XTENT INC
Form 10-K
April 02, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2006

or

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

Commission File Number 001-33282

XTENT, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**41-2047573**
(State of incorporation)	(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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Name of each exchange on which registered:**
Common Stock, par value $0.001	**The NASDAQ Stock Market, LLC**

Securities registered pursuant to Section 12(g) of the Act:

None

(Title of Class)

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

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 requirements for the past 90 days. Yes o No x

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant, based upon the closing sale price of the common stock on March 15, 2007, as reported on the NASDAQ Global Market was approximately $295.4 million. The Registrant was not a public company on the last day of its second fiscal quarter of 2006. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

At March 15, 2007, the Registrant had 22,863,171 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K incorporate information by reference from the registrant s definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this annual report.

XTENT, INC.
FISCAL YEAR 2006 FORM 10-K ANNUAL REPORT
TABLE OF CONTENTS

PART 1

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. These statements include, but are not limited to, those concerning the following: regarding 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 the Management s Discussion and Analysis of Financial Condition and Results of Operations section of this Form 10-K. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-K.

ITEM 1. BUSINESS

Overview

We are a development stage medical device company focused on developing and commercializing our innovative customizable drug eluting stent systems for the treatment of coronary artery disease, or CAD. Our drug eluting stent systems are designed to enable physicians to customize both length and diameter of the stent at the site of the diseased section of the artery, or lesion, which we refer to as in-situ customization. Our stent systems are designed to treat longer lesions than currently available drug eluting stents and multiple lesions with the use of 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 believe our technology, if approved by regulatory authorities, will enable us to compete in the approximately $5.3 billion worldwide drug eluting stent market.

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 Custom NX 36 and the Custom NX 60. We believe that 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 that 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.

XTENT, Inc. was incorporated under the laws of the state of Delaware on June 13, 2002.

Status of Regulatory Approval

Our Custom NX DES Systems are combination devices that include a stent and drug coating, for which we must receive regulatory approval as a medical device before we can market the systems. 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. We completed enrollment of our CUSTOM II and initiated our CUSTOM III clinical trials, which are designed to further evaluate the safety and efficacy of in-situ customization with our stent systems, particularly in long lesions and multiple lesions. Assuming the results from these trials are favorable, we believe that 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. We anticipate applying for our IDE in the first half of 2007 based on the results from our CUSTOM I, II and III clinical trials. We expect to submit a PMA application to the FDA in 2009. We expect to be able to commercialize our products, at the earliest, in the European Union in the second half of 2008 and in the United States in the first half of 2010.

We license our drug coating from, Biosensors Europe SA, an affiliate of Occam International, B.V., or Occam, which is, in turn, a wholly-owned subsidiary of Biosensors International Group, Ltd. We refer to Biosensors Europe SA, Occam and Biosensors International Group, Ltd. collectively as Biosensors in this report. Regulatory approvals of our products are dependent upon Biosensors obtaining a favorable opinion from the relevant drug authority on its drug master file, or DMF, in the European Union and approval from the FDA in the United States.

Market Opportunity

Coronary artery disease, or CAD, is the most common form of cardiovascular disease and the number one cause of death in the United States and Europe. CAD is primarily caused by the accumulation of fat-laden cells, also known as plaque, in the arteries leading to the heart. Over time, the accumulation of plaque in an artery, known as a lesion, narrows the diameter of its lumen, or inner channel, and may significantly reduce or stop blood flow. A reduction in blood flow to the heart can cause chest pain, a heart attack or potentially death. CAD accounts for over 650,000 deaths annually in the United States and, according to the American Heart Association, affects over 13 million Americans. Risk factors for CAD include old age, smoking, diabetes, obesity, sedentary lifestyle and an individual s genetic history.

Evolution of Treatments for Coronary Artery Disease

A number of surgical procedures and interventional therapies have been developed over the past four decades to treat CAD, each with the goal of quickly and safely restoring blood flow. This is accomplished by surgically rerouting the flow of blood around the lesion or using interventional techniques to reopen the artery. The treatment of CAD has experienced significant innovation and has evolved from invasive surgical approaches to minimally-invasive catheter-based therapies. This innovation has generally resulted in less severe procedure-related complications, as well as reduced costs due to shorter procedure and recovery times. We believe that physicians have rapidly adopted these new therapies because of these benefits.

Coronary Artery Bypass Graft Surgery. In the 1960s, coronary artery bypass graft surgery, or CABG, was developed as a treatment for CAD. In this procedure, a healthy vein or artery is taken from another site in the patient s body. The patient s chest is surgically opened and the harvested artery is connected to the aorta and to the heart to provide a pathway for the blood flow around the site of the lesion. For many years, CABG has been considered the standard of care for treating CAD in patients at moderate to high risk of heart attack. However, CABG can be a highly-invasive procedure that is generally associated with long recovery times and hospital stays.

Balloon Angioplasty. In the late 1970s, a significant advancement in the treatment of CAD was developed that provided physicians with a minimally-invasive therapy called percutaneous coronary intervention, or PCI. The initial innovation was balloon angioplasty, in which a physician inserts a flexible catheter with a balloon tip into the femoral artery at the groin and maneuvers the catheter through the vascular system into the coronary arteries. At the site of the lesion, the balloon is inflated, compressing the plaque and stretching the artery wall to create a larger channel to restore blood flow. We believe this therapy was rapidly adopted by physicians because it resulted in shorter hospital and recovery times as compared to CABG. However, while providing advantages over CABG, the long-term effectiveness of balloon angioplasty is limited by restenosis. Restenosis occurs due to two primary causes; the elastic recoil of the artery wall and the formation of scar tissue within the artery and typically requires a repeat of the PCI therapy or CABG. Clinical trials demonstrated that restenosis occurred in up to 57% of balloon angioplasty procedures within six months of treatment.

Bare Metal Stents. The next significant innovation in PCI was the development of stents in the 1990s. Stents are tubular metal devices consisting of interconnected struts that are inserted inside the narrowed artery and expanded to hold it open. During a procedure, a stent mounted on a balloon catheter is delivered to the lesion. The balloon is inflated to expand the stent and is then removed, leaving the stent behind. Bare metal stents lower the occurrence of restenosis by addressing the elastic recoil of the artery wall and quickly replaced the use of balloon angioplasty as the primary interventional therapy for CAD. However, bare metal stents do not address the second cause of restenosis, the formation of scar tissue. Clinical trials have demonstrated that restenosis occurs in up to 35% of bare metal stent procedures within eight months of treatment.

Drug Eluting Stents. The most recent innovation in PCI was the development of drug eluting stents. Drug eluting stents were designed to address both causes of restenosis. Currently marketed drug eluting stents are conventional bare metal stents that are coated with a drug that is designed to reduce the formation of scar tissue in the artery. This advance has resulted in improved patient outcomes due to reduced restenosis. According to published third-party analysis of the data from a number of randomized controlled clinical trials for currently marketed drug eluting stents, the restenosis rate for drug eluting stents was approximately 10.5% as compared with approximately 31.7% for bare metal stents. As a result, following their introduction in Europe in 2002 and in the United States in 2003, drug eluting stents brought about a rapid shift in physician treatment of CAD and were used in 89% of the stent procedures in the United States in 2005. Drug eluting stents were used in approximately 1.5 million of the 2.2 million coronary stent procedures performed worldwide in 2005, and represented a $5.3 billion market according to Millennium Research Group. Existing approved drug eluting stents have demonstrated improved long-term clinical results and lower rates of restenosis in comparison to bare metal stents. However, some recent clinical data indicates higher rates of blood clot formation, or thrombosis, which could lead to heart attacks or death, in patients who received drug eluting stents when compared to patients who received bare metal stents. In response, the FDA evaluated this clinical data during a public meeting of its Circulatory System Devices Advisory Panel on December 7 and 8, 2006. The FDA has not issued final conclusions or recommendations from this meeting. As a result of this clinical data, the use of bare metal stents has reportedly increased, and the use of drug eluting stents has correspondingly decreased, at certain hospitals in the United States and elsewhere. In addition, drug eluting stents are significantly more expensive than bare metal stents, with average costs in the United States that are approximately 2.5 times the cost of a bare metal stent. Additionally, drug eluting stents currently available in the United States use polymer coatings that remain permanently on the stent, and we believe that long-term safety may be diminished because of this characteristic.

Evolution of Delivery Methods for Percutaneous Coronary Interventions

In addition to the advancements in PCI, the methods of their delivery have also improved over time. These improvements have made PCI procedures easier to perform and have reduced the amount of time for a single procedure. Similar to the rapid shift in the PCI therapies utilized with the introduction of each significant procedure innovation, physicians have quickly adopted these improved delivery methods.

Over-the-Wire. Over-the-wire delivery systems represented the first significant innovation for PCI therapy delivery. The original fixed-wire balloon angioplasty devices incorporated the use of a wire attached to the balloon catheter. If a lesion had to be treated more than once or if there were multiple lesions, removal of the entire device was required and a new device had to be inserted and renavigated to the targeted lesion. The fixed-wire approach was time-consuming and could be technically challenging. In the over-the-wire systems, the guidewire is separate from the catheter. The guidewire is used to navigate through the patient s vascular system to and across the targeted lesion, and the catheter slides over the guidewire to the treatment site. The guidewire maintains access to the lesion site so that multiple therapeutic devices can be delivered quickly and safely. This innovation rapidly replaced the fixed-wire delivery method. Though this is an effective method to safely deliver PCI therapies, every device delivered requires an exchange of the catheter and a second operator to hold the guidewire in place, adding time and complexity to the procedure.

Rapid Exchange. Rapid exchange delivery systems were developed to simplify the exchange of catheters by allowing a much shorter length of guidewire to be used in a procedure, thus allowing a single operator in a PCI procedure to manage both the catheter and the guidewire. The improved efficiencies from this innovation have led to the use of rapid exchange delivery systems in the majority of PCI procedures today. According to Millennium Research Group, 70% of the drug eluting stents used in the United States were delivered with a rapid exchange system in 2005. Rapid exchange systems enable quicker changes from one catheter to another, and a third-party study has shown their use results in reduced procedure times and lower radiation exposure from x-ray images taken during stent placement. Despite improving procedural efficiency compared to over-the-wire systems, rapid exchange systems still require time consuming catheter exchanges when multiple devices are needed for a single procedure.

Limitations of Current Percutaneous Coronary Intervention Therapies

Although significant advances have been made with drug eluting stents, we believe the designs of current stents and methods of delivery limit effectiveness for patients and efficiency of the physicians treating CAD, and can result in increased costs for healthcare providers. Current commercially available stent systems include stents with fixed-lengths of up to 33mm, and require a separate device for each stent used. This requires physicians to estimate the size and shape of the artery s lumen, and then use their judgment to select the proper length and diameter stent for the lesion. These characteristics of existing technology lead to the following limitations:

- **Inability to Customize Treatment Options In-Situ.** The effectiveness of drug eluting stents has caused physicians to expand their use beyond the treatment of single or discrete lesions to the treatment of long lesions and multiple lesions. Using currently available technologies, these lesions can require multiple stents, increasing procedure complexity, time and cost. According to a Millennium Research Group survey conducted in May 2006, over 50% of the patients undergoing a PCI procedure had disease in more than one artery and an average of approximately 1.7 stents were used per stent procedure in the United States. Because the procedure is reimbursed at a fixed amount, we believe the cost of the additional stents is incurred by the hospital.

- **Multiple Catheter Exchanges.** Currently available delivery systems require a catheter exchange for every additional balloon or stent used. In addition to the catheter exchanges required by the use of multiple stents, a procedure may require insertion and inflation of a balloon both before and after

placement of each stent. Each catheter exchange increases procedure time, cost and exposure to radiation from additional x-ray imaging.

- **Overlapping of Stents to Cover Long Lesions.** Treatment of longer lesions with current fixed-length stents requires placement of multiple overlapping stents. This can result in reduced therapeutic benefits, and two independent clinical trials have shown this practice is associated with an increased incidence of adverse cardiac events. We believe that the increase in treatment of longer lesions, combined with the length limitations of available stents, has increased the use of this technique, with approximately one in four procedures involving overlapping stents.

- **Inaccurate Placement of Stents.** Inaccurate placement of stents, or geographic miss, results in portions of a lesion remaining exposed, increasing the likelihood of thrombosis and the need for reintervention. We believe that geographic miss occurs due to the difficulty of accurately pre-selecting the necessary stent length and diameter. We believe this is caused by the limitations of two dimensional x-ray images, as well as changes in the shape of the artery that can occur due to device delivery. In addition, we believe that physicians may select shorter stents to ensure deliverability and avoid covering healthy artery side-branches. In Johnson & Johnson s STLLR clinical trial, geographic miss was observed in 44.5% of procedures, resulting in higher rates of thrombosis and reinterventions.

- **Alteration of the Artery Anatomy.** The shape of an artery can include a number of bends, and its movement can include a twisting motion with each contraction of the heart. Many current stents can be rigid and stiff along their entire length, in order to hold open diseased arteries, and can cause a change in the artery s anatomical shape and may inhibit its natural twisting movement. We believe altering the artery s natural anatomy and limiting its movement may adversely impact the long-term safety of the therapy. An independent clinical trial conducted by the Austrian Wiktor Stent Study Group and European Paragon Stent Investigators, showed that changes in artery shape which occurred following stent procedures were associated with major adverse cardiac events, or MACE.

- **Required Physician Planning and Inventories.** Current drug eluting stent offerings are fixed-length and cannot be adjusted, but the size and shape of lesions can vary significantly. In order to choose the correct stent, physicians can spend considerable time attempting to estimate the size and characteristics of the lesion. Additionally, due to the variability of lesions, hospitals must keep a wide variety of stent sizes in inventory resulting in higher inventory management efforts and costs.

We believe that while current stent systems can provide effective therapy for patients, there is significant opportunity for improvement in efficacy, efficiency and cost due to the limitations described above.

The XTENT Solution

Our customizable drug eluting stent systems are designed to enable the treatment of single lesions, long lesions and multiple lesions of varying lengths and diameters, in one or more arteries with a single device. We believe our Custom NX DES Systems ability to customize therapy without the need to exchange catheters may enable physicians to treat patients more effectively and efficiently. Our technology platform is designed to benefit all major constituents in the healthcare system by providing patients with better therapeutic outcomes, giving physicians a more effective and efficient clinical tool and potentially reducing costs for healthcare providers. We believe that the potential benefits provided by our technology include the following:

- **In-Situ Customization.** Our Custom NX DES Systems are designed to allow physicians to determine and deploy the appropriate length of stent for the patient while inside the artery at the site of the lesion, or in-situ. This ability to customize stent length in-situ may help ensure coverage

of the lesion and reduce the planning required prior to catheter insertion. Additionally, because our stents can be customized, we believe our six Custom NX stent configurations, comprised of three different diameters for each of our two lengths, may address the same lesions that could be treated with approximately 33 of the fixed-length stent configurations offered by our competitors.

- **Treatment of Multiple Lesions With a Single Device.** Our stents are comprised of multiple segments that are interdigitated. With the insertion of a single device, the physician can choose to place up to 60mm of stent to treat a single long lesion or distribute the 6mm segments across multiple lesions in a customized manner. Our products may eliminate the need to use a separate post-deployment balloon because the balloon in our catheter can be shortened and reused during the procedure. We believe a single Custom NX 60 or Custom NX 36 can perform the same functions as multiple competing stents and balloon catheters. This may result in significant device cost savings, reduced catheter exchanges and shorter procedure times.

- **Treatment of Long Lesions Without Multiple Overlapping Stents.** Our Custom NX 60 is designed to be able to effectively treat longer sections of diseased artery as compared with current fixed-length alternatives. Our Custom NX 60 can deliver up to 60mm of stent, while currently available drug eluting stents are typically 33mm or shorter. We believe our ability to cover a long lesion with a single stent may reduce the complications from overlapping stents. Two studies support our belief that overlapping stents increase the risk of complications. An analysis from the Real-World Eluting Stent Comparative Italian Retrospective Evaluation Study showed an increase in thrombosis with no increased incidence of heart attack in the stent overlap group and another independent retrospective study conducted by the Washington Hospital Center showed an increase in the incidence of heart attack and no increase in thrombosis in the stent overlap group.

