

XTENT INC  
Form 10-Q  
May 15, 2009  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, DC 20549

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended March 31, 2009

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

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**XTENT, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**41-2047573**  
(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)

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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  NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files). YES  NO

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

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

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

As of April 30 2009, there were 23,352,904 shares of XTENT, Inc. common stock outstanding.

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**XTENT, INC.**

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Table of Contents**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)**

	<b>March 31, 2009</b>	<b>December 31, 2008 (1)</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,960	\$ 13,373
Short-term investments		5,752
Prepaid expenses and other current assets	673	432
Total current assets	12,633	19,557
Property and equipment, net	1,500	4,100
Other non-current assets	45	338
Total assets	\$ 14,178	\$ 23,995
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 216	\$ 943
Accrued liabilities	1,550	1,544
Total current liabilities	1,766	2,487
Commitments and contingencies (note 7)		
Stockholders' Equity:		
Common stock: \$0.001 par value; 100,000 shares authorized at March 31, 2009 and December 31, 2008; 23,337 and 23,325 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	23	23
Additional paid-in capital	156,227	155,511
Deferred stock-based compensation	(1)	(56)
Accumulated other comprehensive income		11
Deficit accumulated during development stage	(143,837)	(133,981)
Total stockholders' equity	12,412	21,508
Total liabilities and stockholders' equity	\$ 14,178	\$ 23,995

(1) The condensed balance sheet at December 31, 2008 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 March 31,		Cumulative Period from June 13, 2002 (Date of Inception) to March 31, 2009
	2009	2008	
Operating expenses:			
Research and development (1)	\$ 4,654	\$ 9,421	\$ 110,238
General and administrative (1)	2,763	3,442	37,223
Loss on impairment of long-lived assets	2,494		2,494
Total operating expenses	9,911	12,863	149,955
Loss from operations	(9,911)	(12,863)	(149,955)
Interest and other income, net	55	406	6,118
Net loss	(9,856)	(12,457)	(143,837)
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock			(13,095)
Net loss attributable to common stockholders	\$ (9,856)	\$ (12,457)	\$ (156,932)
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.42)	\$ (0.54)	
Weighted-average common shares outstanding - basic and diluted	23,324	22,923	
<hr/>			
(1) Includes the following stock-based compensation charges:			
Research and development	\$ 256	\$ 388	\$ 4,735
General and administrative	\$ 508	\$ 650	\$ 6,097

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)

	Three Months Ended March 31,		Cummulative Period from June 13, 2002 (Date of Inception) to March 31, 2009
	2009	2008	
<b>Cash flows from operating activities:</b>			
Net loss	\$ (9,856)	\$ (12,457)	\$ (143,837)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	347	321	4,368
Amortization of securities discount	(9)	(192)	(2,080)
Gain on sale of investments		(26)	(6)
Loss on disposal of property and equipment			188
Impairment of long-lived assets	2,494		2,494
Stock-based compensation expense	764	1,038	10,832
Stock issued in exchange for services			381
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	10	(732)	(702)
Accrued interest receivable on securities	12	213	(16)
Accounts payable	(727)	80	101
Accrued liabilities	8	446	1,664
Net cash used in operating activities	(6,957)	(11,309)	(126,613)
<b>Cash flows from investing activities:</b>			
Purchase of investments		(5,459)	(142,322)
Proceeds from maturities of investments	5,750	9,925	130,459
Proceeds from sale of investments		9,963	13,949
Purchase of property and equipment	(241)	(304)	(8,547)
Restricted cash	30		
Proceeds from sale of property and equipment		2	20
Net cash provided by (used in) investing activities	5,539	14,127	(6,441)
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs			75,592
Proceeds from initial public offering, net of offering costs			68,237
Principal payments on capital lease obligations			(23)
Proceeds from issuance of common stock and exercise of stock options	5	32	1,208
Net cash provided by financing activities	5	32	145,014
Net (decrease) increase in cash and cash equivalents	(1,413)	2,850	11,960
Cash and cash equivalents at beginning of period	13,373	13,366	



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Cash and cash equivalents at end of period	\$	11,960	\$	16,216	\$	11,960
<b>Supplemental disclosure of noncash investing and financing activities:</b>						
Deferred stock-based compensation	\$		\$		\$	1,272
Reversal of deferred stock-based compensation	\$	(22)	\$	(30)	\$	(183)
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	\$	2	\$	23	\$	440
Deferred initial public offering costs	\$		\$		\$	875
Changes in net unrealized gains on investments	\$	(11)	\$	95	\$	

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 March 31, 2009, the Company had an accumulated deficit of \$143.8 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 January 2009, the Company announced a reduction in its headcount of approximately 115 employees, or 94% of its total workforce. As of March 31, 2009, the reduction was substantially complete, with six full-time employees remaining at April 30, 2009. During the first quarter of 2009, the Company was exploring strategic alternatives with the assistance of Piper Jaffray & Co., including, without limitation, a merger, a sale of substantially all Company assets, a financing, or a sale of a portion of the Company's assets, such as its peripheral stent technology, its drug eluting balloon technology, or its bioabsorbable stent technology. On May 11, 2009, the Company's board of directors concluded that it appeared unlikely that a strategic transaction at a valuation materially in excess of the estimated liquidation value would be achieved in the near term. Based on these and other factors, the board of directors concluded that a statutory dissolution and liquidation was in the best interests of the Company and its stockholders and therefore adopted a Plan of Complete Liquidation and Dissolution, or Plan of Dissolution, and recommended approval of the Plan of Dissolution by the Company's stockholders. The Plan of Dissolution is subject to approval at a special meeting of the stockholders, which is expected to be held during the second or third quarter of 2009.

If the Company's stockholders approve the Plan of Dissolution, the Company will not engage in any business activities except for the purpose of preserving the value of the Company's assets, winding up the Company's business and affairs, selling and liquidating all assets, including intellectual property, paying all liabilities, terminating all agreements and preparing to make distributions to stockholders, in accordance with the Plan of Dissolution. The Company believes that the cash and cash equivalents and related interest income are sufficient to meet the anticipated cash requirements under the Plan of Dissolution.

If the Company's stockholders do not approve the Plan of Dissolution, the board of directors will explore the alternatives then available to XTENT. The Company believes that the existing cash and cash equivalents and related interest income are sufficient to meet anticipated cash requirements through at least December 31, 2009.

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The Company continues to report as a development stage company, since planned principal operations have not commenced. The basis of accounting has not changed as a result of the board of director's approval of the Plan of Dissolution as the Plan of Dissolution is subject to stockholder approval. The Company operates in a single segment and management uses one measure of financial performance and does not segment its business for internal reporting.

### **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 months ended March 31, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009, 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, 2008, filed with the Securities and Exchange Commission on March 24, 2009.

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**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 and fixed income securities with original maturity dates of less than three months.

***Short-term Investments***

Short-term 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. 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 short-term investments is based on quoted market prices. As of March 31, 2009, the Company did not have any short-term investments.

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 short-term investments are amortized (or accreted) to interest and other income, net over the life of the investment. Realized gains and losses on short-term 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.

***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 primarily 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 credit losses on such instruments during any of the periods presented and believes that it is not exposed to any significant risk on these instruments.

