XTENT INC
Form 10-K
March 24, 2009
Table of Contents

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, 2008

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 x No o

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. o

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

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

Indicate by check mark whether the Registrant is a shell company (as defined 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 the last day of its second fiscal quarter of 2008 was $12,804,108. 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 5, 2009, the Registrant had 23,324,756 shares of Common Stock outstanding.

Table of Contents

XTENT, INC.

FISCAL YEAR 2008 FORM 10-K ANNUAL REPORT

TABLE OF CONTENTS

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 PART I, ITEM 1A, Risk Factors below in 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, or DES, 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 to treat multiple lesions with the use of a single device. Our stent systems, the Custom NX 36 and the Custom NX 60, include a modular cobalt chromium stent design as well as a proprietary delivery system. In addition, our stents have a drug coating that is made 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 $4 billion worldwide drug eluting stent market.

We are developing our 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 while the device is in the artery. 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 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.

Recent Developments

In January 2009, we notified our employees that we were initiating a headcount reduction that would impact 115 of our 122 employees. The reduction was substantially completed on March 23, 2009, and we expect it to be fully completed by March 31, 2009.

We also engaged Piper Jaffray & Co. in January 2009 to help us explore potential strategic alternatives, which may include, without limitation, a merger, a sale of substantially all our assets, a financing, or a sale of a portion of our assets, such as our peripheral stent technology, our drug eluting balloon technology or our bioabsorbable stent technology. We cannot provide any assurance that we will be able to identify or complete a suitable strategic transaction. If we are unsuccessful in identifying and completing a strategic transaction or securing adequate funding, we may not be able to continue our operations and may need to wind up our business and liquidate our assets.

If we are successful in identifying and completing a suitable strategic transaction, substantial changes may be made to our current operations or they may be completely discontinued. For example, if we are acquired by a third party, that third party may choose not to pursue some or any of our current product development initiatives, such as our Custom NX DES systems, our Custom NXP peripheral stent technology, our customizable drug eluting balloon technology or our bioabsorbable stent technology. In addition, if we sell our Custom NX DES Systems, thereafter, we may focus our efforts on the development of our Custom NXP peripheral stent system. Alternately, if we sell our Custom NXP peripheral product and/or other non-core assets, and we receive sufficient funds from that sale, we may continue to pursue commercialization of our Custom NX DES Systems.

Table of Contents

In connection with the reduction in force and our plans to explore strategic alternatives, we entered into retention and severance agreements with nine of our employees, including our executive officers. Pursuant to these agreements, we have agreed to make retention payments to each of these employees, provided their employment is not terminated for cause prior to the date upon which we complete a strategic transaction, or the employee s expected termination date, whichever is earlier. The expected termination dates for these employees range from March 31, 2009 to July 31, 2009.

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 October 2008, the one year data from our CUSTOM III clinical trial, the two year data from our CUSTOM II clinical trial and the three year data from our CUSTOM I clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. We believe the data from these clinical trials provided preliminary evidence of safety and efficacy and support further development of our in situ customization approach.

In March 2009, we received CE Mark for our Custom NX DES Systems authorizing us to market our products in the European Union and certain other countries that recognize the CE Mark. Even though we have received CE Mark, we will not be able to commercialize our product in the European Union unless we obtain additional financing, or we consummate a strategic transaction that permits us to commercialize in Europe. We can provide no assurance that such a financing or strategic transaction will be available on terms agreeable to us, or at all.

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 a large clinical trial of up to 2,100 patients. We expect to obtain this data through our planned CUSTOM IV clinical trial, but to initiate the CUSTOM IV trial we must first obtain clearance of an investigational device exemption, or IDE, from the FDA. We filed our IDE application in September 2007, and in October 2007, we received questions back from the FDA. In February 2009, we resubmitted our IDE application, and expect to receive a response from the FDA by the end of the first quarter of 2009. Even if we receive IDE approval from the FDA, we will not be able to initiate our IDE trial unless we obtain additional financing, or we consummate a strategic transaction that permits us to initiate our IDE trial. We can provide no assurance that such a financing or strategic transaction will be available on terms agreeable to us, or at all.

We license our drug coating from Biosensors Europe SA, a wholly-owned subsidiary of Biosensors International Group, Ltd. We refer to Biosensors Europe SA and Biosensors International Group, Ltd. together as Biosensors in this report. Because our Custom NX DES Systems are combination devices that include a stent and a drug coating, regulatory approvals of our products are dependent upon Biosensors obtaining a favorable opinion from the FDA on the drug master file, or MAF, it has submitted to the FDA in connection with our regulatory filings in the United States. We believe the FDA considers the MAF that Biosensors submitted in connection with our IDE application to be acceptable for purposes of our IDE, but we expect the FDA to conduct additional assessments of the MAF as part of our PMA review. We cannot guarantee that the MAF Biosensors has submitted to the FDA with respect to our Custom NX DES Systems will be approved for purposes of our PMA.

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.

Table of Contents

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 have demonstrated that restenosis occurs 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 into 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 compared to balloon angioplasty 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, or DES. 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 a significant reduction in restenosis. 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 $4 billion market according to Millennium Research Group. However, in 2006 some clinical data emerged that indicated drug eluting stents were associated with higher rates of late stent thrombosis, which could lead to heart attacks or death, 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. 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. More recent data from 2007 indicate that in spite of a higher incidence of late stent thrombosis, overall rates of death and myocardial infarction for DES are not significantly different than overall rates of death and myocardial infarction for bare metal stents. According to Millennium Research Group, in 2007 drug eluting stents were used exclusively in 65% of all stent procedures in the United States and 53% of stent procedures worldwide (including the US). The total worldwide market for DES in 2007 was $4.56 billion. Drug eluting stents are significantly more expensive than bare metal stents, with average costs in the United States that are approximately 2 to 2.5 times the cost of a bare metal stent.

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.

Table of Contents

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 longitudinal geographic miss, results in portions of a lesion remaining exposed, increasing the likelihood of thrombosis and the need for reintervention. Longitudinal geographic miss occurs when a stent fails to adequately cover a target lesion because the stent is either shorter than the lesion or it is placed in the wrong position, leaving the proximal or distal edge of the lesion untreated. We believe that longitudinal geographic miss occurs due in part 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, longitudinal geographic miss was observed in 47.6% of procedures, resulting in higher rates of thrombosis and reinterventions.

Table of Contents

- ***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 40 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 distribute the 6mm segments across multiple lesions in a customized manner.

- ***Post-Dilatation with a Single Device.*** Our products may eliminate the need to use a separate post-dilatation balloon because the balloon in our catheter can be shortened and reused during the procedure. Post-dilatation can be used to optimize stent expansion and improve stent apposition to the vessel wall. We believe that physicians using our products will be more likely to post-dilatate because our product does not require the use of a second device in order to post-dilatate. Incomplete stent apposition has been associated in recent studies with late and very late stent thrombosis.

- ***Treatment of Long Lesions Without Multiple Overlapping Stents.*** Our Custom NX 60 is designed 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 need to use one or more overlapping stents to treat long lesions. Overlapping stents have been associated with complications such as in-hospital non-Q wave myocardial infarction, subacute thrombosis, non-focal, delayed endothelialization and greater potential for stent fracture.

Table of Contents

- ***Sheath protected stent delivery.*** Our Custom NX delivery system is sheath protected. The sheath that covers the stent segments until deployment protects the drug coating and the arterial wall as the system is delivered to the targeted lesion. Current delivery systems leave stents exposed, which may cause coatings on currently available stents to be scraped off during insertion.

- ***Improved Stent Placement Accuracy.*** Our Custom NX DES Systems are designed to allow the physician to incrementally increase 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 deploy additional stent segments if desired. During deployment, stent diameter can be adjusted by controlling the pressure of the balloon inflation. We believe our products may also eliminate the need to use a separate post-deployment balloon because the balloon in our catheter can be shortened and reused during the procedure. Post-dilatation can be used to optimize stent expansion and improve stent apposition to the vessel wall. Stent under expansion and incomplete stent apposition have been demonstrated to contribute to stent thrombosis. We believe that this post-dilatation capability 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 use a single device to customize the length and diameter 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 this 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. Changes in artery shape following stent procedures have been associated with major adverse cardiac events, or MACE. 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 by a lubriciously coated sheath, which helps the device slide along the vessel walls 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.

- ***Biodegradable Polymer as Our Drug Carrier.*** Late stent thrombosis with DES has multiple causes but may be in part due to physiologic reactions to durable polymers. 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 widely used commercially with any drug eluting stent.

Our Strategy

If we obtain additional funding or complete a strategic transaction that provides adequate resources, our goal would be to become a world leader in the development and commercialization of drug eluting stent systems. We would plan to achieve this goal by pursuing the following business strategies:

- ***Demonstrate the Clinical Safety and Efficacy and Gain Regulatory Approval of Our Custom NX DES Systems.*** We would intend to demonstrate the clinical safety and efficacy of our Custom NX DES Systems through carefully structured clinical studies. Data from these studies would be used to support our IDE application which must be approved before we can initiate the large U.S. pivotal clinical trial to scientifically establish the clinical benefits of our systems. We would expect to use this large study to support U.S. approvals. In March 2009, we obtained CE Mark for our Custom NX DES Systems authorizing us to market our products in the European Union and certain other countries that recognize the CE Mark. Even though we have received

Table of Contents

CE Mark, we will not be able to commercialize our product in the European Union unless we obtain additional financing, or we consummate a strategic transaction that permits us to commercialize in Europe. We can provide no assurance that such a financing or strategic transaction will be available on terms agreeable to us, or at all.

- ***Commercialize and Drive Adoption of Our Custom NX DES Systems.*** Following regulatory approvals, and provided we obtain additional funding or complete a strategic transaction that provides adequate resources, we would plan to commercialize our products worldwide. Our strategy would involve initially commercializing our Custom NX DES Systems in key markets in Europe. We would 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 would plan to build a direct sales organization that would work closely with interventional cardiologists to drive adoption. We would intend to employ professional education specialists who would provide training and education for physicians and technicians. In order to meet commercial demand for our products, we would expect to invest in the expansion of our manufacturing capabilities as necessary. Even though we received CE Mark for our Custom NX DES Systems in March 2009, we will not be able to commercialize our products in the European Union unless we obtain additional financing, or we consummate a strategic transaction that permits us to commercialize in Europe. We can provide no assurance that such a financing or strategic transaction will be available on terms agreeable to us, or at all. Before we can commercialize our products, we will also need to increase our manufacturing capacity and validate our manufacturing processes to demonstrate compliance with applicable quality standards, which may take six to nine months.

- ***Build Awareness and Support Among Leading Physicians.*** Our clinical development strategy would be 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 would 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 would 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 would plan to continue to expand our current intellectual property position. We believe that our current intellectual property position would allow us to effectively market our products for the treatment of CAD. We would 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 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 would intend to build on this foundation by offering only

the highest quality products to patients and physician customers.

Our Technology Platform

We have developed 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 use one device to treat single long lesions or to customize therapy by deploying multiple custom-length stents to more than one lesion without removing or exchanging 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 the radial strength necessary to hold the artery open across multiple segments.

Table of Contents

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 in 2.5mm and 3.0mm diameter versions. We have also developed 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. Before we place the drug coating on our stents, 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 insufficient, the number of segments exposed can be increased 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 initiated several products and projects intended to expand the application of our technology and leverage the advantages of custom stenting in new applications. As a result of our recent reduction in headcount, we have suspended all development work with respect to these projects.

Peripheral Applications. In early 2006, we began developing a product for the peripheral market and looked at new materials such as Nitinol, as well as methods for stent deployment and stent length customization with the use of self-expanding stents. The Custom NX Peripheral, or NXP, stent technology is a modular customizable Nitinol self expanding stent which consists of a series of stent segments. These segments allow the user to customize the length of stent for the lesion treated by controlling the number of discrete segments to be deployed in situ. After the first customizable stent deployment, with the remaining stent segments available inside the catheter, the Custom NXP system can be reset and used

Table of Contents

to treat additional lesions. In addition to allowing for the treatment of single, multiple, or long lesions with one device, the unique modular interdigitated Custom NXP stent segments are designed to prevent fracture and accommodate the significant bending, twisting, and compression forces of the SFA, Custom NXP s initial target opportunity.

Bioabsorbable Stent Technology. 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 that bioabsorbable stents can provide non-inferior safety and efficacy results to current alternatives. Our customizable bioabsorbable stent technology may offer significant potential benefits versus fixed length bioabsorbable stents. It consists of a series of bioabsorbable stent segments. These segments allow the user to customize the length of stent for the lesion treated by controlling the number of discrete segments to be deployed *in situ.* After the first customizable stent deployment, with the remaining stent available inside the catheter, the system can be reset and used to treat additional lesions. To date, we have demonstrated the ability to expand small polymer tube stent proxies infused with gold nanoparticles using low pressure balloons,

Customizable Drug Eluting Balloon Technology. Our customizable drug eluting balloon technology may offer significant potential benefits versus fixed length drug eluting balloons. First, our sheath protected delivery system protects the balloon s drug coating as it is delivered to the target lesion. Second, the ability to customize the length and diameter of the balloon while in the patient s artery may reduce the incidence of geographic miss. Current drug eluting balloons are fixed-length and cannot be adjusted, but the size and shape of lesions can vary significantly. Due to lesion variability, hospitals must keep a wide variety of balloon sizes in inventory, resulting in higher inventory management efforts and costs.

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 CE Mark in the European Union, and 30 days and nine months for clinical trials under an 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. We anticipate that a total of up to approximately 2,100 patients will be necessary to support our FDA approval.

Our Clinical Trials

We have completed enrollment in four clinical trials. 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.

Table of Contents

The following table summarizes our completed and ongoing clinical trials. The data from the CUSTOM I, II and III clinical trials were included in the application we submitted to our designated Notified Body to obtain the CE Mark that we received in March 2009 authorizing us to market our Custom NX DES Systems in the European Union. Additionally, we have used this information to support our 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	Completed
CUSTOM III	90	• Maximum length: 60mm • Diameters: 2.5mm, 3.0mm • 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	Completed
CUSTOM PK	28	• Maximum length: 60mm • Diameters: 2.5mm, 3.0mm • Guide catheter: 6 french • Single deployment	Pharmacokinetics study assessing blood concentration of Biolimus A9 drug at various time-points post stent implantation	Completed
CUSTOM CARE	200	• Maximum length: 60mm • Diameters: 2.5, 3.0, 3.5mm • Guide catheter: 6 french • Multiple deployments	Pre-market registry to confirm device performance, refine user training and prepare product launch	Initiated

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 2.6 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 and annually for another 4 years.