- **Improved Stent Placement Accuracy.** Our Custom NX DES Systems are designed to allow the physician to incrementally adjust the length and diameter of the stent deployed while the delivery catheter is positioned in the patient s diseased artery. Prior to stent deployment, the physician can view the x-ray image to confirm complete coverage of the disease and make any additional length adjustments. During deployment, stent diameter can be adjusted by controlling the pressure of the balloon inflation. We believe that this will enable a single stent deployed by our Custom NX DES Systems to treat a long lesion in an artery of varying diameters with one device. Current stent technologies are fixed-length and cannot be adjusted to address varying diameters with a single device. We believe the ability to customize the length of the stent while in the patient s artery may reduce the incidence of geographic miss and the resulting problems of thrombosis and reinterventions.

- **Increased Stent Flexibility and Deliverability.** Our stents incorporate a modular design consisting of multiple small individual segments that are interdigitated, which we believe provides increased stent flexibility. We believe our stent s flexibility may allow an artery to better maintain its natural shape, as well as move and flex with contractions of the heart, which may improve long-term patient outcomes. Our stent s increased flexibility may be particularly well suited for long lesions where the issues of deliverability and anatomical conformity are more important. In addition, our stent is delivered to the lesion covered inside of a sheath, which helps protect it and its coating from being damaged as it is pushed through a patient s vascular system. Current delivery systems leave stents exposed, which can hinder delivery if stents catch on diseased tissue or on the artery wall and may also cause coatings on currently available stents to be scraped off during insertion.

- **Biodegradable Polymer as Our Drug Carrier.** Our drug coating is biodegradable, leaving behind a thin permanent primer. Our primer has been commonly used for approximately 30 years on cardiac defibrillators, pacemakers and neurostimulators, all of which have been implanted in patients for periods of time at least as long as our stents are intended to be implanted, as well as catheters,

needles and other medical device components. As a result, we believe our primer has insignificant physiological response when used in the body. We believe the biodegradability of the polymer used in our drug coating may reduce the potential for late-stent thrombosis, or the occurrence of thrombosis 30 or more days after the procedure, that may be associated with durable polymers.

The risks associated with using our products include the risks common to other drug eluting stents and stent delivery systems, including the risk of thrombosis. In addition, our products include the risk of movement of stent segments after deployment that may lead to restenosis and the risk of using a new drug and polymer coating formulation that has not been reviewed and approved by any regulatory authority for any use or used commercially with any drug eluting stent.

Our Strategy

Our goal is to become a world leader in the development and commercialization of drug eluting stent systems. To achieve this goal, we are pursuing the following business strategies:

- **Demonstrate the Clinical Safety and Efficacy and Gain Regulatory Approval of Our Custom NX DES Systems.** We intend to demonstrate the clinical safety and efficacy of our Custom NX DES Systems through carefully structured clinical studies. Upon completion of these studies, we intend to develop and initiate a large U.S. pivotal clinical trial to scientifically establish the clinical benefits of our systems. We expect to use these large studies to support U.S. approvals and reimbursement where required. We also plan to complete the regulatory submissions required in order to sell our systems in the European Union, and other markets.

- **Commercialize and Drive Adoption of Our Custom NX DES Systems.** Following regulatory approvals, we plan to rapidly commercialize our products worldwide. Our strategy involves initially commercializing our Custom NX DES Systems in key markets in Europe, Asia Pacific and South America once we obtain appropriate regulatory approvals. We expect to rely on third-party distributors, with our sales and clinical support, in select markets in Europe, Asia Pacific and the rest of the world. In the United States, we plan to build a direct sales organization that will work closely with interventional cardiologists to drive adoption. We intend to employ professional education specialists who will provide training and education for physicians and technicians. In order to meet commercial demand for our products, we will invest to expand our manufacturing capabilities to required levels.

- **Build Awareness and Support Among Leading Physicians.** Our clinical development strategy is to closely collaborate with key opinion leaders in the field of interventional cardiology. We believe these key opinion leaders can be valuable advocates of our technology and be important in gaining widespread adoption once our systems are approved and commercialized. In addition, we intend to look to these physicians to generate and publish scientific data that further support the benefits of our customizable stent technology.

- **Leverage Our Technology Platform into Other Indications.** We believe that our technology is applicable in other therapeutic areas outside of CAD. For example, we intend to pursue the use of our technology for the treatment of peripheral artery disease, or PAD.

- **Expand and Strengthen Our Intellectual Property Position.** We plan to continue to expand our current intellectual property position. We believe that our current intellectual property position will allow us to effectively market our products for the treatment of CAD. We plan to originate, license and acquire additional intellectual property to enhance our existing position and enable us to more effectively protect our technology.

- **Provide the Highest Quality Products for Our Customers.** We have assembled an experienced team of medical device professionals who are focused on patient safety and product quality. We

incorporate these principles in every aspect of our organization including product development, manufacturing, quality assurance and clinical research. We intend to build on this foundation by offering only the highest quality products to patients and physician customers.

Our Technology Platform

We are developing a proprietary percutaneous coronary interventional therapy, consisting of drug eluting stents up to 36mm or 60mm in length and a stent delivery system. The integration of these components as a complete system is designed to provide a physician the ability to customize therapy by deploying multiple custom-length stents to more than one lesion without the removal or exchange of catheters.

Our Stent and Drug Coating

Our stent has a proprietary modular design and consists of multiple 6mm stent segments. The segments are not physically attached to one another, but instead the ends of each segment are interdigitated. This allows for separation at each 6mm segment and the ability for the overall stent length to be customized during a procedure. Our stent s design allows each segment to flex independently of one another, which we believe provides for increased movement between segments during delivery and after implantation. This may allow the stent to better conform to the natural curvature of an artery and accommodate artery movement. In addition, we believe our stents maintain radial strength necessary to hold the artery open across multiple segments.

The stent segments are made of thin cobalt chromium struts designed to provide artery wall coverage. Our stents will be available in customizable lengths of up to 36mm and 60mm, comprised of 6mm segments. We are currently clinically testing 2.5mm and 3.0mm diameter versions of our stent, which will allow physicians to provide therapy to arteries typically treatable with stents ranging from 2.5mm to 3.5mm in diameter. We are also developing a 3.5mm diameter version of our stent that can be expanded up to 4.0mm. Our stents are designed to allow physicians to treat a range of lesion lengths and diameters with a single stent.

The drug coating for our stent consists of the combination of Biolimus A9, an anti-inflammatory drug that is a derivative of rapamycin, and a PolyLactic Acid coating, or PLA, a biodegradable polymer used to release the drug over time. We license our drug coating from Biosensors. The chemical structure of Biolimus A9 was designed specifically for localized drug delivery from the surface of a stent. We first apply a thin permanent primer to our stents, which is designed to improve the ability of the drug coating to adhere to the stent. We believe this primer has an insignificant physiological response when used in the body. The drug coating is biodegradable, dissolving over time and releasing the drug, leaving the bare metal stent with its thin layer of primer coating in place once the drug eluting process is complete.

Our Delivery System

Our delivery system consists of a catheter with a protective sheath that contains our stent segments and balloon and a handle to control delivery of the catheter and deployment of the stent segments. The protective sheath covers the stent segments until the time of deployment and is designed to prevent the stent from scraping the artery wall as it is delivered to the targeted lesion. We believe that this scraping may damage the drug coating or cause the stent to be dislodged during delivery. Our sheath has a slippery coating and smooth outer surface to provide lubrication, and is designed with the column strength and flexibility needed to advance the catheter to the target lesion.

The distal end of the catheter contains a marker for visualization and our proprietary mechanism for separating the interdigitated segments. The method of action for separation is mechanical in nature and can be quickly repeated multiple times. Our delivery system also has a handle attached to the catheter that

is used by the physician to control the deployment and separation of our stents. A dial on the handle allows the precise deployment of the necessary length of stent by pulling back the outer sheath. After deployment, if needed, the physician can shorten and reposition the balloon within the stented segment to further expand a portion of the stent against the artery wall. This feature is not currently offered in any commercially available stent delivery system and is intended to simplify the procedure by avoiding the need for an additional balloon for post-deployment stent diameter adjustments. After treatment of a specific lesion, our Custom NX DES Systems are designed to be reset and used to treat additional lesions, provided that all stent segments have not been deployed.

Our Procedure

Following the placement of a guidewire, a physician inserts our Custom NX DES System into the femoral or radial artery and maneuvers the catheter to the site of the target lesion. Opaque markers on the balloon catheter and the sheath allow for visual assessment of stent length and location relative to the target lesion. The physician then uses the dial on the handle to retract the protective sheath until the desired number of stent segments is exposed. If the physician determines the lesion coverage is inappropriate, the number of segments exposed can be adjusted before separation occurs. After the physician confirms lesion coverage using x-ray imaging, the handle switch is used to separate the exposed stent segments from those remaining protected in the sheath of the catheter. After separation, the physician inflates the balloon to deploy the stent. If needed, the physician can shorten, reposition and reinflate the balloon, in-situ, within the stented segments to further expand a portion of the stent against the artery wall. After the stent segments are deployed and the lesion covered, the physician can move to another lesion if necessary, and repeat the procedure with any remaining stent segments.

Products Under Development

Our goal is to provide physicians with new and proprietary stent platforms that allow customization of treatment options for patients with CAD. Pursuant to this goal we have several products and projects in development to continually improve the ease of use and deliverability of our Custom NX DES Systems, expand the application of our technology and leverage the advantages of custom stenting in new applications.

Expanded Range of Stent Diameters. In our current clinical trials, we are using 2.5mm and 3.0mm diameter stents that can expand up to 3.0mm and 3.5mm, respectively. Additionally, we are developing a 3.5mm stent diameter configuration that can be expanded up to 4.0mm. We believe this will provide the range of sizes sufficient to address most CAD lesions treatable with currently marketed drug eluting stents.

Quick Deployment Handles. Our handle is the key user interface of our Custom NX DES Systems and is the ongoing focus of development for improving ease of use and in helping to prevent operator error. We are currently developing improvements to the mechanism for separating stent segments, which will simplify the process and eliminate manual steps. We believe that reducing the number of steps required by the procedure will improve ease of use, which will in turn drive market adoption.

Peripheral Applications. Our efforts to date have focused on the use of our technology in the coronary arteries. We believe an additional large market opportunity is the use of our long, segmented stent technology to treat peripheral artery disease, or PAD. PAD in the legs is often characterized by long lesions, which are difficult to treat with stents due to fractures in the stent struts that occur as the legs move and bend. We have begun developing this product and we are looking at new materials such as Nitinol, as well as methods for stent deployment and stent length customization with the use of self-expanding stents and we may devote significant resources to development of these products if user preferences shift from drug eluting stents to bare metal stents.

Bioabsorbable Stent Systems. Bioabsorbable stents are designed to remain in the treated artery as long as therapeutically needed, then become fully absorbed by the arterial tissue. Although bioabsorbable stents offer potential promise, further research is required in order to demonstrate bioabsorbable stents can provide non-inferior safety and efficacy results to current alternatives. We have initiated a project to evaluate the feasibility of customizable bioabsorbable stent systems for the treatment of CAD and PAD.

Bare Metal Stent Systems. In some countries conventional bare metal stents are still used in a significant number of PCI procedures. According to Millennium Research Group, bare metal stents were used in approximately 700,000 of the 2.2 million coronary stent procedures performed worldwide in 2005. We believe that during bare metal stent procedures, similar to drug eluting stent procedures, the ability to customize stent length and treat multiple lesions in a single intervention will provide significant advantages over current bare metal stent technologies. Consistent with our goal of offering physicians a range of customizable treatment options for cardiovascular disease, we are currently evaluating the potential for bare metal stent versions of our stent systems.

Clinical Development Program

Description of Common Clinical Measures

The safety, efficacy and performance of drug eluting stents are assessed using common metrics. Data collected at the time of stent implantation is compared with data collected when a patient is reassessed at follow-up. The time periods for follow-up are usually 30 days and six to nine months in pivotal clinical trials for marketing approval in the European Union for CE Mark, and 30 days and nine months for clinical trials under an investigational device exemption, or IDE, application in the United States conducted to support FDA approval of a PMA application. Competitors with drug eluting stents currently being sold in the United States have completed large, prospective, randomized clinical trials that enrolled approximately 1,000 and 1,300 patients each. The common metrics used in these clinical trials to evaluate the safety and efficacy of drug eluting stents include:

- ***Late Loss of Lumen Diameter.*** This is defined as the change in the minimum lumen diameter of the artery from the time of stent implantation to the time of follow-up. Late loss may either be in-stent, analyzing only the lumen within the stent, or in-segment, analyzing the lumen within the stent plus 5mm on either side of the stent. The clinical trials of currently FDA approved drug eluting stents demonstrated in-stent loss of 0.17mm to 0.39mm, and in-segment loss of 0.23mm to 0.24mm at eight to nine months.

- ***Binary Restenosis Rate.*** This is defined as the percentage of patients that have a greater than 50% reduction in the lumen diameter from the time of stent implantation to the time of follow-up. The metric may either be in-stent or in-segment. The clinical trials of currently FDA approved drug eluting stents demonstrated in-stent restenosis of 3.2% to 5.5%, and in-segment restenosis of 7.9% to 8.9% at eight to nine months.

- ***Percent Volume Obstruction.*** This is defined as the volume of the lumen in the stent that is occupied by restenotic tissue. The percent volume lumen obstruction is measured using intravascular ultrasound, or IVUS. The clinical trials of currently FDA approved drug eluting stents demonstrated volume obstruction of 3.1% to 12.2% at eight to nine months.

- ***Target Lesion Revascularization, or TLR, Rate.*** This is defined as the percentage of patients at follow-up who required another coronary intervention, such as balloon angioplasty or a CABG procedure, to treat the same lesion in the artery, within the stent or within 5mm on either side of the stent. The clinical trials of currently FDA approved drug eluting stents demonstrated TLR rates of 3.0% to 3.9% at eight to nine months.

The data generated by comparisons with approved drug eluting stents for the metrics referenced above is the standard against which any new drug eluting stent, including our Custom NX DES Systems, will likely be measured. Also, the data referenced above was collected from large scale clinical trials, which we have not yet performed.

Our Clinical Trials

We are conducting clinical trials to evaluate our Custom NX DES Systems. We have completed enrollment in two clinical trials and are currently conducting additional early feasibility studies of our products in humans for complex disease including long lesions, multiple lesions and a broader range of vessel diameters. We are pursuing a clinical development strategy to demonstrate that our proprietary technology platform permits the customization of certain parameters of the therapy in-situ including length of the stent, diameter of the stent and number of lesions treated. Additionally, we plan to evaluate additional capabilities of our Custom NX DES Systems traditionally not performed by drug eluting stent systems including balloon shortening for partial expansion and post-deployment reinflation.

The following table summarizes our completed and ongoing clinical trials. Assuming favorable results, the data from the CUSTOM I, II and III clinical trials will be included in a submission to our designated Notified Body and used to support an application to obtain the CE Mark that will allow us to commercialize our Custom NX DES Systems in the European Union. Additionally, we expect to use this information to support an IDE application to the FDA for the design of our planned U.S. pivotal clinical trial.