**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 months ended March 31, 2009 and 2008 consisted of:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in thousands)</b>	
Net loss attributable to common stockholders	\$ (9,856)	\$ (12,457)
Change in unrealized gains (losses) on available-for-sale securities	(11)	95
Comprehensive loss	\$ (9,867)	\$ (12,362)

Table of Contents**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.

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

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in thousands, except per share amounts)</b>	
<b>Numerator:</b>		
Net loss attributable to common stockholders	\$ (9,856)	\$ (12,457)
<b>Denominator:</b>		
Weighted-average common shares outstanding	23,326	23,049
Less: Weighted-average unvested common shares subject to repurchase	(2)	(126)
Weighted-average common shares outstanding used in computing basic and diluted net loss per common share	23,324	22,923
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.42)	\$ (0.54)

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:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in thousands)</b>	
Options to purchase common stock	2,060	2,744
Common stock subject to repurchase	1	107
Shares issuable under Employee Stock Purchase Plan	52	

**Recent and Adopted Accounting Pronouncements**

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* ( SFAS No. 159 ). SFAS No. 159 expands the use of fair value accounting but does not affect existing

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standards which require assets or liabilities to be carried at fair value. The objective of SFAS No. 159 is to improve financial reporting by providing companies with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. Under SFAS No. 159, a company may elect to use fair value to measure eligible items at specified election dates and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. Eligible items include, but are not limited to, accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees, issued debt and firm commitments. If elected, SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS 159 has not impacted the Company's results of operations and financial condition as the Company has not elected the fair value option for any of its eligible items.

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In April 2009, the FASB issued FSP SFAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. This FSP amends SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, to require publicly-traded companies, as defined in APB Opinion No. 28, *Interim Financial Reporting*, to provide disclosures on the fair value of financial instruments in interim financial statements. Prior to the issuance of FSP SFAS No. 107-1 and APB Opinion No. 28-1, the fair values of those assets and liabilities were disclosed only once each year. With the issuance of FSP SFAS No. 107-1 and APB Opinion No. 28-1, the Company will now be required to disclose this information on a quarterly basis, providing quantitative and qualitative information about fair value estimates for all financial instruments not measured in the Condensed Consolidated Balance Sheets at fair value. FSP SFAS 107-1 and APB 28-1 are effective for interim periods ending after June 15, 2009. The Company will adopt the new disclosure requirements in the second quarter of fiscal 2009. The Company does not expect the adoption to have a material impact on its condensed financial condition, results of operations, or cash flows.

On January 1, 2009, the Company adopted SFAS No. 157-2, *Effective Date of FASB Statement No. 157*, ( FSP SFAS 157-2 ), which delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis to fiscal years beginning November 15, 2008. The adoption of FSP SFAS No. 157-2 did not have a material impact on the Company's financial position, operating results or cash flows.

On January 1, 2009, the Company adopted SFAS No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, ( FSP SFAS 157-3 ), which clarifies the application of Statement 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. The adoption of FSP SFAS No. 157-3 did not have a material impact on the Company's financial position, operating results or cash flows.

In April 2009, the FASB issued FSP SFAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*, or FSP SFAS 157-4, which provides additional guidance for estimating fair value in accordance with SFAS 157 when the volume and level of activity for the asset or liability have significantly decreased. This FSP re-emphasizes that regardless of market conditions the fair value measurement is an exit price concept as defined in SFAS 157. This FSP clarifies and includes additional factors to consider in determining whether there has been a significant decrease in market activity for an asset or liability and provides additional clarification on estimating fair value when the market activity for an asset or liability has declined significantly. The scope of this FSP does not include assets and liabilities measured under level 1 inputs. FSP SFAS 157-4 is applied prospectively to all fair value measurements where appropriate and will be effective for interim and annual periods ending after June 15, 2009. The Company will adopt the provisions of FSP SFAS 157-4 effective the second quarter of fiscal 2009, and does not expect this to have a material impact on its condensed financial condition, results of operations, or cash flows.

**NOTE 3 - Investments**

The Company had no short term investments as of March 31, 2009. At December 31, 2008, short-term investments, which are classified as available-for-sale, had maturities of less than one year and consisted of the following:

As of March 31, 2009	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
U.S. government and agency securities	\$ 5,741	\$ 11	\$	\$ 5,752





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SFAS No. 157, *Fair Value Measurements*, 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.

*Cash and Cash Equivalents*

The Company's cash equivalents 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 March 31, 2009 and December 31, 2008:

	Balance as of March 31, 2009	Significant Other Observable Inputs (Level 1) (in thousands)	Significant Other Observable Inputs (Level 2)
Money market funds (1)	\$ 8,383	\$ 8,383	\$
U.S. government securities (1)	2,001		2,001
Commercial paper (1)	1,000		1,000
Total	\$ 11,384	\$ 8,383	\$ 3,001

Balance as of	Significant Other Observable Inputs	Significant Other Observable Inputs
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	December 31, 2008		(Level 1) (in thousands)		(Level 2)
Money market funds (1)	\$	11,613	\$	11,613	\$
U.S. Treasury Notes (1)		1,003			1,003
U.S. government and agency securities		5,752			5,752
Total	\$	18,368	\$	11,613	\$

(1) Classified as part of cash equivalents on the balance sheet

**Assets Measured at Fair Value on a Nonrecurring Basis**

As discussed in Note 1, the Company terminated 94% of its workforce during the quarter ended March 31, 2009. The Company evaluates the recoverability of property and equipment in accordance with FAS 144, *Accounting for the impairment, or disposal, of long-lived assets* whenever events or changes in circumstances indicate that the carrying value of a long-lived asset may not be recoverable. The Company recorded a non-cash charge of \$2.5 million relating to the impairment of long-lived assets, which is included in continuing operations for the quarter ended March 31, 2009. An estimate of fair value was based on a market approach obtained through an external assessment of long-lived asset values by considering the market participant assumptions affecting the value to be realized through an auction of property and equipment. In accordance with SFAS 157-2, the \$1.5 million valuation of long-lived assets is assessed based on unobservable inputs, and grouped as level 3 within the fair value hierarchy.

**NOTE 5 - 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*

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*Involving Stock Compensation*, the Company accounts for the cash received in consideration for the early exercised options as a liability. As of March 31, 2009 and December 31, 2008, there were approximately 1,000 and 7,000 shares of common stock, respectively, subject to repurchase, and a related liability of approximately \$1,000 and \$3,000, respectively.

**NOTE 6 - 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 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 does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. Beginning in 2008, the expected term assumption was based on the Company's historical settlement experience. ESPP terms are for 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 ended on November 17, 2008. The ESPP was suspended in January 2009, and all funds for the purchase period that began on November 17, 2008 were refunded to employees.

The expected stock price volatility assumptions for the Company's stock options and ESPP for the three months ended March 31, 2008 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. Volatility for three months ended March 31, 2009 was not assessed, as there were no stock options granted or ESPP requiring measurement during the period.

