XTENT INC
Form 10-Q
May 14, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2007

or

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

For the transition period from to

Commission File Number 001-33282

XTENT, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

125 Constitution Drive

Menlo Park, California 94025-1118

(Address of principal executive offices, including Zip Code)

(650) 475-9400

(Registrant s telephone number, including area code)

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

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

Large accelerated filer o Accelerated filer o Non-accelerated filer x

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

As of May 1, 2007, there were 22,863,666 shares of XTENT, Inc. common stock outstanding.

XTENT, INC.

FORM 10-Q

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PART I: FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

XTENT, INC.
(a development stage company)
CONDENSED BALANCE SHEETS

(unaudited; in thousands, except per share amounts)

	March 31, 2007	December 31, 2006 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 36,242	$ 23,105
Short-term investments	49,436	
Prepaid expenses and other current assets	945	269
Total current assets	86,623	23,374
Property and equipment, net	2,798	2,634
Deferred IPO related costs		990
Other non-current assets	123	123
Total assets	$ 89,544	$ 27,121
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,804	$ 860
Accrued liabilities	1,782	1,448
Total current liabilities	3,586	2,308
Redeemable convertible preferred stock:		
$0.001 par value; 10,000 and 14,874 shares authorized at March 31, 2007 and December 31, 2006, respectively; zero and 14,744 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively (Liquidation preference: $75,899 at December 31, 2006)		75,593
Stockholders Equity (Deficit):		
Common stock: $0.001 par value; 100,000 and 26,000 authorized at March 31, 2007 and December 31, 2006, respectively; 22,263 and 3,352 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively	23	3
Additional paid-in capital	148,557	3,956
Deferred stock-based compensation	(592)	(673)
Other comprehensive loss	(29)	
Deficit accumulated during development stage	(62,001)	(54,066)
Total stockholders equity (deficit)	85,958	(50,780)
Total liabilities, redeemable convertible preferred stock and stockholders equity (deficit)	$ 89,544	$ 27,121

(1)The condensed balance sheet at December 31, 2006 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.

XTENT, INC.
(a development stage company)
CONDENSED STATEMENTS OF OPERATIONS

(unaudited; in thousands, except per share amounts)

	Three Months Ended March 31, 2007 As restated	2006	Cumulative Period from June 13, 2002 (Inception) to March 31, 2007
Operating expenses:			
Research and development (1)	$ 6,223	$ 3,274	$ 49,749
General and administrative (1)	2,461	941	14,735
Total operating expenses	8,684	4,215	64,484
Loss from operations	(8,684)	(4,215)	(64,484)
Other income (expense):			
Interest income	749	108	2,483
Net loss	(7,935)	(4,107)	(62,001)
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock		(5,678)	(13,095)
Net loss attributable to common stockholders	$ (7,935)	$ (9,785)	$ (75,096)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.55)	$ (3.92)	
Weighted-average common shares outstanding	14,482	2,493	
(1) Includes the following stock-based compensation charges:			
Research and development	$ 388	$ 117	$ 1,960
General and administrative	$ 420	$ 55	$ 1,485

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

XTENT, INC.
(a development stage company)
CONDENSED STATEMENTS OF CASH FLOWS

(unaudited; in thousands)

	Three Months Ended March 31,		Cumulative Period from June 13, 2002 (Date of Inception) to March 31,
	2007	2006	2007
Cash flows from operating activities:			
Net loss	$ (7,935)	$ (4,107)	$ (62,001)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	268	154	1,848
Stock based compensation expense	808	172	3,445
Stock issued in exchange for services			230
Amortization of securities discount	(93)		(93)
Loss on disposal of property and equipment		9	82
Prepaid expenses and other current assets	(447)	12	(839)
Accrued interest receivable on securities	(229)		(229)
Accounts payable	944	(36)	1,804
Accrued liabilities	475	446	1,641
Net cash used in operating activities	(6,209)	(3,350)	(54,112)
Cash flows from investing activities:			
Purchase of investments	(49,372)		(49,372)
Purchase of property and equipment	(432)	(251)	(4,723)
Proceeds from sale of property and equipment			18
Net cash used in investing activities	(49,804)	(251)	(54,077)
Cash flows from financing activities:			
Proceeds from initial public offering, net of offering costs	69,112		68,237
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs		9,800	75,593
Principal payments on capital lease obligations			(23)
Proceeds from issuance of common stock to founders and exercise of stock options	38	83	624
Net cash provided by financing activities	69,150	9,883	144,431
Net increase in cash and cash equivalents	13,137	6,282	36,242
Cash and cash equivalents at beginning of period	23,105	6,564	
Cash and cash equivalents at end of period	$ 36,242	$ 12,846	$ 36,242
Supplemental disclosure of noncash investing and financing activities:			
Deferred stock based compensation	$	$	$ 1,272
Reversal of deferred stock-based compensation	$ (9)	$	$ (80)
Conversion of redeemable convertible preferred stock to common stock	$ 75,593	$	$ 75,593
Deferred initial public offering costs	$ 875	$	$
Dividend related to beneficial conversion feature of redeemable convertible preferred stock	$	$ (5,678)	$ (13,095)
Equipment acquired under capital leases	$	$	$ (23)
Vesting of restricted common stock from early exercises	$ 26	$ 30	$ 300
Changes in net unrealized gains (losses) on investments	$ (29)	$	$ (29)

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

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, 2007, the Company had an accumulated deficit of approximately $62.0 million. The Company has not achieved positive cash flows from operations for any year since inception. In May and June 2006, the Company completed a Series D redeemable convertible preferred stock financing and raised approximately $30.0 million in cash and on February 1, 2007 completed its initial public offering raising net proceeds of approximately $68.2 million. In order to continue its operations, the Company must achieve profitable operations, obtain additional debt financing or sell additional shares of its equity. There can be no assurance that the Company will be able to obtain additional debt or equity financing on terms acceptable to the Company, or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company s business, results of operations and financial condition.

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

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared by the Company in accordance with the accounting principles generally accepted in the United States of America for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair statement have been included. The results for the three month period ended March 31, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007, 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, 2006, filed with the Securities and Exchange Commission on April 2, 2007.

NOTE 2 - Summary of Significant Accounting Policy Update:

Investments

Investments consist primarily of fixed income securities. The Company classifies their investments as available-for-sale in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* and they are recorded at fair value. The fair value of investments is based on quoted market prices. Unrealized gains and losses are reported as a separate component of stockholders equity until realized. Premiums (discounts) on investments are amortized (accreted) to interest income over the life of the investment.