Clinical Trial	**Number of Patients**	**Device Characteristics**	**Description**	**Status**
CUSTOM I	30	- Maximum length: 36mm - Diameter: 3.0mm - Guide catheter: 7 french - Single deployment	First-in-man feasibility study to evaluate safety and efficacy in patients with a coronary lesion treatable with 36mm of stent	Completed
CUSTOM II	100	- Maximum length: 60mm - Diameter: 3.0mm - Guide catheter: 6-7 french - Multiple deployments	Feasibility study to evaluate safety and efficacy in patients with long or multiple coronary lesions	Enrollment Completed
CUSTOM III	90 anticipated	- Maximum length: 60mm - Diameters: 2.5mm, 3.0mm, 3.5mm - Guide catheter: 6 french - Multiple deployments	Feasibility study to evaluate safety and efficacy in patients with long or multiple coronary lesions using a range of stent diameters	Ongoing

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

The clinical trial included a patient population considered high risk for CAD, including those with long lesions and lesions in small arteries. The mean reference diameter and lesion length were 2.6mm and

17.7mm, respectively. During hospitalization, two of the patients experienced elevated enzyme levels, characterized as myocardial infarctions, and recovered without further clinical events. These patients were discharged from the hospital within a few days following the procedure. At four, eight and 12 month follow-up, no patients treated with our stent presented binary restenosis and no new major adverse cardiac events, or MACE, were reported. The single MACE event at eight months occurred in the one patient who was enrolled in the clinical trial but could not receive treatment with our device or the stent devices of two of our competitors, due to an inability to reach the treatment site. The patient was treated with balloon angioplasty, subsequently experienced chest pain at five months following the procedure and then underwent bypass surgery for complete revascularization of all coronary arteries. The eight month results were presented at the 2006 Paris Course on Revascularization conference.

The results from our CUSTOM I clinical trial do not necessarily predict the outcome of a large-scale clinical trial, which will be required for obtaining FDA approval for our products in the United States.

Patient Characteristics

Characteristic	Percentages or Numbers	
Age (years)	67.3 ± 7.9	
Gender		
Male	19	
Female	11	
Previous myocardial infarction	16.7	%
Previous intervention	26.7	%
Diabetes	30.0	%
Hyperlipidemia	80.0	%
Hypertension	76.7	%
History of smoking	23.3	%
American Heart Association lesion severity type		
B1	40.1	%
B2/C	59.9	%
Lesion length (mm)	17.7 ± 9.6	
Reference artery diameter (mm)	2.6 ± 0.3	

Efficacy Results

Clinical Measure (Mean±Standard Deviation)	Pre-Procedure	Post-Procedure	4 Months	8 Months	
Minimum lumen diameter (mm)	1.02±0.41	2.48±0.29	2.33±0.29	2.06±0.33	
Late loss of lumen diameter in stent (mm)			0.24±0.23	0.29±0.25	
Late loss of lumen diameter in segment (mm)			0.26±0.14	0.21±0.28	
Late loss of lumen diameter index			0.19	0.18	
Binary restenosis (%)			0.0 %	0.0	%

CUSTOM II. Our CUSTOM II clinical trial is designed to evaluate the safety of in-situ customization for long lesions and multiple lesions using our Custom NX 60. The Custom NX 60 was used to treat patients with long lesions or lesions in multiple diseased coronary arteries ranging from 2.5 to 3.0 mm in diameter. Enrollment of 100 patients was completed in October 2006 at ten cardiology centers in Europe. Patients will be reassessed at 30 days, six months and 12 months. The six month clinical data from 40 patients were presented in October 2006 at the Transcatheter Cardiovascular Therapeutics conference.

The follow up period for all enrolled patients is ongoing. The preliminary results of the first 40 patients having completed their 30 days and six months follow up examination included a patient population considered at high risk for CAD, which are patients with long lesions, multiple lesions and

lesions in small arteries. Of the first 40 patients, 25 were treated for a single long coronary lesion while the remaining 15 patients received treatment in two coronary lesions. The mean reference diameter and lesion length were 2.58mm and 31.92mm, respectively. During hospitalization, the only MACE reported was one cardiac death, which is currently under investigation and could be determined to be related to the procedure involving the use of our Custom NX 60. At six months, the other 39 patients, were alive and underwent clinical and angiographic follow up. A lesion narrowing was reported in one patient resulting in a target lesion revascularization. For other patients, the stent site was free of restenosis. These preliminary results do not necessarily predict the outcome of the CUSTOM II clinical trial or of a large-scale clinical trial, which will be required for obtaining FDA approval for our products in the United States.

Patients Characteristics

Characteristic	Percentages or Numbers	
Age (yrs)	65.2 ± 8.5	
Gender		
Male	32	
Female	8	
Previous myocardial infarction	7.5	%
Previous intervention	27.5	%
Diabetes mellitus	35.0	%
Hyperlipidemia	65.0	%
Hypertension	65.0	%
Family History of CAD	45.0	%
American Heart Association lesion severity type		
B1	21.8	%
B2	45.5	%
C	32.7	%
Lesion Length (mm)	31.92 ± 13.08	
Reference artery diameter (mm)	2.58 ± 0.45	

Efficacy Results

Clinical Measure (Mean±Standard Deviation)	Pre-Procedure	Post-Procedure	6 Months(1)
Minimum lumen diameter (mm)	0.92±0.37	2.35±0.30	2.10±0.43
Late loss of lumen diameter in stent (mm)			0.25±0.34
Late loss of lumen diameter in segment (mm)			0.15±0.33
Late loss of lumen diameter Index			0.16
Binary restenosis (%)			2.5 %

(1) Represents clinical data from 40 patients.

CUSTOM III. Our CUSTOM III clinical trial is designed to evaluate in-situ customization for long lesions and multiple lesions using an expanded range of diameters of our Custom NX DES Systems. The stents deployed will include 2.5mm, 3.0mm and 3.5mm diameters. The enrollment in the CUSTOM III trial began in September 2006, but was delayed in November 2006 following a sterilization validation problem with the devices to be used in the trial. Enrollment was reinitiated on April 2, 2007 and will continue at up to 15 European centers. We expect to complete enrollment of the anticipated 90 patients in the first half of 2007. Patients will be reassessed at 30 days, six months and 12 months.

Entities associated with our principal clinical investigator for our CUSTOM I and CUSTOM II clinical trials hold options to purchase 17,344 shares of our common stock at a weighted-average exercise

price of approximately $0.34 per share, exercised options to purchase 10,156 shares of common stock and purchased 53,345 shares of convertible preferred stock in our preferred stock financings.

Planned Clinical Trials

In order to obtain reimbursement in selected European countries and FDA approval in the United States, we plan to undertake large-scale pivotal studies similar to those conducted by competitors who have marketed drug eluting stents. We expect to enroll approximately 2,500 patients in these studies. The clinical trial design and sample size will be determined based on the safety and efficacy data from our CUSTOM I, II and III clinical trials. We currently anticipate these clinical trials will require evaluating our stent in a randomized, controlled manner against one of the marketed drug eluting stents in patients with CAD. We believe the clinical measures will be the endpoints commonly used in drug eluting stent clinical trials. We expect that safety will be measured through MACE rates or target lesion revascularization while efficacy endpoints will include late loss of lumen diameter, binary restenosis rate or percent volume obstruction.

The two currently marketed drug eluting stents, Johnson & Johnson s Cypher and Boston Scientific s Taxus Express2, have undergone similar evaluations in order to obtain market approvals. However, the Cypher and Taxus Express2 stents were evaluated in comparison to their respective bare metal versions. The SIRIUS and TAXUS IV clinical trials enrolled 1,058 and 1,314 patients, respectively.

CUSTOM IV. Using data generated by our CUSTOM I, II and III clinical trials, we expect to submit an IDE application to the FDA in the first half of 2007 for our planned U.S. pivotal clinical trial, CUSTOM IV, evaluating our Custom NX DES Systems, against a marketed drug eluting stent, for the treatment of CAD. We are preparing for discussions with the FDA on our proposed clinical trial protocol. We expect that similar measures as those used in other large-scale drug eluting stent IDE clinical trials will be evaluated in our CUSTOM IV clinical trial. We anticipate that a total of up to approximately 2,500 patients will be necessary to support FDA approval. If enrollment rates proceed as planned and clinical results are favorable, we anticipate submitting a PMA application to the FDA in 2009.

CUSTOM V. Our CUSTOM V pivotal clinical trial in Europe will be designed to establish specific claims that would be used to seek reimbursement in selected European countries. We believe this clinical trial will be a randomized, controlled trial with marketed drug eluting stents used in the control arm and will include up to approximately 500 CAD patients. We expect to initiate this clinical trial in 2007 after completion of the CUSTOM III clinical trial. We anticipate that the clinical data generated during this trial will be included in our PMA application.

The regulatory filing process for our drug eluting stents assumes a dual filing process in which our filings include our clinical and technical information and cross-references to the information generated by Biosensors on the drug coating. We intend to reference a drug master file, or DMF, for the drug coating and the information contained in the Investigational New Drug, or IND, filed by Biosensors to support its Phase I drug coating evaluation in the United States. We are unable to influence the Biosensors regulatory process, and we have limited insight as to the progress they are making. However, we are aware that they began their clinical and pre-clinical trials in Europe and the United States in 2004 and 2005, respectively. In May of 2006, Biosensors publicly disclosed that the granting of approval from the European Union is dependent on several factors, some of which are out of Biosensors control and as such, they are unable to determine or predict with certainty when such approval will be granted.

Post-Approval Registries

At the time of our product launches in Europe and in the United States we will undertake post-approval surveillance registries to document the performance of our Custom NX DES Systems on an

ongoing basis. We expect that these studies will have large patient population sample sizes, and will focus on identifying and monitoring occurrences of adverse events.

Our Relationship with Biosensors

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 and polymer coating formulation on our products. The drug coating consists of Biolimus A9, an anti-inflammatory drug that is a derivative of rapamycin, and a PolyLactic Acid coating, or PLA, a biodegradable polymer. Biolimus A9 has a chemical structure designed specifically for localized drug delivery from the surface of a stent and to inhibit restenosis. Biolimus A9 has not been approved for any use by any regulatory authority. The PLA polymer degrades over time as the Biolimus A9 is released into the treated area. Our license agreement with Biosensors is a worldwide, non-exclusive, license with royalties payable to Biosensors based on net sales of our products. The field of use in this license is limited to coronary and peripheral delivery of a series of short stent segments on a catheter where the physician has the ability to select the number of segments to be deployed. We are contractually restricted from obtaining Biolimus A9 from any other source or commercializing any products that incorporate rapamycin or its derivatives other than Biolimus A9; however, we have the right to terminate the license if Biolimus A9 has not met approvability requirements for approval by the FDA, a European notified body for CE Mark, or the Japanese Ministry of Health Labor, and Welfare by May 2007. The license expires or is terminable upon, among other things:

- eight years from the date our first stent system obtains regulatory approval anywhere in the world, with an automatic three-year extension unless notice of termination is given by either Biosensors or us;

- in May 2008, if we fail to obtain a CE Mark for our stent systems or fail to begin commercial sales before such date, except that this deadline is extended by one day for each day XTENT s approval is delayed due to Biosensors s failure to obtain approval of Biolimus A9 by May of 2007; or

- upon our failure to pay the minimum annual royalties required by the license.

We are obligated to assign to Biosensors any inventions for which our employees are inventors or co-inventors and which are either derived from Biosensors confidential information or related to the process for applying their drug coating to stents. Biosensors must assign to us any inventions that are determined to be improvements to our stent or stent systems which are derived from our confidential information.

Biolimus A9 is manufactured by a Japanese pharmaceutical company and then shipped to Biosensors to be mixed with the PLA to make their proprietary drug coating. Biosensors ships the drug coating to us and we apply it to our stents prior to final assembly and sterilization. During commercialization, we may be required to ship random samples from each lot of finished product to Biosensors for testing.

In April 2005, Biosensors submitted its first module for the DMF with its designated Notified Body in the European Union in conjunction with its application for CE Mark of its BioMatrix drug eluting stent. This is one of the steps Biosensors must undertake prior to marketing its BioMatrix drug eluting stent in the European Union. In response to requests for additional or revised information from its designated Notified Body or the relevant drug authority, Biosensors submitted additional data in connection with its application for CE Mark during 2006.

In May 2006, Biosensors publicly disclosed that it had responded to all requests for additional information received from its designated Notified Body; however, there can be no assurance that the Notified Body will accept Biosensors DMF in its filed form, even with the inclusion of the additional requested data. 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. If Biosensors experiences delays or problems in obtaining a favorable opinion from the relevant drug

authority on its DMF 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. The designated Notified Body who will be reviewing our CE Mark application will be given access to Biosensors DMF in connection with our applications for CE Mark.

We have granted Biosensors the exclusive right to distribute our stent systems that use their drug coating in Pacific Rim countries for five years following approval by the appropriate regulatory agency in each country. These Pacific Rim countries are: Japan, China, Korea, Taiwan, Hong Kong, India, Pakistan, Thailand, Malaysia, Indonesia, Singapore, Philippines, Australia, New Zealand, Bangladesh, Sri Lanka, Vietnam, Cambodia and Laos. The exclusivity terminates in each country where Biosensors fails to apply for regulatory approval of our products by May 2007. Biosensors holds an aggregate of 207,068 shares of our capital stock.

Manufacturing

We currently occupy a facility of approximately 20,000 square feet in Menlo Park, California, under a lease which expires on May 31, 2007. All of our manufacturing operations take place, and all 49 employees in our manufacturing department work, at this facility. We are in the process of identifying additional manufacturing space in the Menlo Park, California area, including additional space in our current facility.

Final assembly, drug coating, which remains subject to Biosensor s continued consent, and packaging of all of our products take place inside a controlled environment room of approximately 3,000 square feet that satisfies the requirements of a Class 10,000 level clean room. We have no experience manufacturing commercial quantities of our products and we will need additional space and operations personnel to commercialize our products. We believe our manufacturing facilities, processes and quality systems currently meet all regulatory requirements for the manufacture of devices for use in clinical trials and that with further refinements will meet all requirements for products for commercial distribution.

Our components are purchased from outside suppliers who provide both off the shelf materials as well as custom made parts. In some cases, components are provided by single source suppliers due to quality considerations, costs or regulatory requirements. We rely on Biosensors for our drug coating and no alternative source is available. We currently apply the drug coating to our stents; however, Biosensors has the right to require that future drug coating services be performed in their own facilities. Additionally, Biosensors currently relies on Nippon Kayaku to manufacture and supply Biolimus A9, which must meet strictly enforced GMP regulations in its manufacture of Biolimus A9 in order for us to obtain regulatory approval. We do not have the right to manufacture Biolimus A9 or the PLA coating on our own or have the coating services performed by a third party. We rely on SurModics for the lubricious coating that we apply to the sheath. We do not believe that we could replace these single source suppliers without significant effort and delay in production, especially after our products are commercialized because additional FDA approvals may be required. Other products and components come from single suppliers, but we believe alternate suppliers will be readily available, though in many cases we have not yet qualified alternate suppliers. We do not carry a significant inventory of most components used in our products. Most of our suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, any of the components used in our products. Any supply interruption from our suppliers or failure to obtain alternate suppliers for our components would limit our ability to market our products, which could delay completion of our clinical trials or commercialization of our products.

Sterilization services for our products are managed by a third-party supplier. Currently, we apply the drug coating to the stents at our Menlo Park facility, as well as final assembly, inspection and warehousing of our products. We do not have any experience manufacturing commercial quantities of our products.

Our Menlo Park facility was inspected by the California Food and Drug Branch in May 2005 and was issued a device manufacturing license. On June 19, 2006, our manufacturing facility was audited for the purpose of assessing the quality system to ISO 13485:2003 and the Medical Device Directive, or MDD 93/42/EC, requirements, and our registration was subsequently granted on September 20, 2006. The facility has been registered with the FDA since September 2004. A separate FDA inspection of the manufacturing facility and quality system will occur as part of the premarket approval, or PMA, process for our products and is expected to occur in 2009. When we obtain additional manufacturing space, we will need to be inspected by the FDA and if we move to another location, the facility may also need to be ISO recertified and recertified by the California Food and Drug Branch.

Competition

The coronary and peripheral stent industry is highly competitive. Many of our competitors have significantly greater financial resources, human resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Many of these competitors also have more established reputations with our target customers and developed worldwide distribution channels. These competitors include Abbott Laboratories, Boston Scientific, Cook, Johnson & Johnson and Medtronic. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us 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. As a result, we cannot assure you that we will be able to compete effectively against these competitors or their products.

Although the field of interventional cardiology is extremely competitive with high performance requirements for products, interventional cardiologists have historically been rapid adopters of new technology. While physicians may recommend alternative treatments such as drug therapy, CABG, angioplasty or bare metal stenting, we expect the primary competition for our products will be other drug eluting stents.

