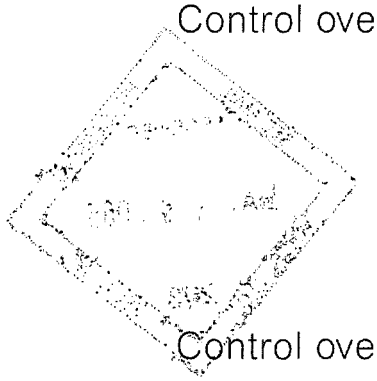
CONOR
MEDSYSTEMS

Arls

Announcing an advance in controlled drug delivery.

Control over multiple drug delivery.



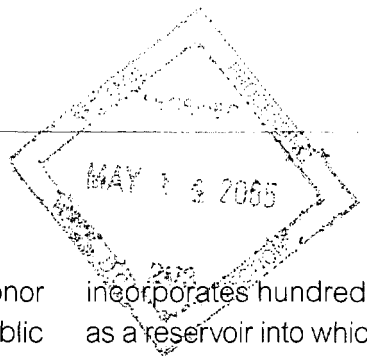
Control over dosage.

Control over direction.

Control over duration.

Imagine where all this can go.

CONOR



To Our Stockholders

I am pleased to provide this annual report of Conor Medsystems for 2004, the year we became a public company.

Conor Medsystems is developing innovative vascular drug delivery products designed to provide significant therapeutic benefits for patients. Our initial focus is on the development of drug-eluting stents to treat coronary artery disease, with the goal of becoming a leading innovator in the field of controlled vascular drug delivery.

In addition to completing a successful initial public offering in 2004, we made important advances in all aspects of our strategy that I am pleased to briefly outline below.

Advancing Our Research & Product Development Pipeline

We have developed a novel stent design that enables a wide range of drug therapies – including combinations of multiple compounds – and provides enhanced control over the direction and rate of drug release. These factors differentiate our stent technology and may allow for more targeted treatment within the artery and for the drug dose to be more closely matched to the optimal therapeutic window.

Our lead product candidate is the CoStar™ cobalt chromium paclitaxel-eluting coronary stent, under development for the treatment of restenosis. In contrast to conventional surface-coated stents, the CoStar stent has been specifically designed for vascular drug delivery. Our CoStar stent incorporates hundreds of small holes, each acting as a reservoir into which drug-polymer compositions can be loaded. The drug inlay design of our CoStar stent allows for greater control of release kinetics – or control over the rate and duration of drug release over time – a factor that we believe can have a direct impact on clinical outcomes.

In 2004, we presented results from several clinical trials that advanced the development of our stent program. In May, we presented positive four-month follow-up results from our PISCES (Paclitaxel In-Stent Controlled Elution Study) drug-eluting stent trial that supported the safety of our stents and, among other things, demonstrated an in-stent binary restenosis rate of 0 percent for one of the lead formulations studied. We believe that PISCES is one of the most comprehensive pilot studies evaluating drug dosing and kinetics with drug-eluting stents conducted to date. The data from the PISCES trial indicate that control of drug delivery, a key point of differentiation of the CoStar stent over conventional drug-eluting stents, can have an effect on treatment outcomes. In early 2005, we presented twelve-month follow-up results from the PISCES trial that confirmed the safety of our stent technology and reinforced optimal dose and kinetic release characteristics. These results also demonstrated an in-stent binary restenosis rate of 0 percent for one of the lead formulations studied.

In late 2004, we announced positive results from the COSTAR I drug-eluting stent trial, designed to evaluate the safety and performance of three formulations using the CoStar stent, and, in early

2005, we presented positive six-month follow-up angiographic and clinical results for the pivotal EuroSTAR clinical study. The EuroSTAR results demonstrated consistently low restenosis and complication rates for the CoStar stent across an array of patients. These results, coupled with the stent's controlled drug release, bioresorbable polymer and ease of deliverability, highlighted the potential of the CoStar stent to provide clear benefits to both patients and physicians.

Based in part on these clinical studies, we received conditional approval from the U.S. Food and Drug Administration of an Investigational Device Exemption to begin our COSTAR II U.S. pivotal clinical trial. The COSTAR II (CObalt chromium STent with Antiproliferative for Restenosis) trial will be a randomized, single-blind, non-inferiority study comparing the CoStar stent with Boston Scientific's TAXUS® Express2™ drug-eluting stent in the treatment of de novo lesions in patients with single or multi-vessel coronary artery disease. We expect to begin the COSTAR II trial by the middle of 2005.

