although we have identified several vendors for the components of our products, some of our components are currently provided by only one vendor, or a single-source supplier. In addition to our reliance on Biosensors as the only source for the supply of our drug coating, we also depend on SurModics, which provides the slippery coating on our sheath. We do not have long-term contracts with some of our third-party suppliers of components used in the manufacture of our stent delivery catheters or the cobalt chromium tubing and laser-precision cutting process required to produce the stent segments included in our device. In addition, we do not have long-term contracts with our third-party suppliers of some of the equipment and components that are used in our manufacturing process and we do not carry a significant inventory of most components used in our products. Establishing additional or replacement suppliers for these components, and obtaining any additional regulatory approvals that may result from adding or replacing suppliers, will take a substantial amount of time. We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or foreign regulatory authorities. Furthermore, since some of these suppliers are located outside of the United States, we are subject to foreign export laws and U.S. import and customs regulations, which complicate and could delay shipments to us. Some of our suppliers are also our competitors and may be reluctant to supply components to us on favorable terms, if at all.

If we have to switch to replacement suppliers, we will face additional regulatory delays and the manufacture and delivery of our Custom NX DES Systems would be interrupted for an extended period of time, which would delay completion of our clinical trials or commercialization of our products. In addition, we will be required to obtain prior regulatory approval from the FDA or foreign regulatory authorities to use different suppliers or components that may not be as safe or as effective. As a result, regulatory approval of our products may not be received on a timely basis or at all.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.

From time to time, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones could include obtaining CE Mark approval in the European Union, the initiation of our pivotal U.S. clinical trial for our Custom NX DES Systems, the enrollment of patients in our clinical trials, the release of data from our clinical trials and other clinical and regulatory events. The actual timing of these milestones could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot assure you that we will meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

We may not be successful in our efforts to expand our portfolio of products and develop additional technologies.

One element of our strategy is to discover, develop and commercialize a portfolio of new products in addition to our Custom NX DES Systems. As our resources permit, we plan to do so through our internal research programs and intend to explore strategic collaborations for the development of new products utilizing our stent technology. Research programs to identify new disease targets, products and delivery techniques require substantial technical, financial and human resources, whether or not any products are ultimately identified. We may determine that one or more of our pre-clinical programs do not have sufficient potential to warrant the allocation of resources, such as the development of our stent technology for the treatment of peripheral artery disease, or PAD, which we suspended in late 2007 in order to focus our resources on the development of our CUSTOM NX systems. Our research programs may initially show promise in identifying potential products, yet fail to yield

products for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential products;
- competitors may develop alternatives that render our products obsolete;
- our products may not be deployed safely or effectively;
- products may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective;
- our clinical trials may not be successful; and
- we may not receive regulatory approval.

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We depend on our officers, and if we are not able to retain them or recruit additional qualified personnel, our business will suffer.

We are highly dependent on our President and Chief Executive Officer, Gregory D. Casciaro and our other officers. Due to the specialized knowledge each of our officers possesses with respect to interventional cardiology and our operations, the loss of service of any of our officers could delay or prevent the successful completion of our clinical trials and the commercialization of our Custom NX DES Systems. Each of our officers may terminate their employment without notice and without cause or good reason. We carry key person life insurance on Mr. Casciaro but not on our other officers.

Upon receiving regulatory approval for our products, we expect to rapidly expand our operations and grow our research and development, product development and administrative operations. Our growth will require hiring a significant number of qualified clinical, scientific, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. Our offices are located in the San Francisco Bay Area, where competition for personnel with healthcare industry skills is intense. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

Risks Related to Our Industry

If we fail to obtain an adequate level of reimbursement for our products from third-party payors, there may be no commercially viable markets for our products or the markets may be much smaller than expected.

Our failure to receive adequate reimbursement or pricing approvals in the United States or internationally would negatively impact market acceptance of our products in the markets in which those approvals are sought. The efficacy, safety, performance and cost-effectiveness of our products under development and of any competing products are some of the factors that will determine the availability of coverage and level of reimbursement. In the United States, a preliminary threshold for coverage and payment of medical devices and drugs generally includes approvals or clearances from the FDA. In addition, there is significant uncertainty concerning third-party coverage and reimbursement of newly approved medical products and drugs. Future legislation, regulation or coverage and reimbursement policies of third-party payors may adversely affect the demand for our products currently under development and limit our ability to profitably sell our products. Third-party payors continually attempt to contain or reduce healthcare costs by challenging the prices charged for healthcare products and services, resulting in a downward pressure of reimbursement rates generally. Under recent regulatory changes to the methodology for calculating payments for current inpatient procedures in certain hospitals, Medicare payment rates for surgical and cardiac procedures have been decreased, including approximately 10% to 14% reductions for those procedures using drug eluting stents. The reductions are to be transitioned over the three year period that began in fiscal year 2007. The Centers for Medicare and Medicaid Services, or CMS, responsible for administering the Medicare program, also indicated it will begin to move forward with developing revised reimbursement codes that better reflect the severity of the patient s condition in the hospital inpatient prospective payment system for fiscal year 2008. If coverage and reimbursement for our products is unavailable, insufficient or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired and our future revenues, if any, would be adversely affected.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In the United States and in certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the regulatory and healthcare systems in ways that could impact our ability to sell our products profitably, if at all. In the United States in recent years, new legislation has been proposed at the federal and state levels that would effect major changes in the healthcare system. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted. Post-payment reviews of claims also are conducted. For example, in 2005 the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, audited certain sample claims paid by Medicare contracts for in-patient and out-patient claims involving arterial stent implantation to determine whether Medicare payments for these services were appropriate. The OIG found that 20 of 72 reviewed claims did not meet Medicare reimbursement requirements. Findings of ongoing or widespread inappropriate billing of arterial stents could lead to increased scrutiny in this area, which in turn, could affect our ability to raise capital, obtain additional collaborators and market our products. We also expect to experience pricing pressures in connection with the future sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. Our results of operations could be adversely affected by these and other future healthcare reforms.