Because of the size of the CAD and PAD market opportunities, competitors have historically dedicated and will continue to dedicate significant resources to aggressively promote their products. New product developments that could compete with us more effectively are likely because the CAD treatment market is characterized by extensive research efforts and technological progress. Competitors may develop technologies and products that are safer, more effective, easier to use or less expensive than our Custom NX DES Systems.

There are a number of companies developing or marketing treatments for coronary restenosis that are directly competitive with our technology. In particular, Boston Scientific has developed a paclitaxel eluting stent, the Taxus Express2 stent, which is marketed in the United States, Europe and other international markets. The Taxus Liberte, its next generation Taxus stent, is marketed in Europe and other international markets. Johnson & Johnson has developed a stent coated with rapamycin, the Cypher stent, which is marketed in the United States, Europe and other international markets. The Taxus Express2 stent and the Cypher stent are currently the only FDA approved drug eluting stents in the United States. Conor Medsystems, which was recently acquired by Johnson & Johnson, has developed a paclitaxel eluting stent, CoStar, which Conor has stated does not leave any permanent residual polymers at the target site. Conor markets the CoStar in Europe and other international markets. Biosensors has developed a paclitaxel eluting stent, Axxion, which is marketed in Europe and other international markets and is also developing another drug eluting stent that uses the drug coating we plan to use on our products. Sorin Group has developed a tacrolimus eluting stent, Janus, which is marketed in Europe. Medtronic has developed a zotarolimus eluting stent, Endeavor, which is marketed in Europe and other international markets. Abbott

Laboratories has CE Mark for Xience, an everolimus eluting stent, which we believe will be commercialized in the near-term. Additionally, many of the companies referenced above, and other potential competitors including Microport, are in the process of developing new drug eluting stents. Competitors with stents used in PAD applications include Abbott Laboratories, C.R. Bard, Boston Scientific, Cook Group, Edwards Lifesciences, ev3, Johnson & Johnson, Medtronic and W.L. Gore & Associates.

Our success will be driven by, and depend on, our ability to innovate, manufacture in commercial quantities, obtain regulatory approvals and successfully market and sell our Custom NX DES Systems. We expect to encounter potential customers who, due to existing relationships with our competitors, are committed to or prefer the products offered by these competitors. To compete effectively, we must demonstrate that our products are attractive alternatives to other devices and treatments by differentiating our products on the basis of safety, efficacy, performance, ease of use, brand and name recognition, reputation, service and cost-effectiveness.

Research and Development

Since inception, we have devoted a significant amount of resources to develop our Custom NX DES Systems. Our research and development expenses were $7.1 million in 2004, $12.1 million in 2005 and $18.9 million in 2006. We expect our research and development expenditures to increase as we continue to devote significant resources to developing our products, in particular, completing the clinical trials necessary to support regulatory approval.

Sales and Marketing

We have a limited sales and marketing organization and have no experience in the sale, marketing and distribution of stent systems. To achieve commercial success for any approved product we must further develop a sales and marketing organization or enter into arrangements with others to market and sell our products.

We intend to commercialize our Custom NX DES Systems in certain key markets in both Europe and Asia Pacific following receipt of required regulatory approval. We expect to rely on Biosensors and other 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. We plan to market our products to physicians who perform interventional procedures in hospitals and to other personnel who make purchasing decisions on behalf of hospitals. In order for physicians to adopt our Custom NX DES Systems, we must show strong clinical evidence that our products are safe and effective. In addition, we must show that the product is easy to use and cost-effective. Because our products are based on a new technology, we will provide focused high level training and support. We plan to hire and include within the sales organization clinical specialists who are skilled in training cardiologists in the use of our products.

Intellectual Property

We believe that our competitive position will depend substantially upon our ability to obtain and enforce intellectual property rights protecting our technology. We file for patents expeditiously upon discovery of new patentable technologies and utilize other forms of intellectual property protection to strategically protect our proprietary technology. We maintain vigilance for third-party patents and applications and attempt to acquire rights to them when such intellectual property is strategically valuable to us.

As of December 31, 2006, we had five issued U.S. patents, 44 pending U.S. patent applications, 22 pending international patent applications filed pursuant to the Patent Cooperation Treaty, or PCT, and one pending Israeli patent application. Three of our issued U.S. patents will expire in 2021. Our other two issued U.S. patents, which cover devices, systems, and methods in which a radially expansible sleeve adapted to hold a stent is placed over a balloon catheter used to expand the stent, which we at present are not pursuing commercially, expire in 2014 and 2016, respectively. In addition, we have one U.S. patent under exclusive license covering methods of performing angioplasty on multiple lesions of varying lengths, which expires in 2012. As of December 31, 2006, three of our pending U.S. patent applications had been allowed by the U.S. Patent and Trademark Office, or USPTO. We are prosecuting or intend to prosecute our PCT patent applications in the national phase in Europe, Japan, Canada and Australia. Our pending U.S. and international patent applications, if issued, will expire between 2021 and 2026.

Two of our issued U.S. patents cover certain aspects of our Custom NX DES Systems, including the deployment of multiple stents from a balloon catheter with a separation mechanism on the catheter to separate a stent to be deployed from an adjacent stent. Our pending U.S. patent applications, if issued with their present claims, will cover various other aspects of our Custom NX DES Systems, including customization of stent length through selected deployment of stent segments, manipulation of stent segments within the catheter, separation of deployed stents from the undeployed stents and the interdigitation of the stent segments. Other pending patent applications in our portfolio, if issued with their present claims, will cover various other drug eluting stent technologies including detachable linked stent segments, self-expanding stents and delivery systems for PAD treatment applications, durable and bioabsorbable polymer stents molded at the site of treatment, stent coating technologies for creating topographical features such as drug reservoirs on the stent surface and for elution of multiple drugs, and bifurcation stents and delivery systems.

We have entered into a license agreement with Biosensors for non-exclusive rights to use its drug coating on our stents. See Our Relationship with Biosensors.

We have also entered into a license agreement with SurModics giving us non-exclusive rights in certain of its patents and patent applications to allow us to coat our catheter s sheath with SurModics lubricous coating. This agreement terminates upon the expiration of the last-to-expire patent licensed to us under the agreement, or earlier if we fail to begin bona-fide commercial sales by March 31, 2008 or thereafter if we have four consecutive quarters during which we fail to pay a royalty to SurModics. We have also entered into a license agreement with Millimed giving us non-exclusive rights in certain Millimed patent applications that relate to segmented stent designs, which terminates upon the expiration of the last-to-expire patent licensed thereunder.

We do not know if any of our patent applications will be issued, nor do we know whether our patents, if issued, will cover our technology or will be able to be successfully enforced. Even if valid and enforceable, our patents may not be sufficiently broad to prevent others from inventing a stent like ours, despite our patent rights. We have received no communications from third parties concerning the patentability, validity or enforceability of our patents or patent applications.

The industry we operate in has been subject to a large number of patent filings and patent infringement litigation. Whether we would, upon commercialization, infringe any patent claim will not be known with certainty unless and until a court interprets the patent claim in the context of litigation. If an infringement allegation is made against us, we may seek to invalidate the asserted patent claim and may allege non-infringement of the asserted patent claim. In order for us to invalidate a U.S. patent claim, we would need to rebut the presumption of validity afforded to issued patents in the United States with clear and convincing evidence of invalidity, which is a high burden of proof. To date none of our patents or patent applications have been subject to reexamination, interference, or other legal challenge.

We require all employees to sign confidentiality and invention assignment agreements under which they are bound to assign to us inventions made during the term of their employment unless excluded pursuant to California Labor Code Section 2870. These agreements further prohibit our employees from using, disclosing, or bringing onto the premises any proprietary information belonging to a third party. In addition, most of our consultants are required to sign agreements under which they must assign to us any inventions that relate to our business. These agreements also prohibit our consultants from incorporating into any inventions the proprietary rights of third parties without informing us. It is our policy to require all employees to document potential inventions and other intellectual property in laboratory notebooks and to disclose inventions to patent counsel using invention disclosure forms.

We also rely on confidentiality restrictions and trade secret protection to protect our technology. We generally require our consultants and other parties who may be exposed to our proprietary technology to sign non-disclosure agreements which prohibit such parties from disclosing or using our proprietary information except as may be authorized by us.

XTENT® is a registered trademark of our company in the United States, the European Union and Australia. Applications for our XTENT trademark are pending in Canada and Japan. CUSTOM NX® is a registered trademark of our company in Australia, the European Union and Japan. Applications for our CUSTOM NX trademark are pending in the United States and Canada. We have also applied to register NX as a trademark in the United States.

Third-Party Patent Rights

Cardiovascular stents and stent delivery systems are the subjects of numerous patents, and patent litigation has been prevalent in the industry. We are aware of a number of patents and patent applications held by potential competitors and others that contain subject matter that might be considered relevant to our technology. Each of these patents contains multiple claims any or all of which could be found to cover our technology. The owners of these patents may allege that our activities infringe their patent rights. We may be sued in the United States or elsewhere for patent infringement. Defending such infringement suits is costly and may be distracting to our employees. If a patent owner prevailed in such a suit, we could be enjoined from making, using or selling our products and required to pay substantial monetary damages.

A number of third-party patents are summarized below that others may allege cover our technology. Although we have attempted to include the patents that we believe present a material risk of litigation due to their subject matter or claims, this list may not be comprehensive. Given the large numbers of patents in the stent field, we may not be aware of all patents that may be alleged to cover our technology. Further, patent applications relevant to our technology may be pending which remain unpublished or of which we are otherwise unaware.

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 and its analogs 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.

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 we believe 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 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. 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.

Third Party Reimbursement

In most countries throughout the world, a significant portion of a patient s medical expenses is covered by third-party payors. In many countries including the United States, third-party payors consist of both government funded insurance programs and private insurance programs. While each payor develops and maintains its own coverage and reimbursement policies, the vast majority of payors have established policies for drug eluting stents. We believe that our products generally will fall within the existing reimbursement guidelines, although some refinement in policies may be indicated for our products. Before reimbursement may be obtained for our Custom NX DES Systems in the United States, FDA approval will be required.

In the United States, the Centers for Medicare and Medicaid Services, or CMS, is the government entity responsible for administering the Medicare program. CMS establishes Medicare coverage and reimbursement policies for medical products and procedures and such policies are periodically reviewed and updated. While private payors vary in their coverage and payment policies, the Medicare program is viewed as a benchmark. Both CMS and commercial payors have established coverage and reimbursement policies for drug eluting stents currently on the market. There also are established reimbursement codes describing current products and procedures using those existing products. There are no assurances that existing policies or reimbursement codes would be used for the systems we are currently developing. There are also no assurances that existing payment rates for such reimbursement codes will continue to be at the same levels. For example, under recent regulatory changes to the methodology for calculating payments for current inpatient procedures for 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. CMS 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.

Outside of the United States, there are many reimbursement programs through private payors as well as government programs. In some countries, government reimbursement is the predominant program available to patients and hospitals. While the vast majority of countries have existing reimbursement for drug eluting stents, a small number of countries may require us to gather additional clinical data before recognizing coverage and reimbursement for our products. It is our intent to complete the requisite clinical

studies and obtain coverage and reimbursement approval in countries where it makes economic sense to do so.

In addition, in the United States, governmental and private sector payors have instituted initiatives to limit the growth of health care costs, using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use such devices or therapies. Providers also have sought ways to manage costs, such as through the use of group purchasing organizations. It is our belief that the economic benefits provided by our Custom NX DES Systems to physicians and hospitals through shorter procedure times and lower overall procedure costs will be viewed by providers and third-party payors as cost-effective. However, there remains uncertainty whether our products will be viewed as sufficiently cost-effective to warrant adequate coverage and reimbursement levels.

Government Regulation

United States

Our products are combination products because they are comprised of two or more regulated components, a drug and a device, that are physically combined and produced as a single product. In the United States, a combination product is assigned by the FDA to one of the Agency s Centers, such as the Center for Drug Evaluation and Research, or CDER, or the Center for Devices and Radiological Health, or CDRH. The Center to which the product is assigned will have primary jurisdiction over the premarketing review and approval of the combination product. The FDA identifies the Center with primary authority over a combination product based on an assessment of the combination product s primary mode of action. Because the primary mode of action for our products is that of a medical device, they will be regulated as devices by the FDA under the Federal Food, Drug, and Cosmetic Act, and CDRH will have primary jurisdiction over our PMA application. We believe that the drug component of our products will be reviewed by CDER, which will consult with and assist CDRH in its review of our PMA applications. The drug will not require separate FDA approval. Biosensors will be responsible for filing with the FDA a drug master file, or DMF, for our drug coating. In connection with our device application, we intend to make reference to the DMF and the information contained in the IND generated by Biosensors to support their Phase I drug coating evaluation. We will not have direct access to the contents of the DMF, and any deficiencies indentified by regulatory authorities in the DMF will be addressed by Biosensors alone, without our input.

FDA regulations govern the following activities that we and our suppliers, licensors and partners perform and will continue to perform to ensure that products we distribute domestically or export internationally are safe and effective for their intended uses:

- product design and development;
- product testing;
- product manufacturing;
- product safety;
- product labeling;
- product storage;
- recordkeeping;
- premarket approval;
- advertising and promotion;

- production; and

- product sales and distribution.

FDA s Premarket Clearance and Approval Requirements. The FDA classifies medical devices into one of three classes. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in class III, requiring premarket approval. All of our current products are class III devices and will require FDA approval after submission and review of a PMA application. PMA must be supported by extensive data, including but not limited to, technical, pre-clinical, clinical trials, manufacturing and labeling to demonstrate to the FDA s satisfaction the safety and efficacy of the device. The PMA must also contain a full description of the device and its components and a full description of the methods, facilities and controls used for manufacturing.

Product Modifications. New PMAs or PMA supplements are required for all significant modifications to the manufacturing process, labeling, use and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an initial application for PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials. A clinical trial is almost always required to support a PMA application. Clinical trials for our product candidates require the submission of an application for an investigational device exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Our IDE application must also cross reference Biosensors DMF for the drug coating aspects of our products. The IDE must be approved in advance by the FDA for a specified number of patients. Clinical trials may begin once the application is reviewed and cleared by the FDA and the appropriate institutional review boards at the clinical trial sites. Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an institutional review board at the relevant clinical trial site and in accordance with applicable regulations and policies including, but not limited to, the FDA s good clinical practice, or GCP, regulations. We, the FDA or the institutional review board at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to clinical trial subjects outweigh the anticipated benefits.

Pervasive and Continuing Regulation. After a device is placed on the market, numerous regulatory requirements apply. These include:

- Good Manufacturing Practices regulations, or GMP, and Quality System regulations or QSR, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for unapproved or off-label uses;

- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and efficacy data for the device.

The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Health Services, or CDHS, to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our subcontractors. The supplier and manufacturers of the drug and drug coating used by us will be subject to inspections by the FDA and other regulatory authorities to determine their compliance with strictly enforced GMP regulations.

In addition, discovery of previously unknown problems with a medical device, manufacturer, or facility may result in restrictions on the marketing or manufacturing of an approved device, including costly recalls or withdrawal of the device from the market. For instance, Boston Scientific and Johnson & Johnson have experienced safety and manufacturing problems with their drug eluting stent products, and have conducted significant and costly recalls in response to these issues. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- fines, injunctions, consent decrees and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for premarket approval or new intended uses;
- withdrawing premarket approvals that are already granted; and
- criminal prosecution.

The FDA also has the authority to require us to repair, replace or refund the cost of any medical device that we have manufactured or distributed. If any of these events were to occur, they could have a material adverse effect on our business.

We are also subject to a wide range of federal, state and local laws and regulations, including those related to the environment, health and safety, and land use.

Fraud and Abuse. Our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales and marketing programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Department of Health and Human Services, Office of Inspector General, or OIG, to issue a series of regulations, known as the safe harbors. These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. Penalties for violations of the

federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the False Claims Act, known as qui tam actions, can be brought by any individual on behalf of the government and such individuals, sometimes known as relators or, more commonly, as whistleblowers , may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing of qui tam actions has increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a False Claim action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $5,500 to $11,000 for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

In addition to the laws described above, the Health Insurance Portability and Accountability Act of 1996 created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

If our operations are found to be in violation of any of the laws described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare programs, and the curtailment or restructuring of our operations.