The risk-free interest rate assumption at the date of grant is based on the interest rate on U.S Treasury instruments whose term is 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, forfeitures are estimated at the time of grant based on historical experience and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock option activity for the three months ended March 31, 2009 was as follows:

	Shares Available for Grant (in thousands, except	Number of Shares	Options Outstanding Weighted Average Exercise Price (in thousands, except weighted average exercise price)	
<b>Balance as of December 31, 2008</b>	1,364	2,516	\$	5.47
Additional shares reserved	933			

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Options granted				
Options exercised		(12)		0.43
Options forfeited/expired	444	(444)		6.61
<b>Balance as of March 31, 2009</b>	2,741	2,060	\$	5.25

*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.

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 March 31, 2009. For the three months ended March 31, 2009 and 2008, the Company recorded stock-based compensation charges for non-employees of approximately \$1,000 and \$5,000, respectively.

Table of Contents**NOTE 7 - 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. In September 2008, a second amendment extended the lease termination option such that the Company may terminate the lease for any reason on or after May 1, 2010, and the landlord may terminate the lease on or after that date provided it has obtained certain redevelopment rights with respect to the leased premises.

As of March 31, 2009, future minimum lease payments under non-cancelable operating leases are as follows:

	Total	2009	2010 (in thousands)	2011	2012
Minimum lease commitments	\$ 1,576	\$ 361	\$ 493	\$ 508	\$ 214

*License Agreements*

The Company has entered into license 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 March 31, 2009 future minimum royalty payments to these suppliers are approximately \$1.7 million. During the year ended December 31, 2008 and the three months ended March 31, 2009, the Company made minimum royalty payments of \$80,000 and \$20,000, respectively. Under the terms of the license agreement with SurModics, an additional \$20,000 milestone payment is payable to SurModics once the Company receives regulatory approval authorizing it to market its products, and this amount was accrued for the three months ended March 31, 2009 based upon the Company's receipt of CE Mark in March 2009. No milestone payments were made on this license agreement during the year ended December 31, 2008. Minimum royalty payments to Biosensors of \$100,000 per year would begin upon achievement of certain milestones.

In July 2006, the Company entered into a license agreement with Millimed, Inc. for certain intellectual property related to the Company's business. In consideration for this license, the Company made an initial payment of \$350,000 in cash and issued 15,000 shares of common stock during the year ended December 31, 2006. In addition, the license agreement provided for an additional payment of \$200,000 upon achievement of certain milestones. On July 24, 2008, the Company entered into an assignment agreement with Millimed, assigning to the Company the entire and exclusive right, title and interest in previously licensed intellectual property. 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.

*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 March 31, 2009, 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. As of March 31, 2009, there were no outstanding purchase commitments with Biosensors. The Company will pay royalties to Biosensors under the license agreement when revenues are generated from product sales.

***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.

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***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 8 - 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 March 31, 2009, 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 March 31, 2009 or December 31, 2008.

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 9 - 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, of which \$170,000 was included in research and development and \$40,000 was included in general and administrative in the Statement of Operations. The total expense included approximately \$7,000 of non-cash expenses. All amounts were paid during the quarter ended September 30, 2008.



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On January 21, 2009 the Company announced an initiative to reduce employee headcount by 115 employees or 94% of the total workforce. As of March 31, 2009, the reduction was substantially complete, and the related expense recognized for the three month period ending on that date was approximately \$1.0 million, of which \$0.6 million was included in research and development and \$0.4 million was included in general and administrative in the Statement of Operations. A portion of these costs in the amount of \$0.2 million was still payable at March 31, 2009.

As of March 31, 2009, the Company has six remaining employees, all of whom have retention agreements to secure their continued service through the completion of a strategic transaction, or in the absence thereof, to wind down and liquidate the Company. The related expense associated with these agreements is being expensed over the related retention periods. As of March 31, 2009, we have recorded a liability of \$0.5 million associated with these agreements. The expected termination dates for these employees range from April 30, 2009 to July 31, 2009.

### **NOTE 10 - Subsequent Event**

On May 11, 2009, the board of directors adopted a Plan of Complete Liquidation and Dissolution, or Plan of Dissolution, and recommended approval of the Plan of Dissolution to the Company's stockholders. The Plan of Dissolution is subject to approval by stockholders at a special meeting of stockholders which is expected to be held in the second or third quarter of 2009. The Company expects to file a preliminary proxy statement with the United States Securities and Exchange Commission on or about May 15, 2009 for the purpose of obtaining stockholder approval of the Plan of Dissolution.

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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, 2008 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 that has 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 in the United States.

Over the past four years, we have been conducting clinical trials to evaluate our Custom NX 36 and Custom NX 60 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 support further development of our in-situ customization approach. In March 2009, we received CE Mark approval for our Custom NX DES Systems authorizing us to market our products in the European Union and certain other countries that recognize CE Mark. Even though we have received CE Mark, we do not have adequate resources to commercialize our products in Europe.

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 would require data from a large clinical trial of up to 2,100 patients. We expected to obtain this data through our planned CUSTOM IV clinical trial, but to initiate the CUSTOM IV trial, we would first need to obtain clearance of an investigational device exemption, or IDE, from the FDA. We filed our IDE application in September 2007, and in October 2007, we received questions back from the FDA. In February 2009, we resubmitted our IDE application, and received questions back from the FDA in April 2009. Even if we receive IDE approval from the FDA, we do not have adequate resources to initiate our IDE trial.

To date, we have not generated any revenue from our development activities and will not be able to generate revenue unless we obtain additional financing to support commercialization of our products in the European Union. We have incurred net losses in each year since our inception in

June 2002. Through March 31, 2009, we had an accumulated deficit of \$143.8 million.

**RECENT DEVELOPMENTS**

In January 2009, we notified our employees that we were initiating a headcount reduction that would impact 94% of our 122 employees. The reduction was substantially completed in March 2009. In connection with the reduction in force and our plans to explore strategic alternatives, we entered into retention and severance agreements with nine of our employees, including our executive officers. Pursuant to these agreements, we have agreed to make retention payments to each of these employees, provided their employment is not terminated for cause prior to the date upon which we complete a strategic transaction, or the employee's expected termination date, whichever is earlier. Three of these employees were terminated on March 31, 2009, one was terminated on April 30, and the remaining five employees have expected termination dates that range from June 30, 2009 to July 31, 2009.

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In January 2009, we engaged Piper Jaffray & Co. to help us explore potential strategic alternatives, including, without limitation, a merger, a sale of substantially all our assets, a financing, or a sale of a portion of our assets, such as our peripheral stent technology, our drug eluting balloon technology or our bioabsorbable stent technology. On May 11, 2009, our board of directors concluded that it appeared unlikely that a strategic transaction at a valuation materially in excess of the estimated liquidation value could be achieved in the near term. This conclusion was based on the lack of success, despite concerted efforts through the fourth quarter of 2008 and first quarter of 2009, to secure additional financing or identify a strategic transaction that would provide value to our stockholders or reduce the risks of our ongoing operations, including the risks associated with technology in a relatively early state of development, the time and cash requirements associated with commercializing our Custom NX DES Systems, the need for additional financing, and the highly uncertain and currently unfavorable financing and economic climate. Based on this and other factors, our board of directors concluded that a statutory dissolution and liquidation was in the best interests of XTENT and its stockholders and therefore adopted a Plan of Complete Liquidation and Dissolution, or Plan of Dissolution, and recommended approval of the Plan of Dissolution by our stockholders.