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We face the risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices. We may be subject to product liability claims if our stents cause, or merely appear to have caused, an injury. Claims may be made by patients, consumers, healthcare providers, third-party strategic collaborators or others selling our products. Although we have product liability and clinical trial liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverages may not be adequate to protect us against any future product liability claims. In addition, if any of our products are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims against us even if the apparent injury is due to the actions of others. For example, we rely on the expertise of physicians, nurses and other associated medical personnel to perform the medical procedure and related processes to implant our coronary stents into patients. If these medical personnel are not properly trained or are negligent, the therapeutic effect of our stents may be diminished or the patient may suffer critical injury, which may subject us to liability. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with cobalt chromium tubing for our stents, those that laser cut our stents or the supplier of our drug coating, may be the basis for a claim against us. Pursuant to some of the written agreements that we have entered into with medical institutions and physicians participating in our clinical trials, we have agreed to indemnify those institutions and physicians from and against losses that result from third party claims seeking compensation for certain injuries incurred by study subjects. We may have to indemnify medical institutions and physicians in connection with future clinical trials.

These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management s attention from our business and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial patient participants or result in reduced acceptance of our products in the market.

Risks Related to Our Operations

Our operations involve hazardous materials, and we must comply with environmental laws and regulations, which can be expensive.

We are subject to a variety of federal, state and local regulations relating to the use, handling, storage, disposal, and human exposure to hazardous and toxic materials. We could incur costs, fines, and civil and criminal sanctions, third-party property damage or personal injury claims, or could be required to incur substantial investigation or remediation costs, if we were to violate or become liable under environmental laws. We do not have insurance for environmental liabilities and liability under environmental laws can be joint and several and without regard to comparative fault. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations, which could harm our business. Compliance with current or future environmental and safety laws and regulations could restrict our ability to expand our facilities, impair our research, development or production efforts, or require us to incur other significant expenses. There can be no assurance that violations of environmental laws or regulations will not occur in the future as a result of the inability to obtain permits, human error, accident, equipment failure or other causes.

We have limited experience complying with public company obligations, including recently enacted changes in securities laws and regulations. Compliance with these requirements will increase our costs and require additional management resources, and we still may fail to comply.

We operated as a private company until February 2007 and prior to that, we were not subject to many of the requirements applicable to public companies. Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules related to corporate governance and other matters subsequently adopted by the SEC and NASDAQ Global Market, will result in increased administrative costs to us and increased legal and accounting fees. The impact of these events and heightened corporate governance standards could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring us to include a report of management on our internal control over financial reporting in our annual reports on Form 10-K. In addition, in our annual report on Form 10-K for the year ending December 31, 2009, the independent registered public accounting firm auditing our financial statements must attest to the effectiveness of our internal control over financial reporting. We may be unable to comply with these requirements by the applicable deadlines. We will be testing our internal control over financial reporting in connection with Section 404 requirements and could, as part of that documentation and testing, identify material weaknesses, significant deficiencies or other areas requiring further attention or improvement.

We expect that the price of our common stock will fluctuate substantially.

There has been a public market for our common stock for a limited amount of time. The market price for our common stock will be affected by a number of factors, including:

- the results of our clinical trials;

- the timing of our regulatory approvals;

- announcements related to litigation;

- statements made by Biosensors relating to regulation or supply of the drug coating;

- the announcement of new products or service enhancements by us or our competitors;

- quarterly variations in our or our competitors results of operations;

- changes in earnings estimates, investors perceptions, recommendations by securities analysts or our failure to achieve analysts earning estimates;

- the low trading volume of our common stock;

- developments in our industry, including changes in third-party reimbursement; and

• general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

These factors may materially and adversely affect the market price of our common stock.

Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of September 30, 2008, our officers, directors and principal stockholders each holding more than 5% of our common stock collectively will control approximately 65.1% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

Volatility in the stock price of other companies may contribute to volatility in our stock price.