International

International sales of medical devices are subject to foreign governmental regulations, which vary substantially from country to country. The time required to obtain clearance or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may be different.

The primary regulatory environment in Europe is that of the European Union, which consists of twenty five countries encompassing most of the major countries in Europe. Three member states of the European Free Trade Association, Norway and Lichtenstein, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Other countries, such as Switzerland, have entered into Mutual Recognition Agreements and allow the marketing of medical devices that meet E.U. requirements. The European Union has adopted numerous directives and the European Committees for Standardization, or CEN, have promulgated voluntary standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directives will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the European Union, the member states of the European Free Trade Association and countries which have entered into a Mutual Recognition Agreement. The method of assessing conformity varies depending on the type and class of the

product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a designated Notified Body, an independent and neutral institution appointed in one of the countries in the European Union to conduct the conformity assessment. This assessment is conducted by the designated Notified Body in one member state of the European Union, the European Free Trade Association or one country which has entered into a Mutual Recognition Agreement and is required for most of the medical devices in order for a manufacturer to obtain CE Marking and to commercially distribute the product throughout these countries. This assessment may also consist of an audit of the manufacturer s quality system and specific testing of the manufacturer s device so as to ensure compliance with ISO 13485 certification, which are voluntary harmonized standards. Compliance with these ISO certifications establishes that some of the general requirements of the directives are presumed to be fulfilled. See Manufacturing.

Employees

As of December 31, 2006, we had 108 employees, with seven employees in sales and marketing, 49 employees in manufacturing, 27 employees in research and development, 10 employees in general and administrative and 15 employees in clinical, regulatory and quality assurance. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees are represented by a labor union, and we believe our employee relations are good.

Available Information

We are subject to the reporting requirements under the Securities Exchange Act of 1934. Consequently, we are required to file reports and information with the Securities and Exchange Commission (SEC), including reports on the following forms: annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. These reports and other information concerning the company may be accessed through the SEC s website at http://www.sec.gov.

You may also find on our website at http://www.xtentinc.com/ electronic copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC. The charters for our Audit, Compensation and Nominating and Corporate Governance Committees and our Code of Ethics are available on our website. In the event that we grant a waiver under our Code of Ethics, to any of our officers or directors, we will publish it on our website.

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 December 31, 2006, we had an accumulated deficit of $54.1 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 DMF 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 DMF 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 DMF 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 DMF in connection with our applications for CE Mark. Biosensors will have to obtain a favorable opinion from the relevant drug authority on its DMF before our designated Notified Body can provide us with CE Mark approval. In the United States, we do not know what filings Biosensors has made with the FDA in connection with their DMF for the drug coating. If Biosensors experiences delays or problems in developing a DMF 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 drug master file, or DMF, 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 DMF, 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 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 compiling, submitting and obtaining PMA from the FDA. The PMA process requires us to demonstrate the safety and efficacy of our products to the FDA s satisfaction. This process is expensive and uncertain and requires detailed and comprehensive scientific and human clinical data. While the FDA review process generally takes one to three years after filing the PMA application, our PMA application review could take much longer and may never result in the FDA granting PMA. The FDA 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 DMF 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, or fails to test samples of our products accurately or in a timely manner, 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 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. In addition, Biosensors has indicated to us that it intends to control the process of certain testing related to the drug coating and its application to our products. This may result in our inability to commercially release a lot prior to receiving the test results. Any inaccuracy or delay in receiving the test results could negatively affect our ability to commercialize our products.

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 DMF 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;

- 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 only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals, and our clinical, regulatory and quality assurance personnel is currently composed of only 14 employees. 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.

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 stent and stent delivery systems 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.

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 we believe 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, the FDA exemptions 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 December 31, 2006 we have two issued patents covering certain aspects of the technology that we intend to commercialize and a number of other pending patent applications in the United States and abroad. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering medical devices and pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any of our issued patents may not provide us with commercially meaningful protection for our products or afford us a commercial advantage against our competitors or their competitive products or processes. In addition, patents may not issue from any pending or future patent applications owned by or licensed to us, and moreover, patents that have issued to us or may issue in the future may not be valid or enforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing products like ours, despite our patent rights.

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the validity of our issued patents or the patentability of our pending patent applications. For example, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the United States Patent and Trademark Office, or USPTO, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, 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. Many other large companies, including Medtronic and Abbott Laboratories, among others, are reportedly developing 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 in 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 that the net proceeds from our initial public offering, together with 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 18 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 public companies to include a report of management on the company s internal control over financial reporting in their annual reports on Form 10-K. In addition, 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. Both we and our independent registered public accounting firm will be testing our internal controls over financial reporting in connection with Section 404 requirements and could, as part of that documentation and testing, identify material weaknesses, significant deficiencies or other areas requiring further attention or improvement.

We are recording compensation expense that may result in an increase in our net losses for a given period.

Deferred stock-based compensation represents the difference between the deemed fair value of common stock at the time of a stock option grant and the option exercise price. Deferred stock-based compensation is amortized over the vesting period of the option. At December 31, 2005 and 2006, deferred stock-based compensation related to options granted to employees prior to January 1, 2006 totaled approximately $1.0 million and $673,000, respectively. Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment* (SFAS 123(R)) and during the year ended December 31, 2006, we granted options to employees with a grant date fair value of $10.1 million, which is being expensed over the four-year vesting period of the options on a straight-line basis. We also record non-cash compensation expense for equity stock-based instruments issued to non-employees. Non-cash compensation expense associated with future equity compensation awards may result in an increase in our net loss, and adversely affect our reported results of operations.

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 year ended December 31, 2006 was $1.4 million. 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 March 15, 2007, our officers, directors and principal stockholders each holding more than 5% of our common stock collectively will control approximately 68.0% 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 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently occupy a facility of approximately 20,000 square feet in Menlo Park, California, under a lease which expires on May 31, 2007. We are in the process of identifying additional manufacturing space in the Menlo Park, California area, including additional space in our current facility. However, we believe that our existing facility is adequate to meet our needs through at least December 2007 and we expect that it will be available to us through such period. We cannot assure you that suitable additional space will be available in the future on commercially reasonable terms as needed.

ITEM 3. LEGAL PROCEEDINGS

We are not party to any material pending or threatened litigation.

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

None.

PART II

ITEM 5. MARKET FOR THE REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

We had our initial public offering on February 1, 2007. Our Common Stock is traded on the NASDAQ Global Market under the symbol XTNT.

As of March 15, 2007, the closing price of our Common Stock on the NASDAQ Global Market was $12.92 per share, and the number of stockholders of record was approximately 166.

On January 26, 2006 we sold 10 accredited investors an aggregate of 1,808,115 shares of our Series C Convertible Preferred Stock at a purchase price per share of $5.42 for an aggregate purchase price of $9,799,997. On May 5, 2006 and June 13, 2006 we issued and sold to 49 accredited investors an aggregate of 3,370,758 shares of our Series D Convertible Preferred Stock at a purchase price per share of $8.90 for an aggregate purchase price of $29,999,875. In connection with the closing of our initial public offering, all of our preferred stock outstanding at the time of the offering was automatically converted into shares of our common stock.

Since our incorporation, we have never declared or paid any dividends on our capital stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

On February 1, 2007, we sold 4.7 million shares at $16.00 per share in the initial public offering of our common stock. Net cash proceeds from the offering were $68.2 million, after deducting approximately $7.0 million of underwriting discounts and commissions and other offering costs. The managing underwriters of the offering were Piper Jaffray & Co., Cowen and Company, LLC, Lazard Capital Markets LLC and RBC Capital Markets Corporation.

ITEM 6. SELECTED FINANCIAL DATA

We derived the selected statements of operations data for the years ended December 31, 2004, 2005 and 2006 and balance sheet data as of December 31, 2005 and 2006 from our audited financial statements that are included elsewhere in this report. We derived the selected statements of operations data for the period from June 13, 2002 (Inception) to December 31, 2002 and the year ended December 31, 2003 and the balance sheet data as of December 31, 2002, 2003 and 2004 from our audited financial statements that do not appear in this report. Our historic results are not necessarily indicative of the results that may be expected in the future. You should read this data together with our financial statements and related notes included elsewhere in this report and the information under Management s Discussion and Analysis of Financial Condition and Results of Operations.

	Period from June 13, 2002 (Date of Inception) to December 31, 2002	**Year Ended December 31, 2003**	**2004**	**2005**	**2006(2)**	**Cummulative Period from June 13, 2002 (Date of Inception) to December 31, 2006**
	(in thousands, except per share data)					
Operating expenses:						
Research and development	$ 1,993	$ 3,353	$ 7,118	$ 12,139	$ 18,923	$ 43,526
General and administrative	159	760	1,883	2,214	7,258	12,274
Total operating expenses	2,152	4,113	9,001	14,353	26,181	55,800
Loss from operations	(2,152)	(4,113)	(9,001)	(14,353)	(26,181)	(55,800)
Interest income (expense), net	28	136	110	323	1,137	1,734
Net loss	(2,124)	(3,977)	(8,891)	(14,030)	(25,044)	(54,066)
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock					(13,095)	(13,095)
Net loss attributable to common stockholders	$ (2,124)	$ (3,977)	$ (8,891)	$ (14,030)	$ (38,139)	$ (67,161)
Net loss per share attributable to common stockholders basic and diluted(1)	$ (2.51)	$ (2.34)	$ (5.00)	$ (6.84)	$ (13.96)	
Weighted-average common shares outstanding	846	1,702	1,779	2,052	2,732	

(1) See Note 2 of the notes to our financial statements for a description of the method used to compute basic and diluted net loss per share attributable to common stockholders.

(2) The Company adopted the provisions of SFAS 123(R) starting January 1, 2006.

	December 31, 2002	2003	2004	2005	2006
	(in thousands)				
Balance Sheet Data					
Cash and cash equivalents	$ 3,127	$ 14,003	$ 4,761	$ 6,564	$ 23,105
Working capital	3,025	13,747	4,143	5,588	21,066
Total assets	3,240	14,661	6,136	8,675	27,121
Reedeemable convertible preferred stock	5,218	20,406	20,406	35,900	75,593
Total stockholders deficit	(2,118)	(6,081)	(14,925)	(28,372)	(50,780)

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a development stage medical device company focused on developing and commercializing our proprietary Custom NX 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 length with a single device. We have not yet received any government regulatory approvals necessary to commercialize any of our products.

We are conducting clinical trials to evaluate our Custom NX 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. We completed enrollment of our CUSTOM II and initiated our CUSTOM III clinical trials, which are designed to further evaluate the safety and efficacy of in-situ customization with our stents, particularly in long lesions and multiple lesions. Assuming the results from these trials are favorable, we believe that 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. We anticipate applying for our IDE in the first half of 2007 based on the results from our CUSTOM I, II and III clinical trials.

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 December 31, 2006, we had an accumulated deficit of $54.1 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. In May and June 2006, we raised aggregate net cash proceeds of approximately $30.0 million in a private placement of shares of our Series D convertible preferred stock. On February 1, 2007 we completed our initial public offering of our common stock which raised net proceeds of $68.2 million.

In May 2004, we entered into a license agreement with Biosensors. Pursuant to the agreement, we obtained worldwide non-exclusive rights to use Biosensors s 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, 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 December 31, 2006, we incurred $43.5 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 December 31, 2006, we incurred $12.3 million in general and administrative expenses.

Results of Operations

Comparison of Years Ended December 31, 2005 and 2006

Revenue. We did not generate any revenue during the years ended December 31, 2005 or 2006.

Research and Development. Research and development expenses were $12.1 million for 2005, compared to $18.9 million for 2006. The increase of $6.8 million was primarily due to higher personnel expenses of $2.2 million for additional employees hired in our research and development department, $3.5 million for prototype parts, supplies, and outside services related to product development for our Custom NX DES systems, $477,000 due to increased spending on clinical research studies and $571,000 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 $2.2 million for 2005, compared to $7.3 million for 2006. The increase of $5.1 million was primarily due to higher personnel expenses of $2.4 million for additional employees hired in marketing and administration, $956,000 due to increased spending for consulting, trade shows and marketing materials, and $1.7 million due to increased legal and professional expenses. 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.

Interest Income. Interest income was $323,000 for 2005, compared to $1.1 million for 2006. The increase of $814,000 was due primarily to higher cash balances for 2006 as well as a modest increase in interest rates.

Income Taxes. Due to uncertainty surrounding the realization of deferred tax assets through future taxable income, we have provided a full valuation allowance and no benefit has been recognized for our net operating loss and other deferred tax assets.

As of December 31, 2006, we had net operating loss carry-forwards of approximately $33.1 million available to reduce future taxable income, if any, for Federal and California state income tax purposes. The Federal income tax net operating loss carry-forward begins expiring in 2022, and the California state income tax net operating loss carry-forward begins expiring in 2013. As of December 31, 2006, we had research and development credit carry-forwards of approximately $1.7 million and $1.8 million available to reduce future taxable income, if any, for Federal and California state income tax purposes, respectively. The Federal income tax credit carry-forwards begin expiring in 2022, and the California state income tax credits carry-forward indefinitely.

Section 382 of the Internal Revenue Code generally imposes an annual limitation on the amount of net operating loss carryforwards that may be used to offset taxable income when a corporation has undergone significant changes in its stock ownership. We have internally reviewed the applicability of the annual limitations imposed by Section 382 caused by previous changes in our stock ownership and believe such limitations should not be significant. Future ownership changes, including changes resulting from or affected by our initial public offering, may adversely affect our ability to use our remaining net operating loss carryforwards. If our ability to use net operating loss carryforwards is limited, we may be subject to tax on our income earlier than we would otherwise be had we been able to fully utilize our net operating loss carryforwards.

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 June 2006, we completed the issuance and sale of 3,370,758 shares of Series D convertible preferred stock at $8.90 per share, which price was determined by our board of directors pursuant to negotiations with a new investor and existing 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, in May 2006 to be $11.08 per share and in June 2006 to be $11.70 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, and approximately $7.4 million in connection with our Series D convertible preferred stock financing in May and June 2006.

Comparison of the Years Ended December 31, 2004 and 2005

Revenue. We did not generate any revenue during the years ended December 31, 2004 or 2005.

Research and Development. Research and development expenses were $7.1 million for 2004, compared to $12.1 million for 2005. The increase of $5.0 million was primarily due to a $2.6 million increase in spending on animal studies, consulting and materials. The remaining $2.4 million of increase was primarily due to higher compensation expenses for additional employees hired in our research and development department to accelerate the development of our Custom NX DES Systems.

General and Administrative. General and administrative expenses were $1.9 million for 2004, compared to $2.2 million for 2005. The increase of $331,000 was primarily due to higher spending for travel to support our clinical trials and due to increased legal expenses.

Interest Income. Interest income was $110,000 for 2004, compared to $323,000 for 2005. The increase of $213,000 was primarily due to higher cash balances from the first closing of our Series C convertible preferred stock financing as well as modest increases in interest rates.

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 December 31, 2006 we had an accumulated deficit of $54.1 million. We have 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.

As of December 31, 2006, we did not have any outstanding or available debt financing arrangements, we had working capital of $21.1 million, and our primary source of liquidity was $23.1 million in cash and cash equivalents. On February 1, 2007, we completed our initial public offering, raising $68.2 million in net proceeds.

Cash Flows

Cash Flows from Operating Activities. Net cash used in operating activities was $8.2 million in 2004, $13.0 million in 2005 and $20.9 million for 2006. The net cash used in 2004 primarily reflects expenditures related to the development of our products. The net cash used in 2005 and 2006 primarily reflects expenditures related to product development and clinical trials. These expenditures were offset in part by depreciation, 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 was $1.0 million in 2004, $1.1 million in 2005 and $1.5 million for 2006. Cash used in investing activities is primarily related to purchases of property and equipment.