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 gain (loss) on investments represents the only component of other comprehensive loss that is excluded from the Company s net loss. Total comprehensive loss during the three months ended March 31, 2007 and 2006 consists of:

	Three Months Ended March 31,	
	2007	2006
	(in thousands)	
Net loss	$ (7,935)	$ (4,107)
Unrealized loss on investments	(29)	
Comprehensive loss	$ (7,964)	$ (4,107)

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 securities consisting of stock options, common stock subject to repurchase and redeemable convertible preferred stock 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:

	Three Months Ended March 31,	
	2007	2006
	(in thousands, except per share amounts)	
		As restated
Numerator:		
Net loss attributable to common stockholders	$ (7,935)	$ (9,785)
Denominator:		
Weighted-average common shares outstanding	14,854	3,083
Weighted-average unvested common shares subject to repurchase	(372)	(590)
Weighted-average number of common shares outstanding used in computing basic and diluted net loss per common share	14,482	2,493
Basic and diluted net loss per common share	$ (0.55)	$ (3.92)

The Condensed Statement of Operations for the three months ended March 31, 2006 has been restated from the amounts previously reflected in the Company s Registration Statement on Form S-1 to reflect a revision in the weighted-average common shares outstanding, and the related net loss per share attributable to common stockholders. Subsequent to the filing of the Registration Statement on Form S-1 on August 7, 2006, and the subsequent amendments thereto, the Company discovered an error in the calculation of the weighted-average common shares outstanding, related to treatment of the restricted stock from early exercise of stock options. As a result, the weighted-average shares has been adjusted from approximately 2.02 million post-split shares to approximately 2.5 million shares, and the net loss per share from $4.83 per share to $3.92 per share.

The following table contains selected unaudited condensed statement of operations data:

	Fiscal 2006 Quarter Ended March 31, 2006 As Restated (in thousands, except per share amounts)	As Previously Reported
Net Loss	$ (4,107)	$ (4,107)
Net loss attibutable to common stockholders	$ (9,785)	$ (9,785)
Basic and diluted net loss per share attibutable to common stockholders	$ (3.92)	$ (4.83)
Weighted average common shares outstanding	2,493	2,024

The following redeemable convertible preferred stock and stock options were excluded from the computation of diluted net loss per common share for the periods presented because including them would have an antidilutive effect:

	Three Months Ended March 31, 2007 (in thousands)	2006
Redeemable convertible preferred stock		11,373
Options to purchase common Stock	1,853	1,047
Common stock subject to repurchase	350	635
Shares issuable through Employee Stock Purchase Plan	9	

Recent Accounting Pronouncements

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 159, *The fair Value Option for Financial Assets and Financial Liabilities including an amendment of FAS115* (SFAS No. 159). SFAS No. 159 allows companies to choose, at specified election dates, to measure eligible financial assets and liabilities at fair value that are not otherwise required to be measured at fair value. Unrealized gains and losses shall be reported on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS No. 159 also establishes presentation and disclosure requirements. SFAS No. 159 is effective for the Company in fiscal year 2008 and will be applied prospectively. The Company is currently evaluating the impact of adopting SFAS No. 159 on its financial statements.

NOTE 3 - Investments

The fair value of investments as of March 31, 2007 is summarized below:

	Amortized Cost (in thousands)	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 11,853	$	$ (18)	$ 11,835
US Government securities (maturities less than one year)	27,173	3	(6)	27,170
Corporate bonds (maturities less than one year)	10,439		(8)	10,431
Total	$ 49,465	$ 3	$ (32)	$ 49,436

NOTE 4 - Common Stock

On January 22, 2007, the Company effected a 1-for-2 reverse stock split of its common stock and redeemable convertible preferred stock pursuant to the filing of an Amended and Restated Certificate of Incorporation. Such Amended and Restated Certificate of Incorporation also provided for the automatic conversion of the then outstanding shares of redeemable convertible preferred stock into shares of common stock. All share and per share amounts included in the Company s condensed financial statements have been adjusted to reflect this reverse stock split for all periods presented.

On February 1, 2007, the Company sold 4,700,000 shares of its common stock at a public offering price of $16.00 per share. Net cash proceeds from the initial public offering were approximately $68.2 million, after deducting underwriting discounts and commissions and other offering costs. In connection with the closing of the initial public offering, all of the Company s shares of Series A, B, C and D redeemable convertible preferred stock outstanding at the time of the offering were automatically converted into 14,744,196 shares of common stock.

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

Restricted common stock

Certain common stock option holders have the right to exercise unvested options, subject to a repurchase right held by the Company to repurchase the stock, at the original exercise price, in the event of voluntary or involuntary termination of employment of the stockholder. In accordance with Emerging Issues Task Force Issue No. 00-23, *Issues Related to the Accounting for Stock Compensation* under APB 25 and FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, the Company accounts for the cash received in consideration for the early exercised options as a liability. As of March 31, 2007 and December 31, 2006, there were approximately 350,000 and 417,000 shares of common stock, respectively, subject to repurchase, and a related liability of $141,000 and $167,000, respectively.

NOTE 5 - Stock Option Plans

Stock option activity for the three month period ended March 31, 2007 is as follows:

		Options Outstanding	
	Shares Available for Grant	**Number of Shares**	**Weighted Average Exercise Price**
	(in thousands, except weighted average exercise price)		
Balances, December 31, 2006	132	1,894	$ 3.09
Additional shares reserved	400		
Options granted	(65)	65	15.01
Options exercised		(67)	0.57
Options forfeited/expired	39	(39)	3.80
Balances, March 31, 2007	506	1,853	$ 3.59

2006 Employee Stock Purchase Plan

In August 2006, the Company adopted the 2006 Employee Stock Purchase Plan (ESPP), which became effective upon the Company s initial public offering on February 1, 2007. A total of 500,000 shares of common stock have been reserved for issuance. In addition, the 2006 Employee Stock Purchase Plan provides for annual increases in the number of shares available for issuance under the Plan on the first day of each fiscal year, beginning with the Company s fiscal year 2008, equal to the lesser of: 3% of the outstanding shares of the Company s common stock on the first day of the fiscal year; 1,000,000 shares; or such other amount as the Company s Board of Directors may determine. All of the Company s employees are eligible to participate if they are customarily employed by the Company for at least 20 hours per week and more than five months in any calendar year. However, an employee may not be granted an option to purchase stock if such employee, immediately after grant, owns stock possessing 5% or more of the total combined voting power or value of all classes of the Company s capital stock, or whose rights to purchase stock under all of the Company s employee stock purchase plans accrues at a rate that exceeds $25,000 worth of stock for each calendar year.

Offering periods are scheduled to start on the first trading day on or after May 15 and November 15 of each year, except for the first such offering period, which commenced on February 1, 2007, upon completion of the Company s initial public offering, and will end on the first trading day on or after May 15, 2007. The 2006 Employee Stock Purchase Plan permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation which includes a participant s base salary, wages, overtime and shift premium, commissions, but exclusive of payments for incentive compensation, bonuses and other compensation. A Participant may purchase a maximum of 1,250 shares during a six-month purchase period.