The NASDAQ Global Market, particularly in recent years, has experienced significant volatility with respect to medical technology, pharmaceutical, biotechnology and other life science company stocks. The volatility of medical technology, pharmaceutical, biotechnology and other life science company stocks often does not relate to the operating performance of the companies represented by the stock. Further, there has been particular volatility in the market price of securities of early stage and development stage life science companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a company s securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management s attention and resources.

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Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws, and Delaware law, contain provisions that could discourage a takeover.

Anti-takeover provisions of our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. The provisions of our charter documents include:

- a classified board so that only one of the three classes of directors on our board of directors is elected each year;

- elimination of cumulative voting in the election of directors;

- procedures for advance notification of stockholder nominations and proposals;

- the ability of our board of directors to amend our bylaws without stockholder approval;

- a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and our amended and restated bylaws; and

- the ability of our board of directors to issue up to 10,000,000 shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our board of directors may determine.

In addition, as a Delaware corporation, we are subject to Delaware law, including Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless certain specific requirements are met as set forth in Section 203. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic

factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On February 1, 2007, we sold 4.7 million shares at $16.00 per share in the initial public offering of our common stock. Net cash proceeds from the offering were $68.2 million, after deducting approximately $7.0 million of underwriting discounts and commissions and other offering costs. We registered the Initial Public Offering of our common stock, par value $0.001 per share, on a Registration Statement on Form S-1, as amended, (Registration No. 333-136371), which was declared effective on January 31, 2007. Of the $68.2 million in net proceeds, all of which has been used as of September 30, 2008. We used $4.6 million for sales and marketing initiatives not including $0.4 million of stock compensation expense, $49.8 million for research and development activities not including $2.6 million of stock compensation expense, $10.2 million for operating and general corporate purposes not including $3.6 million of stock compensation expense and $3.6 million for property and equipment in order to expand our manufacturing capability to conduct our CUSTOM III, IV and V clinical trials and prepare for commercialization outside the United States. In addition, we invested the proceeds from the offering in short-term, investment grade, interest-bearing instruments.

On July 24, 2008, we issued 50,000 unregistered shares of our common stock to an accredited investor for total consideration with a value of $150,000. The investor delivered a payment of $150,000 to Millimed, A/S. In turn, Millimed assigned exclusive rights in certain patents and patent applications to us. The issuance was made in reliance on Section 4(2) of the Securities Act of 1933, as amended, and was made without general solicitation or advertising. The recipient was an accredited investor with access to all relevant information necessary to evaluate the investment, who represented to us that the shares were being acquired for investment purposes.

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ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description
3.2(1)	Amended and Restated Certificate of Incorporation.
3.4(1)	Amended and Restated Bylaws.
4.1(1)	Specimen Common Stock certificate of the Registrant.
10.1(1)	Form of Indemnification Agreement for directors and executive officers.
10.2(1)	2002 Stock Plan and form of stock option agreements used thereunder.
10.3(1)	2006 Equity Incentive Plan and form of stock option agreement used thereunder.
10.4(1)	2006 Employee Stock Purchase Plan.
10.5(1)	Amended and Restated Investor Rights Agreement dated May 5, 2006 by and among the Registrant and certain stockholders.
10.6(1)	Business Park Lease dated September 15, 2003, as amended November 22, 2005, by and between the Registrant and 125 Constitution Associates, L.P. for office space located at 125 Constitution Drive, Menlo Park, California, 94025-1118.
10.8(1)	Master License Agreement dated December 30, 2002, as amended June 30, 2006, by and between the Registrant and SurModics, Inc.
10.9(1)	License Agreement dated July 10, 2006 by and between the Registrant and Millimed A/S.
10.10(2)	Supply Agreement dated April 2, 2007 by and between Registrant and Fortimedix B.V.
10.11(3)	Second Amendment to Lease dated May 17, 2007 by and between the Registrant and 125 Constitution Associates, L.P.
10.12(4)	Amended and Restated License Agreement dated December 3, 2007 by and between Registrant, Biosensors International Group, Ltd. and Biosensors Europe S.A.
10.13	Amended 2006 Equity Incentive Plan and form of stock option agreement used thereunder.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	

Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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(1) Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-136371), which was declared effective on January 31, 2007.

(2) Incorporated by reference from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, filed May 14, 2007.

(3) Incorporated by reference from our Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed August 13, 2007.

(4) Incorporated by reference from our Annual Report on Form 10-K for the year ended December 31, 2007, filed March 17, 2008.

Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.

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SIGNATURES

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

XTENT, Inc.

Date: November 12, 2008	By:	/s/ GREGORY D. CASCIARO **GREGORY D. CASCIARO** **President and Chief Executive Officer** **(Principal Executive Officer)**
Date: November 12, 2008	By:	/s/ TIMOTHY D. KAHLENBERG **TIMOTHY D. KAHLENBERG** **Chief Financial Officer** **(Principal Accounting and Financial Officer)**