Cash Flows from Financing Activities. Net cash provided by financing activities was $15.9 million in 2005 and $39.0 million in 2006. Net cash used in financing activities was $5,000 in 2004. Net cash provided by financing activities in 2005 and for 2006 was primarily attributable to our issuance of convertible preferred stock.

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 that the net proceeds from our initial public offering, together with our existing cash and cash equivalents, which include the proceeds from our May and June 2006 Series D convertible preferred stock financing, and interest income we earn on these balances, will be sufficient to meet our anticipated cash requirements for at least the next 18 months. If our available cash and cash equivalents and net proceeds from our initial public offering 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 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;
- licensing technologies for future development; and

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

The following table discloses aggregate information about our contractual obligations and the periods in which payments are due as of December 31, 2006:

	Payments Due by Period (in thousands)				
Contractual Obligations	**Total**	**2007**	**2008 to 2010**	**2011 to 2013**	**2014 and Later**
Operating lease	$ 96	$ 96	$	$	$
Minimum royalty obligations	2,100	40	490	540	1,030
Total	$ 2,196	$ 136	$ 490	$ 540	$ 1,030

The long-term commitments under operating leases shown above consist of payments related to our real estate lease in Menlo Park, California, which expires in May 2007.

The minimum royalty payments that are listed above consist of payments related to license agreements we have with Biosensors and SurModics. The total royalty payments for these licenses are based on our net revenues and therefore have no maximum. To date, we have paid $20,000 in royalty payments. We also have contingent payments that are payable to licensors upon the achievement of certain milestones. $550,000 in milestone payments have been made to date. There could be an additional $220,000 in milestone payments if all milestones are achieved.

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.

While our significant accounting policies are more fully described in Note 2 to our financial statements included elsewhere in this report, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

Clinical Trial Accruals

We record accruals for estimated clinical trial expenses, comprised of payments for work performed by participating trial centers. These costs are a significant component of our research and development expenses. The costs of our clinical trials are contractually determined based on the nature of the services to be provided. We accrue expenses for clinical trials based on estimates of work performed under our clinical trial contracts. These estimates are based on information provided by participating clinical trial centers. If the information provided is incomplete or inaccurate, we may underestimate expenses at a given point in time. To date, our estimates have not differed significantly from actual costs.

Stock-Based Compensation

Beginning on January 1, 2006, we began accounting for stock options granted to employees under the provisions of the Financial Accounting Standards Board, or FASB, Statement No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123(R), which require the recognition of the fair value of stock-based compensation. The fair value of stock options was estimated using a Black-Scholes option pricing model. This model requires the input of subjective assumptions in implementing SFAS 123(R), including expected stock price volatility, expected life and estimated forfeitures of each award. The fair value of equity-based awards is amortized over the vesting period of the award, and we have elected to use the straight-line method of amortization. Due to the limited amount of historical data available to us, particularly with respect to stock-price volatility, employee exercise patterns and forfeitures, actual results could differ from our assumptions.

Through December 31, 2005, we accounted for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB No. 25, Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, an interpretation of APB No. 25, and related interpretations. For periods prior to January 1, 2006, we have complied with the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended.

Under APB No. 25, we recognize stock-based compensation expense when we issue employee stock option grants at exercise prices that, for financial reporting purposes, are deemed to be below the estimated fair value of the underlying common stock on the date of grant. We did not obtain contemporaneous valuations by an unrelated valuation specialist that we could rely on during this period. Instead, we relied on our board of directors, which includes several venture capitalists who have considerable experience in the valuation of emerging companies and several members with extensive experience in the medical device industry. Given the absence of an active market for our common stock and uncertainty prior to the second quarter of 2006 as to whether we would pursue an initial public offering, our board of directors, with input from management, determined the estimated fair value of our common stock on the date of grant based on several factors, including:

- the grants involved illiquid securities in a private company;
- the options to acquire shares of our common stock were subject to vesting, generally vesting over a four-year period;
- our performance and the status of our research and development efforts;

- our stage of development and business strategy, including the status and timing of expected CE Mark clearance and our 510(k) submission with the FDA and the likelihood and timing of product launch;

- the composition and changes in the management team, including the need to recruit additional members;

- the likelihood of achieving a liquidity event for the shares of our common stock, such as an initial public offering or sale of our company, given market conditions; and

- the market prices of comparable publicly held medical device companies.

In accordance with the preparation of financial statements necessary for our initial public offering, we reassessed the estimated fair value of our common stock. In accordance with the requirements of APB No. 25 through December 31, 2005, we have recorded deferred stock-based compensation expense for the difference between the exercise price of the stock options granted during the year ended December 31, 2005 and the reassessed fair market value of our common stock at the date of grant and we amortize that amount over the vesting period of the stock options and include it as a component of stock-based compensation.

Effective January 1, 2006, we adopted SFAS 123(R) using the prospective transition method, which requires the measurement and recognition of compensation expense for all shared-based payment awards granted, modified and settled to our employees and directors after January 1, 2006. During 2006, we granted stock options to employees to purchase approximately 1,115,000 shares of common stock with a weighted-average grant date fair value of $9.07 per share under the Black-Scholes valuation model.

As of December 31, 2006, we had total unamortized employee stock-based compensation expense of approximately $9,205,000 arising from stock option grants to employees through December 31, 2006, which is expected to be amortized as follows (in thousands):

Year Ending December 31, 2007	Year Ending December 31, 2008	Year Ending December 31, 2009	Year Ending December 31, 2010
$2,884	$2,875	$2,614	$832

Determining the reassessed fair value of our common stock required our board of directors and management to make complex and subjective judgments, assumptions and estimates, which involved inherent uncertainty. Had our board of directors and management used different assumptions and estimates, the resulting fair value of our common stock and the resulting stock-based compensation expense could have been different.

Recent Accounting Pronouncements

In February 2007, the FASB issued SFAS No. 159, *The fair Value Option for Financial Assets and Financial Liabilities including an amendment of FAS115* (SFAS No. 159). SFAS No. 159 allows companies to chose, 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 fiscal years beginning after November 15, 2007 and will be applied prospectively. We are currently evaluating the impact of adopting SFAS No. 159 on its financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, or SFAS No. 157, which defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value

measurements. SFAS No. 157 does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. SFAS No. 157 is effective commencing with our fiscal year 2009 annual financial statements. We are currently assessing the potential impact that the adoption of SFAS No. 157 will have on our financial statements.

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes: An Interpretation of FASB Statement No. 109*, or FIN No. 48. FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*, by defining the minimum recognition threshold a tax position is required to meet before being recognized in our financial statements. FIN No. 48 is effective commencing with our fiscal year 2007 annual financial statements. We are currently evaluating the effect that the adoption of FIN No. 48 will have on our financial position and results of operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and investments in a variety of marketable securities, including commercial paper, money market funds and U.S. government securities. Our cash and cash equivalents as of December 31, 2006, included liquid money market accounts. Due to the short-term nature of our investments, we believe that there is no material exposure to interest rate risk.

ITEM 8. FINANCIAL STATEMENTS

XTENT, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Xtent, Inc.
(a development stage company)

In our opinion, the accompanying balance sheets and the related statements of operations, of stockholders deficit and of cash flows present fairly, in all material respects, the financial position of XTENT, Inc. (a development stage company) at December 31, 2005 and 2006, and the results of its operations and its cash flows, for each of the three years in the period ended December 31, 2006 and, cumulatively for the period from June 13, 2002 (Inception) to December 31, 2006, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s managcment. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 2 to the financial statements, the Company changed the manner in which it accounts for stock-based compensation in 2006.

/s/ PRICEWATERHOUSECOOPERS LLP

San Jose, California
March 29, 2007

64

XTENT, INC.
(a development stage company)
BALANCE SHEETS
(in thousands, except per share amounts)

	December 31, 2005	2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,564	$ 23,105
Prepaid expenses and other current assets	171	269
Total current assets	6,735	23,374
Property and equipment, net	1,775	2,634
Restricted cash	150	
Deferred initial public offering related costs		990
Other non-current assets	15	123
Total assets	$ 8,675	$ 27,121
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 413	$ 860
Accrued liabilities	734	1,448
Total current liabilities	1,147	2,308
Commitments and contingencies (note 5)		
Redeemable convertible preferred stock:		
$0.001 par value; 11,538 and 14,874 shares authorized at December 31, 2005, December 31, 2006 and 9,565 and 14,744 shares issued and outstanding at December 31, 2005 and December 31, 2006, respectively (Liquidation preference: $75,899 at December 31, 2006)	35,900	75,593
Stockholders deficit:		
Common stock: $0.001 par value		
26,000 and 24,700,authorized at December 31, 2005 and December 31, 2006, respectively; 2,983 and 3,352 shares issued and outstanding at December 31, 2005 and 2006, respectively	3	3
Additional paid-in capital	1,693	3,956
Deferred stock-based compensation	(1,046)	(673)
Deficit accumulated during development stage	(29,022)	(54,066)
Total stockholders deficit	(28,372)	(50,780)
Total liabilities, redeemable convertible preferred stock and stockholders deficit	$ 8,675	$ 27,121

The accompanying notes are an integral part of these financial statements

XTENT, INC.
(a development stage company)
STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Year Ended December 31,			Cummulative Period from June 13, 2002 (Inception) to December 31,
	2004	2005	2006	2006
Operating expenses:				
Research and development	$ 7,118	$ 12,139	$ 18,923	$ 43,526
General and administrative	1,883	2,214	7,258	12,274
Total operating expenses	9,001	14,353	26,181	55,800
Loss from operations	(9,001)	(14,353)	(26,181)	(55,800)
Interest income (expense), net	110	323	1,137	1,734
Net loss	(8,891)	(14,030)	(25,044)	(54,066)
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock			(13,095)	(13,095)
Net loss attributable to common stockholders	$ (8,891)	$ (14,030)	$ (38,139)	$ (67,161)
Net loss per share attributable to common stockholders basic and diluted	$ (5.00)	$ (6.84)	$ (13.96)	
Weighted-average common shares outstanding	1,779	2,052	2,732	

The accompanying notes are an integral part of these financial statements

XTENT, INC.
(a development stage company)
STATEMENTS OF STOCKHOLDERS DEFICIT
(in thousands, except per share amounts)

	Common Stock Shares	Amount	Additional Paid-in Capital	Deferred Stock-Based Compensation	Deficit Accumulated During the Development Stage	Total Stockholders Deficit
Inception:						
Issuance of common stock to founders at $0.001 per share in exchange for cash	1,625	$ 2	$ 2	$	$	$ 4
Exercise of stock options for cash at $0.001 per share	62					
Stock-based compensation for non employees			2			2
Net loss					(2,124)	(2,124)
Balance at December 31, 2002	1,687	2	4		(2,124)	(2,118)
Issuance of common stock for services received in July 2003	15		6			6
Stock-based compensation for non-employees			6			6
Exercise of stock options for cash at $0.20 per share	10		2			2
Net loss					(3,977)	(3,977)
Balance at December 31, 2003	1,712	2	18		(6,101)	(6,081)
Issuance of common stock for services received in May 2004	100		40			40
Exercise of stock options for cash at $0.20 and $0.40 per share	10		2			2
Stock-based compensation for non-employees			5			5
Net loss					(8,891)	(8,891)
Balance at December 31, 2004	1,822	2	65		(14,992)	(14,925)
Exercise of stock options for cash at $0.20 and $0.40 per share	1,161	1	43			44
Vesting of restricted common stock from early exercises			159			159
Deferred stock based compensation			1,272	(1,272)		
Amortization of deferred stock-based compensation				226		226
Stock-based compensation for non-employees			154			154
Net loss					(14,030)	(14,030)
Balance at December 31, 2005	2,983	3	1,693	(1,046)	(29,022)	(28,372)
Issuance of common stock for license received in July 2006	15		185			185
Exercise of stock options for cash at $0.20 to $3.50 per share	354		92			92
Vesting of restricted common stock from early exercises			115			115
Amortization of deferred stock-based compensation				302		302
Reversal of deferred stock-based compensation			(71)	71		
Stock based compensation for non-employees			539			539
Employee stock-based compensation under SFAS No. 123R			1,403			1,403
Beneficial conversion feature on issuance of Series C & D redeemable convertible preferred stock			13,095			13,095
Deemed dividend related to Beneficial conversion feature on the issuance of Series C & D redeemable convertible preferred stock			(13,095)			(13,095)
Net loss					(25,044)	(25,044)
Balance at December 31, 2006	3,352	$ 3	$ 3,956	$ (673)	$ (54,066)	$ (50,780)

The accompanying notes are an integral part of these financial statements

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

	Year Ended December 31, 2004	2005	2006	Cummulative Period from June 13, 2002 (Date of Inception) to December 31, 2006
Cash flows from operating activities:				
Net loss	$ (8,891)	$ (14,030)	$ (25,044)	$ (54,066)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	262	465	789	1,580
Stock based compensation expense	5	380	2,244	2,637
Stock issued in exchange for services and license	40		185	231
Loss on disposal of property and equipment	27	45	10	82
Prepaid expenses and other current assets	42	(148)	(206)	(392)
Accounts payable	108	163	332	745
Accrued liabilities	218	93	783	1,281
Net cash used in operating activities	(8,189)	(13,032)	(20,907)	(47,902)
Cash flows from investing activities:				
Purchase of property and equipment	(1,048)	(963)	(1,661)	(4,291)
Restricted cash		(150)	150	
Proceeds from sale of property and equipment		15	3	18
Net cash used in investing activities	(1,048)	(1,098)	(1,508)	(4,273)
Cash flows from financing activities:				
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs		15,495	39,692	75,592
Payment of initial public offering costs, deferred			(875)	(875)
Principal payments on capital lease obligations	(7)			(23)
Proceeds from issuance of common stock	2	438	139	586
Net cash provided by (used in) financing activities	(5)	15,933	38,956	75,280
Net increase (decrease) in cash and cash equivalents	(9,242)	1,803	16,541	23,105
Cash and cash equivalents at beginning of period	14,003	4,761	6,564	
Cash and cash equivalents at end of period	$ 4,761	$ 6,564	$ 23,105	$ 23,105
Supplemental disclosure of noncash investing and financing activities:				
Deferred stock-based compensation	$	$ 1,272	$	$ 1,272
Reversal of deferred stock-based compensation	$	$	$ (71)	$ (71)
Dividend related to beneficial conversion feature of redeemable convertible preferred stock	$	$	$ (13,095)	$ (13,095)
Equipment acquired under capital leases	$	$	$	$ (23)
Vesting of restricted common stock from early exercises	$	$ 159	$ 115	$ 274

The accompanying notes are an integral part of these financial statements

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS

1. Description of Business

The Company

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 December 31, 2006, the Company had an accumulated deficit of $54.1 million. The Company has not achieved positive cash flows from operations for each of the last three fiscal years. 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 $68.2 million (note 12). In order to continue its operations, the Company must achieve profitable operations, obtain additional debt financing or sell additional shares of its equity accounts. 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.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements or the original issuance date, if later, and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The Company deposits cash and cash equivalents with high credit quality financial institutions.

Restricted Cash

In May 2005, the Company was assigned rights to a patent application submitted by Cardiosafe, Ltd. (Cardiosafe). Pursuant to the assignment agreement, the Company established an escrow account in the amount of $150,000. Cardiosafe was to be paid $100,000 upon issuance of the patent by the U.S. or European patent office while the remaining $50,000 was to be paid to Cardiosafe upon the issuance of a

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

patent in the United States or the European Union, upon the earlier of the Company s grant of a CE Mark in the European Union. As of December 31, 2005, the Company had paid neither amount to Cardiosafe and the amount remaining in escrow was included in restricted cash on the accompanying balance sheet. As of December 31, 2006, the $150,000 has been paid to Cardiosafe.

Concentration of Credit Risk

The Company s financial instruments that are exposed to concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains its cash and cash equivalents in bank accounts which at times exceed federally insured limits. The Company has not recognized any losses from credit risks on such accounts during any of the periods presented. The Company believes it is not exposed to significant credit risk from its cash and cash equivalents.

Risks and Uncertainties

The Company is subject to risks common to companies in the development stage including, but not limited to, development of new products, development of markets and distribution channels, dependence on key personnel and the ability to obtain additional capital as needed to fund its product plans and operations. The Company expects to continue to incur losses and have negative cash flows from operations in the foreseeable future as it engages in the development and clinical trial activities for its products.