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. In October 2008, the three year data from our CUSTOM I clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. There were a total of four MACE events reported 36 months after the treatment procedure. 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.

CUSTOM II. Our CUSTOM II clinical trial was designed to evaluate the safety of in situ customization for long lesions and multiple lesions using our Custom NX 60 DES catheter system. The Custom NX60 was used to treat patients with long lesions or lesions in multiple diseased coronary arteries ranging from 2.5 to 3.0mm in diameter and up to two lesions. Enrollment of 100 patients was completed in October 2006 at ten cardiology centers in Europe. Of the 100 patients enrolled in CUSTOM II, 69 patients were enrolled in the long lesion cohort that consisted of patients with lesions greater than 20mm in length. The remaining 31 patients were enrolled in the two-lesion cohort. Patients were reassessed at 30 days, six months and 12 months. Follow up is scheduled to occur annually for five years. In October 2008, the two year data from our CUSTOM II clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. There were a total of 15 MACE events reported at two years post treatment procedure. The results from our CUSTOM II 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.

CUSTOM III. Our CUSTOM III clinical trial was designed to evaluate in situ customization for long lesions and multiple lesions using an enhanced version of our Custom NX DES Systems. The enhanced version included a number of changes to the handle improving ease-of-use for physicians. The primary endpoint of the study was safety with secondary endpoints. Enrollment in the CUSTOM III trial began in September 2006 and was completed in August 2007. In October 2008, the one year data from our CUSTOM III clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. There were a total of 11 MACE events reported at one year post treatment procedure. The results from our CUSTOM II 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.

Table of Contents

CUSTOM Pk. Our CUSTOM Pk clinical trial was designed as a pharmacokinetic study to evaluate the blood concentration of Biolimus A9 at different time points following treatment of coronary lesions with the Custom NX DES Systems. The study was initiated in December 2007 in Europe, and a total of 28 patients were enrolled in the study. Patients were assessed at 28 days, six months and 12 months following initial treatment and will be assessed yearly thereafter, for a total duration of 5 years. The results from our CUSTOM Pk clinical trial will be used to characterize the properties of the drug coating formulation applied to our stents and to support regulatory approvals. In October 2008, the six months data from our CUSTOM Pk clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. No MACE events were reported at six months post procedure.

CUSTOM CARE. Our CUSTOM CARE clinical trial was designed to confirm the Custom NX DES Systems performance characteristics while preparing for the European market launch of the products. The study is scheduled to enroll 200 patients at multiple sites across Europe. The final version of the device used in this study incorporated final product changes and represented the product configurations that we intend to market. The primary endpoint of the study was safety with secondary endpoints. The study was initiated in December 2008 but has been suspended in light of our decision to seek strategic alternatives.

The table below provides a summary of the cumulative long term safety results to date for our CUSTOM I, CUSTOM II and CUSTOM III clinical trials. This information demonstrates the overall safety profile of the Custom NX DES Systems for their intended use. The results from our CUSTOM I, II and III clinical trials do not necessarily predict the outcome of a large-scale clinical trial, which will be required for obtaining FDA approval for our products in the United States.

CUSTOM I, II and III Summary of Clinical Trial Results

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

Entities associated with our principal clinical investigator for our CUSTOM I and CUSTOM II clinical trials hold options to purchase 5,209 shares of our common stock at a weighted-average exercise price of $0.40 per share.

Required Clinical Trials

In order to obtain reimbursement in selected European countries and FDA approval in the United States, we will need to undertake large-scale pivotal studies similar to those conducted by competitors who have marketed drug eluting stents. We anticipate that a total of up to approximately 2,100 patients will be necessary to support FDA approval. 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 evaluation of 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.

Two of the 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. Medtronic s Endeavor, has undergone evaluation where it was compared to the Cypher or Taxus drug eluting stents. The ENDEAVOR III and IV Trials enrolled 436 and 1,548 patients respectively. Abbott Laboratories Xience V stent obtained market approval on the basis of the SPIRIT First, SPIRIT II and SPIRIT III trials enrolling an aggregate of 1,362 patients. The SPIRIT III trial enrolled 1,002 patients and compared Xience V to the Taxus stent.

Table of Contents

CUSTOM IV. Using data generated by our CUSTOM I, II and III clinical trials, we submitted an IDE application to the FDA in September 2007. In October 2007, we received questions back from the FDA. In February 2009, we resubmitted our IDE application, and expect to receive a response from the FDA by the end of the first quarter of 2009. We will not be able to initiate our CUSTOM IV trial until we receive IDE approval, and even if we receive IDE approval, we will not be able to initiate our IDE trial unless we obtain additional financing, or we consummate a strategic transaction that permits us to initiate our IDE trial. Our planned U.S. pivotal clinical trial, CUSTOM IV, will enroll approximately 2,100 patients and will evaluate our Custom NX DES Systems against a marketed drug eluting stent for the treatment of CAD. 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 submitting a PMA application to the FDA approximately 24 months after the initiation of the CUSTOM IV trial.

CUSTOM V. Our CUSTOM V pivotal clinical trial will be designed to generate additional data supporting additional claims that could be used to support market approvals or to seek reimbursement in selected European countries. We believe this clinical trial will be a prospective, controlled trial that will include up to approximately 1,500 CAD patients.

Regulatory Filing Process

The regulatory filing process for our drug eluting stents is a dual filing process in which our filings include the clinical data and technical information related to our devices, which we submit to the regulatory authorities and the drug master file, or MAF, related to the drug coating, which Biosensors generates and submits to the regulatory authorities on our behalf. In Europe, our Notified Body assessed our combined device and drug and provided the drug related information to a European drug regulatory authority, in our case the Medicines Evaluation Board, or MEB, in the Netherlands for its assessment. The MAF that Biosensors filed on our behalf had to obtain a favorable opinion from the MEB, and the entire application for the combination device had to be approved by the Notified Body in order for us to obtain CE Mark approval, which we received in March 2009. In the United States, Biosensors has also submitted a MAF to the FDA on our behalf in order for us to obtain IDE approval. As a result of this dual filing process, we rely on Biosensors to timely file acceptable MAFs on our behalf, with the applicable regulatory authorities, and to respond to any questions or comments the authorities may have concerning those MAFs. We have already received CE Mark, and we believe the MAF which Biosensors has submitted to the FDA for purposes of our IDE application is sufficient to support an IDE approval, but we expect the FDA to conduct additional assessments of the MAF as part of our PMA review, and they may have additional questions at that time.

Post-Approval Registries

At the time of our product launches in Europe and in the United States we expect to 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. The estimated size of the post market registry to be undertaken upon European launch is approximately 1,000 patients.

Our Relationship with Biosensors

In May 2004, we entered into a license agreement with Biosensors and in December 2007, we entered into an amended and restated license agreement with Biosensors which superseded the original license agreement.

Pursuant to the agreement, we received a worldwide, non-exclusive, license to use Biosensors drug coating, with royalties payable to Biosensors based on net sales of our products. The field of use for 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. In Japan, our field of use is further limited to treating long lesions, multiple vessels or small vessels in coronary and peripheral applications.

The agreement also gives us the right to purchase the drug and polymer components of our stent coating separately from Biosensors for the sole purpose of mixing the drug/polymer formulation and coating our stents for use and sale within our licensed field of use. Under the terms of the agreement, we also have the right to use certain technology owned by Biosensors to mix the drug coating, to apply the drug coating to our stents and to perform certain necessary testing of the drug coating, each within our licensed field of use. Biosensors is not required to provide support services except for testing that is required by the relevant regulatory agencies to develop the drug master files submitted by Biosensors on our behalf for regulatory approvals in the United States, Europe and Japan.

Table of Contents

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. Biolimus A9 has a chemical structure designed specifically for localized drug delivery from the surface of a stent and to inhibit restenosis. 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. The license expires or is terminable upon, among other things:

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

- one year after the date the regulatory packages for the drug and polymer submitted by Biosensors on our behalf are approved by the MEB, if we fail to obtain a CE Mark for our stent systems before such date; or

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

In addition to paying royalties to Biosensors for the license, we also purchase the drug and polymer components exclusively from Biosensors. Our agreement with Biosensors prohibits us from making, using or selling a stent coated with rapamycin or a derivative of rapamycin other than Biolimus A9. We are obligated to assign to Biosensors any inventions for which our employees are inventors or co-inventors and which are either (i) derived from Biosensors confidential information or, (ii) related to the process for applying their drug coating to stents if developed prior to the effective date of the restated agreement or if co-invented with Biosensors. 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 or the components of the coating to us and we apply it to our stents prior to final assembly and sterilization. Biosensors will perform stability testing of the drug and polymer and any other testing required to respond to agency questions about the MAF as required for approval of our DES systems in the United States, Japan, and Europe. Our agreement with Biosensors allows us to perform all other testing of the drug coating required for regulatory approvals and for lot release during commercialization.

Manufacturing

We currently occupy a facility of approximately 50,000 square feet in Menlo Park, California, under a lease which expires on May 31, 2012. Under the terms of our lease agreement for these facilities, our landlord may terminate our lease at any time on or after May 1, 2010 if it has obtained certain redevelopment rights with respect to the leased premises, and we may terminate the lease at anytime on or after May 1, 2010 for any reason. All of our manufacturing operations take place at this facility.

Final assembly, drug coating, and packaging of all of our products take place inside a controlled environment room of approximately 8,000 square feet that satisfies the requirements of a Class 10,000 level clean room. We have no experience manufacturing commercial quantities of our products. 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 to supply our drug coating or the components thereof and no alternative source is available. 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. 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 manufacture our products, which could delay completion of our clinical trials or commercialization of our products.

Table of Contents

Sterilization services for our products are performed 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. In June 2008, 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 recertified. We expect to be audited again in the second or third quarter of 2009, but we do not believe that we have adequate personnel to pass the audit. We will not be able to commercialize our product until we successfully pass the audit. 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. 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 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 companies 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 market, 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 the United States, Europe and other international markets. Medtronic received FDA approval for its zotarolimus eluting stent, Endeavor, in February 2008 and immediately began marketing the product. Johnson & Johnson has developed a stent coated with rapamycin, the Cypher stent, which is marketed in the United States, Europe and other international markets. Abbott Laboratories Everolimus eluting stent, Xience V, received FDA approval in July 2008 and is marketed in the United States, Europe and other international markets. The Taxus Express2 stent, the Taxus Liberte stent, the Cypher stent, the Abbott Xience V stent and the Endeavor stent are currently the only FDA approved drug eluting stents in the United States. Conor

Medsystems, which was acquired by Johnson & Johnson in January 2007, also developed a paclitaxel eluting stent, CoStar. In 2006, Conor received CE Mark for the CoStar stent in Europe and other international markets and began marketing through distribution partners. Conor also completed the COSTAR II randomized controlled trial in the United States comparing Costar stent versus Taxus Express-2. Costar failed to meet its primary endpoint in COSTAR II and Johnson & Johnson has since decided to stop marketing Costar outside the United States and redesigned the product with a drug coating based on sirolimus rather than paclitaxel.

Table of Contents

Outside the United States, there are a number of additional stents that have marketing approval. In January 2008, Biosensors and Terumo both received CE Mark for their Biolimus A9-eluting stents. Biosensors markets its BioMatrix stent through a direct sales force and distributors. Terumo primarily uses distributors to market its NOBORI stent internationally. Biosensors also markets a paclitaxel eluting stent, Axxion, in Europe and other international markets. Sorin Group has developed a tacrolimus eluting stent, Janus, which is marketed in Europe. In addition to its Endeavor stent, Medtronic has another zotarolimus eluting stent named Endeavor CR (Resolute) which has received CE Mark and which has a different polymer than the one used on the Endeavor stent. Additionally, many of the companies referenced above, and other potential competitors 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.

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 $31.2 million in 2008, $30.9 million in 2007 and $18.9 million in 2006. If we are able to obtain additional funding or complete a strategic transaction that provides adequate resources, 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 no experience in the sale, marketing and distribution of stent systems. To achieve commercial success for any approved product we must develop a sales and marketing organization or enter into arrangements with others to market and sell our products.

If we are able to obtain additional funding or complete a strategic transaction that provides adequate resources, we intend to commercialize our Custom NX DES Systems in certain 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. 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 would need to 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, 2008, we had 19 issued U.S. patents, 62 pending U.S. patent applications, one pending Israeli patent application, and 40 pending international patent applications filed pursuant to the Patent Cooperation Treaty, or PCT, 27 of which have entered the national phase in Europe, Japan, Canada, and Australia. All of our issued U.S. patents except two will expire between 2021 and 2023. Our other two issued U.S. patents, which cover technologies that 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, 2008, one 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 2027.

Six 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; a deployment mechanism on the catheter that allows application of a radially-outward force along a selected length of stent while a portion of the stent remains unexpanded; a stop member on the balloon catheter for stopping a stent at a selected position for deployment; a valve member on the balloon catheter for separating stents from each other; and a garage member attached to the sheath of the balloon catheter for constraining balloon expansion. Our pending U.S. patent applications, if issued with their present claims, will cover various other aspects of our Custom NX DES Systems, including

Table of Contents

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. Under this agreement we have a non-exclusive license to certain issued patents owned by Biosensors covering Biolimus A9 and stent coatings containing Biolimus A9 and certain polymers.

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 lubricious 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 July 1, 2009 or thereafter if we have four consecutive quarters during which we fail to pay a royalty to SurModics.

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, Japan and Australia. An application for our XTENT trademark is pending in Canada. CUSTOM NX is a registered trademark of our company in the United States, Australia, the European Union and Japan. An application for our CUSTOM NX trademark is pending in Canada. Our NX trademark is registered in the European Union. 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.

Table of Contents

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, there may be pending patent applications relevant to our technology that 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 subsidiary of Boston Scientific whose stent technology has been acquired by Abbott Vascular subject to certain rights retained by Boston Scientific, which are directed to flexible stent structures. The Boneau family of patents, owned by Medtronic, are directed to stents comprising multiple closed-loop elements.