Amounts deducted and accumulated by the participant are used to purchase shares of the Company s common stock at the end of each six-month purchase period. The purchase price of the shares will be 85% of the lower of the fair market value of the Company s common stock on the first trading day of each offering period or on the exercise date. If the fair market value of the Company s common stock on the exercise date is less than the fair market value on the first trading day of the offering period, participants will be withdrawn from the current offering period following their purchase of shares on the purchase date and will be automatically re-enrolled in a new offering period. Participants may end their participation at any time during an offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon termination of employment with the Company. The 2006 Employee stock purchase plan will automatically terminate in 2016, unless the Company terminates it sooner. Through March 31, 2007, no shares have been issued in connection with the 2006 Employee Stock Purchase Plan.

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 January 1, 2007, the Company has no unrecognized tax benefit. The adoption of FIN 48 resulted in no change to the reserve for unrecognized tax benefits that existed at January 1, 2007, and there is no change recorded to the beginning retained earnings as a result of the adoption of FIN 48.

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, 2007.

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

NOTE 9 - Subsequent Event

In April 2007, the Company entered into a supply agreement with Fortimedix B.V., a company organized under the laws of the Netherlands, under which Fortimedix agreed to manufacture and deliver stents for use in the Company s products. The terms of the agreement require minimum purchases over the next two years at contractual prices set in Euros. The Company estimates that the total minimum obligation under this agreement will be at least $6.4 million through the end of the calendar year 2008, calculated using the Euro to dollar exchange rate as of the date the agreement was signed.

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, 2006 and in our other filings with the Securities and Exchange Commission (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.

Overview

We are a development stage medical device company focused on developing and commercializing our proprietary Custom NX® drug eluting stent, or DES, Systems to treat coronary artery disease, or CAD. Since inception we have devoted substantially all of our resources to start-up activities, raising capital and 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 lengths with a single device. Our stent systems, the Custom NX 36 and the Custom NX 60, incorporate a modular cobalt chromium stent design as well as a proprietary delivery system. In addition, our stents have a drug coating that is made up of Biolimus A9, an anti-inflammatory drug, and PolyLactic Acid, a biodegradable polymer, which in combination are intended to reduce the incidence of restenosis, or renarrowing of the previously treated artery over time. We have not yet received any government regulatory approvals necessary to commercialize any of our products.

We are developing 36mm and 60mm stent systems based on our proprietary technology platform. Our stent design is modular in that it consists of multiple 6mm segments in which the ends of each segment interleave with the ends of the adjacent segments, or are interdigitated. This interdigitated modular stent design allows the physician to customize the stent length and deploy the necessary stent segments in the artery in-situ. Our delivery system incorporates a protective sheath and a proprietary mechanism to control the number of stent segments deployed. Our first two stent systems in development are the 36mm Custom NX 36 and the 60mm Custom NX 60. We believe these two systems will enable physicians to provide a therapeutic solution for the majority of CAD patients treated with currently marketed drug eluting stents. Our Custom NX 36 is customizable in length and designed to treat single or multiple lesions. Our Custom NX 60 is designed to give physicians a suitable length stent to treat one long lesion or multiple smaller lesions with the use of one device, reducing the need for multiple catheter exchanges and related device costs. We believe the ability to customize our stent and potentially treat multiple lesions and long lesions with one catheter may improve procedural efficacy and efficiency and lower costs.

We are conducting clinical trials to evaluate our Custom NX 36 and Custom NX 60 stent and stent delivery systems. In May 2006, the eight month clinical data from our CUSTOM I clinical trial was presented at the 2006 Paris Course on Revascularization conference and in October 2006, six month clinical data from our CUSTOM II clinical trial for 40 patients was presented at the 2006 Transcatheter Cardiovascular Therapeutics conference. We believe the data from these clinical trials provided preliminary evidence of safety and efficacy and supports further development of our in-situ customization approach. In 2006 we completed enrollment of our CUSTOM II clinical trial and initiated our CUSTOM III clinical trial, both of which are designed to further evaluate the safety and efficacy of in-situ customization with our stents, particularly in patients with long lesions and multiple lesions. Assuming the results from these trials are favorable, we believe the data from our CUSTOM I, II and III clinical trials will be sufficient to support our submission to our designated Notified Body in the European Union for CE Mark. We expect to submit our application for CE Mark in late 2007. We will need premarket approval, or PMA, from the U.S. Food and Drug Administration, or FDA, before we can market our products in the United States, which we expect will require data from large clinical trials of up to 2,500 patients. To initiate these clinical trials, we must first obtain clearance of an investigational device exemption, or IDE, from the FDA.

In anticipation of approval of our products, we plan to increase our manufacturing capacity and personnel to enable us to produce commercial quantities of our products. We anticipate that it will take time to increase our capacity and, as a result, expansion will be initiated prior to the anticipated approval of our products. Prior to obtaining regulatory approval, we may also begin to hire sales and marketing personnel. Following CE Mark approval in the European Union, we intend to commercialize our Custom NX DES Systems in key markets in both Europe and Asia Pacific. We expect to rely on third-party distributors, with our sales and clinical support, in select markets in Europe, all of Asia Pacific and the rest of the world. Following FDA approval, we expect to market our products in the United States through a direct sales force.

To date, we have not generated any revenue from our development activities and will not be able to generate revenue until one of our products is approved, if ever. We have incurred net losses in each year since our inception in June 2002. Through March 31, 2007, we had an accumulated deficit of approximately $62.0 million. We expect our losses to continue to increase as we expand our clinical trial

activities and initiate commercialization activities. Since inception we have financed our operations primarily through private placements of equity securities, and on February 1, 2007 we completed the initial public offering of our common stock which raised net proceeds of approximately $68.2 million.

In May 2004, we entered into a license agreement with Biosensors International Group Ltd. (formerly Sun Biomedical Ltd.) and Biosensors Europe S.A. (formerly Occam International B.V.). Pursuant to the agreement, we obtained worldwide non-exclusive rights to use Biosensors drug coating on our products, and agreed to pay specified minimum royalties and royalties based on net sales of our products.

Financial Operations

Revenue

To date, we have not generated any revenue from the sale of our stent systems. We do not expect to generate revenue until 2008 at the earliest, subject to obtaining CE Mark.

Research and Development

Our research and development expenses consist primarily of product development, pre-clinical trials, clinical trials and regulatory expenses as well as the cost of manufacturing products for clinical trials. Research and development expenses include employee compensation including stock-based compensation, supplies and materials, consulting expenses, license payments for acquired technology, travel and facilities. We also incur significant expenses to operate our clinical trials including trial design, clinical site reimbursement, data management and travel expenses. From our inception through March 31, 2007, we incurred $49.7 million in research and development expenses.

General and Administrative

General and administrative expenses consist primarily of compensation for executive, finance, marketing and administrative personnel including stock-based compensation. Other significant expenses include professional fees for accounting and legal services associated with our efforts to obtain and maintain protection for intellectual property related to our Custom NX DES Systems. From our inception through March 31, 2007, we incurred $14.7 million in general and administrative expenses.