If our stockholders approve our Plan of Dissolution, we will file a Certificate of Dissolution with the Delaware Secretary of State. Thereafter, we will not engage in any business activities except for the purpose of preserving the value of our assets, prosecuting and defending lawsuits by or against us, winding up our business and affairs, selling and monetizing our non-cash assets, including our intellectual property, paying or otherwise settling our liabilities, including contingent liabilities, terminating agreements and relationships, and preparing to make distributions to our stockholders, in accordance with the Plan of Dissolution.

**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. Revenue generation is subject to commercial launch of our product in Europe. Even though we received CE Mark in March 2009, we do not have adequate resources to commercialize our product in the European Union.

*Research and Development*

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Since inception, we have devoted a significant amount of resources to develop our Custom NX DES Systems. From our inception through March 31, 2009, we incurred \$110.2 million in research and development expenses related to developing our products, including the clinical trials necessary to support regulatory approval. We expect our research and development expenses to decrease due to the reduction in force we substantially completed in March 2009.

### ***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 March 31, 2009, we incurred \$37.2 million in general and administrative expenses. We expect our general and administrative expenses to decrease due to the reduction in force we substantially completed in March 2009.

### ***Loss on Impairment of Long-Lived Assets***

During the quarter ended March 31, 2009, we terminated 94% of our workforce. We evaluate the recoverability of property and equipment in accordance with FAS 144, *Accounting for the impairment, or disposal, of long-lived assets* whenever events or changes in circumstances indicate that the carrying value of a long-lived asset may not be recoverable.

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We have recorded a non-cash charge of \$2.5 million relating to the impairment of long-lived assets, which is included in continuing operations for the quarter ended March 31, 2009. An estimate of fair value was based on a market approach obtained through an external assessment of long-lived asset values by considering the market participant assumptions affecting the value to be realized through an auction of property and equipment. In accordance with SFAS 157-2, the \$1.5 million valuation of long-lived assets is assessed based on unobservable inputs, and grouped as level 3 within the fair value hierarchy.

**RESULTS OF OPERATIONS****COMPARISON OF THREE MONTHS ENDED MARCH 31, 2009 AND 2008***Revenue*

We did not generate any revenue during the three months ended March 31, 2009 or 2008.

*Research and Development*

	Three Months Ended March 31,		
	2009	2008	Dollar Change
	(in thousands)		
Research and development expenses	\$ 4,654	\$ 9,421	\$ (4,767)

The \$4.8 million decrease in research and development expenses for the three months ended March 31, 2009, compared to the three months ended March 31, 2008, was primarily attributable to:

- A decrease of \$3.1 million for prototype parts, supplies, and outside services related to product development for our Custom NX DES systems, based on the reduced operations activity related to the reduction in force substantially completed during the three months ended March 31, 2009;
- A decrease of \$1.5 million in personnel costs offset by a \$0.6 million increase in costs related to the reduction in force completed in March 2009;

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- A decrease of \$0.4 million in expenses related to the support of our clinical research studies in 2009 as compared to the first quarter of 2008 due to activity in the first quarter of 2008 related to studies conducted to support our IDE application;
- A decrease of \$0.1 million in employee stock-based compensation; and
- A decrease of \$0.3 million in facilities and other miscellaneous expenses.

We expect our research and development expenses to continue to decrease as we wind up our operations in 2009.

### *General and Administrative*

	Three Months Ended March 31,		Dollar Change
	2009	2008	
	(in thousands)		
General and administrative expenses	\$ 2,763	\$ 3,442	\$ (679)

The \$0.7 million decrease in general and administrative expenses for the three months ended March 31, 2009, compared to the three months ended March 31, 2008, was primarily attributable to:

- A decrease of \$0.6 million in personnel costs, facilities, insurance and other miscellaneous spending, offset by a \$0.4 million increase in costs related to the reduction in force substantially completed in March 2009;
- A decrease of \$0.2 million in legal and accounting expenses;

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- A decrease of \$0.2 million due to spending for trade shows, travel and marketing materials; and
- A decrease of \$0.1 million in employee stock-based compensation expense.

We expect our general and administrative expenses to continue to decrease as we wind up our operations in 2009.

*Loss on Impairment of Long-Lived Assets*

	Three Months Ended March 31,		Dollar
	2009	2008	Change
	(in thousands)		
Loss on impairment of long-lived assets	\$ 2,494	\$	\$ 2,494

The \$2.5 million increase in loss on impairment of long-lived assets for the three months ended March 31, 2009, compared to the three months ended March 31, 2008, was attributable to the non-cash charge of \$2.5 million relating to the impairment of long-lived assets which have been determined to be impaired. The fair value of long-lived assets was based on a market approach obtained through an external assessment of long-lived assets values by considering the market participant assumptions affecting the value to be realized through an auction of property and equipment.

*Interest and Other Income, Net*

	Three Months Ended March 31,		Dollar
	2009	2008	Change
	(in thousands)		
Interest and other income, net	\$ 55	\$ 406	\$ (351)

The \$0.4 million decrease in interest and other income, net, for the three months ended March 31, 2009, compared to the three months ended March 31, 2008, 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**



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Our cash and cash equivalents, and short-term investments balances as of March 31, 2009 and December 31, 2008 are summarized as follows:

	As of March 31, 2009		As of December 31, 2008
	(in thousands)		
Cash and cash equivalents	\$ 11,960	\$	13,373
Short-term investments			5,752
Total cash and cash equivalents and short-term investments	\$ 11,960	\$	19,125

### *Sources of Liquidity*

We are in the development stage and have incurred losses since our inception in June 2002. As of March 31, 2009, we had an accumulated deficit of \$143.8 million. Prior to our Initial Public Offering in February 2007, 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. Upon completion of the reduction in force in April 2009, our cash requirements were greatly reduced. On May 11, 2009, our board of directors concluded that a statutory dissolution and liquidation was the preferred strategy and therefore adopted a Plan of Complete Liquidation and Dissolution, or Plan of Dissolution, and recommended approval of the Plan of Dissolution by our stockholders. The Plan of Dissolution is subject to approval at a special meeting of our stockholders, which is expected to be held during the second quarter of 2009.

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As of March 31, 2009, we did not have any outstanding or available debt financing arrangements, we had working capital of \$10.9 million, and our primary source of liquidity was \$12.0 million in cash and cash equivalents.

*Cash Flows*

Our operating, investing and financing activities for the three months ended March 31, 2009 and March 31, 2008 are summarized as follows:

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in thousands)</b>	
Net cash used in operating activities	\$ (6,957)	\$ (11,309)
Net cash provided by investing activities	5,539	14,127
Net cash provided by financing activities	5	32
Net (decrease) increase in cash and cash equivalents	\$ (1,413)	\$ 2,850

*Operating Activities*

Net cash used in operating activities was \$7.0 million for the three months ended March 31, 2009, compared to \$11.3 million for the three months ended March 31, 2008. The net cash used in operating activities for the three months ended March 31, 2009 and 2008 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 charges in operating assets and liabilities, including an asset impairment charge of \$2.5 million, based on the estimated liquidation value of long-lived assets.