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

Other third-party patents are directed to stent delivery catheter technology. There are 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,

Table of Contents

under 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 being transitioned over a three year period that began in fiscal year 2007. In 2007, CMS also implemented revised reimbursement codes that better reflect the severity of the patient s condition in the hospital inpatient prospective payment system.

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 majority of countries have existing reimbursement for drug eluting stents, a 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.

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;

Table of Contents

- advertising and promotion; 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 includes the MAF for the drug coating aspects of our products that Biosensors submits to the FDA on our behalf. We filed our IDE application in September 2007, and in October 2007, we received questions back from the FDA. In February 2009, we resubmitted our IDE application, and expect to receive a response from the FDA by the end of the first quarter of 2009. We will not be able to initiate our CUSTOM IV trial until we receive IDE approval, and even if we receive IDE approval, we will not be able to initiate our IDE trial unless we obtain additional financing, or we consummate a strategic transaction that permits us to initiate our IDE trial. 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.

Table of Contents

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.

Table of Contents

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 directive will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directive 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, 2008, we had 127 employees, with three employees in sales and marketing, 66 employees in manufacturing, 24 employees in research and development, 13 employees in general and administrative and 21 employees in clinical, regulatory and quality assurance. In January 2009, we announced an initiative to reduce our headcount by 115 positions to be completed during March 2009.

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, or 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 also 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.

Table of Contents

ITEM 1A. RISK FACTORS

Risks Related to Our Business

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

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

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

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

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

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

We have significantly reduced our headcount and limited our business activities. Before we could resume the operations required in order to commercialize our product, we would need to rehire a significant number of employees or hire and train new employees that can perform their jobs according to our specifications. There can be no assurance that we will be able to rehire our former employees or hire and train qualified

new employees in a timely manner, or at all. In addition, before we can commercialize our product in Europe, we need to increase our manufacturing capacity and validate our manufacturing process to demonstrate compliance with applicable quality standards. This validation would likely take six to nine months to complete. Further, under the terms of the agreements we have with several of our suppliers, we are required to provide regular forecasts of the components we plan to purchase from them during a particular period. These suppliers are obligated to supply us only with the number of components that we previously forecasted. Therefore, once manufacturing operations commence, it may take several months before we have adequate supplies of critical components required to make our products.

Table of Contents

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

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

- fund our operations and clinical trials;

- continue our research and development;

- scale-up our manufacturing operations;

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

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

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

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

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

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

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

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

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

• the cost and timing of regulatory approvals;

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

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

• the effect of competing technological and market developments;

• licensing technologies for future development; and

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

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

Table of Contents

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

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

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

We have incurred net losses since our inception in June 2002. For the years ended December 31, 2008, 2007, and 2006, we had net losses of $41.1 million, $38.8 million and $25.0 million, respectively. As of December 31, 2008, we had an accumulated deficit of $134.0 million. To date, we have financed our operations primarily through private placements of our equity securities and our Initial Public Offering, completed on February 1, 2007, and have devoted substantially all of our resources to research and development and clinical studies related to our Custom NX DES Systems, which consist of the Custom NX 36 and the Custom NX 60. Since we have only recently received CE Mark and we do not have approval from the Food and Drug Administration, or FDA, or any other regulatory authority for our products, we are only authorized to market our current products in the European Union and certain other countries that recognize CE Mark, and we have not generated any revenues since our inception. We expect our research and development expenses to increase significantly in connection with our clinical trials and other product development activities. If we obtain additional funding or complete a strategic transaction that provides adequate resources, we expect to incur significant sales and marketing expenses and manufacturing expenses as we commercialize our products. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses will continue to have an adverse effect on our stockholders equity.

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

In May 2004, we entered into a license agreement with Biosensors. In December 2007, we entered into an amended and restated license agreement with Biosensors which superseded the prior agreement. Pursuant to the agreement, we obtained non-exclusive rights to use Biosensors drug coating on our stent platform. The drug coating consists of Biolimus 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. In January 2008, Biosensors announced that it had received CE Mark approval for its BioMatrix drug eluting stent which uses the Biolimus A9 and PLA drug coating. The drug coating has not been approved for any use in the United States or any jurisdiction other than the European Union. In March 2009, we received CE Mark approval for our Custom NX DES Systems authorizing us to market our Custom NX DES Systems in the European Union and certain other countries that recognize CE Mark.

In order to obtain IDE approval from the FDA allowing us to initiate our CUSTOM IV clinical trial in the United States and in order to obtain the premarket approval, or PMA, allowing us to commercialize our Custom NX DES Systems in the United States, we need Biosensors to submit acceptable MAFs related to our drug coating to the FDA on our behalf. We believe the MAF which Biosensors has submitted to the FDA for purposes of our IDE application is sufficient to support an IDE approval, but we expect the FDA to conduct additional assessments of the MAF as part of our PMA review, and they may have additional questions at that time. Any delays Biosensors experiences or problems it has in responding to questions the FDA may have concerning the MAF may substantially delay the commercial launch of our product in the United States.

Table of Contents

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We do not currently have the necessary regulatory approvals to market our Custom NX DES Systems or any other products in the United States or in any foreign markets, other than the European Union and certain other countries that recognize CE Mark. If we obtain the necessary regulatory approvals and provided we obtain additional funding or complete a strategic transaction that provides adequate resources, we plan initially to launch our products in the European Union and later in the United States.

Table of Contents

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

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

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

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

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

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

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

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

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

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

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

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

- Engineering testing,

- Biocompatibility testing,

- Animal studies,

- Chemistry and manufacturing controls,

Table of Contents

- Clinical pharmacology and drug release,

- Drug pharmacology, toxicology and safety data,

- Clinical studies, and

- Post approval studies.

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

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

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

We obtain our entire supply of the drug coating, PLA and BA9 for our stents from Biosensors and we are unaware of any alternative source for this drug coating. Under the amended and restated license agreement which we entered into with Biosensors in December 2007, we have the right to purchase the components of the drug coating, which are the drug and the PLA, from Biosensors in order to perform the coating formulation ourselves. We have completed the work necessary to perform the formulation ourselves, but we will continue to purchase the formulated drug coating from Biosensors until we obtain certain regulatory approvals necessary in order to perform our own formulation for commercial use outside the United States. We do not have the right to use alternate suppliers for this drug coating that we obtain from Biosensors, or the components of the drug coating which we plan to purchase from them in the future. In addition, there is no other source for the drug coating or components and we are contractually restricted from obtaining Biolimus A9 from any other source and we have not in-licensed an alternative drug for use in the event we are unable to obtain a sufficient supply of Biolimus A9. Currently, Biosensors relies on a sole-source, Nippon Kayaku, a third-party Japanese pharmaceutical company, to manufacture and supply them with Biolimus A9, which Biosensors mixes with the PLA. We have no relationship with, control over, or contact with this pharmaceutical company and cannot contract directly with it to obtain Biolimus A9 if we are unable to obtain Biolimus A9 from Biosensors. In addition, the pharmaceutical company is subject to significant legal and regulatory requirements with regard to the production of Biolimus A9, including onerous current Good Manufacturing Practices regulations, or GMP, which are strictly enforced by the FDA, and the Ministry of Health, Labor, and Welfare in Japan and any failure on the part of the pharmaceutical company to comply with these requirements may interrupt Biosensors supply of Biolimus A9 and ultimately, our supply of the drug coating. Biosensors has also entered into, and may continue to enter into, agreements to supply the drug coating to other licensees. Our clinical trials and the development and commercialization of our Custom NX DES Systems could be prevented or delayed if:

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

• our license agreement with Biosensors terminates for any reason, including insolvency; or

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

To date, our drug coating requirements have been limited to small quantities that we need to conduct our development and pre-clinical and clinical trials. If we obtain market approval for our products, and we are able to launch our product commercially, we would require substantially larger quantities of the drug coating or the components of the drug coating. Biosensors may not provide us with sufficient quantities of the drug coating or components and such supply may not meet our quality requirements or other specifications. For example, we have, in the past, experienced interruptions in the supply of adequate quantities of acceptable drug coating. In the event we do not receive adequate supplies of acceptable drug coating or components, we will likely be unable to locate an alternative supplier, or any alternative drug, in a timely manner or on commercially reasonable terms, if at all. Any additional new source for Biolimus A9, the PLA or the drug coating will

Table of Contents

require the consent of Biosensors and prior FDA approval, which will require significant time and effort to obtain and there can be no assurance that we will obtain such regulatory approval. The inability to obtain sufficient quantities of the drug coating or components, or any delay in obtaining such supply could delay our clinical trials or affect the commercialization of our Custom NX DES Systems, which could have a significant adverse affect on our future operations.

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

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

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

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

If, in our large-scale comparative pivotal clinical trial, we fail to demonstrate restenosis and reintervention rates, as well as other clinical trial end-points and performance, comparable to other drug eluting and bare metal stents that have been approved by the FDA, our ability to successfully market our Custom NX DES Systems may be significantly limited. If the long-term rates of restenosis and reintervention do not meet regulators or physicians expectations, our Custom NX DES Systems may not receive regulatory approval or, if approved, may not become widely adopted and physicians may recommend that patients receive alternative drug eluting stents, such as the Cypher ® stent, the Taxus ® Express2 stent, the Taxus Liberte stent, the Endeavor ® stent, the Xience™ V stent and the Promus™ stent, the six drug eluting stents currently marketed in the United States. Another important factor upon which the safety and efficacy of our Custom NX DES Systems will be measured is the incidence of late-stent thrombosis following procedures using our drug eluting stents. Some clinical data suggests a small but significant increase in the rate of death and heart attack associated with drug eluting stents when compared to bare metal stents, possibly due to late-stent thrombosis. The FDA convened a public meeting of its Circulatory System Devices Advisory Panel on December 7 and 8, 2006 with the intention of obtaining additional information on the risks, timing and incidence rates of late-stent thrombosis. In March 2008, the FDA published draft guidance regarding non-clinical and clinical studies

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

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

Table of Contents

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

Before marketing and selling our Custom NX DES Systems or any other products, we must successfully complete pre-clinical studies and clinical trials that demonstrate that our products are safe and effective. We currently have a very limited amount of clinical data regarding the safety and efficacy of our Custom NX DES Systems, and no published data beyond three years. The results from our limited short-term clinical experience for our Custom NX DES Systems do not necessarily predict long-term clinical benefit and may not be replicated in subsequent clinical trials. Furthermore, all of our existing data has been produced in studies that involve relatively small patient groups, and the data may not be reproduced in wider patient populations. We need to conduct additional large-scale clinical trials to determine whether our products are safe and effective and to support our applications for regulatory approval in the United States. We expect that one or more of these additional clinical studies will be a comparative study comparing the safety and efficacy of our stents to the Xience V stent, the Promus stent, the Cypher stent, the Taxus Express2 stent, the Taxus Liberte stent or the Endeavor ® stent, the six drug eluting stents marketed in the United States, or to other stents that may become approved for marketing in the United States, and that these studies will involve large patient populations of approximately 2,100 patients implanted with our device.

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

• insufficient personnel and financial resources to conduct and fund our clinical trials;

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

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

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

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

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

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

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

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

• changes in governmental regulations or administrative actions;

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

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

Before we can commence our planned pivotal clinical trial in the United States for our Custom NX DES Systems, we must receive the FDA s approval of our IDE application. We filed our IDE application in September 2007, and in October 2007, we received questions back from the FDA. In February 2009, we resubmitted our IDE application, and expect to receive a response from the FDA by the end of the first quarter of 2009. Even if we receive IDE approval from the FDA, we will not be able to initiate our IDE trial unless we obtain additional funding or complete a strategic transaction that provides adequate resources. We cannot guarantee that such a financing or strategic transaction will be available on terms agreeable to us, or at all.

Table of Contents

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

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

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

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

Physicians tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party coverages and reimbursement. We believe that physicians will not widely adopt our Custom NX DES Systems unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our Custom NX DES Systems provides a safe and effective alternative to other existing treatments for coronary artery disease, including coronary artery bypass grafting, or CABG, balloon angioplasty, bare metal stents and other drug eluting stents, such as Johnson & Johnson s Cypher stent and Boston Scientific s Taxus Express2 stent. In particular, the use of bare metal stents has reportedly increased, and the use of drug eluting stents has reportedly decreased, at certain hospitals in the United States and elsewhere as a result of recent clinical data indicating a higher incidence rate of late stent thrombosis. We cannot predict the effect that this or other data questioning the safety of drug eluting stents will have on the drug eluting stent market.

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

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

Table of Contents

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

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

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

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

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

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

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

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

Table of Contents

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.

Table of Contents

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

Other third-party patents are directed to stent delivery catheter technology. There are also a number of patents that were held by Guidant Corporation directed to rapid exchange catheters for angioplasty and stent delivery. These include, without limitation, the Yock and Horzewski families of patents, directed to rapid exchange angioplasty catheters, and the Lau family of patents directed to rapid exchange stent catheters. Boston Scientific owns other patents directed to rapid exchange angioplasty catheters, including, the Bonzel family of patents. Medtronic owns certain patents directed to guidewire handling technology in stent delivery catheters, including certain patents issued to Crittenden and Kramer. A patent issued to

Table of Contents

Fischell is directed to a sheathed stent delivery catheter. Guidant Corporation also held a patent issued to Cox, directed to a stent delivery catheter having an adjustable-length balloon. Certain patents owned by Boston Scientific or its subsidiaries are also directed to stent delivery catheters having adjustable-length balloons. Certain patents owned by third parties relate to methods for coating stents. For example, the Hossainy family of patents that were held by Guidant Corporation are directed to methods of coating stents with a primer layer and a reservoir layer.

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

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

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

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

These companies have maintained their position in the market by, among other things, establishing intellectual property rights relating to their products and enforcing these rights aggressively against their competitors and new entrants into the market. All of the major companies in the stent and related markets, including Abbott Vascular (which acquired Guidant s stent technology), Boston Scientific, Johnson & Johnson and Medtronic, have been repeatedly involved in patent litigation relating to stents since at least 1997. For example, in the past year Boston Scientific, Medtronic, and Abbott Vascular have each been sued by Johnson & Johnson and/or Wyeth for infringement of the Morris, Wright, and/or Falotico patents. The stent and related markets have experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay the introduction of new products and technologies. We may pose a competitive threat to many of the companies in the stent and related markets. Accordingly, many of these companies will have a strong incentive to take steps, through patent litigation or otherwise, to prevent us from commercializing our products.