Results of Operations

Comparison of Three Months Ended March 31, 2007 and 2006

Revenue. We did not generate any revenue during the three months ended March 31, 2007 or 2006.

Research and Development. Research and development expenses were $6.2 million for the three months ended March 31, 2007, compared to $3.3 million for the three months ended March 31, 2006. The increase of $2.9 million was primarily due to higher personnel expenses of $1.2 million for additional employees hired in our research and development department, $1.3 million for prototype parts, supplies, and outside services related to product development for our Custom NX DES systems, $154,000 of expenses related to the support of our clinical research studies, and $143,000 due to increased depreciation on equipment and facilities expenses. We expect our research and development expenses to increase significantly as we continue the development of our Custom NX DES Systems and conduct additional clinical trials.

General and Administrative. General and administrative expenses were $2.5 million for the three months ended March 31, 2007, compared to $941,000 for the three months ended March 31, 2006. The increase of $1.5 million was primarily due to higher personnel expenses of $748,000 for additional employees hired in marketing and administration, $358,000 due to increased spending for consulting, trade shows and marketing materials, $295,000 due to increased legal and professional expenses related to operating as a public company, and an increase of $120,000 related to insurance and other administrative expenses related to becoming a public company. We expect our general and administrative expenses to increase significantly due to the costs associated with operating as a publicly traded company and the costs associated with the commercialization of our products.

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Interest Income. Interest income was $749,000 for the three months ended March 31, 2007, compared to $108,000 for the three months ended March 31, 2006. The increase of $641,000 was due primarily to higher cash balances as a result of our initial public offering as well as a modest increase in interest rates.

Beneficial Conversion Feature. In January 2006, we completed the issuance and sale of 4,684,892 shares of Series C convertible preferred stock at $5.42 per share, which price was determined by our board of directors pursuant to negotiations with the investors in that round of financing. In connection with our preparation of the financial statements necessary for our public offering, we reassessed the fair value of our common stock for financial accounting purposes. Based on this reassessment, we determined the fair value of our common stock in January 2006 to be $8.56 per share. When we issue equity securities that are convertible into common stock at a discount from the common fair value at the commitment date, the difference between the fair value of the common stock and the conversion price multiplied by the number of shares issuable upon conversion is recognized as a beneficial conversion feature. The beneficial conversion feature is presented as a deemed dividend to the related security holders with an offsetting amount to additional paid in capital and will be amortized over the period from the issue date to the first conversion date. Since the equity securities are immediately convertible into common stock by the holder at any time, we recorded and immediately amortized a beneficial conversion charge, or deemed dividend, of approximately $5.7 million in connection with our Series C convertible preferred stock financing in January 2006. No beneficial conversion charge has been recognized in the three month period ending March 31, 2007.

Liquidity and Capital Resources

Sources of Liquidity

We are in the development stage and have incurred losses since our inception in June 2002. As of March 31, 2007, we had an accumulated deficit of $62.0 million. Prior to our initial public offering, we funded our operations from the private placements of our convertible preferred stock resulting in aggregate net proceeds of $75.6 million through December 31, 2006. On February 1, 2007, we completed our initial public offering, raising $68.2 million in net proceeds.

As of March 31, 2007, we did not have any outstanding or available debt financing arrangements, we had working capital of $83.0 million, and our primary source of liquidity was $85.7 million in cash and cash equivalents and short term investments.

Cash Flows

Cash Flows from Operating Activities. Net cash used in operating activities was $6.2 million for the three months ended March 31, 2007, compared to $3.4 million for the three months ended March 31, 2006. The net cash used in operating activities primarily reflects expenses related to product development and clinical trials. These expenses were offset in part by depreciation and amortization, non-cash stock-based compensation and non-cash changes in operating assets and liabilities.

Cash Flows from Investing Activities. Net cash used in investing activities during the three months ended March 31, 2007 was $49.8 million compared to $251,000 for the three months ended March 31, 2006. Cash used in investing activities for the three months ended March 31, 2007 reflects $49.4 million related to purchases of investments with cash raised by our initial public offering in February 2007. Purchases of property and equipment were $432,000 and $251,000 in the three months ending March 31, 2007 and 2006, respectively.

Cash Flows from Financing Activities. Net cash provided by financing activities for the three months ended March 31, 2007 was $69.2 million, compared with $9.9 million for the three months ended March 31, 2006. Net cash provided by financing activities for the three months ended March 31, 2007 was primarily attributable to our initial public offering in February 2007. Net cash provided by financing activities for the three months ended March 31, 2006 was primarily attributable to the issuance of convertible preferred stock.

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Operating Capital and Capital Expenditure Requirements

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

We believe our cash and cash equivalents and short term investments and interest income we earn on these balances, will be sufficient to meet our anticipated cash requirements for at least the next 14 months. If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, or if we develop additional products or pursue additional applications for our products, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. For example, we will need to raise additional funds in order to build our sales force and commercialize our products. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned clinical trials, research, development and commercialization activities, which could materially harm our business.

We anticipate spending approximately $40.0 million to complete our CUSTOM III, IV and V clinical trials. In addition, we will spend additional funds for regulatory approvals and for activities to commercialize our Custom NX DES Systems, if approved. The development of any new applications of our custom length stent technology and new products will also require the expenditure of significant financial resources and take several years to complete. We expect to fund the development of potential products with the proceeds from our initial public offering together with our existing cash and cash equivalents balances and revenue from the sales of our Custom NX DES Systems, if approved.

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

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

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our products and any products that we may develop;
- the effect of competing technological and market developments; and
- licensing technologies for future development.

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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

In April 2007, we entered into a supply agreement with Fortimedix B.V., a company organized under the laws of the Netherlands, under which Fortimedix agreed to manufacture and deliver stents designed by us for use in our Custom NX DES system. The supply agreement requires that we purchase a certain minimum number of the stents during each period at contractual prices set in Euro and also requires Fortimedix to build and maintain the production capacity to meet these minimum volume purchase requirements. The initial term of the agreement ends on March 18, 2010 and will be automatically extended for successive one year periods unless either party terminates the agreement by giving notice at least six months prior to the initial term or any extension period. We estimate that our total minimum obligation under this agreement will be at least $6.4 million through the end of the calendar year 2008. This amount was calculated using the Euro to dollar exchange rate as of the date the agreement was signed. After the end of the calendar year 2008, we have no further obligation to purchase stents from Fortimedix unless the parties otherwise agree in writing on or before January 31, 2008.

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).

Critical Accounting Policies and Estimates

Our management s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenue and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ materially from these estimates under different assumptions or conditions.