The Company has a limited operating history and has yet to generate any revenues from customers. To date, the Company has been funded by private equity financings. The Company may be required to raise additional funds through public or private financings, strategic relationships, or other arrangements and cannot assure that the funding will be available on attractive terms. Additional equity funding may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants. Failure to raise capital as and when needed could have a negative impact on the Company s financial condition and business strategy.

The Company is aware of U.S. and foreign issued patents and pending patent applications owned by third parties with patent claims in areas that are the focus of the Company s product development efforts. The Company is aware of patents owned by third parties, to which the Company does not have licenses, that relate to, among other things, stent structure, catheters used to deliver stents and the stent manufacturing process.

The Company is wholly dependent on a sole vendor for the development, manufacture and supply of the drug coating placed on the Company s stents and any delay or failure to adequately develop or supply the drug coating by this vendor or the submission of a drug master file, or DMF, to regulatory authorities could delay the Company s clinical trials or prevent or delay commercialization of the Company s product.

Based on the prolific litigation that has occurred in the stent industry and the fact that the Company may pose a competitive threat to some large and well-capitalized companies who own or control patents relating to stents and their use, manufacture and delivery, one or more third parties may assert a patent infringement claim against the Company based on one or more of these patents. A number of these patents are owned by very large and well-capitalized companies that are active participants in the stent market. Because patent applications can take many years to issue, there may be currently pending

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

applications, unknown to the Company, which may later result in issued patents that pose a material risk to the Company.

Before marketing and selling the Company s products, the Company must successfully complete pre-clinical studies and clinical trials that demonstrate that its products are safe and effective. Product development, including pre-clinical studies and clinical testing, is a long, expensive and uncertain process and is subject to delays. It may take the Company several years to complete its testing, if the Company completes it at all, and the Company s clinical trials may fail at any stage. Furthermore, data obtained from any clinical trial may be inadequate to support a PMA application.

Segment Information

The Company currently operates as one business segment focusing on the development and commercialization of innovative drug eluting stent systems for the treatment of coronary artery disease. The Company is not organized by market and is managed and operated as one business. A single management team reports to the chief operating decision maker who comprehensively manages the entire business. The Company does not operate any separate lines of business or separate business entities with respect to its products. Accordingly, the Company does not accumulate discrete financial information with respect to separate product lines and does not have separately reportable segments.

Fair Value of Financial Instruments

The carrying amounts of the Company s financial instruments including cash and cash equivalents, accounts payable, and accrued liabilities approximate fair value due to their short maturities.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation, subject to review of impairment. Depreciation and amortization is generally calculated using the straight-line method over the estimated useful lives of the related assets ranging from two to five years. Leasehold improvements and assets acquired under capital leases are amortized on a straight-line basis over the term of the lease, or the useful life of the assets, whichever is shorter. Costs associated with maintenance and repairs are charged to expense as incurred, and improvements are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is reflected in the statement of operations in the period realized.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets for indicators of possible impairment by comparison of the carrying amounts to future net undiscounted cash flows expected to be generated by such assets when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the asset over the asset s fair value or discounted estimates of future cash flows.

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

Research and Development

Research and development expenses consist of costs incurred to further the Company s research and development activities and include salaries and related employee benefits, costs associated with clinical trials, non-clinical activities, regulatory activities, research-related overhead expenses and fees paid to external service providers and contract research organizations which conduct certain research and development activities on behalf of the Company. Costs incurred in the research and development of products are charged to research and development expense as incurred.

Income Taxes

Income taxes are accounted for using the liability approach. Deferred tax assets and liabilities are determined based on the difference between financial statement and tax bases of assets and liabilities using current tax laws and rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

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. For the years ended December 31, 2004, 2005 and 2006, the Company did not have any significant components of comprehensive income (loss) other than its net loss. Therefore, no separate statement of comprehensive income (loss) has been presented.

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

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:

	Years Ended December 31,		
	2004	2005	2006
	(in thousands)		
Numerator:			
Net loss	$(8,891)	$(14,030)	$(25,044)
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock			(13,095)
Net loss attributable to common stockholders	$ (8,891)	$ (14,030)	$ (38,139)
Denominator:			
Weighted-average common shares outstanding	1,779	2,864	3,264
Less: Weighted-average unvested common shares subject to repurchase		(812)	(532)
Weighted-average number of common shares outstanding used in computing basic and diluted net loss per common share	1,779	2,052	2,732

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:

	Years Ended December 31,		
	2004	2005	2006
	(in thousands)		
Redeemable convertible preferred stock	6,689	9,565	14,744
Options to purchase common stock	1,731	1,125	1,894
Common stock subject to repurchase		601	417

Stock-Based Compensation

The Company maintains performance incentive plans under which incentive and non-qualified stock options are granted primarily to employees and non-employee consultants. Prior to January 1, 2006, the Company accounted for stock-based compensation in accordance with Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations, to account for stock options granted to employees. Under APB 25, stock-based compensation expense is recognized over the vesting period of the option to the extent that the fair value of the stock exceeds the exercise price of the stock option at the date of the grant.

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

Effective January 1, 2006, the Company adopted SFAS 123(R), requiring measurement of the cost of employee services received in exchange for all equity awards granted based on the fair market value of the award on the grant date. Under this standard, the fair value of each employee stock option is estimated on the date of grant using an options pricing model. The Company currently uses the Black Scholes valuation model to estimate the fair value of their share-based payments. The model requires management to make a number of assumptions including expected volatility, expected life, risk-free interest rate and expected dividends. Given the Company s limited history, the Company used comparable companies to determine volatility. The expected life of the options is based on the average period the stock options are expected to remain outstanding based on the options vesting term, contractual terms, and industry peers as the Company did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. The risk-free interest rate assumption is based on published interest rates for U.S. Treasury zero-coupon issues with a remaining term equal to the expected life assumed at the date of grant appropriate for the terms of the Company s stock options. The dividend yield assumption is based on the Company s history and expectation of dividend payouts.

Stock-based compensation expense recognized in the Company s financial statements starting on January 1, 2006 and thereafter is based on awards that are expected to vest. These amounts have been reduced by using an estimated forfeiture rate. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company will evaluate the assumptions used to value stock awards on a quarterly basis.

To the extent that the Company grants additional equity securities to employees, the stock-based compensation expense will be increased by the additional compensation resulting from those additional grants and assumptions.

The Company accounts for stock-based compensation arrangements with the non-employees in accordance with the Emerging Issues Task Force Abstract No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. The Company records the expense of such services based on the estimated fair value of the equity instrument using the Black-Scholes pricing model. The value of the equity instrument is charged to earnings over the term of the service agreement.

Beneficial Conversion Feature

When the Company issues equity securities which 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, the Company recorded and immediately amortized a beneficial conversion charge (deemed dividend) of approximately $13.1 million in connection with its Series C and D redeemable convertible preferred stock financings in January, May and June 2006.

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

Recent Accounting Pronouncements

In February 2007, the FASB issued SFAS No. 159, *The fair Value Option for Financial Assets and Financial Liabilities including an amendment of FAS115* (SFAS No. 159). SFAS No. 159 allows companies to chose, 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 fiscal years beginning after November 15, 2007 and will be applied prospectively. The Company is currently evaluating the impact of adopting SFAS No. 159 on its financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS No. 157), which defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. SFAS No. 157 is effective commencing with the Company s fiscal year 2009 annual financial statements. The Company is currently assessing the potential impact that the adoption of SFAS No. 157 will have on its financial statements.

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes: An Interpretation of FASB Statement No. 109* (FIN No. 48). FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*, by defining the minimum recognition threshold a tax position is required to meet before being recognized in our financial statements. FIN No. 48 is effective commencing with the Company s fiscal year 2007 annual financial statements. The Company is currently evaluating the effect that the adoption of FIN No. 48 will have on its financial position and results of operations.

3. Property and Equipment

Property and equipment consists of the following:

	December 31, 2005	2006
	(in thousands)	
Property and equipment, net:		
Computer equipment	$ 340	$ 538
Machinery and equipment	1,824	3,113
Furniture and fixtures	81	149
Leasehold improvements	257	343
	2,502	4,143
Less: Accumulated depreciation and amortization	(727)	(1,509)
	$ 1,775	$ 2,634

Depreciation and amortization expense for the years ended December 31, 2004, 2005 and 2006 and cumulatively, for the period from June 13, 2002 (Inception) to December 31, 2006 was approximately $262,000, $465,000, $789,000 and $1,580,000, respectively.

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

4. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2005	2006
	(in thousands)	
Compensation and benefits	$ 340	$ 581
Stock exercises subject to repurchase	236	167
Clinical trials	26	348
Professional Fees	10	197
Accrued accounts payable	42	
Sales taxes payable	42	99
Other accrued liabilites	38	56
	$ 734	$ 1,448

5. Commitments and Contingencies

Leases

The Company leases office space with an expiration date of May 2007. Rent expense for the years ended December 31, 2004, 2005 and 2006, and cumulatively for the period from June 13, 2002 (Inception) to December 31, 2006 was approximately $166,000, $173,000, $224,000 and $584,000, respectively. The terms of the facility lease provide for rental payments on a monthly basis and on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid. Future minimum lease payments under noncancelable operating leases for the year ended December 31, 2007 are approximately $96,000.

Royalty and Milestone Obligations

The Company has entered into royalty agreements with two key suppliers for proprietary materials that are critical to the success of the Company s products. The terms of the agreements call for milestone payments prior to achieving sales, and quarterly royalty payments based on the greater of specified minimums or a percentage of net sales. As of December 31, 2006, future minimum royalty payments for these suppliers approximate $2.1 million, and minimum royalty payments of $20,000 were made in the year ended December 31, 2006.

The Company also has contingent milestone payments that are payable to licensors upon the achievement of certain milestones. As of December 31, 2005 and 2006, milestone payments of $55,000 and $500,000, respectively, have been made. There could be an additional $220,000 in milestone payments if all milestones are achieved.

License Agreement

In July 2006, the Company entered into a license agreement with Millimed, Inc. for certain intellectual property related to the Company s business. In consideration for this license, the Company made an initial payment of $350,000 in cash, and has issued 15,000 shares of common stock and is obligated to make a future cash payment of $200,000 contingent upon the issuance of certain patents.

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

Contingencies

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

Indemnification

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

In accordance with the Company s amended and restated certificate of incorporation (the Restated Certificate) and bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company s request in such capacity. There have been no claims to date and the Company has a Director and Officer Insurance Policy that may enable it to recover a portion of any amounts paid for future claims.

6. Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock at December 31, 2005 and December 31, 2006, consists of the following:

	December 31, 2005 (in thousands, except original issue price)					
Series	**Original Issue Price**	**Shares Authorized**	**Outstanding**	**Carrying Amount**	**Liquidation Amount**	**Proceeds Net of Issuance Costs**
A	$ 2.00	2,638	2,637	$ 5,242	$ 5,275	$ 5,242
B	$ 3.76	4,100	4,051	15,164	15,232	15,164
C	$ 5.42	4,800	2,877	15,494	15,592	15,494
		11,538	9,565	$ 35,900	$ 36,099	$ 35,900

	December 31, 2006 (in thousands, except original issue price)					
Series	**Original Issue Price**	**Shares Authorized**	**Outstanding**	**Carrying Amount**	**Liquidation Amount**	**Proceeds Net of Issuance Costs**
A	$ 2.00	2,638	2,637	$ 5,242	$ 5,275	$ 5,242
B	$ 3.76	4,051	4,051	15,164	15,232	15,164
C	$ 5.42	4,685	4,685	25,295	25,392	25,295
D	$ 8.90	3,500	3,371	29,892	30,000	29,892
		14,874	14,744	$ 75,593	$ 75,899	$ 75,593

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

The holders of redeemable convertible preferred stock have various rights and preferences as follows:

Voting

Each share of Series A, B, C and D redeemable convertible preferred stock has voting rights equal to an equivalent number of shares of common stock into which it is convertible. The redeemable convertible preferred stock generally votes together as one class with the common stock, as long as 20% of the redeemable convertible preferred stock issued remains outstanding. The Company must obtain approval from more than 60% of the holders of redeemable convertible preferred stock in order to alter the Restated Certificate or bylaws, change the authorized number of shares of redeemable convertible preferred stock or common stock, repurchase any shares of common stock or other shares subject to the right of repurchase by the Company, change the authorized number of Board of Directors, authorize a dividend for any class or series, create a new class of stock or effect a merger, consolidation or sale of assets where the existing stockholders retain less than 50% of the voting stock of the surviving entity or liquidate or dissolve.

Dividends

The holders of Series A, B, C and D redeemable convertible preferred stock are entitled to receive non-cumulative dividends on a pro rata basis in proportion to the dividend rates of $0.16 for Series A, $0.30 for Series B, $0.44 for Series C and $0.72 for Series D (as adjusted for stock dividends, stock splits, recapitalizations and the like), when and if declared by the Board of Directors. The holders of Series A, B, C and D redeemable convertible preferred stock will also be entitled to participate in dividends on common stock, when and if declared by the Board of Directors, based on the number of shares of common stock held on an as-if converted basis. No dividends have been paid or declared since inception through December 31, 2006.

Liquidation

In the event of any liquidation, dissolution or winding up of the Company, including a merger, acquisition or sale of assets where the beneficial owners of the Company s common stock and redeemable convertible preferred stock own less than 50% of the resulting voting power of the surviving entity, the holders of Series A, B, C and D redeemable convertible preferred stock are entitled to receive an amount of $2.00, $3.76, $5.42 and $8.90 per share, respectively, plus any declared but unpaid dividends prior to and in preference to any distribution to the holders of common stock. Thereafter, if assets remain in the Company, the holders of the Company s common stock and redeemable convertible preferred stock will receive all the remaining assets of the Company pro rata based on the number of shares of common stock (on an as-convertible to common stock basis) held by each. If, upon the occurrence of such event, the assets and funds thus distributed among the holders of the redeemable convertible preferred stock shall be insufficient to permit the payment to such holders of the full preferential amounts, then the entire assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of Series A, B, C and D redeemable convertible preferred stock in proportion to the preferential amount each such holder is otherwise entitled to receive.

Conversion

Each share of Series A, B, C and D redeemable convertible preferred stock is convertible, on a one-to-one basis, at the option of the holder thereof, at any time, into such numbers of fully paid and non-

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

assessable shares of common stock as is determined by dividing the conversion price applicable at the time of conversion into the original issue price. The initial conversion price per share of the Series A redeemable convertible preferred stock is $2.00, the initial conversion price per share of the Series B redeemable convertible preferred stock is $3.76, the initial conversion price per share of the Series C redeemable convertible preferred stock is $5.47 and the initial conversion price per share of the Series D redeemable convertible preferred stock is $8.90. Each share of Series A, B, C and D redeemable convertible preferred stock is convertible into common stock on a one-to-one basis. Each share of Series A, B, C and D redeemable convertible preferred stock automatically converts into the number of shares of common stock into which such shares are convertible at the then effective conversion ratio upon the earlier of: (1) the closing of a firm commitment underwritten initial public offering of common stock at a per share price of at least $18.00 per share (as adjusted for stock dividends, stock splits, recapitalizations and the like) with aggregate proceeds of at least $60.0 million or (2) the consent of the holders of 60% of redeemable convertible preferred stock.

Upon completion of the Company s initial public offering on February 1, 2007, all of the Company s outstanding shares of redeemable convertible preferred stock converted on a one-to-one basis into 14,744,196 shares of common stock (see note 12).

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

7. Common Stock

The Restated Certificate authorizes the Company to issue 24,700,000 shares of $0.001 par value common stock. The majority of the outstanding common stock has been issued to the founders, employees and consultants of the Company. Each share of common stock is entitled to one vote. Subject to the prior rights of all holders of redeemable convertible preferred stock, the holders of the common stock are entitled to receive dividends with the holders of redeemable convertible preferred stock, when and as declared by the Board of Directors, out of any assets of the Company legally available.