*Investing Activities*

Net cash provided by investing activities was \$5.5 million for the three months ended March 31, 2009, compared to \$14.1 million for the three months ended March 31, 2008. Net cash provided by investing activities for the three months ended March 31, 2009 was attributable to the proceeds from the maturities of investments of \$5.7 million, which were partially offset by the purchase of property and equipment of \$0.2 million. Net cash provided by investing activities for the three months ended March 31, 2008 was primarily attributable to the sale of investments of \$10.0 million and the proceeds from maturities of investments of \$9.9 million, which were partially offset by the purchase of short-term investments of \$5.5 million and the purchase of property and equipment of \$0.3 million.

*Financing Activities*

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Net cash provided by financing activities for the three months ended March 31, 2009 was \$5,000, compared to \$32,000 for the three months ended March 31, 2008. Net cash provided by financing activities for each of the three months ended March 31, 2009 and 2008 was attributable to the proceeds from the exercise of stock options.

### *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 secure additional funding to commercialize our products in the European Union and obtain FDA marketing approval for, and begin selling, our Custom NX DES Systems. If we were to continue our operations, we anticipate that we would 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. Our current cash and cash equivalents are not sufficient to meet the cash requirements of these activities.

In January 2009, we notified our employees that we were initiating a headcount reduction that would impact 94% of our employees. We substantially completed this reduction on March 31, 2009 and expect to fully complete it by April 30, 2009. With this reduction, we believe that our cash and cash equivalents and short-term investments will be sufficient to meet our anticipated cash requirements through at least December 31, 2009. Our board of directors approved the Plan of Dissolution on May 11, 2009 and on May 15, 2009 we filed a preliminary proxy with the SEC for the purpose of obtaining stockholder

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approval of the Plan of Dissolution. If, on the other hand, we identify and complete a strategic transaction, substantial changes may be made to our current operations or they may be completely discontinued. For example, if we are acquired by a third party, that third party may choose to not pursue some or any of our current product development initiatives, such as our Custom NX drug eluting stent systems, our Custom NX peripheral stent technology, our customizable drug eluting balloon technology or our bioabsorbable stent technology.

Our forecasts for the period of time through which our financial resources will be adequate to support our operations 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 I 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. If we do not dissolve and liquidate our assets, 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 March 31, 2009 consist of obligations under operating leases and purchase obligations that we enter into through the normal course of business. See Note 7 of our Notes to Condensed Financial Statements for more detailed information.

#### ***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 February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* ( SFAS No. 159 ). SFAS No. 159 expands the use of fair value accounting but does not affect existing standards which require assets or liabilities to be carried at fair value. The objective of SFAS No. 159 is to improve financial reporting by providing companies with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex

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hedge accounting provisions. Under SFAS No. 159, a company may elect to use fair value to measure eligible items at specified election dates and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. Eligible items include, but are not limited to, accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees, issued debt and firm commitments. If elected, SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS 159 has not impacted our results of operations and financial condition as we have not elected the fair value option for any of our eligible items.

In April 2009, the FASB issued FSP SFAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. This FSP amends SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, to require publicly-traded companies, as defined in APB Opinion No. 28, *Interim Financial Reporting*, to provide disclosures on the fair value of financial instruments in interim financial statements. Prior to the issuance of FSP FAS No. 107-1 and APB Opinion No. 28-1, the fair values of those assets and liabilities were disclosed only once each year. With the issuance of FSP FAS No. 107-1 and APB Opinion No. 28-1, we will now be required to disclose this information on a quarterly basis, providing quantitative and qualitative information about fair value estimates for all financial instruments not measured in the Condensed Consolidated Balance Sheets at fair value. FSP SFAS 107-1 and APB 28-1 are effective for interim periods ending after June 15, 2009. We will adopt the new disclosure requirements in the second quarter of fiscal 2009. We do not expect the adoption to have a material impact on our condensed financial condition, results of operations, or cash flows.

On January 1, 2009, we adopted SFAS No. 157-2, *Effective Date of FASB Statement No. 157*, ( FSP SFAS 157-2 ), which delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis to fiscal years beginning November 15, 2008. The adoption of FSP SFAS No. 157-2 did not have a material impact on our financial position, operating results or cash flows.

On January 1, 2009, we adopted SFAS No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, ( FSP SFAS 157-3 ), which clarifies the application of Statement 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. The adoption of FSP SFAS No. 157-3 did not have a material impact on our financial position, operating results or cash flows.

In April 2009, the FASB issued FSP SFAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*, or FSP SFAS 157-4, which provides additional guidance for estimating fair value in accordance with SFAS 157 when the volume and level of activity for the asset or liability have significantly decreased. This FSP re-emphasizes that regardless of market conditions the fair value measurement is an exit price concept as defined in SFAS 157. This FSP clarifies and includes additional factors to consider in determining whether there has been a significant decrease in market activity for an asset or liability and provides additional clarification on estimating fair value when the market activity for an asset or liability has declined significantly. The scope of this FSP does not include assets and liabilities measured under level 1 inputs. FSP SFAS 157-4 is applied prospectively to all fair value measurements where appropriate and will be effective for interim and annual periods ending after June 15, 2009. We will adopt the provisions of FSP SFAS 157-4 effective the second quarter of fiscal 2009, which we do not expect to have a material impact on our condensed financial condition, results of operations, or cash flows.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

**Interest rate risk**

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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 March 31, 2009 consist of liquid money market funds, U.S. government securities and commercial paper. We did not have short-term investments as of March 31, 2009. Due to the short-term nature of our investments, we believe that there is no material exposure to interest rate risk.

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**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.

**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 March 31, 2009.

**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 March 31, 2009 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**

On May 11, 2009 our board of directors approved the Plan of Dissolution and we plan to file a preliminary proxy with the SEC on or about May 15, 2009 for the purpose of obtaining stockholder approval of the Plan of Dissolution. If our stockholders approve the Plan of Dissolution, we will pursue a revenue clearance certificate from the Department of Finance of the State of Delaware and, once received, file a Certificate of Dissolution with the State of Delaware Secretary of State. The risks described below under the caption Risks Related to the Plan of Dissolution address risks we and our stockholders face if the Plan of Dissolution is approved.

**Risks Related to Our Plan of Dissolution**

*The amount we distribute to our stockholders pursuant to the Plan of Dissolution may be substantially less than the amount we currently estimate if the amounts of our liabilities, other obligations and expenses and claims against us are higher than we currently anticipate.*

The amount of cash ultimately distributed to stockholders pursuant to the Plan of Dissolution depends on the amount of our liabilities, obligations and expenses and claims against us, and contingency reserves that we establish, during the liquidation process, and the amount we generate from the sale of our remaining non-cash assets and intellectual property. We have attempted to estimate reasonable reserves for such

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liabilities, obligations, expenses and claims against us. However, those estimates may be inaccurate. Factors that could impact our estimates include the following:

- If any of the estimates regarding the Plan of Dissolution, including the net proceeds from the sale of our tooling and manufacturing and test equipment, furniture and supplies, and the expense of satisfying outstanding obligations, liabilities and claims during the liquidation process are inaccurate, the amount we distribute to our stockholders may be substantially less than the amount we currently estimate. Given the current macroeconomic conditions, for purposes of our estimates we have assigned no value to our drug eluting stent systems and related intellectual property. If claims are asserted against us, including any claims related to payments to suppliers or other vendors or claims from patients in our clinical trials, we will have to defend or resolve such claims before making distributions to our stockholders, which will reduce amounts otherwise available for distribution to our stockholders;
- We have made estimates regarding the expense of personnel required and other operating expenses (including legal, accounting and other professional fees) necessary for us to dissolve and liquidate. Our actual expenses could vary significantly and depend on the timing and manner of the sale of our non-cash assets. If the timing differs from our plans, we may incur additional expenses above our current estimates, which could substantially reduce funds available for distribution to our stockholders; and
- We have assumed that all material contract rights can be effectively transferred to third parties. If we are unable to obtain any required consents with the counterparties to those contracts, our ability to transfer such rights may be impaired.