A critical part of our business strategy includes partnering with other companies to extend our research and development efforts. In March 2005, we announced an agreement with Novartis Pharma AG that granted us the right to evaluate three Novartis pharmaceutical compounds. Our agreement with Novartis has the potential to expand our development pipeline by combining Novartis' compounds with our proprietary stent platform to create products for the treatment of restenosis and related vascular diseases.

Beyond applications for restenosis, we are seeking to capitalize on the full therapeutic potential of our drug-eluting stent technology through the development of products for other cardiovascular indications. One program currently undergoing pre-clinical evaluation is a drug-eluting stent for the treatment of an acute myocardial infarction.

Strengthening Our Global Commercialization Capabilities

As our clinical program advances, we are also strengthening our ability to reliably and efficiently manufacture and distribute the CoStar stent.

We believe that our manufacturing capability is a true competitive advantage. The proprietary manufacturing technologies that we have developed result in high precision, uniformity and manufacturing yields. We believe that our manufacturing process permits efficient scale-up for commercial manufacturing requirements. To support the international launch of the CoStar stent, we recently established a manufacturing facility in Athlone, Ireland.

We are also extending our ability to commercialize the CoStar stent globally. In May 2004, we entered into an agreement with Biotronik that lays the foundation for international distribution of the CoStar stent pending regulatory approval. Biotronik will be the exclusive distributor of the CoStar stent in the European Community, Latin America and certain parts of Asia. Under another agreement finalized in 2004, St. Jude Medical, Inc. will be the exclusive distributor of our CoStar stent in Japan and several

other countries in the Pacific Rim. We have already begun a limited market release of our CoStar stent in India under a distribution agreement with Interventional Technologies Pvt. Ltd., our exclusive distributor in India and other countries in that region.

Assuming that our clinical trials proceed as scheduled and the outcomes of these trials are favorable, we anticipate receiving regulatory approval for the CoStar stent in the European Community in late 2005 and in the United States in late 2007.

2004 Financial Results

Our financial results reflect those of a growing company making major investments to advance a product candidate to market.

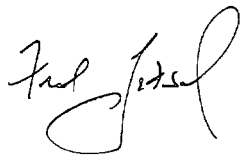
In 2004, we reported a net loss of $25.9 million as compared to a net loss of $11.0 million in 2003. Our R&D expenses increased to $18.8 million in 2004 from $9.2 million in 2003, primarily due to an increase in our R&D staff and investment in clinical development. General and administrative expenses increased to $7.6 million in 2004 from $1.8 million in 2003, primarily due to higher payroll and non-cash stock-based compensation expenses.

The most significant financial activity of 2004 was the completion of our initial public offering of 6,000,000 shares of common stock during the fourth quarter. The net proceeds from the initial public offering were approximately $70.3 million, and we ended 2004 with $117.7 million in cash and cash equivalents.

Ultimately, it is the strength of our people who develop and execute our strategy that will enable us to succeed. I am privileged to work with the nearly 100 employees at Conor who are all dedicated to advancing our technology and product candidates. Our team includes some of the most experienced individuals in their field. In addition, we have assembled an international and distinguished group of scientific advisors to provide guidance to our programs and to explore various aspects of advancing our business. Everyone at Conor is committed to advancing our goal of delivering innovative products with significant clinical benefits to patients suffering from coronary artery disease.

We believe that there is a medical need for improvements in vascular therapies. At Conor, we have every reason to believe that we are developing innovative drug delivery technologies that will deliver these improvements and ultimately find applications in a variety of therapeutic settings.

Sincerely,



Frank Litvack, MD
Chairman & Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K
FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(MARK ONE)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE TRANSITION PERIOD FROM TO
COMMISSION FILE NUMBER 000-51066

CONOR MEDSYSTEMS, INC.
(Exact name of Registrant as Specified in its Charter)

DELAWARE	94-3350973
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)

1003 HAMILTON COURT
MENLO PARK, CA 94025
(Address of Principal Executive Offices including Zip Code)
(650) 614-4100
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:
None
Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $.001 par value per share
(Title of Class)

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

Indicate by check mark 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 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. ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant on December 31, 2004, based upon the closing price of $13.85 as reported on the Nasdaq National Market, was approximately $307.6 million. Excludes 10,244,113 shares of the registrant's common stock held by current executive officers, directors, and stockholders whose ownership exceeds 5% of the common stock outstanding at December 31, 2004. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant. The registrant has elected to use December 31, 2004 as the calculation date, as on June 30, 2004 (the last business day of the registrant's second fiscal quarter), the registrant was a privately-held concern.