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

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

Table of Contents

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

• discontinue manufacturing or other processes incorporating infringing technology; or

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

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

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

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

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

Our ability to protect our products from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. As of December 31, 2008 we had seven issued U.S. patents, one of which is under exclusive license, covering certain aspects of the technology that we intend to commercialize and a number of other issued patents and pending patent applications in the United States and abroad. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering

medical devices and pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any of our issued patents may not provide us with commercially meaningful protection for our products or afford us a commercial advantage against our competitors or their competitive products or processes. In addition, patents may not issue from any pending or future patent applications owned by or licensed to us, and moreover, patents that have issued to us or may issue in the future may not be valid or enforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing products like ours, despite our patent rights.

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the validity of our issued patents or the patentability of our pending patent applications. For example, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the United States Patent and Trademark Office, or USPTO, for the entire time prior to issuance as a U.S.

Table of Contents

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.

Table of Contents

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

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

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

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

Subject to the availability of adequate resources, after establishing our European sales channels, if our Custom NX DES Systems are approved for commercial sale in the United States, we currently plan to establish our own direct U.S. sales force. If we develop our own marketing and sales capabilities, our sales force will be competing with the experienced and well-funded marketing and sales operations of our more established competitors. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. We may not be able to develop this capacity on a timely basis or at all. If we are unable to establish sales and marketing capabilities, we will need to contract with third parties to market and sell our products in the United States. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services in the United States or internationally, our product revenue could be lower than if we directly marketed and sold our products, or any other stent system or related device that we may develop. Furthermore, to the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. Some of our future distributors may market their own products or distribute other companies products that compete with ours, and they may have an incentive not to devote sufficient efforts to marketing our products. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

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

We currently have limited resources, facilities and experience to commercially manufacture the device component of our products and apply the drug coating to the stents. In addition, pursuant to the terms of the restated license agreement with Biosensors, we plan to perform our own drug coating formulation. Furthermore, effective March 23, 2009, we substantially completed a reduction in our headcount from 122 to 7 employees, and we expect to fully complete that reduction by March 31, 2009. None of the remaining employees will be manufacturing personnel. In order to produce our Custom NX DES Systems in the quantities that we anticipate will be required to meet anticipated market demand, we will need to increase, or scale-up, the production process by a significant factor over our current level of production. There are technical challenges to scaling-up manufacturing capacity and developing commercial-scale manufacturing facilities that will require the investment of substantial additional funds and hiring and retaining additional management and technical personnel who have the

Table of Contents

necessary manufacturing experience. We may not successfully complete any required scale-up in a timely manner or at all. If we are unable to do so, we may not be able to produce products in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, if at all. If we develop and obtain regulatory approval for our products and are unable to manufacture a sufficient supply of our products, our revenue, business and financial prospects would be adversely affected. In addition, if the scaled-up production process is not efficient or produces stents that do not meet quality and other standards, our future gross margins may decline.

We currently assemble our Custom NX DES Systems and apply the drug coating at our facilities in Menlo Park, California. Under the terms of our lease agreement for these facilities, our landlord may terminate our lease at any time on or after May 1, 2010 by giving us 180 days notice, if it has obtained certain redevelopment rights with respect to the leased premises. Prior to the commercial launch of our product, our leased premises will have to be inspected and approved by the FDA, and will likely require additional certifications by the State of California Department of Health Services, or CDHS. Our facility and quality systems are also required to pass annual audits for purposes of International Standardisation Organization, or ISO, compliance. We expect to be audited in the second or third quarter of 2009, but we do not believe that we have adequate personnel to pass the audit. We will not be able to commercialize our product until we successfully pass the audit. If audits and inspections of our facilities determine that our facility does not meet applicable standards, or if there is a disruption to our existing manufacturing facility, or if our landlord elects to terminate our lease on or after May 1, 2010, we will have no other means of manufacturing our products until we are able to restore the manufacturing capability at our facility or lease alternative manufacturing facilities and obtain regulatory approval for these facilities. Because our Menlo Park facilities are located in a seismic zone, we face the risk that an earthquake may damage our facilities and disrupt our operations. If we are unable to produce sufficient quantities of our products for use in our current and planned clinical trials, if we obtain regulatory approval of our products and are unable to produce sufficient quantities of our products to support our planned commercial activities or if our manufacturing process yields substandard products, our development and commercialization efforts would be delayed.

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

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

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

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

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

Although we have identified several vendors for the components of our products, some of our components are currently provided by only one vendor, or a single-source supplier. In addition to our reliance on Biosensors as the only source for the supply of our drug coating, we also depend on SurModics, which provides the slippery coating on our sheath. Our current agreement with SurModics, allows SurModics to terminate the agreement if we do not commercialize our product by July 1, 2009. We do not expect to commercialize our product by that date. We do not have long-term contracts with some of our third-party suppliers of components used in the manufacture of our stent delivery catheters or the cobalt chromium tubing and laser-precision cutting process required to produce the stent segments included in our device. In addition, we do not have long-term contracts with our third-party suppliers of some of the equipment and

Table of Contents

components that are used in our manufacturing process and we do not carry a significant inventory of most components used in our products. Establishing additional or replacement suppliers for these components, and obtaining any additional regulatory approvals that may result from adding or replacing suppliers, will take a substantial amount of time. We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or foreign regulatory authorities. Furthermore, since some of these suppliers are located outside of the United States, we are subject to foreign export laws and U.S. import and customs regulations, which complicate and could delay shipments to us. Some of our suppliers are also our competitors and may be reluctant to supply components to us on favorable terms, if at all.

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

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

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

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

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

- the research methodology used may not be successful in identifying potential products;

- competitors may develop alternatives that render our products obsolete;

• our products may not be deployed safely or effectively;

• products may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective;

• our clinical trials may not be successful; and

• we may not receive regulatory approval.

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

We are dependent on our President and Chief Executive Officer, Gregory D. Casciaro and our Vice President, Quality Assurance, Clinical and Regulatory Affaires, Philippe Marco, M.D. Due to the specialized knowledge both of these officers possesses with respect to interventional cardiology and our business activities, the loss of service of either of these officers could delay or prevent the successful completion of a fundraising event, a strategic transaction, or provided that we can continue with our ongoing operations, our clinical trials and the commercialization of our Custom NX DES Systems. Either of these officers may terminate their employment without notice and without cause or good reason. We carry key person life insurance on Mr. Casciaro but not on Philippe Marco, M.D. In connection with our reduction in force and our plans to

Table of Contents

explore strategic alternatives, we entered into retention and severance agreements with nine of our employees, including our executive officers. Pursuant to these agreements, we have agreed to make retention payments to each of these employees, provided their employment is not terminated for cause prior to the date upon which we complete a strategic transaction, or the employee s expected termination date, whichever is earlier. The expected termination dates for these employees range from March 31, 2009 to July 31, 2009.

Risks Related to Our Industry

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

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

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

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

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

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

Table of Contents

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

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

Risks Related to Our Operations

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

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

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

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

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring us to include a report of management on our internal control over financial reporting in our annual report on Form 10-K for the year ended December 31, 2008. In addition, in our annual report on Form 10-K for the year ending December 31, 2009, the independent registered public accounting firm auditing our financial statements must attest to the effectiveness of our internal control over financial reporting. We may be unable to comply with these requirements by the applicable deadlines. We will be testing our internal control over financial reporting in connection with Section 404 requirements and could, as part of that documentation and testing, identify material weaknesses, significant deficiencies or other areas requiring further attention or improvement.

Table of Contents

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

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

- the results of our clinical trials;
- the timing of our regulatory approvals;
- announcements related to litigation;
- statements made by Biosensors relating to regulation or supply of the drug coating;
- the announcement of new products or service enhancements by us or our competitors;
- quarterly variations in our or our competitors results of operations;
- changes in earnings estimates, investors perceptions, recommendations by securities analysts or our failure to achieve analysts earning estimates;
- the low trading volume of our common stock;
- developments in our industry, including changes in third-party reimbursement; and
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

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

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

As of January 31, 2009, our officers, directors and principal stockholders each holding more than 5% of our common stock collectively controlled approximately 75.6% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

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

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

Table of Contents

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 50,000 square feet in Menlo Park, California, under a lease which expires on May 31, 2012. Under the terms of our lease agreement for these facilities, our landlord may terminate our lease at any time on or after May 1, 2010 if it has obtained certain redevelopment rights with respect to the leased premises, and we may terminate the lease at anytime on or after May 1, 2010 for any reason. We believe that our existing facility is adequate to meet our needs for at least the next 12 months and we expect that it will be available to us through such period. As we begin commercialization of our products, we expect that we will need additional space. 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.

Table of Contents

PART II

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

Stock Information

Our Common Stock, par value $0.001, is traded on the NASDAQ Global Market under the symbol XTNT.

As of March 4, 2009, the closing price of our Common Stock on the NASDAQ Global Market was $0.41 per share, and the number of stockholders of record was approximately 109.

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.

The following table sets forth for the periods indicated the high and low closing sale prices of our common stock, as reported by the NASDAQ Global Market:

Year Ended December 31, 2007	High	Low
First Quarter (beginning February 1, 2007)	$ 16.48	$ 11.23
Second Quarter	13.97	8.74
Third Quarter	10.54	7.74
Fourth Quarter	10.84	8.50

Year Ended December 31, 2008	High	Low
First Quarter	$ 10.00	$ 4.60
Second Quarter	6.52	2.50
Third Quarter	3.14	1.05
Fourth Quarter	1.31	0.25

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information regarding common stock that may be issued upon the exercise of options, warrants and rights under our 2002 Stock Plan, 2006 Equity Incentive Plan and 2006 Employee Stock Purchase Plan as of December 31, 2008:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights(1) (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)(2) (c)
Equity compensation plans approved by security holders	2,510,678	$ 5.48	2,442,643
Equity compensation plan not approved by security holders		N/A	
Total	2,510,678		2,442,643

(1) Does not include an outstanding option to purchase 5,209 shares which was issued outside of the approved option plans.

(2) Securities remaining available for future issuance under equity compensation plans includes 1,078,547 shares available for issuance under the 2006 Employee Stock Purchase Plan.

Table of Contents

Stock Performance Graph

The following graphic representation shows a comparison of total stockholder returns for holders of our common stock from February 2007, the date of our initial public offering, through December 31, 2008, compared with the NASDAQ Composite Index and the NASDAQ Medical Equipment Index. This graphic comparison is presented pursuant to the rules of the Securities and Exchange Commission.

XTENT, Inc.

Nasdaq Medical Devices, Instruments and Supplies, Manufacturers

and Distributers Stocks Index

Nasdaq Stock Market - U.S. Index

ITEM 6. SELECTED FINANCIAL DATA

We derived the selected statements of operations data for the years ended December 31, 2008, 2007 and 2006 and the period from June 13, 2002 (Inception) to December 31, 2008 and balance sheet data as of December 31, 2008 and 2007 from our audited financial statements that are included elsewhere in this Form 10-K. We derived the selected statements of operations data for the years ended December 31, 2005 and 2004

and the balance sheet data as of December 31, 2006, 2005, and 2004 from our audited financial statements not included in this Form 10-K.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.

Table of Contents

	Cummulative Period from June 13, 2002 (Date of Inception) to December 31, 2008	Year Ended December 31,				
		2008	2007	2006 (2)	2005	2004
	(in thousands, except per share data)					
Operating expenses:						
Research and development	$ 105,584	$ 31,170	$ 30,888	$ 18,923	$ 12,139	$ 7,118
General and administrative	34,460	10,917	11,269	7,258	2,214	1,883
Total operating expenses	140,044	42,087	42,157	26,181	14,353	9,001
Loss from operations	(140,044)	(42,087)	(42,157)	(26,181)	(14,353)	(9,001)
Interest and other income, net	6,063	966	3,363	1,137	323	110
Net loss	(133,981)	(41,121)	(38,794)	(25,044)	(14,030)	(8,891)
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock	(13,095)			(13,095)		
Net loss attributable to common stockholders	$ (147,076)	$ (41,121)	$ (38,794)	$ (38,139)	$ (14,030)	$ (8,891)
Net loss per share attributable to common stockholders - basic and diluted (1)		$ (1.78)	$ (1.87)	$ (13.96)	$ (6.84)	$ (5.00)
Weighted-average common shares outstanding - basic and diluted		23,116	20,703	2,732	2,052	1,779

(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,				
	2008	2007	2006	2005	2004
			(in thousands)		
Balance Sheet Data					
Cash and cash equivalents	$ 13,373	$ 13,366	$ 23,105	$ 6,564	$ 4,761
Short-term investments	5,752	44,394			
Working capital	17,070	54,581	21,066	5,588	4,143
Total assets	23,995	62,415	27,121	8,675	6,136
Reedeemable convertible preferred stock			75,593	35,900	20,406
Total stockholders equity (deficit)	21,508	58,331	(50,780)	(28,372)	(14,925)

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

Business 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.

Table of Contents

Over the past four years, we have been conducting clinical trials to evaluate our Custom NX 36 and Custom NX 60 stent and stent delivery systems. In October 2008, the one year data from our CUSTOM III clinical trial, the two year data from our CUSTOM II clinical trial and the three year data from our CUSTOM I clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. We believe the data from these clinical trials provided preliminary evidence of safety and efficacy and support further development of our in situ customization approach. In March 2009, we received CE Mark for our Custom NX DES Systems authorizing us to market our products in the European Union and certain other countries that recognize the CE Mark. Even though we have received CE Mark, we will not be able to commercialize our products in the European Union unless we obtain additional financing, or we consummate a strategic transaction that permits us to commercialize in Europe. We can provide no assurance that such a financing or strategic transaction will be available on terms agreeable to us, or at all.

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 a large clinical trial of up to 2,100 patients. We expect to obtain this data through our planned CUSTOM IV clinical trial, but to initiate the CUSTOM IV trial, we must first obtain clearance of an investigational device exemption, or IDE, from the FDA. We filed our IDE application in September 2007, and in October 2007, we received questions back from the FDA. In February 2009, we resubmitted our IDE application, and expect to receive a response from the FDA by the end of the first quarter of 2009. Even if we receive IDE approval from the FDA, we will not be able to initiate our IDE trial unless we obtain additional financing, or we consummate a strategic transaction that permits us to initiate our IDE trial. We cannot guarantee that such a financing or strategic transaction will be available on terms agreeable to us, or at all.