*We may continue to incur the expenses of complying with public company reporting requirements, which may be economically burdensome.*

Whether or not the Plan of Dissolution is approved, we have an obligation to continue to comply with the applicable reporting requirements of the Exchange Act, even though compliance with such reporting requirements may be economically burdensome and of minimal value to our stockholders. If the Plan of Dissolution is approved by our stockholders, in order to curtail expenses, we intend, on or about the Effective Date, to seek relief from the SEC to suspend our reporting obligations under the Exchange Act, and ultimately to terminate the registration of our common stock. We anticipate that, if granted such relief, we would continue to file current reports on Form 8-K to disclose material events relating to our dissolution and liquidation along with any other reports that the SEC might require. To the extent that we are unable to suspend our obligation to file periodic reports with the SEC, we will be obligated to continue complying with the applicable reporting requirements of the Exchange Act and, as a result, will be required to continue to incur the expenses associated with these reporting requirements, which will reduce the cash available for distribution to our stockholders. These expenses include, among others, those costs relating to:

- the preparation, review, filing and dissemination of SEC filings;
- maintenance of effective internal controls over financial reporting; and
- audits and reviews conducted by our independent registered public accountants.

***If the amount of our contingency reserve is insufficient to satisfy the aggregate amount of our liabilities and other obligations, each stockholder may be liable to our creditors for the amount of liquidating distributions received by such stockholder under the Plan of Dissolution, which could also have adverse tax consequences.***

After the Effective Date, our corporate existence will continue, but we will not be able to carry on any business except for the purpose of winding up our business and affairs. Following the Effective Date, we will pay or make reasonable provision to pay all claims and obligations, including all contingent, conditional or unmatured contractual or statutory claims, known to us. We also may obtain and maintain insurance coverage or establish and set aside a reasonable amount of cash or other assets as a contingency reserve to satisfy claims against us or other obligations. In the event that the amount of the contingency reserve, insurance and other measures calculated to provide for the satisfaction of liabilities and claims are insufficient to satisfy the aggregate amount ultimately found payable in respect of our liabilities and claims against us, each stockholder could be held liable for amounts due to creditors up to the amounts distributed to such

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stockholder under the Plan of Dissolution. In such event, a stockholder could be required to return all amounts received as distributions pursuant to the Plan of Dissolution and ultimately could receive nothing under the Plan of Dissolution. Moreover, for U.S. federal income tax purposes, payments made by a stockholder in satisfaction of our liabilities not covered by the cash or other assets in our contingency reserve or otherwise satisfied through insurance or other reasonable means generally would produce a capital loss for such stockholder in the year the liabilities are paid. The deductibility of any such capital loss generally would be subject to limitations under the Internal Revenue Code of 1986, as amended, or the Code.

*Liquidating distributions to our stockholders could be delayed or diminished.*

All or a portion of any distributions to our stockholders could be delayed, depending on many factors, including, without limitation:

- if a creditor or other third party seeks an injunction against the making of distributions to our stockholders on the ground that the amounts to be distributed are needed to provide for the satisfaction of our liabilities or other obligations;
- if we become a party to lawsuits or other claims asserted by or against us, including any claims or litigation arising in connection with our decision to liquidate and dissolve, payments to suppliers or other vendors or claims from patients in our clinical trials;
- if we are unable to sell our remaining non-cash assets or if such sales take longer than expected;
- if we are unable to resolve claims with creditors or other third parties, or if such resolutions take longer than expected; or
- if the issuance of the revenue clearance certificate required to file our certificate of dissolution with the Secretary of State is delayed.

Any of the foregoing could delay or substantially diminish the amount available for distribution to our stockholders. In addition, under the Delaware General Corporation Law, or DGCL, claims and demands may be asserted against us at any time during the three years following the Effective Date. Accordingly, our board of directors may obtain and maintain insurance coverage or establish and set aside a reasonable amount of cash or other assets as a contingency reserve to satisfy claims against us or other obligations that may arise during the three-year period following the Effective Date. As a result of these factors, we may retain for distribution at a later date, some or all of the estimated amounts that we expect to distribute to stockholders.

*Stockholders will lose the opportunity to capitalize on potential growth opportunities from the continuation of our business.*

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Although our board of directors believes that the Plan of Dissolution is more likely to result in greater returns to stockholders than if we continued as a stand-alone entity or pursued other alternatives, if the Plan of Dissolution is approved, stockholders will lose the opportunity to capitalize on our business and possible future growth opportunities that may have arisen if we had continued our drug eluting stent business or pursued other alternatives. It is possible that these opportunities could prove to be more valuable than the liquidating distributions our stockholders would receive pursuant to the Plan of Dissolution.

*Stockholders may not be able to recognize a loss for U.S. federal income tax purposes until they receive a final distribution from us.*

As a result of our dissolution and liquidation, for U.S. federal income tax purposes, our stockholders generally will recognize gain or loss equal to the difference between (i) the sum of the amount of cash and the fair market value (at the time of distribution) of property, if any, distributed to them, and (ii) their tax basis for their shares of our common stock. Liquidating distributions pursuant to the Plan of Dissolution may occur at various times and in more than one tax year. Any loss generally will be recognized by a stockholder only when the stockholder receives our final liquidating distribution to stockholders, and then only if the aggregate value of all liquidating distributions with respect to a share is less than the stockholder's tax basis for that share. Stockholders are urged to consult their own tax advisors as to the specific tax consequences to them of our dissolution and liquidation pursuant to the Plan of Dissolution.

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***Recordation of transfers of our common stock on our stock transfer books will be restricted as of a future date that our board of directors will determine, and thereafter it generally will not be possible for stockholders to change record ownership of our stock.***

Our board of directors may direct that our stock transfer books be closed and recording of transfers of common stock discontinued as of the earliest of (x) the close of business on the record date fixed by our board of directors for the first or any subsequent installment of any liquidating distribution, (y) the close of business on the date on which our remaining assets are transferred to a liquidating trust, or (z) the date on or as reasonably practicable after the date on which we file our certificate of dissolution under the DGCL. We expect that our board of directors will close our stock transfer books on or around the Effective Date. The Effective Date will be determined following the receipt of a revenue clearance certificate from the Department of Finance and will be announced as soon as reasonably practicable after that time. Thereafter, certificates representing shares of our common stock will not be assignable or transferable on our books except by will, intestate succession or operation of law, and we will not issue any new stock certificates, other than replacement certificates. In addition, we anticipate that we will request that our common stock be delisted from the NASDAQ Global Market and that trading will be suspended on the Effective Date or as soon thereafter as is practicable.