Recent Accounting Pronouncements

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The fair Value Option for Financial Assets and Financial Liabilities including an amendment of FAS115*, or SFAS No. 159. SFAS No. 159 allows companies to choose, at specified election dates, to measure eligible financial assets and liabilities at fair value that are not otherwise required to be measured at fair value. Unrealized gains and losses shall be reported on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS No. 159 also establishes presentation and disclosure requirements. SFAS No. 159 is effective for us in fiscal year 2008 and will be applied prospectively. We are currently evaluating the impact of adopting SFAS No. 159 on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to interest rate risk at March 31, 2007 is related primarily to our investment portfolio. Our investment portfolio includes a variety of marketable securities, including commercial paper and U.S. government securities. A change in prevailing interest rates may cause the fair value of our investments to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing rate rises, the fair value of the principal amount of our investment will probably decline. To minimize this risk, investments are generally held to maturity, and we balance portfolio maturities to both meet cash flow requirements and limit possible long term interest rate risks.

We have entered into a supply agreement with Fortimedix B.V. which requires that we purchase certain minimum volumes of stents at contractual prices set in Euro. We estimate that our total minimum

obligation under this agreement will be at least $6.4 million through the end of the calendar year 2008, and this could increase based on foreign currency rate fluctuations. For the purposes of the foregoing estimate, we have used the Euro to dollar exchange rate as of the date the agreement was signed. We do not believe this presents a material financial exposure, and do not plan to hedge against foreign currency fluctuations.

ITEM 4T. 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, 2007.

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None

ITEM 1A. RISK FACTORS

Risks Related to Our Business

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

We have incurred net losses since our inception in June 2002. For the years ended December 31, 2004, 2005, and 2006, we had net losses of $8.9 million, $14.0 million and $25.0 million, respectively. Through March 31, 2007, we had an accumulated deficit of $62.0 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 of our Custom NX DES Systems, which consist of the Custom NX 36 and the Custom NX 60. Since we have not received a CE Mark or approval from the U.S. Food and Drug Administration, or FDA, or any other regulatory authority for our products, we are unable to market our current products and have not generated any revenue since our inception. We expect our research and development expenses to increase significantly in connection with our clinical trials and other product development activities. If we receive CE Mark or FDA approval of our Custom NX DES Systems, we expect to incur significant sales and marketing expenses and manufacturing expenses as we commercialize our products. Additionally, we expect that our general and administrative expenses will increase due to the additional operational and reporting costs associated with being a public company. 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 an acceptable MAF to regulatory authorities could delay our clinical trials or prevent or delay commercialization of our Custom NX DES Systems.

In May 2004, we entered into a license agreement with Biosensors. Pursuant to the agreement, we obtained non-exclusive rights to use Biosensors s drug coating on our stent platform. The drug coating consists of Biolimus A9®, an anti-inflammatory drug that is a derivative of rapamycin, and PolyLactic Acid, or PLA, a biodegradable polymer used to release the drug over time. The drug coating has not been approved for any use in the European Union, the United States or any other jurisdiction. In April 2005, Biosensors submitted its first module for the master file, or MAF, for the Biolimus A9 and PLA formulation with its designated Notified Body, an independent third party appointed by regulatory authorities to conduct the requisite conformity assessment, in conjunction with Biosensors application for CE Mark of its BioMatrix drug eluting stent. Biosensors does not have any prior experience in developing or manufacturing drugs or obtaining regulatory approval for drugs or drugs used in combination with a medical device in any jurisdiction.

In May 2006, Biosensors publicly disclosed that it had responded to all requests for additional information received from its designated Notified Body or the relevant drug authority; however, there can be no assurance that the Notified Body will accept Biosensors MAF in its filed form, even with the inclusion of the additional requested data. We have not been involved with, or had access to, any of Biosensors filings with its designated Notified Body or the relevant regulatory authorities in the European Union. There is a significant chance that the designated Notified Body, after continued deliberations, may request additional data or tests that could be time consuming for Biosensors to provide. The designated Notified Body who will be reviewing our CE Mark application will be given access to Biosensors MAF in connection with our applications for CE Mark. Biosensors will have to obtain a favorable opinion from the relevant drug authority on its MAF before our designated Notified Body can provide us with CE Mark approval. Biosensors has made no public disclosure regarding any filings it may have made with the FDA in connection with its MAF for the drug coating. If Biosensors experiences delays or problems in developing a MAF that we need to reference in our application for CE Mark in the European Union or our

PMA application in the United States, our currently planned clinical trials and the development of our products may be substantially delayed and we may be required to restart clinical programs with an alternative drug coating. In the event we experience these delays or need to restart clinical programs our regulatory and commercialization timelines will need to be extended and we may experience a significant decline in our stock price.

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 master file, or MAF, for the drug coating to the regulatory authorities;
- we may not be able to obtain regulatory approvals for our products, or the approved indications for our products may be narrower than we seek;
- we may experience delays in our development program, including initiation and completion of our clinical trials;
- any products that are approved may not be accepted in the marketplace by physicians and patients;
- physicians may not receive adequate coverage and reimbursement for procedures using our products;
- any rapid technological change may make our technology and products obsolete;
- we may not be able to manufacture our Custom NX DES Systems in commercial quantities or at an acceptable cost;
- we may not have adequate financial or other resources to complete the development and commercialization of our Custom NX DES Systems; and
- we may be sued for infringement of intellectual property rights and could be enjoined from manufacturing or selling our products.

We cannot market our products in the European Union until we receive a CE Mark or in the United States until we receive premarket approval, or PMA. The earliest we expect to be able to commercialize our products in the European Union is in the second half of 2008, if at all, and in the United States is in the first half of 2010, if at all. 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.

In addition to the submission of a MAF, that is acceptable to regulatory authorities, by the supplier for the drug coating that we use on our products, which we intend to reference in the regulatory applications for our products, we must obtain regulatory approval to market our drug eluting stents. Our Custom NX

None

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. The drug coating for our stents will be reviewed by the FDA s Center for Drug Evaluation and Research, or CDER, and the device will be reviewed by the FDA s Center for Devices and Radiological Health, or CDRH, with the overall product approved by CDRH as a medical device. We believe that no separate approval for the drug independent of the device is required.

We do not currently have the necessary regulatory approvals to market our Custom NX DES Systems or any other products in the United States or in any foreign market, including the European Union. If we obtain the necessary regulatory approvals, we plan initially to launch our products in the European Union and later in the United States. Regulatory approval in the European Union for our products will require us to successfully obtain CE Mark from a designated Notified Body. The regulatory approval process in the United States for our products involves, among other things, successfully receiving authorization from the FDA to conduct clinical trials under an investigational device exemption, or IDE, completing pre-clinical and clinical trials, and applying for and obtaining pre-market approval, or 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 can 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 its MAF may be inadequate; and
- changes in FDA approval policies or adoption of new regulations may require us to provide additional data.

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

Preliminary third-party data has raised concerns that drug eluting stents may cause an increase in late-stent thrombosis. In the event that regulatory authorities determine that such concerns are valid or otherwise require additional study and analysis, we may experience a delay in obtaining or we may be unable to obtain regulatory clearances for our products and, even if approved, the market acceptance of our products may be significantly impaired.