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, 2008, we had an accumulated deficit of $134.0 million. Provided we are able to obtain adequate financing, we expect our losses to continue to increase as we expand our clinical trial activities and initiate commercialization activities. Since inception we have financed our operations primarily through the sale of our equity securities. 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.

Recent Developments

In January 2009, we notified our employees that we were initiating a headcount reduction that would impact 115 of our 122 employees. The reduction was substantially completed on March 23, 2009, and we expect it to be fully completed by March 31, 2009.

We also engaged Piper Jaffray & Co. in January 2009 to help us explore potential strategic alternatives, which may include, without limitation, a merger, a sale of substantially all our assets, a financing, or a sale of a portion of our assets, such as our peripheral stent product, our drug eluting balloon product or our bioabsorbable stent product. Although we cannot be sure that we will be able to identify or complete a suitable strategic transaction, we believe that we have retained sufficient employees to facilitate such a transaction.

If we are successful in identifying and completing a strategic transaction, substantial changes may be made to our current operations or they may be completely discontinued. For example, if we are acquired by a third party, that third party may choose not to pursue some or any of our

current product development initiatives, such as our Custom NX drug eluting stent systems, our Custom NX peripheral stent technology, our customizable drug eluting balloon technology or our bioabsorbable stent technology.

In connection with the reduction in force and our plans to explore strategic alternatives, we entered into retention and severance agreements with nine of our employees, including our executive officers. Pursuant to these agreements, we have agreed to make retention payments to each of these employees, provided their employment is not terminated for cause prior to the date upon which we complete a strategic transaction, or the employee s expected termination date, whichever is earlier. The expected termination dates for these employees range from March 31, 2009 to July 31, 2009.

Table of Contents

Financial Operations

Revenue

To date, we have not generated any revenue from the sale of our stent systems. Revenue generation is subject to commercial launch of our product in Europe. Even though we received CE Mark in March 2009, we will not be able to commercialize our product in the European Union unless we obtain additional financing, or we consummate a strategic transaction that permits us to commercialize in Europe. We can provide no assurance that such a financing or strategic transaction will be available on terms agreeable to us, or at all.

Research and Development

Since inception, we have devoted a significant amount of resources to develop our Custom NX DES Systems. From our inception through December 31, 2008, we incurred $105.6 million in research and development expenses related to developing our products, including the clinical trials necessary to support regulatory approval. We expect our research and development expenses to decrease due to the reduction in force that we substantially completed on March 23, 2009, and we expect to fully complete by March 31, 2009.

General and Administrative

General and administrative expenses consist primarily of compensation for executive, finance, marketing and administrative personnel including stock-based compensation. Other significant expenses include professional fees for accounting and legal services associated with our efforts to obtain and maintain protection for intellectual property related to our Custom NX DES Systems. From our inception through December 31, 2008, we incurred $34.5 million in general and administrative expenses. We expect our general and administrative expenses to decrease due to the reduction in force we plan to complete in March 2009.

Results of Operations

Comparison of Years Ended December 31, 2008 And 2007

Revenue. We did not generate any revenue during the years ended December 31, 2008 or 2007.

Research and Development

	Years Ended December 31,				Dollar Change
	2008		2007		
	(in thousands)				
Research and development expenses	$	31,170	$	30,888	$ 282

The $0.3 million increase in research and development expenses for the year ended December 31, 2008, compared to the year ended December 31, 2007, was primarily attributable to:

- An increase of $1.6 million in personnel costs related to the hiring of additional employees in our research and development and manufacturing departments prior to the reduction in force completed in July 2008, and;

- An increase of $0.6 million in rent, depreciation on equipment and facilities costs due to the expansion of our manufacturing capacity prior to the reduction in force in July 2008, and;

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

- A decrease of $1.5 million for prototype parts, supplies, and outside services related to product development as we implemented spending decreases in the last half of 2008, and;

- A decrease of $0.6 million in expenses related to the support of our clinical research studies in 2008 as compared to the higher expense related to support of our CUSTOM III clinical trial during 2007.

Table of Contents

We expect our research and development expenses to decrease significantly as we implement additional cost savings measures in early 2009 associated with the March 2009 reduction in force.

General and Administrative

	Years Ended December 31,		Dollar Change
	2008	2007	
	(in thousands)		
General and administrative expenses	$ 10,917	$ 11,269	$ (352)

The $0.4 million decrease in general and administrative expenses for the year ended December 31, 2008, compared to the year ended December 31, 2007, was primarily attributable to:

- A decrease of $0.5 million in consulting and other administrative services due to cost saving measures associated with the reduction in force in July 2008, and;

- A decrease of $0.2 million due to reductions in spending for trade shows, travel and marketing materials; partially offset by

- An increase of $0.2 million in rent, depreciation on equipment and facilities costs due to expansion of our manufacturing capacity prior to the reduction in force in July 2008, and;

- An increase of $0.1 million in personnel costs related to an increase of $0.3 million in stock compensation expense related to higher stock option grants in 2008 as compared to 2007, offset by a decrease of $0.2 million in personnel costs as a result of our reduction in force in July 2008.

We expect our general and administrative expenses to decrease significantly as we implement additional cost savings measures in early 2009 associated with the March 2009 reduction in force.

Interest and Other Income, Net

	Years Ended December 31, 2008	2007	Dollar Change
	(in thousands)		
Interest and other income, net	$ 966	$ 3,363	$ (2,397)

The $2.4 million decrease in interest and other income for the year ended December 31, 2008, compared to the year ended December 31, 2007, was primarily attributable to a decrease in the average levels of cash, cash equivalents and short-term investments as well as lower average 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, 2008, we had net operating loss carry-forwards of approximately $94.8 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 2015. As of December 31, 2008, we had research and development credit carry-forwards of approximately $4.2 million and $4.4 million available to reduce future taxable income, if any, for Federal and California state income tax purposes, respectively. The Federal income tax research and development credits carry-forwards begin expiring in 2022, and the California state income tax research and development credits carry-forward indefinitely.

Section 382 of the Internal Revenue Code generally imposes an annual limitation on the amount of net operating loss carry-forwards 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 any future sales of our equity securities, may adversely affect our ability to use our

Table of Contents

remaining net operating loss carry-forwards. If our ability to use net operating loss carry-forwards 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 carry-forwards.

Comparison of Years Ended December 31, 2007 And 2006

Revenue. We did not generate any revenue during the years ended December 31, 2007 or 2006.

Research and Development

	Years Ended December 31,		Dollar Change
	2007	2006	
	(in thousands)		
Research and development expenses	$ 30,888	$ 18,923	$ 11,965

The $12.0 million increase in research and development expenses for the year ended December 31, 2007, compared to the year ended December 31, 2006, was primarily attributable to:

- An increase of $5.3 million for prototype parts, supplies, and outside services related to product development for our Custom NX DES Systems, net of a $0.4 million decrease in non-employee stock-based compensation;

- An increase of $4.2 million in personnel costs related to the hiring of additional employees in our research and development and manufacturing departments;

- An increase of $1.7 million in expenses related to the support of our clinical research studies;

- An increase of $0.8 million in depreciation on equipment and facilities costs as we expanded our manufacturing capacity; and

- An increase of $0.7 million in employee stock-based compensation expense.

- These increases were partially offset by a $0.7 million decrease in patent and licensing fees in the year ended December 31, 2007. We did not make a license payment to these two licensors during the year ended December 31, 2007.

General and Administrative

	Years Ended December 31,		
	2007	2006	Dollar Change
	(in thousands)		
General and administrative expenses	$ 11,269	$ 7,258	$ 4,011

The $4.0 million increase in general and administrative expenses for the year ended December 31, 2007, compared to the year ended December 31, 2006, was primarily attributable to:

- An increase of $1.5 million in personnel costs related to the hiring of additional employees in our finance and administration and marketing departments;

- An increase of $1.1 million in employee stock-based compensation expense;

- An increase of $0.8 million in consulting, legal and professional services associated with operating as a public company;

- An increase of $0.6 million due to spending for trade shows, travel and marketing materials; and

- An increase of $0.5 million in insurance and other administrative expenses associated with operating as a public company.

Table of Contents

- These increases were partially offset by a $0.3 million decrease in accounting fees in the year ended December 31, 2007, compared to the year ended December 31, 2006. Higher accounting fees were incurred during the year ended December 31, 2006 while preparing for our Initial Public Offering in February 2007.

- These increases were also partially offset by a $0.2 million decrease in compensation costs in the year ended December 31, 2007, compared to the year ended December 31, 2006, due to a $0.2 million relocation bonus that was paid to our Chief Financial Officer in April 2006.

Interest and Other Income, Net

	Years Ended December 31,		Dollar Change
	2007	2006	
	(in thousands)		
Interest and other income, net	$ 3,363	$ 1,137	$ 2,226

The $2.2 million increase in interest and other income for the year ended December 31, 2007, compared to the year ended December 31, 2006, was primarily attributable to an increase in the levels of cash, cash equivalents and short-term investments as a result of our Initial Public Offering in February 2007.

Liquidity And Capital Resources

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

	As of December 31, 2008	As of December 31, 2007
	(in thousands)	
Cash and cash equivalents	$ 13,373	$ 13,366
Short-term investments	5,752	44,394
Total cash and cash equivalents and short-term investments	$ 19,125	$ 57,760

Sources of Liquidity

We are in the development stage and have incurred losses since our Inception in June 2002. As of December 31, 2008, we had an accumulated deficit of $134.0 million. Prior to our Initial Public Offering, we funded our operations from the private placements of our convertible preferred stock resulting in aggregate net proceeds of $75.6 million through December 31, 2006. On February 1, 2007, we completed our Initial Public Offering, raising $68.2 million in net proceeds. Upon completion of the reduction in force in March 2009, our cash requirements will be greatly reduced and we are working with Piper Jaffray & Co. to explore potential strategic alternatives, which may include, without limitation, a merger, a sale of substantially all our assets, a financing, or a sale of a portion of our assets, such as our peripheral stent product, our drug eluting balloon product or our bioabsorbable stent product. If we are not successful in identifying and completing a strategic transaction or securing adequate funding, we may not be able to continue our operations and may need to wind up our business and liquidate our assets.

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

As of December 31, 2008, we did not have any outstanding or available debt financing arrangements, we had working capital of $17.1 million, and our primary source of liquidity was $19.1 million in cash and cash equivalents and short-term investments.

Table of Contents

Summary of Cash Flows

Our operating, investing and financing activities for the year ended December 31, 2008 and December 31, 2007 are summarized as follows:

	Year Ended December 31,	
	2008	2007
	(in thousands)	
Net cash used in operating activities	$ (37,401)	$ (34,353)
Net cash provided by (used in) investing activities	37,151	(44,858)
Net cash provided by financing activities	257	69,472
Net increase (decrease) in cash and cash equivalents	7	$ (9,739)

Operating Activities

Net cash used in operating activities was $37.4 million for the year ended December 31, 2008, compared to $34.4 million for the year ended December 31, 2007. The net cash used in operating activities for the years ended December 31, 2008 and December 31, 2007 primarily reflects expenses related to product development and clinical trials. These expenses were offset in part by depreciation and amortization, non-cash stock-based compensation and non-cash changes in operating assets and liabilities.

Investing Activities

Net cash provided by investing activities was $37.2 million for the year ended December 31, 2008, compared to net cash used in investing activities of $44.9 million for the year ended December 31, 2007. Net cash provided by investing activities for the year ended December 31, 2008 was attributable to the maturity of short-term investments of $53.1 million and the proceeds from the sale of investments of $10.0 million, which were partially offset by the purchase of short-term investments of $24.1 million and the purchase of property and equipment of $1.8 million. The net cash used to purchase investments of $118.2 million during the year ended December 31, 2007 was derived from the cash raised by our Initial Public Offering in February 2007. Net cash used in investing activities for the year ended December 31, 2007 was primarily attributable to the purchase of property and equipment totaling $2.2 million. Net cash provided by investing activities for the year ended December 31, 2007 was attributable to the maturity of short-term investments of $71.6 million and the proceeds from the sale of investments of $4.0 million.

Financing Activities

Net cash provided by financing activities was $0.3 million for the year ended December 31, 2008, compared to $69.5 million for the year ended December 31, 2007. Net cash provided by financing activities for the year ended December 31, 2008 was primarily attributable to $0.3 million related to the issuance of common stock through the exercise of stock options and the Employee Stock Purchase Plan. Net cash provided by financing activities for the year ended December 31, 2007 was primarily attributable to our Initial Public Offering in February 2007.

Operating Capital and Capital Expenditure Requirements

To date, we have not commercialized any products. Even though we received CE Mark in March 2009 authorizing us to market our products in the European Union, we will not be able to commercialize our product unless we obtain additional financing, or we consummate a strategic transaction that permits us to commercialize in Europe. We can provide no assurance that such a financing or strategic transaction will be available on terms agreeable to us, or at all. 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. Our current cash and cash equivalents and short-term investments are not sufficient to meet the cash requirements of these activities.

In January 2009, we notified our employees that we were initiating a headcount reduction that would impact 115 of our 122 employees. We substantially completed this reduction on March 23, 2009 and expect to fully complete it by March 31, 2009. With this reduction, we believe that our cash and cash equivalents and short-term investments will be sufficient to meet our anticipated cash requirements through December 31, 2009, although our operations will be limited until such time

Table of Contents

as a strategic transaction is achieved. If we are successful in identifying and completing a strategic transaction, substantial changes may be made to our current operations or they may be completely discontinued. For example, if we are acquired by a third party, that third party may choose to not pursue some or any of our current product development initiatives, such as our Custom NX drug eluting stent systems, our Custom NX peripheral stent technology, our customizable drug eluting balloon technology or our bioabsorbable stent technology. If we are not successful in identifying and completing a strategic transaction or securing adequate funding, we may not be able to continue our operations and may need to wind up our business and liquidate our assets.

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

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

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

- the effect of competing technological and market developments; and

- licensing technologies for future development.