***Further stockholder approval may not be required in connection with the implementation of the Plan of Dissolution, including for the sale of all or substantially all of our non-cash assets as contemplated in the Plan of Dissolution.***

The approval of the Plan of Dissolution by our stockholders also will authorize, without further stockholder action, our board of directors to do and perform, or to cause our officers to do and perform, any and all acts and to make, execute, deliver or adopt any and all agreements, resolutions, conveyances, certificates and other documents of every kind that our board of directors deems necessary, appropriate or desirable, in the absolute discretion of the board of directors, to implement the Plan of Dissolution and the transactions contemplated thereby, including, without limitation, all filings or acts required by any state or federal law or regulation to wind up its affairs. Accordingly, depending on the timing of a stockholder vote on the Plan of Dissolution, we may dispose of our drug eluting stent systems and related intellectual property and any and all of our other remaining non-cash assets without further stockholder approval. As a result, our board of directors may authorize actions in implementing the Plan of Dissolution, including the terms and prices for the sale of our drug eluting stent systems and related intellectual property and our other remaining non-cash assets, with which our stockholders may not agree.

***Our board of directors may revoke implementation of the Plan of Dissolution even if it is approved by our stockholders.***

Even if our stockholders approve the Plan of Dissolution at the special meeting of our stockholders, if for any reason our board of directors determines that such action would be in our best interests and the best interests of our stockholders, our board of directors may, in its sole discretion and without requiring further stockholder approval, revoke the Plan of Dissolution and all action contemplated thereunder, to the extent permitted by the DGCL. A revocation of the Plan of Dissolution would result in our stockholders not receiving any liquidating distributions pursuant to the Plan of Dissolution.

**Risks Related to Our Continuing Business Operations if the Plan of Dissolution is Not Approved by Our Stockholders**

If our stockholders do not approve the Plan of Dissolution, our board of directors will explore what, if any, alternatives are available for our future, particularly in light of the fact that we have terminated substantially all of our employees, would need significant additional capital to

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support our U.S. pivotal clinical trial and efforts to commercialize our products in Europe, commenced the process of winding up our business and will continue to incur net losses for the foreseeable future. There is currently no active business left to operate and rehiring employees may not be possible, or would take several months at a cost we are unable to estimate.

Possible alternatives include selling all of our stock or assets, changing our business focus, conducting an issuer tender offer, continuing our efforts to identify a merger partner or a reverse merger partner, or seeking voluntary dissolution at a later time and with diminished assets. At this time, our board of directors has considered all of these options and has determined that it is in the best interests of our stockholders for us to dissolve and return the cash to stockholders. The board of directors, however, retains the right to consider other alternatives should a more attractive offer arise before or after the filing of our Certificate of Dissolution, if the Plan of Dissolution is approved by our stockholders. If our stockholders do not approve the Plan of Dissolution, we expect that our cash resources will continue to diminish and we would face risks related to continuing our historical business described below. These risks could materially and adversely affect our business, financial condition or operating results and the value of our common stock, and you may lose all or part of your investment. Moreover, any alternative we select may have unanticipated negative consequences.

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**The risks below describe the risks related to our business if the Plan of Dissolution is not approved and we continue to pursue a strategy of using our cash on hand, any cash generated from financing activities, and any cash that may be generated by our drug eluting stent business to support our continued operations while we continue to explore whether there may be opportunities to realize potential value from our remaining business assets.**

The risks and uncertainties described below are not the only ones facing us, and our risks and uncertainties may change if the Plan of Dissolution is not approved and we alter our business strategy. Additional considerations not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occurs, our business, financial condition or operating results could be materially and adversely affected, the value of our common stock could decline and our stockholders may lose all or part of their investment.

**Risks Related to Our Business**

**We are exploring strategic alternatives such as a potential merger or a sale of some or all of our assets, and have reduced our headcount significantly. If we are not successful in completing a strategic transaction or securing adequate funding, we may have to wind up and liquidate our business.**

We engaged Piper Jaffray & Co. to help us explore potential strategic alternatives such as a sale of some or all of our assets or a merger transaction. There can be no assurance that we will be able to complete such a transaction on terms acceptable to us, or at all. We do not have sufficient cash to commercialize our product in Europe or, even if we are successful in obtaining an investigational device exemption, or IDE, to initiate our U.S. pivotal clinical trial. If we are unsuccessful in identifying and completing a strategic transaction or securing adequate funding, we may not be able to continue our operations and may need to wind up our business and liquidate our assets.

In January 2009, we notified our employees that we would reduce our headcount by eliminating 115 of 122 positions, effective March 23, 2009. The significant reduction in headcount may make it less likely that we will be able to complete a strategic transaction. Certain third parties who might otherwise consider a strategic transaction may be unwilling to do so if they are not able to retain certain of our employees. Likewise, certain third parties who might otherwise consider a strategic transaction may be unwilling to do so in light of the fact that we have announced the approval of the Plan of Dissolution by our board of directors.

**Even if we are successful in completing a strategic transaction, the nature of such a transaction may require us to significantly alter or cease our current operations.**

Among other strategic alternatives, we are considering the sale of individual assets, such as our Custom NXP peripheral stent technology, our bioabsorbable stent technology, our customizable drug eluting balloon technology and our principal product, the Custom NX coronary stent system. To date, our activities have primarily focused on the development of the Custom NX systems. If we sell our Custom NX product, we will need to refocus our efforts and dedicate significant resources to the development of one or more of our non-core products. There can be no assurance that we will be able to successfully develop, market and commercialize any or all of such products. If, pursuant to a strategic transaction, we sell one of our non-core products, we may not receive sufficient consideration to fund the European commercialization of our Custom NX system or the initiation of our IDE trial.



**Even if we obtain additional funding or complete a strategic transaction that provides adequate resources, it may be a year or more before we are able to commercialize our product in Europe.**

We have significantly reduced our headcount and limited our business activities. Before we could resume the operations required in order to commercialize our product, we would need to rehire a significant number of employees or hire and train new employees that can perform their jobs according to our specifications. There can be no assurance that we will be able to rehire our former employees or hire and train qualified new employees in a timely manner, or at all. In addition, before we can commercialize our product in Europe, we need to increase our manufacturing capacity and validate our manufacturing process to demonstrate compliance with applicable quality standards. This validation would likely take six to nine months to complete. Further, under the terms of the agreements we have with several of our suppliers, we are required to provide regular forecasts of the components we plan to purchase from them during a particular period. These suppliers are obligated to supply us only with the number of components that we previously forecasted. Therefore, once manufacturing operations commence, it may take several months before we have adequate supplies of critical components required to make our products.

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**We need substantial additional funding and may be unable to raise capital in adequate amounts, or at all, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.**

Due to the ongoing credit crisis and general deterioration of the capital markets we have been unable to date to secure additional financing. We have engaged Piper Jaffray & Co. to help us explore strategic alternatives, including raising additional capital, however we can provide no assurance that any strategic alternative will result in adequate, or any, capital being made available to us. We need to raise substantial additional capital to:

- fund our operations and clinical trials;
  
- continue our research and development;
  
- 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.