On September 14, 2006, the FDA issued a *Statement on Coronary Drug-Eluting Stents*, which discusses recent clinical data presented at the March 2006 American College of Cardiology Scientific Sessions in Atlanta, Georgia and 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 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. The Panel made the following statements in response to the FDA s questions:

- The Panel was in general agreement that drug eluting stents, when used in accordance to their FDA approved labeled indications, are associated with a clinically important numerical excess of late-stent thromboses (after one year post-implantation) compared to bare metal stents; however, the magnitude of this excess is uncertain and additional data is needed.

- Based on the analyses presented by the two manufactures of currently marketed drug eluting stents in the United States, the Panel concluded that drug eluting stents were not associated with an increased risk of death or heart attacks compared to bare metal stents despite an apparent increase in late-stent thrombosis rates after one year following implantation of the devices.

- The Panel requested longer-term follow-up and an increased number of patients in future drug eluting stent clinical trials.

- The Panel reached consensus that the drug eluting stent safety concerns do not outweigh their benefits compared to bare metal stents when used within the limits of the currently approved FDA indications.

- The Panel discussed different options for modifying the labeling of drug eluting stents, and was in consensus that labels should include a reference to the current PCI Practice Guidelines for the duration of antiplatelet therapy following the implantation of a drug eluting stent.

The Panel s opinion is advisory and the FDA has not issued final conclusions or recommendations from this meeting. We cannot assure you that any long-term data produced in response to the Panel s request will support its current conclusions and the FDA may determine to alter or change its determination regarding the safety and efficacy of drug eluting stents. Any adverse determination by the FDA regarding the safety and efficacy of drug eluting stents would have a significant adverse impact on our business.

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 for our stents from Biosensors and we are unaware of any alternative source for this drug coating. We do not have the right to use alternate suppliers for the drug coating that we obtain from Biosensors. In addition, there is no other source for the drug coating and we are contractually restricted from commercializing any of our products that incorporate a rapamycin drug or any derivative thereof or 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

None

with it to obtain Biolimus A9 if we are unable to obtain Biolimus A9 from Biosensors. In addition, the pharmaceutical company is subject to significant legal and regulatory requirements with regard to the production of Biolimus A9, including onerous current Good Manufacturing Practices regulations, or GMP, which are strictly enforced by the FDA, and the Ministry of Health, Labor, and Welfare in Japan and any failure on the part of the pharmaceutical company to comply with these requirements may interrupt Biosensors supply of Biolimus A9 and ultimately, our supply of the drug coating. Biosensors has also entered into, and may continue to enter into, agreements to supply the drug coating to other licensees. Our clinical trials and the development and commercialization of our Custom NX DES Systems could be prevented or delayed if:

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

- our license agreement with Biosensors terminates for any reason, including insolvency or our failure to obtain CE Mark or commercialize our products before May 2008; or

- the supplier of our drug coating does not meet regulatory quality requirements and other specifications.

To date, our drug coating requirements have been limited to small quantities that we need to conduct our development and pre-clinical and clinical trials. If we obtain market approval for our products, we anticipate that we will require substantially larger quantities of the drug coating. Biosensors may not provide us with sufficient quantities of the drug coating and such supply may not meet our quality requirements or other specifications. In the event we do not receive adequate supply of the drug coating, we will likely be unable to locate an alternative supplier of the drug coating, or any alternative drug, in a timely manner or on commercially reasonable terms, if at all. Any additional new source for Biolimus A9, the PLA or the drug coating will require the consent of Biosensors and prior FDA approval, which will require significant time and effort to obtain and there can be no assurance that we will obtain such regulatory approval. The inability to obtain sufficient quantities of the drug coating or 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 U.S. clinical trials or approved for commercial sale. The Company and Biosensors have agreed that the Company will be responsible for performing some of these tests. We have not developed the technology or methods to perform this testing in-house, and plan to rely on third parties to conduct the testing. We have identified certain third parties who we believe have the capability to conduct this testing using methods that do not violate the proprietary rights of others. We can provide no assurance, however, that these testing methods will not violate such rights. If others assert rights to these testing methods, we may need to obtain a license giving us the right to use the testing methods or identify or develop other methods for performing the required testing. We cannot assure you that a license will be available to us or that it will be available on terms that are agreeable to us. If we are unable to obtain a license, we cannot assure you that we will be able to identify or develop alternate testing methods that meet our needs without delaying our regulatory submissions or approvals. This may result in a delay in the release of, or an inability to release, our stents for use in U.S. clinical trials or commercial products and our ability to generate revenue would be adversely affected as a result.

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

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

If, in our planned large-scale comparative pivotal clinical trial, we fail to demonstrate restenosis and reintervention rates, as well as other clinical trial end-points and performance, comparable to other drug eluting and bare metal stents that have been approved by the FDA, our ability to successfully market 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 and the Taxus® Express2™ stent, the two 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. Recent clinical data suggests a small but significant

increase in the rate of death and heart attack, 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. See Preliminary third-party data has raised concerns that drug eluting stents may cause an increase in late-stent thrombosis.

We cannot assure you that our long-term data, once obtained, will be different than that suggested in the recent studies regarding late-stent thrombosis.

Additionally, other efficacy factors may influence a physician s decision over what stents to deploy. Our Custom NX DES Systems stent segments may separate 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. Another significant factor that physicians and regulators will consider is acute safety data on complications that occur with the use of our products. Two of the patients in our CUSTOM I clinical trial experienced elevated enzyme levels following the procedure, which are technically considered to be heart attacks. In addition, one of the patients in our CUSTOM II clinical trial died as a result of a major adverse cardiac event, or MACE, which is currently under investigation and could be determined to be related to the procedure involving the use of our Custom NX 60. If the results obtained from our clinical trials indicate that our products are not as safe or effective as other treatment options or as current short-term data would suggest, our products may not be approved, adoption of our products may suffer and our business would be harmed.

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

Before marketing and selling our Custom NX DES Systems or any other products, we must successfully complete pre-clinical studies and clinical trials that demonstrate that our products are safe and effective. We currently have a very limited amount of clinical data regarding the safety and efficacy of our Custom NX DES Systems, and no data beyond eight months including no data on the incidence of late-stent thrombosis. The results from our limited short-term clinical experience for our Custom NX DES Systems do no necessarily predict long-term clinical benefit and may not be replicated in subsequent clinical trials. Furthermore, all of our existing data has been produced in studies that involve relatively small patient groups, and the data may not be reproduced in wider patient populations. We plan to conduct additional large-scale clinical trials to determine whether our products are safe and effective and to support our applications for regulatory approval in the European Union and 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 Cypher stent or the Taxus Express2 stent, the two drug eluting stents marketed in the United States, and that these studies will involve large patient populations of approximately 2,500 patients.