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 EITF 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 December 31, 2005 and 2006, there were approximately 601,000 and 417,000 shares of common stock, respectively, subject to repurchase.

8. Stock Option Plans

In July 2002, the Company adopted the 2002 Stock Option Plan (the Plan). The Plan provides for the granting of stock options to employees and consultants of the Company. Options granted under the Plan may be either incentive stock options or nonqualified stock options. Incentive stock options (ISO) may be granted to Company employees. Nonqualified stock options (NSO) may be granted to Company employees and consultants. The Company has reserved 3,595,500 shares of common stock for issuance under the Plan.

Options under the Plan may be granted for periods of up to ten years and at prices not less than 85% of the fair value of the shares on the date of grant as determined by the Board of Directors, provided, however, that (i) the exercise price of an ISO and NSO shall not be less than 100% and 85% of the fair value of the shares on the date of grant, respectively, and (ii) the exercise price of an ISO and NSO granted to a 10% stockholder shall not be less than 110% of the fair value of the shares on the date of grant, respectively. Certain options to key employees are exercisable immediately, but subject to repurchase by the Company. To date, options granted generally vest ratably over four years.

In August 2006, the Company adopted the 2006 Equity Incentive Plan. A total of 125,000 shares of common stock were reserved for issuance, and no options have been granted pursuant to this plan.

In August 2006, the Company adopted the 2006 Employee Stock Purchase Plan. A total of 500,000 shares of common stock have been reserved for issuance, and no shares have been issued, pursuant to this plan.

The Company also reserved 27,500 shares of common stock for the exercise of stand-alone options existing outside of the Plan. These shares were granted to a non-employee during 2002, and the terms are similar to the terms listed above under the Plan.

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

Stock option activity is as follows:

		Options Outstanding			
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (years)	Aggregate Intrinsic Value
	(in thousands, except weighted average exercise price)				
Shares reserved at plan inception	625				
Options granted	(178)	178	$ 0.20		
Options exercised		(62)	0.20		
Balances, December 31, 2002	447	116	0.20		
Additional shares reserved	435				
Options granted	(493)	493	0.34		
Options exercised		(10)	0.20		
Balances, December 31, 2003	389	599	0.32		
Additional shares reserved	1,050				
Options granted	(1,162)	1,162	0.40		
Options exercised		(10)	0.20		
Options forfeited/expired	20	(20)	0.24		
Balances, December 31, 2004	297	1,731	0.38		
Additional shares reserved	1,013				
Options granted	(686)	686	0.42		
Options exercised		(1,161)	0.38		
Options forfeited/expired	131	(131)	0.40		
Balances, December 31, 2005	755	1,125	0.40		
Additional shares reserved	500				
Options granted	(1,166)	1,166	4.80		
Options exercised		(354)	0.39		
Options forfeited/expired	43	(43)	1.50		
Balances, December 31, 2006	132	1,894	$ 3.09	8.51	$ 21,421
Options vested and expected to vest at December 31, 2006		1,202	$ 2.20	8.22	$ 14,660
Option vested at December 31, 2006		463	$ 1.31	8.21	$ 6,058

The total intrinsic value of options exercised during the year ended December 31, 2006 was $758,000. The total fair value of options granted to employees that vested during the year ended December 31, 2006 was $1,591,000.

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

The following is a summary of the status of stock options outstanding and exercisable by exercise price:

Options Outstanding at December 31, 2005 (in thousands, except weighted average remaining contractual life and weighted average exercise price)			Options Exercisable and Vested at December 31, 2005	
Exercise Price	Number	Weighted-Average Remaining Contractual Life (Years)	Number	Weighted-Average Exercise Price
$0.20	105	6.95	69	$0.20
$0.40	883	8.71	279	0.40
$0.54	137	9.66	4	0.54
	1,125	8.66	352	$0.36

Options Outstanding at December 31, 2006 (in thousands, except weighted average remaining contractual life and weighted average exercise price)			Options Exercisable and Vested at December 31, 2006	
Exercise Price	Number	Weighted-Average Remaining Contractual Life (Years)	Number	Weighted-Average Exercise Price
$ 0.20	65	5.83	63	$ 0.20
0.40	576	7.67	261	0.40
0.54	96	8.63	27	0.54
1.50	174	9.09	26	1.50
3.50	549	9.32	43	3.50
5.20	180	9.43	21	5.20
7.20	32	9.53		7.20
7.82	36	9.66	21	7.82
9.20	105	9.66	1	9.20
11.20	36	9.77		11.20
12.32	45	9.96		12.32
	1,894	8.51	463	$ 1.31

The weighted-average per share fair value of options granted to employees during the years ending December 31, 2004, 2005 and 2006 was $0.40, $2.50, and $9.07 per share, respectively.

Deferred Stock-Based Compensation

In May 2003, the Company determined the fair value of common stock to be $0.40 per share, upon issuance of its Series B redeemable convertible preferred stock. At December 31, 2005, the fair value of the common stock was determined to be $7.94 per share. All options granted were intended to be exercisable at a price per share not less than fair market value of the shares of the Company s stock

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

underlying those options on their respective dates of grant. The Board of Directors determined these fair market values in good faith based on the best information available to the Board of Directors and Company s management at the time of the grant. Although the Company believes these determinations accurately reflect the historical value of the Company s common stock, management has retroactively revised the valuation of its common stock for the purpose of calculating stock-based compensation expense for all grants after December 31, 2004. The Company s progress against milestones in these areas was used to estimate the fair value of its common stock. In accordance with the requirements of APB 25, the Company has recorded deferred stock-based compensation for the difference between the exercise price of the stock options and the fair value of the Company s common stock at the date of grant for options granted during 2004 and 2005. This deferred stock-based compensation is amortized to expense on a straight-line basis over the period during which the options vest, generally over four years. During the year ended December 31, 2005, the Company has recorded deferred stock-based compensation related to these stock options of approximately $1,272,000, net of cancellations. During the year ended December 31, 2006, the Company recorded cancellations of deferred stock-based compensation of approximately $71,000. Amortization of deferred stock-based compensation was approximately $226,000 and $302,000 for the years ended December 31, 2005 and 2006, respectively. For options granted during 2006, the fair value of the stock on the date of grant is considered when determining the fair value of the stock option under the provisions of SFAS 123(R).

The Company granted stock options to employees with exercise prices below the fair value on the date of grant as follows:

Grants Made during the Quarter Ended	Number of Options Granted	Weighted-Average Exercise Price Per Share	Weighted-Average Fair Value Per Share	Weighted-Average Intrinsic Value Per Share
	(in thousands, except weighted average prices)			
March 31, 2005	515	$ 0.40	$ 1.66	$ 1.26
June 30, 2005	23	0.54	4.16	3.62
September 30, 2005	79	0.54	5.42	4.88
December 31, 2005	30	0.54	7.48	6.94
March 31, 2006	174	1.50	9.20	7.70
June 30, 2006	735	3.92	11.19	7.27
September 30, 2006	190	8.74	12.32	3.58
December 31, 2006	67	11.94	13.85	1.91

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

Stock-Based Compensation After Adoption of SFAS 123(R)

Effective January 1, 2006, the Company adopted SFAS 123(R), *Share-Based Payment*, using the prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards granted, modified and settled to the Company s employees and directors after January 1, 2006. The Company s financial statements as of the year ended December 31, 2006, reflect the impact of SFAS 123(R). In accordance with the prospective transition method, the Company s financial statements for prior periods have not been restated to reflect and do not include, the impact of SFAS 123(R). Stock-based compensation expense recognized during the year ended December 31, 2006 includes:

- Compensation expense for stock-based awards granted to employees subsequent to January 1, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R) of approximately $1,403,000;

- Amortization of deferred stock-based compensation based on the intrinsic value method for stock options granted to employees prior to January 1, 2006 of approximately $302,000; and

- Compensation expense for stock-based awards granted to non-employees prior and subsequent to January 1, 2006 that were earned during the year ended December 31, 2006 of approximately $539,000.

Total stock-based compensation expense recorded under APB 25, SFAS 123(R) and EITF 96-18 related to options granted to employees and non-employees was allocated to research and development and general and administrative expense as follows:

	Year Ended December 31,		
	2004	2005	2006
	(in thousands)		
Research and development	$	$ 300	$ 1,258
General and administrative	5	80	986
Total stock-based compensation expense	$ 5	$ 380	$ 2,244

No income tax benefit has been recognized relating to stock-based compensation expense and no tax benefits have been realized from exercised stock options. The implementation of SFAS 123(R) did not have an impact on cash flows from financing activities during the year ended December 31, 2006.

During the year ended December 31, 2006, the Company granted stock options to employees to purchase 1,115,000 shares of common stock with a weighted-average grant date fair value of $9.07 per share. As of December 31, 2006, there were total unrecognized compensation costs of approximately $9,205,000 related to these stock options. These costs are expected to be recognized over a period of four years.

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

The Company estimated the fair value of stock options using the Black-Scholes option valuation model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee stock options was estimated using the following weighted-average assumptions for the year ended December 31, 2006:

	Year Ended December 31, 2006
Expected volatility	58.4% to 70%
Risk free rate	4.38% 4.95%
Dividend yield	0%
Expected term (in years)	5.75 to 6.25

The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding and is based on the options vesting term, contractual terms and industry peers as the Company did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. The expected stock price volatility assumptions for the Company s stock options for the year ended December 31, 2006 were determined by examining the historical volatilities for industry peers, as the Company did not have any trading history for the Company s common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company s common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company s stock options. The expected dividend assumption is based on the Company s history and expectation of dividend payouts.

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

Non-Employee Stock-based Compensation

During the periods ended December 31, 2004, 2005 and 2006, the Company granted 20,000, 39,750 and 51,000 shares, respectively, of common stock at exercise prices ranging from $0.40 to $11.20 per share in exchange for services from consultants. Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services rendered.

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

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

	Year Ended December 31,		
	2004	2005	2006
Risk-free interest rate	3.76 to 4.96%	3.84 to 4.67%	4.53 to 5.25%
Expected life (in years)	8 to 10	7 to 10	6 to 10
Dividend yield	0%	0%	0%
Expected volatility	70%	70%	57.5% to 70%

The stock-based compensation expense will fluctuate as the estimated fair value of the common stock fluctuates. In connection with the grant of stock and stock options to non-employees, the Company recorded stock-based compensation charges of approximately $5,000, $154,000, $539,000 and $706,000 for the years ended December 31, 2004, 2005, and 2006, and cumulatively, for the period from June 13, 2002 (Inception) to December 31, 2006, respectively.

9. Income Taxes

Due to the Company s operating loss, there was no provision for federal or state income taxes for the years ended December 31, 2004, 2005 and 2006. The tax effects of temporary differences and carry-forwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	December 31,	
	2005	2006
Deferred tax assets:		
Net operating loss carryforwards	$ 8,159	$ 13,183
Research & development credit carryforwards and other	1,638	2,866
Capitalized start-up costs	3,148	7,276
Other	105	749
	13,050	24,074
Valuation allowance	(13,050)	(24,074)
Net deferred tax assets	$	$

The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of such assets. The valuation allowance increased $3,856,000, $6,353,000 and $11,024,000 during the years ended December 31, 2004, 2005 and 2006, respectively.

As of December 31, 2006, the Company had net operating loss carry-forwards of approximately $33.1 million available to reduce future taxable income, if any, for federal and California state income tax purposes. The federal net operating loss carry-forward begins expiring in 2022, and state net operating loss carry-forward begins expiring in 2013.

As of December 31, 2006, the Company had research and development credit carry-forwards of approximately $1.7 million and $1.8 million available to reduce future taxable income, if any, for federal and California state tax purposes, respectively. The federal credit carry-forwards begin expiring in 2022, and the state credits carry-forward indefinitely.

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

The Tax Reform Act of 1986 limits the use of net operating loss carry-forwards in certain situations where changes occur in the stock ownership of a company. In the event the Company has had a change in ownership, utilization of the carry-forwards could be limited.

10. Related Party Transactions

Since its inception through September 2004, the Company s then president and chief executive officer was an employee of The Foundry, Inc., which provided management services and office space to the Company. The Company reimbursed The Foundry for salary and other expenses on a monthly basis. Total expenses incurred for those transactions were approximately $164,000 for the year ended December 31, 2004, zero for all subsequent years and $582,000 for the period from June 13, 2002 (inception) to December 31, 2006.

11. Employee Benefit Plans

The Company adopted a 401(k) Profit Sharing Plan and Trust covering substantially all of its employees. Company contributions to the plan are discretionary and as of December 31, 2006, no contributions have been made.

12. Subsequent Events

Amendment to Equity Incentive Plan

On January 10, 2007, the Board of Directors approved an increase of 275,000 shares to the authorized number of shares under our 2006 Equity Incentive Plan, increasing the total authorized number of shares from 125,000 shares to 400,000 shares.

One for Two Reverse Stock Split

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 financial statements have been adjusted to reflect this reverse stock split for all periods presented.

Initial Public Offering

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.

XTENT, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS (Continued)

13. Restatement of Q1 2006 Quarterly Financial Statements and Selected Quarterly Financial Data (Unaudited)

The 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 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 related to 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 a 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 2005 Quarters Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share amounts)			
Net loss	$ (3,101)	$ (3,744)	$ (3,420)	$ (3,765)
Net loss attributable to common stockholders	$ (3,101)	$ (3,744)	$ (3,420)	$ (3,765)
Basic and diluted net loss per share attributable to common stockholders	$ (1.65)	$ (1.81)	$ (1.57)	$ (1.60)
Weighted average common shares outstanding	1,885	2,069	2,184	2,351

	Fiscal 2006 Quarters Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share amounts) As restated			
Net loss	$ (4,107)	$ (5,730)	$ (8,042)	$ (7,165)
Net loss attributable to common stockholders	$ (9,785)	$ (13,147)	$ (8,042)	$ (7,165)
Basic and diluted net loss per share attributable to common stockholders	$ (3.92)	$ (4.89)	$ (2.84)	$ (2.46)
Weighted average common shares outstanding	2,493	2,686	2,830	2,909

The effect of the restatement adjustment on the previously reported amounts for the quarter ended March 31, 2006 is set forth on the following table:

	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 attributable to common stockholders	$ (9,785)	$ (9,785)
Basic and diluted net loss per share attributable to common stockholders	$ (3.92)	$ (4.83)
Weighted average common shares outstanding	2,493	2,024

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. 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) as of the end of our most recent fiscal year. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2006.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fourth quarter of 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

This annual report on Form 10-K does not include a report of management s assessment regarding internal control over financial reporting or an attestation report by the Company s registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2007 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our 2006 fiscal year (the 2007 Proxy Statement).

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the 2007 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is incorporated by reference to the 2007 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated by reference to the 2007 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to the 2007 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(1) The financial statements required by Item 15(a) are filed in Item 8 of this Annual Report on Form 10-K.

(2) All schedules are omitted because they are not applicable. All the required information is shown in the financial statements or notes thereto.

(3) 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.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
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 Section 13(a) or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on our behalf by the undersigned, thereunto duly authorized.

Date: April 2, 2007

XTENT, Inc.

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

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Gregory D. Casciaro and Timothy D. Kahlenberg, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this annual report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated:

Signature		**Title**		**Date**
/s/ GREGORY D. CASCIARO		President, Chief Executive Officer and		April 2, 2007
Gregory D. Casciaro		Director (Principal Executive Officer)		
/s/ TIMOTHY D. KAHLENBERG		Chief Financial Officer		April 2, 2007
Timothy D. Kahlenberg		(Principal Accounting Officer)		
/s/ HENRY A. PLAIN, JR.		Director		April 2, 2007
Henry A. Plain, Jr.				
/s/ ROBERT C. BELLAS, JR.		Director		April 2, 2007
Robert C. Bellas, Jr.				
		Director		April , 2007
Michael A. Carusi				
/s/ ROBERT F. FLAHERTY		Director		April 2, 2007
Robert F. Flaherty				
		Director		April , 2007
Partrick F. Latterell				
/s/ EDWARD W. UNKART		Director		April 2, 2007
Edward W. Unkart				
		Director		April , 2007
Allan R. Will				