After our reduction in headcount, we believe our existing cash and cash equivalent balances and interest we earn on these balances will be sufficient to meet our cash requirements for the next 12 months, although our business activities will be limited until such time as further financing is obtained, if at all. Our future funding requirements will depend on many factors, including:

- the nature and timing of any strategic transaction we may complete, if any;
  
- 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;

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- 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.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders, or may not be available at all. 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.

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We require additional capital beyond our current cash balance. For example, we will need to raise additional funds in order to commercialize our products. Any such required additional capital may not be available on reasonable terms, if at all. We estimate that it would cost approximately \$45.0 million to complete our CUSTOM IV and V clinical trials. In addition, we would need to 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.

**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, 2008, 2007, and 2006, we had net losses of \$41.1 million, \$38.8 million and \$25.0 million, respectively. As of March 31, 2009, we had an accumulated deficit of \$143.8 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 only recently received CE Mark and we do not have approval from the Food and Drug Administration, or FDA, or any other regulatory authority for our products, we are only authorized to market our current products in the European Union and certain other countries that recognize CE Mark, and we have not generated any revenues since our inception. If we continue as an operating business, we expect our research and development expenses to increase significantly in connection with our clinical trials and other product development activities. If we obtain additional funding or complete a strategic transaction that provides adequate resources, 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 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 commercialization of our Custom NX DES Systems in the United States.**

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 A<sup>®</sup>, an anti-inflammatory drug that is a derivative of rapamycin, and PolyLactic Acid, or PLA, 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 jurisdiction other than the European Union. In March 2009, we received CE Mark approval for our Custom NX DES Systems authorizing us to market our Custom NX DES Systems in the European Union and certain other countries that recognize 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 premarket approval, or 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. We believe the MAF which Biosensors has submitted to the FDA for purposes of our IDE application is sufficient to support an IDE approval, but we expect the FDA to conduct additional assessments of

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the MAF as part of our PMA review, and they may have additional questions at that time. Any delays Biosensors experiences or problems it has in responding to questions the FDA may have concerning the MAF may substantially delay the commercial launch of our product in the United States.

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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

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- 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 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 markets, other than the European Union and certain other countries that recognize CE Mark. If we obtain the necessary regulatory approvals and provided we obtain additional funding or complete a strategic transaction that provides adequate resources, we plan initially to launch our products in the European Union and later in the United States.

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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 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 United States or in foreign markets other than the European Union and certain other countries that recognize CE Mark. 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,



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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 became 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,
- Animal studies,
- Chemistry and manufacturing controls,

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

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, and we are able to launch our product commercially, we would 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 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

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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 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 Endeavo® 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-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.

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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.

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**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 three 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 need 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 V 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 2,100 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:

- insufficient personnel and financial resources to conduct and fund our clinical trials;
  
- in connection with our PMA application, 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;
  
- 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;

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- 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;
- 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. We filed our IDE application in September 2007, and in October 2007, we received questions back from the FDA. In February 2009, we resubmitted our IDE application, and in April 2009, we received additional comments from the FDA. Even if we receive IDE approval from the FDA, we will not be able to initiate our IDE trial unless we obtain additional funding or complete a strategic transaction that provides adequate resources. We cannot guarantee that such a financing or strategic transaction will be available on terms agreeable to us, or at all.

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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 need to provide the FDA with data on approximately 2,100 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 favorable than typical results of practicing physicians, which could negatively impact rates of adoption of our products. In addition to



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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.

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**Problems with the stent to be used in the control group during our 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. Treatments may exhibit a favorable measure using one metric 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.

**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

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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.

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.

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

Subject to the availability of sufficient resources, we intend to market our products in international markets. Although we have received CE Mark authorizing us to market our Custom NX DES Systems in the European Union and certain other countries that recognize CE Mark, in order to market our products in 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 markets other than the European Union.

**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.

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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 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 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

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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.**



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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 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;

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- 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 December 31, 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 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,

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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:

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- 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;
- 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.

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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 Liberté 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. Subject to the availability of adequate resources, we plan to market our product in Europe through independent distributors. We have not hired any European sales people or entered into any third-party distribution agreements.

Subject to the availability of adequate resources, 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.

**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.**

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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. Furthermore, effective March 23, 2009, we substantially completed a reduction in our headcount from 122 to 5 employees, and we fully completed that reduction by April 30, 2009. None of the remaining employees will be manufacturing personnel. 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

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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. We expect to be audited in the third quarter of 2009, but we do not believe that we have adequate personnel to pass the audit. We will not be able to commercialize our product until we successfully pass the audit. 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.



**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. Our current agreement with SurModics, allows SurModics to terminate the agreement if we do not commercialize our product by July 1, 2009. We do not expect to commercialize our product by that date. 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

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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 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. If we continue as an operating business, as our resources permit, we would plan to conduct such activities 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. 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.

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

We are dependent on our President and Chief Executive Officer, Gregory D. Casciaro and our Vice President, Quality Assurance, Clinical and Regulatory Affairs, Philippe Marco, M.D. Due to the specialized knowledge both of these officers possesses with respect to interventional cardiology and our business activities, the loss of service of either of these officers could delay or prevent the successful completion of a fundraising event, a strategic transaction, or provided that we can continue with our ongoing operations, our clinical trials and the commercialization of our Custom NX DES Systems. Either of these 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 Philippe Marco, M.D. In connection with our reduction in force and our plans to explore strategic alternatives, we entered into retention and severance agreements with nine of our employees, including our executive officers. Pursuant to these agreements, we have agreed to make retention payments to each of these employees,

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provided their employment is not terminated for cause prior to the date upon which we complete a strategic transaction, or the employee's expected termination date, whichever is earlier. The expected termination dates for these employees range from March 31, 2009 to July 31, 2009.

**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 being transitioned over a three year period that began in fiscal year 2007. In 2007, The Centers for Medicare and Medicaid Services, or CMS, which is responsible for administering the Medicare program, also implemented revised reimbursement codes that better reflect the severity of the patient's condition in the hospital inpatient prospective payment system. 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.

**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.

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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 report on Form 10-K for the year ended December 31, 2008. 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;

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- 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' earnings 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 March 31, 2009, our officers, directors and principal stockholders each holding more than 5% of our common stock collectively controlled approximately 75.6% 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 months, has experienced significant volatility, including 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.

**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;

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- 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**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

None

**ITEM 5. OTHER INFORMATION**

None.

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**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
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(5)	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.

(5) Incorporated by reference from our Quarterly Report on Form 10-Q for the quarter ended September 30, 2008, filed on November 12, 2008.

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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: May 15, 2009

By:

/s/ GREGORY D. CASCIARO  
**GREGORY D. CASCIARO**  
**President and Chief Executive Officer**  
**(Principal Executive Officer)**

Date: May 15, 2009

By:

/s/ TIMOTHY D. KAHLENBERG  
**TIMOTHY D. KAHLENBERG**  
**Chief Financial Officer**  
**(Principal Accounting and Financial Officer)**