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

- Biosensors fails to submit in a timely fashion, if at all, its MAF for the drug coating with its designated Notified Body in the European Union or the FDA, or such filings fail to meet regulatory requirements;

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

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

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

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

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

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

None

- 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, an IDE application must be submitted and approved by the FDA, which we currently anticipate submitting in the first half of 2007. 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 and the Taxus Express2 stent, which are approved by the FDA and currently marketed, involved patient populations of approximately 1,000 and 1,300, respectively. We expect that we will provide the FDA with data on approximately 2,500 patients 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. 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 Systems provides a safe and effective alternative to other existing treatments for coronary artery disease.

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 adoptions of our products. We also believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our Custom NX DES Systems will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published.

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

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

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

We do not have the ability to independently conduct clinical trials for our products, and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and

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

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

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

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

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

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

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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.

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

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

Risks Related to Our Intellectual Property

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

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

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

- use of rapamycin or its analogs to treat restenosis;
- stent structures and materials;
- catheters used to deliver stents; and
- stent manufacturing and coating processes.

Cordis, a subsidiary of Johnson & Johnson, is the owner of a number of patents and patent applications directed to the use and delivery of rapamycin or its analogs as a stand-alone therapy or as part of a drug eluting stent for the treatment of restenosis as well as stents incorporating such materials. These include, without limitation, the Morris family of patents, the Wright family of patents and the Falotico family of patents.

None

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

Various patents owned by third parties are directed to stent structures and materials. These patents include a group of Lau patents that were owned by Guidant Corporation, a newly acquired subsidiary of Boston Scientific whose stent technology has been acquired by Abbott Vascular subject to certain rights retained by Boston Scientific, which are directed to flexible stent structures. The Boneau family of patents, owned by Medtronic, are directed to stents comprising multiple closed-loop elements. The Fariabi family of patents, owned by Guidant, are directed to stents comprising cobalt-chromium alloys. The Israel and Pinchasik families of patents, owned by Medinol, are directed to stents with meandering strut patterns. A patent owned by Wall is directed to a radially collapsible mesh sleeve.

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

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, 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 (formerly Guidant), Boston Scientific, Johnson & Johnson and Medtronic, have been repeatedly involved in patent litigation relating to stents since at least 1997. The stent and related markets have experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay the introduction of new products and technologies. We may pose a competitive threat to many of the companies in the stent and related markets. Accordingly, many of these companies will have a strong incentive to take steps, through patent litigation or otherwise, to prevent us from commercializing our products.

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

In any infringement lawsuit, a third party could seek to enjoin, or prevent, us from commercializing our Custom NX DES Systems or any future products, may seek damages from us and any such lawsuit would likely be expensive for us to defend against. Our involvement in intellectual property litigation could result in significant expense. Some of our competitors, such as Boston Scientific, Johnson & Johnson, Abbott Vascular and Medtronic, have considerable resources available to them and a strong economic incentive to undertake substantial efforts to stop or delay us from bringing our Custom NX DES Systems to market and achieving market acceptance. We, on the other hand, are a development stage company with comparatively few resources available to us to engage in costly and protracted litigation. A court may determine that patents held by third parties are valid and infringed by us and we may be required to:

- pay damages, including up to treble damages and the other party s attorneys fees, which may be substantial;
- cease the development, manufacture, use and sale of products that infringe the patent rights of others, including our Custom NX DES Systems, through a court-imposed sanction called an injunction;
- expend significant resources to redesign our technology so that it does not infringe others patent rights, or to develop or acquire non-infringing intellectual property, which may not be possible;
- discontinue manufacturing or other processes incorporating infringing technology; or
- obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

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

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

In addition, some of our agreements, including our agreement with Biosensors for the supply of the drug coating, our agreement with SurModics for the supply of the lubricious coating on our catheter and our agreement with Millimed for the license of patents related to segmented stent designs 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 March 31, 2007 we have four 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 patent applications pending 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, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO to determine priority of invention in the United States. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the United States. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

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

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

We are aware that another medical business that holds patents to certain stent designs has used the name XTENT for limited purposes in the past. If it turns out that the other business has superior trademark rights in the name, and if the other business were to challenge our use of the XTENT name, we would then

need to convince a court that there is no likelihood of consumer confusion. If we were unsuccessful in court, then we could be held liable for trademark infringement and we might then have to change our name as well as pay monetary damages. If we were forced to change our name, we may suffer from a loss of brand recognition, we may be required to retrieve product and interrupt supply, and may have to devote substantial resources advertising and marketing our products under a new brand name.

Risks Related to Commercialization

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

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

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

- greater financial and human resources for product development, sales and marketing, and patent litigation;
- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;
- established distribution networks; and
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products and marketing approved products.

For example, Johnson & Johnson and Boston Scientific, two companies with far greater financial and marketing resources than we possess, have both 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 or Boston Scientific s Taxus Express2 stent. Other large companies, including Medtronic and Abbott Laboratories, are developing and commercializing drug eluting stents. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with, or mergers with or acquisitions by, large and established companies or through the development of novel products and technologies.

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

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

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

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.

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 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. During a routine audit, we discovered that our new device configuration required revised sterilization procedures, which were successfully validated in March 2007. In the event that we encounter similar challenges in the future, we may experience interruptions in the supply of our devices and as a result may be unable to meet demand. If we develop and obtain regulatory approval for our products and are unable to manufacture a sufficient supply of our products, our revenue, business and financial prospects would be adversely affected. In addition, if the scaled-up production process is not efficient or produces stents that do not meet quality and other standards, our future gross margins may decline.

We currently assemble our Custom NX DES Systems and apply the drug coating at our facilities in Menlo Park, California. The lease on our current facility expires at the end of May 2007, and the size of our current facility is insufficient to support manufacturing on a commercial scale. Prior to the commercial launch of our product we will need to locate additional space, which 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, and International Standardisation Organization, or ISO. We cannot assure you that additional manufacturing space will be available on commercially reasonable terms, if at all, or that we will be able to obtain the appropriate approvals from the FDA, CDHS or ISO within the time necessary for us to

commence commercial manufacturing if at all. If there were a disruption to our existing manufacturing facility, we would have no other means of manufacturing our products until we were able to restore the manufacturing capability at our facility or develop alternative manufacturing facilities and obtaining 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. Finally, based on a verbal agreement with Biosensors, we currently apply the drug coating to our stents in our Menlo Park facilities. Our license agreement with Biosensors does not expressly permit us to apply the drug coating to our stents except under certain limited conditions and we do not have any other written agreement that would allow this to continue to occur. 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.

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

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

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

From time to time, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones could include our submission for CE Mark in the European Union, the submission to the FDA of an IDE application to commence our pivotal 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.

A key element of our strategy is to discover, develop and commercialize a portfolio of new products in addition to our Custom NX DES Systems. We are seeking to do so through our internal research programs and intend to explore strategic collaborations for the development of new products utilizing our stent technology. Research programs to identify new disease targets, products and delivery techniques require substantial technical, financial and human resources, whether or not any products are ultimately identified. We may determine that one or more of our pre-clinical programs do not have sufficient potential to warrant the allocation of resources, such as the potential development of our stent technology for the treatment of peripheral artery disease, or PAD. 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 our officers, and if we are not able to retain them or recruit additional qualified personnel, our business will suffer.