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

Contractual Obligations

The following table discloses aggregate information about our contractual obligations and the periods in which payments are due as of December 31, 2008:

		Payments Due by Period			
Contractual Obligations	**Total**	**2009**	**2010 to 2012**	**2013 to 2015**	**2016 and Later**
			(in thousands)		
Operating lease	$ 1,694	$ 479	$ 1,215	$	$
Minimum royalty obligations	1,680	155	540	540	445
Total	$ 3,374	$ 634	$ 1,755	$ 540	$ 445

The long-term commitments under operating leases shown above consist of payments related to our real estate lease in Menlo Park, California, which was amended in May 2007, extending the term of the lease through May 31, 2012. We may terminate the lease for any reason on or after May 1, 2010, and the landlord may terminate the lease on or after that date provided that the landlord has obtained certain redevelopment rights with respect to the leased premises.

Table of Contents

We have license agreements with Bisensors and SurModics under which we have minimum royalty commitments. The total royalty payments for these licenses are based on our net revenues and therefore have no maximum. To date, we have paid $140,000 in royalty payments to SurModics, and future commitments are shown in the table above, including an additional $20,000 milestone payment upon regulatory approval of our products. Minimum royalty payments to Biosensors of $100,000 per year begin upon CE Mark approval. In addition, we have paid $555,000 in milestone payments to date under license agreements with two other licensors.

In April 2007, we entered into a supply agreement with Fortimedix B.V., under which Fortimedix B.V. agreed to manufacture and deliver stents for use in our products. The terms of the agreement required minimum purchases over two years at contractual prices set in Euros. As of December 31, 2008, $5.6 million had been paid for purchases under this supply agreement. Based on the contract, any further purchase commitments have been delayed until we receive approval from the FDA to begin clinical trials in the United States.

In December 2007, we entered into the Amended and Restated License Agreement with Biosensors International Group, Ltd., under which we purchase the drug and polymer components for our drug coating. As of December 31, 2008, we have purchase commitments to Biosensors of approximately $43,000.

In October 2007, we entered into a Contract Research Organization Agreement with Bailer Research, Inc., under which Bailer agreed to provide certain monitoring services with respect to our then planned U.S. clinical trial. At the time of signing, the commitment under this contract was estimated to be from $11 to $13 million over a period of 79 months. Payments were to be made in installments based on trial related milestones, and were to begin upon approval from the FDA to begin the clinical trial. In December 2008, we provided Bailer with the 30-day notice to terminate this contract. No payments have been paid or are owed under the contract.

In January 2008, we entered into a contract with Cardiovascular Research Foundation, or CRF, under which CRF was to perform certain data coordination and analysis services in connection with our then planned clinical trial in the United States. We estimated that we would pay a total of $6.9 to $7.7 million to CRF over a period of approximately 75 months. Payments were to be made in installments based on related trial milestones. Upon signing this contract, we paid CRF approximately $638,000 as a prepayment against the initiation of the related services. In January 2009, we provided CRF with the 60-day notice to terminate this contract, and no further amounts are owed under the contract.

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.

Table of Contents

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 PMA 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 share-based payment awards granted, modified and settled to our employees and directors after January 1, 2006. During 2008, we granted stock options to employees to purchase approximately 1,079,000 shares of common stock with a weighted-average exercise price of $6.04 per share under the Black-Scholes valuation model.

Table of Contents

As of December 31, 2008, we had total unrecognized stock-based compensation costs of approximately $5.2 million arising from stock option grants through December 31, 2008, which is expected to be amortized as follows (in thousands):

Year Ending December 31, 2009	Year Ending December 31, 2010	Year Ending December 31, 2011	Year Ending December 31, 2012
$ 3,066	$ 1,667	$ 453	$ 43

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

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

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

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS No. 159). SFAS No. 159 expands the use of fair value accounting but does not affect existing standards which require assets or liabilities to be carried at fair value. The objective of SFAS No. 159 is to improve financial reporting by providing companies with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. Under SFAS No. 159, a company may elect to use fair value to measure eligible items at specified election dates and report unrealized gains and losses on items for which the fair value option has been elected in earnings at

each subsequent reporting date. Eligible items include, but are not limited to, accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees, issued debt and firm commitments. If elected, SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. Currently, we have not expanded our eligible items subject to the fair value option under SFAS No. 159. The adoption of SFAS 159 has not impacted our results of operations and financial condition.

In June 2007, the FASB ratified EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF No. 07-3). EITF No. 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development

Table of Contents

activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF No. 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. We are currently evaluating the effect that the adoption of EITF No. 07-3 will have on our results of operations and financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS No. 141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS No. 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of fiscal 2010. We continue to evaluate the potential impact of the adoption of SFAS No. 141(R) on our results of operations and financial condition.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest rate risk

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and investments in a variety of marketable securities, including commercial paper, money market funds and U.S. government securities. Our cash and cash equivalents as of December 31, 2008 consisted primarily of liquid money market funds and certificates of deposits and U.S. Treasury notes. Our short-term investments as of December 31, 2008 consisted primarily of U.S. government and agency securities. Due to the short-term nature of our investments, we believe that there is no material exposure to interest rate risk.

Exchange rate risk

Under our Supply Agreement with Fortimedix, we have market risk exposure to adverse changes in foreign exchange rates. The cost of the stents we purchase from Fortimedix requires payment in Euros. Fluctuations in the Euro to U.S. dollar exchange rate therefore impacts the cost of our product. In addition, we have expenses accrued in Euros for payments related to our Custom I, II, III and PK clinical trials. To date, we have not experienced any significant negative foreign exchange transaction losses. As a policy, we do not engage in speculative or leveraged transactions, nor do we hold financial instruments for trading purposes.

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

Table of Contents

ITEM 8. FINANCIAL STATEMENTS

XTENT, INC.

INDEX TO FINANCIAL STATEMENTS

Table of Contents

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 equity (deficit) and of cash flows present fairly, in all material respects, the financial position of XTENT, Inc. (a development stage company) at December 31, 2008 and 2007, and the results of its operations and its cash flows, for each of the three years in the period ended December 31, 2008 and, cumulatively for the period from June 13, 2002 (Inception) to December 31, 2008, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. 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.

/s/ PRICEWATERHOUSECOOPERS LLP

San Jose, California
March 24, 2009

Table of Contents

XTENT, INC.

(a development stage company)

BALANCE SHEETS

(in thousands, except per share amounts)

	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,373	$ 13,366
Short-term investments	5,752	44,394
Prepaid expenses and other current assets	432	905
Total current assets	19,557	58,665
Property and equipment, net	4,100	3,601
Other non-current assets	338	149
Total assets	$ 23,995	$ 62,415
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 943	$ 1,960
Accrued liabilities	1,544	2,124
Total current liabilities	2,487	4,084
Commitments and Contingencies (note 6)		
Stockholders equity		
Common stock: $0.001 par value 100,000 shares authorized at December 31, 2008 and December 31, 2007 23,325 and 23,015 shares issued and outstanding at December 31, 2008 and December 31, 2007, respectively	23	23
Additional paid-in capital	155,511	151,496
Deferred stock-based compensation	(56)	(364)
Accumulated other comprehensive income	11	36
Deficit accumulated during the development stage	(133,981)	(92,860)
Total stockholders equity	21,508	58,331
Total liabilities and stockholders equity	$ 23,995	$ 62,415

The accompanying notes are an integral part of these financial statements

Table of Contents

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,
	2008	2007	2006	2008
Operating expenses:				
Research and development (1)	$ 31,170	$ 30,888	$ 18,923	$ 105,584
General and administrative (1)	10,917	11,269	7,258	34,460
Total operating expenses	42,087	42,157	26,181	140,044
Loss from operations	(42,087)	(42,157)	(26,181)	(140,044)
Interest and other income, net	966	3,363	1,137	6,063
Net loss	(41,121)	(38,794)	(25,044)	(133,981)
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock			(13,095)	(13,095)
Net loss attributable to common stockholders	$ (41,121)	$ (38,794)	$ (38,139)	$ (147,076)
Net loss per share attributable to common stockholders - basic and diluted	$ (1.78)	$ (1.87)	$ (13.96)	
Weighted-average common shares outstanding - basic and diluted	23,116	20,703	2,732	
(1) Includes the following stock-based compensation charges:				
Research and development	$ 1,418	$ 1,490	$ 1,258	$ 4,479
General and administrative	$ 2,435	$ 2,088	$ 986	$ 5,589

The accompanying notes are an integral part of these financial statements

Table of Contents

XTENT, INC.

(a development stage company)

STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

(in thousands, except per share amounts)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders Equity (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 services	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)
Common stock issued in connection with our Initial Public Offering	4,700	5	68,232				68,237
Conversion of redeemable convertible preferred stock to common stock upon Initial Public Offering	14,744	15	75,578				75,593
Exercise of stock options for cash at $0.20 to $3.50 per share	192		111				111
Issuance of common stock under employee stock purchase plan	27		249				249
Vesting of restricted common stock from early exercises			101				101
Amortization of deferred stock-based compensation				285			285
Reversal of deferred stock-based compensation			(24)	24			
Stock-based compensation for non-employees			155				155
Employee stock-based compensation under SFAS No. 123R			3,138				3,138
Net loss						(38,794)	(38,794)
Net unrealized gains on available-for-sale securities					36		36
Total comprehensive loss							(38,758)
Balance at December 31, 2007	23,015	23	151,496	(364)	36	(92,860)	58,331
Exercise of stock options for cash at $0.20 to $9.20 per share	175		106				106
Issuance of common stock under employee stock purchase plan	85		151				151
Issuance of common stock for patent rights	50		150				150
Vesting of restricted common stock from early exercises			63				63
Amortization of deferred stock-based compensation				242			242
Reversal of deferred stock-based compensation			(66)	66			
Stock-based compensation for non-employees			21				21
Employee stock-based compensation under SFAS No. 123R			3,590				3,590
Net loss						(41,121)	(41,121)
Net unrealized loss on available-for-sale securties					(25)		(25)
Total comprehensive loss							(41,146)
Balance at December 31, 2008	23,325	$ 23	$ 155,511	$ (56)	$ 11	$ (133,981)	$ 21,508

The accompanying notes are an integral part of these financial statements

Table of Contents

XTENT, INC.

(a development stage company)

STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,			Cummulative Period from June 13, 2002 (Date of Inception) to December 31,
	2008	2007	2006	2008
Cash flows from operating activities:				
Net loss	$ (41,121)	$ (38,794)	$ (25,044)	$ (133,981)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	1,304	1,137	789	4,021
Accretion of securities discount	(366)	(1,705)		(2,071)
Loss (gain) on sale of investments	(26)	20		(6)
Loss on disposal of property and equipment	25	81	10	188
Stock-based compensation expense	3,853	3,578	2,244	10,068
Stock issued in exchange for services and patents	150		185	381
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(30)	(290)	(206)	(712)
Accrued interest receivable on securities	344	(372)		(28)
Accounts payable	(1,017)	1,100	332	828
Accrued liabilities	(517)	892	783	1,656
Net cash used in operating activities	(37,401)	(34,353)	(20,907)	(119,656)
Cash flows from investing activities:				
Purchase of investments	(24,084)	(118,238)		(142,322)
Proceeds from maturities of investments	53,130	71,579		124,709
Proceeds from sale of investments	9,963	3,986		13,949
Purchase of property and equipment	(1,830)	(2,185)	(1,661)	(8,306)
Restricted cash	(30)		150	(30)
Proceeds from sale of property and equipment	2		3	20
Net cash provided by (used in) investing activities	37,151	(44,858)	(1,508)	(11,980)
Cash flows from financing activities:				
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs			39,692	75,592
Proceeds from initial public offering, net of offering costs		69,112	(875)	68,237
Principal payments on capital lease obligations				(23)
Proceeds from issuance of common stock and exercise of stock options	257	360	139	1,203
Net cash provided by financing activities	257	69,472	38,956	145,009
Net increase (decrease) in cash and cash equivalents	7	(9,739)	16,541	13,373
Cash and cash equivalents at beginning of period	13,366	23,105	6,564	

Cash and cash equivalents at end of period	$ 13,373	$ 13,366	$ 23,105	$ 13,373
Supplemental disclosure of noncash investing and financing activities:				
Deferred stock-based compensation	$	$	$	$ 1,272
Reversal of deferred stock-based compensation	$ (66)	$ (24)	$ (71)	$ (161)
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	$ 63	$ 101	$ 115	$ 438
Deferred initial public offering costs	$	$ 875	$	$ 875
Changes in net unrealized gains on investments	$ (25)	$ 36	$	$ 11

The accompanying notes are an integral part of these financial statements

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

NOTE 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, 2008, the Company had an accumulated deficit of $134.0 million and cash and cash equivalents and short term investments of $19.1 million. The Company has not achieved positive cash flows from operations. 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 (the Initial Public Offering). In January 2009, the Company announced an initiative to reduce its workforce by 115, or 94%. See Note 13. The Company plans to explore strategic financing alternatives in the first half of 2009, which may include, without limitation, a merger, a sale of substantially all Company assets, a financing, or a sale of a portion of Company assets, such as the peripheral stent product, the drug eluting balloon product, or the bioabsorbable stent product. If the Company is successful in identifying and completing a suitable strategic transaction, substantial changes may be made in its operations. Upon completion of the headcount reduction in the first quarter of 2009, the Company expects that it will have enough cash and cash equivalents to fund limited operations through at least December 31, 2009. If a strategic transaction is not completed or adequate funding is not obtained, the Company will be unable to continue operations and may need to wind up its business and liquidate its assets. .

Management continues to work toward its objective of creating corporate value 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.

NOTE 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. The primary estimates underlying our financial statements include the fair value of our investment portfolio, income tax valuation, and assumptions regarding variables used in calculating the fair value of our equity awards. 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 at the date of purchase to be cash equivalents. The Company deposits cash and cash equivalents with high credit quality financial institutions. Cash equivalents consist primarily of money market funds and U.S. Treasury notes.

Investments

Investments with an original maturity of more than three months and less than one year at the date of purchase are considered to be short-term. Investments consist primarily of fixed income securities. The Company classifies its investments as available-for-sale in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities,* and they are recorded at fair value. The fair value of investments is based on quoted market prices. As of December 31, 2008, all of the Company s investments were short-term in nature.

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

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

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

Restricted Cash

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

Concentration of Credit Risk

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

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.

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 and its Initial Public Offering in February 2007. The Company plans to explore strategic financing alternatives in the first half of 2009, which may include, without limitation, a merger, a sale of substantially all Company assets, a financing, or a sale of a portion

of Company assets, such as the peripheral stent product, the drug eluting balloon product, or the bioabsorbable stent product.