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

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

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

We will 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.

We believe our existing cash and cash equivalent balances and interest we earn on these balances, will be sufficient to meet our anticipated cash requirements for at least the next 14 months. However, our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our products and any products that we may develop;
- the effect of competing technological and market developments;
- licensing technologies for future development; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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. 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.

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 supports or other resources devoted to our products. Any of these factors could harm our financial condition.

If we are unable to manage our expected growth, we may not be able to commercialize our products, including our Custom NX DES Systems.

If we obtain CE Mark and FDA approval for our products, we intend to continue to rapidly expand our operations and grow our research and development, product development and administrative operations and invest substantially in our manufacturing facilities. This expansion has and is expected to continue to place a significant strain on our management and operational and financial resources. In particular, the commencement of our planned pivotal clinical trial in the United States will consume a significant portion of management s time and our financial resources. To manage any expected growth and to commercialize our Custom NX DES Systems, we will be required to improve existing, and implement new, operational and financial systems, procedures and controls and expand, train and manage our growing employee base. Our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth. If we are unable to manage our growth effectively, our business could be harmed.

Risks Related to Our Industry

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

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

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

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

experience pricing pressures in connection with the future sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. Our results of operations could be adversely affected by these and other future healthcare reforms.

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

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

We may be subject to claims against us even if the apparent injury is due to the actions of others. For example, we rely on the expertise of physicians, nurses and other associated medical personnel to perform the medical procedure and related processes to implant our coronary stents into patients. If these medical personnel are not properly trained or are negligent, the therapeutic effect of our stents may be diminished or the patient may suffer critical injury, which may subject us to liability. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with cobalt chromium tubing for our stents, those that laser cut our stents or the supplier of our drug coating, may be the basis for a claim against us.

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. For example, we had a chemical spill at our Menlo Park facility in February 2006, and although we believe that we took all appropriate actions to respond to the accident and that there is no remaining liability, we can provide no assurance that these actions were sufficient to prevent future chemical spills.

Because we have operated as a private company, we have no 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 have operated as a private company, and we have not been 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.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring XTENT to include a report of management on the company s internal control over financial reporting in our annual reports on Form 10-K. In addition, in our 2008 report on Form 10-K, the independent registered public accounting firm auditing a company s financial statements must attest to and report on management s assessment of the effectiveness of a company s internal control over financial reporting. We may be unable to comply with these requirements by the applicable deadlines beginning with our Form 10-K for the period ending December 31, 2007. 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.

Changes in, or interpretations of, accounting rules and regulations, such as expensing of stock options, could result in unfavorable accounting charges or require us to change our compensation policies.

The Financial Accounting Standards Board has adopted a new accounting pronouncement requiring the recording of expense for the fair value of stock options granted to employees. The impact of the adoption of SFAS No. 123(R) on the quarter ended March 31, 2007 was $632,000 and $1.4 million for the year ended December 31, 2006. We rely heavily on stock options to motivate current employees and to attract new employees. As a result of the requirement to expense stock options, we may choose to reduce our reliance on stock options as a motivational tool. If we reduce our use of stock options, it may be more difficult for us to attract and retain qualified employees. However, if we do not reduce our reliance on stock options, our reported net losses may increase, which may have an adverse effect on our reported results of operations.

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

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

- the results of our clinical trials;
- the timing of our regulatory approvals;
- announcements related to litigation;
- statements made by Biosensors relating to regulation or supply of the drug coating;
- the announcement of new products or service enhancements by us or our competitors;
- quarterly variations in our or our competitors results of operations;
- changes in earnings estimates, investors perceptions, recommendations by securities analysts or our failure to achieve analysts earning estimates;
- 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.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

If our stockholders sell substantial amounts of our common stock in the public market, including shares issued upon the exercise of options, the market price of our common stock could decline. There will be approximately 18,163,171 shares of common stock eligible for sale upon the expiration of lock-up arrangements between our stockholders and underwriters. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

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 May 1, 2007, our officers, directors and principal stockholders each holding more than 5% of our common stock collectively will control approximately 68.1% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

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

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

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

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

- a classified board so that only one of the three classes of directors on our board of directors is elected each year;
- elimination of cumulative voting in the election of directors;
- procedures for advance notification of stockholder nominations and proposals;
- the ability of our board of directors to amend our bylaws without stockholder approval;
- a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and our amended and restated bylaws; and
- the ability of our board of directors to issue up to 10,000,000 shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our board of directors may determine.

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

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

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

We registered the initial public offering of our common stock, par value $0.001 per share, on a Registration Statement on Form S-1, as amended, (Registration No. 333-136371), which was declared effective on January 31, 2007. On February 1, 2007, we completed the initial public offering of our common stock by selling 4.7 million shares at $16.00 per share. Net cash proceeds from the initial public offering were approximately $68.2 million, after deducting underwriting discounts and commissions and other offering costs.

Of the $68.2 million in net proceeds, through March 31, 2007, we have spent approximately $6.7 million including: $500,000 for sales and marketing initiatives, $4.6 million for research and development activities, $1.3 million for operating and general corporate purposes and $286,000 for property and equipment in order to expand our manufacturing capability to complete our CUSTOM III, IV and V clinical trials.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS

Exhibit Number	**Description**
3.2*	Amended and Restated Certificate of Incorporation.
3.4*	Amended and Restated Bylaws.
4.1*	Specimen Common Stock certificate of the Registrant.
10.1*	Form of Indemnification Agreement for directors and executive officers.
10.2*	2002 Stock Plan and form of stock option agreements used thereunder.
10.3*	2006 Equity Incentive Plan and form of stock option agreement used thereunder.
10.4*	2006 Employee Stock Purchase Plan.

10.5*	Amended and Restated Investor Rights Agreement dated May 5, 2006 by and among the Registrant and certain stockholders.
10.6*	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.
10.7 *	License Agreement dated May 4, 2004 as amended February 9, 2005, by and between the Registrant, Biosensors International Group, Ltd. (formerly Sun Biomedical, Ltd.), and Biosensors Europe SA (an affiliate of Occam International, B.V.)
10.8 *	Master License Agreement dated December 30, 2002, as amended June 30, 2006, by and between the Registrant and SurModics, Inc.
10.9*	License Agreement dated July 10, 2006 by and between the Registrant and Millimed A/S.
10.10	Supply Agreement dated April 2, 2007 by and between Registrant and Fortimedix B.V.
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.

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

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

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 14, 2007	By:	/s/ GREGORY D. CASCIARO **GREGORY D. CASCIARO** **President and Chief Executive Officer** **(Principal Executive Officer)**
Date: May 14, 2007	By:	/s/ TIMOTHY D. KAHLENBERG **TIMOTHY D. KAHLENBERG** **Chief Financial Officer** **(Principal Accounting and Financial Officer)**