If the Company is successful in identifying and completing a strategic transaction, substantial changes may be made to its current operations or the Company may discontinue its operations entirely if an acquiring Company does not pursue some or all of the ongoing product development initiatives. See Subsequent Events, Note 13.

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, drug coating for stents, stent structure, catheters used to deliver stents and the stent manufacturing process.

The Company is wholly dependent on Biosensors, the sole vendor for the development, manufacture and supply of the drug coating placed on the Company s stents, and no alternative source is available. Any delay or failure to adequately develop or supply the drug coating by this vendor or the submission of a drug master file, or MAF, to regulatory authorities could delay the Company s clinical trials or prevent or delay commercialization of the Company s product. The loss of this sole vendor, the deterioration of the Company s relationship with this sole vendor, or a significant increase in the price of the drug coating that we purchase from this sole vendor could have a material adverse effect on the Company s financial position and results of operations.

The Company also depends on other vendors as sole suppliers of materials used in manufacturing the Company s product. The loss of any of these vendors could cause delays in the production of the Company s product and have a material adverse effect on the Company s financial position, results of operations, or cash flows.

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

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

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 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. If additional funding is obtained, 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.

Fair Value of Financial Instruments

The carrying amounts of the Company s financial instruments including cash and cash equivalents, accounts payable, and accrued liabilities which approximate fair value due to their short maturities. The Company s short-term investments are valued at fair value based on quoted market prices.

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.

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, manufacturing of clinical and prototype units, 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.

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

Comprehensive Income (Loss)

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

Net Loss per Common Share

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

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

	Years Ended December 31,		
	2008	2007	2006
	(in thousands, except per share amounts)		
Numerator:			
Net loss	$ (41,121)	$ (38,794)	$ (25,044)
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock			(13,095)
Net loss attributable to common stockholders	$ (41,121)	$ (38,794)	$ (38,139)
Denominator:			
Weighted-average common shares outstanding	23,175	20,979	3,264
Less: Weighted-average unvested common shares subject to repurchase	(59)	(276)	(532)
Weighted-average common shares outstanding used in computing basic and diluted net loss per common share	23,116	20,703	2,732
Net loss per share attributable to common stockholders - basic and diluted	$ (1.78)	$ (1.87)	$ (13.96)

67

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

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

	Years Ended December 31,		
	2008	2007	2006
		(in thousands)	
Redeemable convertible preferred stock			14,744
Options to purchase common stock	2,516	2,167	1,894
Common stock subject to repurchase	7	164	417
Shares issuable under Employee Stock Purchase Plan	57	11	

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 Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations, with disclosures in accordance with Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), 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.

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 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 uses 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 does 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 evaluates the

assumptions used to value stock awards on a quarterly basis.

The Company accounts for stock-based compensation arrangements with 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 fair value of the equity instrument as estimated using the Black-Scholes pricing model. The fair value of the equity instrument is charged to operating expense 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 were 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.

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

Recent Accounting Pronouncements

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

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

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS No. 159). SFAS No. 159 expands the use of fair value accounting but does not affect existing standards which require assets or liabilities to be carried at fair value. The objective of SFAS No. 159 is to improve financial reporting by providing companies with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. Under SFAS No. 159, a company may elect to use fair value to measure eligible items at specified election dates and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. Eligible items include, but are not limited to, accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees, issued debt and firm commitments. If elected, SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. Currently, The Company has not expanded its eligible items subject to the fair value option under SFAS No. 159. The adoption of SFAS 159 has not impacted the Company s results of operations and financial condition.

In June 2007, the FASB ratified EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF No. 07-3). EITF No. 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF No. 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007. The Company is currently evaluating the effect that the adoption of EITF No. 07-3 will have on the Company s results of operations and financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS No. 141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS No. 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008, and will be adopted by the Company in the first quarter of fiscal 2010. The Company continues to evaluate the potential impact of the adoption of SFAS No. 141(R) on its results of operations and financial condition.

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

NOTE 3. INVESTMENTS

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

As of December 31, 2008	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(in thousands)		
U.S. government and agency securities	$ 5,741	$ 11	$	$ 5,752

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

Fair Value Measurements

On January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements* for financial assets and liabilities. This standard defines fair value as the price that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). SFAS No. 157 classifies the inputs used to measure fair value into the following hierarchy:

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

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

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

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

The Company s cash equivalents and short-term investments are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The fair value hierarchy of the Company s marketable securities at fair value in connection with the adoption of SFAS No. 157 consisted of the following as of December 31, 2008:

	Balance as of December 31, 2008	Significant Other Observable Inputs (Level 1) (in thousands)	Significant Other Observable Inputs (Level 2)
Money market funds (1)	$ 11,613	$ 11,613	$
U.S. Treasury Notes (1)	1,003		1,003
U.S. government and agency securities	5,752		5,752
Total	$ 18,368	$ 11,613	$ 6,755

(1) Amounts are classified as part of cash equivalents on the balance sheet

NOTE 4. PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	December 31,	
	2008	2007
	(in thousands)	
Computer equipment	$ 779	$ 765
Machinery and equipment	4,672	4,225
Furniture and fixtures	482	379
Construction in progress	1,544	377
Leasehold improvements	443	403
	7,920	6,149
Less: Accumulated depreciation and amortization	(3,820)	(2,548)
Property and equipment, net	$ 4,100	$ 3,601

Depreciation and amortization expense for the years ended December 31, 2008, 2007 and 2006 and cumulatively, for the period from June 13, 2002 (Inception) to December 31, 2008 was approximately $1.3 million, $1.1 million, $0.8 million and $4.0 million, respectively.

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

NOTE 5. ACCRUED LIABILITIES

Accrued liabilities consist of the following:

	As of December 31,	
	2008	**2007**
	(in thousands)	
Compensation and benefits	$ 572	$ 671
Stock options exercised subject to repurchase	3	66
Clinical trials	760	1,077
Contributions under Employee Stock Purchase Plan	32	89
Sales taxes payable	16	38
Professional fees	117	123
Other accrued liabilities	44	60
	$ 1,544	**$ 2,124**

NOTE 6. COMMITMENTS AND CONTINGENCIES

Operating Lease Commitments

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

Future minimum lease payments under non-cancelable operating leases are as follows:

	Total	**2009**	**2010**	**2011**	**2012**
			(in thousands)		
Minimum lease commitments	**$ 1,694**	**$ 479**	**$ 493**	**$ 508**	**$ 214**

Rent expense for the years ended December 31, 2008, 2007, and 2006, and cumulatively for the period from June 13, 2002 (Inception) to December 31, 2008 was approximately $407,000, $333,000, $224,000 and $1.3 million, 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.

License Agreements

The Company has entered into license agreements with Biosensors and SurModics for proprietary materials that are critical to the success of the Company s products. The terms of the agreements call for milestone payments prior to achieving sales, and quarterly royalty payments based on the greater of specified minimums or a percentage of net sales. As of December 31, 2008, future minimum royalty payments these suppliers are approximate $1.7 million, and minimum royalty payments during the years ended December 31, 2008, 2007 and 2006 were $80,000, $40,000 and $20,000, respectively. An additional $20,000 milestone payment is payable to SurModics upon achievement of certain milestones. Minimum royalty to Biosensors payments of $100,000 per year will begin upon achievement of certain milestones.

In July 2006, the Company entered into a license agreement with Millimed, Inc. for certain intellectual property related to the Company s business. In consideration for this license, the Company made an initial payment of $350,000 in cash and issued 15,000 shares of common stock during the year ended December 31, 2006. In addition, the license agreement

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

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

Purchase Commitments

In April 2007, the Company entered into a supply agreement with Fortimedix B.V, under which Fortimedix B.V. agreed to manufacture and deliver stents for use in the Company s products. The terms of the agreement required minimum purchases over two years at contractual prices set in Euros. As of December 31, 2008, there were no outstanding purchase order commitments for stents. Under the terms of the supply agreement, any further annual purchase commitments have been delayed until the Company receives approval from the FDA to begin clinical trials in the United States.

In December 2007, the Company entered into the Amended and Restated License Agreement with Biosensors International Group, Ltd., under which the Company purchases the drug coating used on its stents under purchase commitments which totaled approximately $43,000 as of December 31, 2008. In addition, the Company will also pay royalties to Biosensors under the license agreement when revenues are generated from product sales.

On October 17, 2007, the Company entered into a Contract Research Organization Agreement with Bailer Research, Inc., under which Bailer will provide certain monitoring services with respect to the Company s United States clinical trial when approval is received from the FDA to begin the clinical trial. The commitment under this contract is estimated to be from $11 to $13 million over a period of 79 months. Payments will be made in installments based on trial related milestones. On December 19, 2008, the Company provided to Bailer a 30-day termination notice with respect to the Contract Research Organization Agreement under which Bailer was to provide certain monitoring services with respect to the planned U.S. clinical trial. No payments have been made and no expense has been incurred related to this contract.

On January 28, 2008 the Company entered into a contract with Cardiovascular Research Foundation (CRF) under which CRF will perform certain data coordination and analysis services in connection with the Company s clinical trial in the United States. The Company estimates that a total of $6.9 to $7.7 million will be paid to CRF over a period of approximately 75 months. Payments will be made in installments based on related trial milestones. See Note 13, Subsequent Events.

On April 7, 2008, the Company entered into an agreement with Vascotube GMBH under which the Company has committed to purchase minimum quantities of material over the next twelve month period. As of December 31, 2008, the Company has a remaining commitment in the

amount of approximately $389,000 remaining under this agreement. See Note 13, Subsequent Events.

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.

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

NOTE 7. PREFERRED STOCK

Our certificate of incorporation, as amended and restated, authorizes us to issue 10 million shares of $.001 par value preferred stock. As of December 31, 2008 or 2007, no preferred stock was issued or outstanding.

NOTE 8. COMMON STOCK

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

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

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

Restricted common stock

Certain common stock option holders have the right to exercise unvested options, subject to a repurchase right held by the Company to repurchase the stock, at the original exercise price, in the event of voluntary or involuntary termination of employment of the stockholder. In accordance with Emerging Issues Task Force Issue No. 00-23, *Issues Related to the Accounting for Stock Compensation* under APB 25 and FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, the Company accounts for the cash received in consideration for the early exercised options as a liability. As of December 31, 2008 and December 31, 2007, there were approximately 7,000 and 164,000 shares of common stock, respectively, subject to repurchase, and a related liability of $3,000 and $66,000, respectively.

NOTE 9. STOCK PLANS

Employee Stock Purchase Plan

In August 2006, the Company adopted the 2006 Employee Stock Purchase Plan (ESPP), which became effective upon the Company s Initial Public Offering on February 1, 2007. A total of 1,190,000 shares of common stock have been reserved for issuance pursuant to the ESPP. In addition, the ESPP provides for annual increases in the number of shares available for issuance under the ESPP on the first day of each fiscal year, beginning with the Company s fiscal year 2008, equal to the lesser of: 3% of the outstanding shares of the Company s common stock on the first day of the fiscal year; 1,000,000 shares; or such other amount as the Company s Board of Directors may determine. All of the Company s employees are eligible to participate if they are customarily employed by the Company for at least 20 hours per week and more than five months in any calendar year. However, an employee may not be granted an option to purchase stock under the ESPP if such employee, immediately after grant, owns stock possessing 5% or more of the total combined voting power or value of all classes of the Company s capital stock, or whose rights to purchase stock under all of the Company s employee stock purchase plans accrues at a rate that exceeds $25,000 worth of stock for each calendar year.

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

Amounts deducted and accumulated by the participant are used to purchase shares of the Company s common stock at the end of each six-month purchase period. The purchase price of the shares will be 85% of the lower of the fair market value of the Company s common stock on the first trading day of each offering period or on the exercise date. Participants may end their participation at any time during an offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon termination of employment with the Company. The ESPP will automatically terminate in 2026, unless the Company terminates it sooner.

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

During the years ended December 31, 2008 and 2007, we issued approximately 85,000 and 27,000 shares, respectively, under the ESPP, representing $151,000 and $249,000, respectively, of employee contributions. As of December 31, 2008, 1,078,000 shares were available for issuance under the ESPP.

Stock Option Plans

In July 2002, the Company adopted the 2002 Stock Option Plan (the 2002 Plan). The 2002 Plan was terminated upon completion of the Company s initial public offering on February 1, 2007. No shares of common stock are available under the 2002 Plan other than to satisfy the exercises of stock options granted under the 2002 Plan prior to its termination. Under the 2002 Plan, incentive stock options (ISO) and nonqualified stock options (NSO) were granted to employees, officers, and directors of, or consultants to, the Company. Options granted under the 2002 Plan expire no later than 10 years from the date of grant.

In August 2006, the Company adopted the 2006 Equity Incentive Plan (the 2006 Plan), which became effective upon the Company s Initial Public Offering on February 1, 2007. The shares reserved for issuance under the 2006 Plan include (a) those shares reserved but unissued under the 2002 Stock Plan as of January 31, 2007 (b) shares returned to the 2002 Stock Plan as the result of termination of options or the repurchase of shares (provided that the maximum number of shares that may be added to the 2006 Equity Incentive Plan pursuant to (a) and (b) is 600,000 shares). Beginning in 2008, the number of shares available for issuance under the 2006 Equity Incentive Plan will be increased annually on the first day of each fiscal year by an amount equal to the lesser of (i) 4% of the outstanding shares of common stock as of the last day of our immediately preceding fiscal year; (ii) 1,500,000 shares; or (iii) such other amount as the Company s board of directors may determine.

During the year ended December 31, 2008, 1,821,000 shares were added to the shares reserved for issuance under the 2006 Plan, and 1,079,000 stock options were granted under the 2006 Plan during the year ended December 31, 2008. Through December 31, 2008, the Company had reserved 5,816,000 shares of common stock for issuance under both the 2002 Plan and 2006 Plan. As of December 31, 2008, 2,511,000 shares were outstanding and 1,364,000 shares were available for future issuance under the 2006 Plan.

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

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

Stock option activity is as follows:

	Shares Available for Grant	Options Outstanding			
		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 cancelled	43	(43)	1.50		
Balances, December 31, 2006	132	1,894	$ 3.09		
Additional shares reserved	400				
Options granted	(561)	561	10.32		
Options exercised		(192)	0.58		
Options cancelled	96	(96)	4.57		
Balances, December 31, 2007	67	2,167	$ 5.12		
Additional shares reserved	1,821				
Options granted	(1,079)	1,079	6.04		
Options exercised		(175)	0.61		

Options cancelled	555	(555)		6.75		
Balances, December 31, 2008	1,364	2,516	$	5.47	7.91	$ 1
Options vested and expected to vest at December 31, 2008		2,429	$	5.45	7.87	$ 1
Options vested and exercisable at December 31, 2008		1,209	$	4.75	7.03	$ 1

The total intrinsic value of options exercised during the years ended December 31, 2008 and December 31, 2007 was approximately $0.7 million and $2.2 million, respectively. The intrinsic value is calculated as the difference between the market value on the date of exercise and the exercise price of the shares. The market value of the Company s common stock as of December 31, 2008 was $0.27. The total fair value of options granted to employees and which vested during the years ended December 31, 2008 and December 31, 2007 was $3.5 million and $3.1 million, respectively.

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

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

	Options Outstanding at December 31, 2008			Options Vested and Exercisable at December 31, 2008	
Exercise Price	Number	Weighted - Average Remaining Contractual Life (Years)	Number		Weighted - Average Exercise Price
	(in thousands, except weighted average remaining contractual life and weighted average exercise price)				
$0.20 - $0.20	304	5.42	292	$	0.39
$0.54 - $1.5	190	6.98	137		1.19
$2.10 - $2.99	339	9.45	22		2.50
$3.50 - $4.56	408	7.61	227		3.52
$5.00 - $5.20	339	8.50	125		5.15
$6.52 - $7.82	62	7.99	43		7.72
$8.00 - $8.94	114	7.72	78		8.77
$9.06 - $9.99	548	8.66	191		9.67
$10.08 - $11.20	134	8.15	58		10.78
$12.32 - $16.00	78	7.99	36		13.39
	2,516	7.91	1,209	$	4.75

	Options Outstanding at December 31, 2007			Options Vested and Exercisable at December 31, 2007	
Exercise Price	Number	Weighted - Average Remaining Contractual Life (Years)	Number		Weighted - Average Exercise Price
	(in thousands, except weighted average remaining contractual life and weighted average exercise price)				
$0.20 - $0.20	35	5.08	35	$	0.20
$0.40 - $0.40	426	6.61	312		0.40
$0.54 - $1.50	217	7.90	103		1.13
$3.50 - $3.50	522	8.32	209		3.50
$5.20 - $7.82	239	8.47	111		6.05
$8.00 - $9.20	300	9.30	36		9.20
$9.58 - $10.52	244	9.77	5		9.99
$11.00 - $13.00	143	9.03	25		11.86
$15.44 - $15.44	11	9.11			0

$16.00 - $16.00	30	9.08			0
	2,167	8.27	836	$	2.79

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

The weighted-average per share fair value of options granted to employees during the years ending December 31, 2008, 2007 and 2006 was $3.04, $5.11, 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 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 through our Initial Public Offering on February 1, 2007. 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 recorded deferred stock-based compensation related to these stock options of approximately $1,272,000, net of cancellations. During the years ended December 31, 2008 and 2007, the Company recorded cancellations of deferred stock-based compensation of approximately $66,000 and $24,000, respectively.

Amortization of deferred stock-based compensation was approximately $242,000, $285,000 and $302,000 for the years ended December 31, 2008, 2007 and 2006, respectively. For options granted during 2007 and 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
March 31, 2007	66	15.01	15.82	0.81

Subsequent to the Company s Initial Public Offering, no further stock options were granted with exercise prices below fair value.

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

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,		
	2008	2007	2006
		(in thousands)	
Research and development	$ 1,418	$ 1,490	$ 1,258
General and administrative	2,435	2,088	986
Total stock-based compensation expense	$ 3,853	$ 3,578	$ 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.

As of December 31, 2008, there was total unrecognized stock-based compensation costs of approximately $5.2 million related to outstanding stock options. These costs are expected to be recognized over a period of 2.6 years.

The Company estimates 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 and stock purchase rights granted under the Company s employee stock purchase plan was estimated using the following weighted-average assumptions for the years ended December 31, 2008, 2007 and 2006:

	Year Ended December 31, 2008	Year Ended December 31, 2007	Year Ended December 31, 2006
Stock Options:			
Expected volatility	60% to 76%	51% to 54%	58% to 70%
Risk free rate	2.45% to 3.57%	3.51% 5.10%	4.38% 4.95%
Dividend yield	0%	0%	0%
Expected term (in years)	4.5 to 4.65	4.65	5.75 to 6.25
ESPP:			
Expected volatility	42% to 120%	42% to 50%	N/A

Risk free rate	.81% to 3.56%	3.56% 5.13%	N/A
Dividend yield	0%	0%	N/A
Expected term (in years)	0.5	.49 to .79	N/A

The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding and is based on the option vesting term, contractual terms and industry peers as the Company did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. Beginning in 2008, the expected term assumption was derived based on the Company s historical settlement experience. ESPP terms are for the purchase periods starting February 1, 2007 (Initial Public Offering) and May 15, 2007, both of which ended on November 15, 2007, and the purchase periods starting November 15, 2007 and May 18, 2008 which ended on May 15, 2008 and November 17, 2008, respectively, and the purchase period beginning November 17, 2008 will end on May 15, 2009.

The expected stock price volatility assumptions for the Company s stock options and ESPP for the years ended December 31, 2008, 2007 and 2006 were determined by examining the historical volatilities for industry peers and subsequent to the Initial Public Offering on February 1, 2007, in combination with the historical volatility of the Company s stock. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company s common stock becomes available.

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

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

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

Non-Employee Stock-based Compensation

No shares of common stock were granted to non-employees during the years ended December 31, 2008 or 2007. During the years ended December 31, 2006 and 2005, the Company granted 51,000 and 39,750 shares, respectively, of common stock at exercise prices ranging from $0.40 to $11.20 per share in exchange for services from consultants. In connection with the change of status from employee to consultant for an employee, the Company allowed for the continued vesting of equity instruments over the designated consulting period. Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services rendered.

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

	Year Ended December 31,		
	2008	**2007**	**2006**
Risk-free interest rate	1.92% to 4.25%	3.83% to 5.00%	4.53% to 5.25%
Expected life (in years)	6 to 10	6 to 10	6 to 10
Dividend yield	0%	0%	0%
Expected volatility	56% to 65%	56% to 57%	58% to 70%

Stock-based compensation expense will fluctuate as the fair value of the common stock fluctuates. In connection with the grant of stock and stock options to non-employees, the Company recorded stock-based compensation charges of approximately $21,000, $0.1 million, $0.5 million and $0.8 million for the years ended December 31, 2008, 2007, and 2006, and cumulatively, for the period from June 13, 2002 (Inception) to December 31, 2008, respectively.

NOTE 10. 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, 2008, 2007 and 2006. The Company recorded a tax benefit of $39,000 for the year ended December 31, 2008 primarily due to recognition of a benefit of $39,000 for a U.S. federal refundable credit as provided by the Housing and Economic Recovery Act of 2008 (The Recovery Act). The Recovery Act, signed into law in July 2008, allows taxpayers to claim refundable alternative minimum tax or research and development credit carryovers if they forego bonus depreciation on certain qualified fixed assets placed in service from the period between April and December 2008.

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

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,	
	2008	2007
Deferred tax assets:		
Net operating loss carryforwards	$ 37,754	$ 25,321
Research & development credit carryforwards and other	7,111	5,257
Capitalized start-up costs	10,917	8,515
Other	2,384	1,749
	58,166	40,842
Valuation allowance	(58,166)	(40,842)
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 $17,324,000, $16,768,000 and $11,024,000 during the years ended December 31, 2008, 2007 and 2006, respectively.

As of December 31, 2008, the Company had net operating loss carry-forwards of approximately $94.8 million each 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 2015.

As of December 31, 2008, the Company had research and development credit carry-forwards of approximately $4.2 million and $4.4 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.

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.

Effective January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board Interpretation No. 48 (FIN No. 48), Accounting for Uncertainty in Income Taxes, which provisions included a two-step approach to recognizing, de-recognizing and measuring uncertain tax positions accounted for in accordance with SFAS No. 109 (SFAS No. 109), Accounting for Income Taxes. Before the adoption of FIN No. 48, the Company had no liability for unrecognized tax benefits. As a result of the implementation of FIN No. 48, the Company recognized no change in the liability for unrecognized tax benefits. As of December 31, 2008, the liability for unrecognized tax benefits was $0.

Our continuing practice is to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2008, the Company had no accrued interest and penalties related to uncertain tax matters.

The Company does not have any unrecognized tax liabilities that would be reduced as a result of a lapse of the applicable statute of limitations during the next twelve months.

NOTE 11. REDUCTION IN FORCE

On July 10, 2008, the Company announced an initiative to reduce employee headcount by eliminating 46 regular jobs and 26 temporary positions. This reduction represented approximately 34% of the total workforce and was completed in July 2008. The total cash payments and expenses incurred in connection with this reduction in workforce was approximately $210,000, of which $170,000 was included in research and development and $40,000 was included in general and administrative in the Statement of Operations. The total expense included approximately $7,000 of non-cash expenses. All amounts were paid during the quarter ended September 30, 2008. See Note 13.

NOTE 12. 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, 2008, no contributions have been made.

Table of Contents

XTENT, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

NOTE 13. SUBSEQUENT EVENTS

On January 7, 2009, the Company provided to Cardiovascular Research Foundation (CRF) a 60-day termination notice with respect to the contract under which CRF was to perform certain data coordination and analysis services in connection with the planned U.S. clinical trial. A payment of $638,000 had been made upon the signing of this contract, and no further amounts are owed.

On January 21, 2009, the Company approved an initiative to reduce its headcount by 115, or 94% of the Company s workforce. The total expense to be incurred in connection with the initiative is estimated at approximately $1.1 to $1.2 million, all of which are expected to be cash expenditures. Most of the expenses are expected to be incurred in the first quarter of 2009.

In February 2009, the Letter of Intent with Vascotube was terminated, and all related purchase commitment under the agreement were released.

NOTE 14. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

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

	Fiscal 2008 Quarters Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share amounts)			
Net loss	$ (12,457)	$ (12,886)	$ (8,665)	$ (7,113)
Net loss attibutable to common stockholders	$ (12,457)	$ (12,886)	$ (8,665)	$ (7,113)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.54)	$ (0.56)	$ (0.37)	$ (0.31)
Weighted-average common shares outstanding used in computing basic and diluted net loss per common share	22,923	23,033	23,211	23,294

	Fiscal 2007 Quarters Ended			
	March 31,	June 30,	September 30,	December 31,
	(in thousands, except per share amounts)			
Net loss	$ (7,935)	$ (9,456)	$ (9,539)	$ (11,864)

Net loss attibutable to common stockholders	$ (7,935)	$ (9,456)	$ (9,539)	$ (11,864)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.55)	$ (0.42)	$ (0.42)	$ (0.52)
Weighted-average common shares outstanding used in computing basic and diluted net loss per common share	14,482	22,551	22,656	22,790

Table of Contents

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, 2008.

Changes in Internal Control Over Financial Reporting

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

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2008. This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by our independent registered public accounting firm

pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management s report in this Annual Report on Form 10-K.

ITEM 9B. OTHER INFORMATION

None.

Table of Contents

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 2009 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our 2008 fiscal year (the 2009 Proxy Statement).

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the 2009 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 2009 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated by reference to the 2009 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to the 2009 Proxy Statement.

Table of Contents

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	(1)	Amended and Restated Certificate of Incorporation.
3.4	(1)	Amended and Restated Bylaws.
4.1	(1)	Specimen Common Stock certificate of the Registrant.
10.1	(1)	Form of Indemnification Agreement for directors and executive officers.
10.2	(1)	2002 Stock Plan and form of stock option agreements used thereunder.
10.3	(1)	2006 Equity Incentive Plan and form of stock option agreement used thereunder.
10.4	(1)	2006 Employee Stock Purchase Plan.
10.5	(1)	Amended and Restated Investor Rights Agreement dated May 5, 2006 by and among the Registrant and certain stockholders.
10.6	(1)	Business Park Lease dated September 15, 2003, as amended November 22, 2005, by and between the Registrant and 125 Constitution Associates, L.P. for office space located at 125 Constitution Drive, Menlo Park, California, 94025-1118.
10.7	(1)	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	(1)	Master License Agreement dated December 30, 2002, as amended June 30, 2006, by and between the Registrant and SurModics, Inc.
10.9	(1)	License Agreement dated July 10, 2006 by and between the Registrant and Millimed A/S.
10.10	(2)	Supply Agreement dated April 2, 2007 by and between Registrant and Fortimedix B.V.
10.11	(3)	Second Amendment to Lease dated May 17, 2007 by and between the Registrant and 125 Constitution Associates, L.P.
10.12	(4)	Amended and Restated License Agreement dated December 3, 2007 by and between Registrant, Biosensors International Group, Ltd. and Biosensors Europe S.A.
10.13	(5)	Amended 2006 Equity Incentive Plan and form of stock option agreement used thereunder.
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.

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

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

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

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

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

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

Table of Contents

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: March 24, 2009

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 Gregory D. Casciaro	President, Chief Executive Officer and Director (Principal Executive Officer)	March 24, 2009
/s/ TIMOTHY D. KAHLENBERG Timothy D. Kahlenberg	Chief Financial Officer (Principal Accounting Officer)	March 24, 2009
/s/ HENRY A. PLAIN, JR. Henry A. Plain, Jr.	Director	March 24, 2009
/s/ MICHAEL A. CARUSI Michael A. Carusi	Director	March 24, 2009
/s/ MICHAEL L. EAGLE Michael L. Eagle	Director	March 24, 2009
/s/ ROBERT E. FLAHERTY Robert E. Flaherty	Director	March 24, 2009
/s/ CHRISTOPHER M. SMITH Christopher M. Smith	Director	March 24, 2009
/s/ ARTHUR T. TAYLOR Arthur T. Taylor	Director	March 24, 2009

/s/ EDWARD W. UNKART Edward W. Unkart	Director	March 24, 2009
/s/ ALLAN R. WILL Allan R. Will	Director	March 24, 2009