The number of outstanding shares of the registrant's common stock on March 15, 2005 was 33,100,130.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2005 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K are incorporated by reference in Part III, Items 10-14 of this Form 10-K.

CONOR MEDSYSTEMS, INC.

2004 ANNUAL REPORT ON FORM 10-K

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PART I

Forward Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management and are contained principally in the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." Forward-looking statements include, but are not limited to, statements about:

- our expectations with respect to regulatory submissions and approvals and our clinical trials;
- our expectations with respect to our intellectual property position; and
- our estimates regarding our capital requirements and our need for additional financing.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading "Risk Factors." Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Annual Report on Form 10-K and the documents that we have incorporated by reference, completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify all of our forward-looking statements by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Item 1. Business.

Overview

We develop innovative controlled vascular drug delivery technologies. We have initially focused on the development of drug eluting stents to treat coronary artery disease. Our stents have been specifically designed for vascular drug delivery, in contrast to currently available drug eluting stents, which are conventional bare metal stents coated with a drug and a polymer. A polymer is a substance used to adhere a drug to the surface of a stent and to modulate its release. Our stents incorporate hundreds of small holes, each acting as a reservoir into which we can load a drug-polymer composition. Through this proprietary design, we can better control drug release kinetics, or the rate and direction of drug release over time. Our clinical efforts are currently focused on the development and commercialization of our CoStar stent, which is a cobalt chromium paclitaxel eluting stent, for the treatment of restenosis. While we believe that our stent technology can support a wide range of drugs, our initial clinical efforts have focused on the use of paclitaxel, an anti-proliferative drug initially developed to treat certain types of cancer. To date, we have conducted clinical trials involving over 800 patients using our drug eluting stents, including more than 300 patients with our CoStar stent. We are also investigating the potential applicability of our stent technology to the treatment of an acute myocardial infarction, or AMI, commonly known as a heart attack.

We believe that our drug eluting stents offer significant advantages over conventional surface-coated stents. Our stent design enables a wide range of drug release kinetics by allowing us to select the pattern in which drug-polymer compositions are inlayed into the reservoirs. The design of our stents also provides greater directional control over the release of the drug, which we believe allows for more targeted treatment within the artery and more efficient use of the therapeutic agent. A highly distinguishing characteristic of our stent is its use of "ductile hinges," which are specially contoured, proprietary features that localize stress applied to the stent when the stent is expanded inside the coronary artery. This feature is designed to ensure that the drug-polymer composition inlayed into the reservoirs is not extruded, fractured or otherwise disrupted during stent expansion. As a result, we are able to use a wider range of polymers and drugs, including water-soluble compounds, as compared to conventional surface-coated stents. Further, we believe that our proprietary manufacturing technology, coupled with our stent design, allow us to benefit from high throughput, high uniformity and high manufacturing yield.

In March 2005, we announced twelve-month follow-up data from our PISCES clinical trial, which was designed to evaluate the safety and performance of paclitaxel delivered at different release kinetics and doses using our stainless steel stent. In the PISCES trial, we enrolled 191 patients divided into six groups, each receiving a different formulation of paclitaxel that varied by dose, duration of drug release and direction of delivery. The results from our PISCES trial indicate that drug release kinetics have an effect on treatment outcomes. The formulations that demonstrated the most favorable clinical outcomes are the focus of our subsequent EuroSTAR and COSTAR I trials, as well as our planned U.S. pivotal clinical trial, which are designed to further evaluate the safety and efficacy of our CoStar stent. We anticipate that our EuroSTAR trial will ultimately involve up to 320 patients at up to 20 sites. The EuroSTAR trial supported our submission in February 2005 of an application to a designated Notified Body in the European Community, which is one of the steps we must undertake prior to marketing our CoStar stent in the European Community. In March 2005, we announced six-month follow-up data from the first arm of our EuroSTAR trial. The COSTAR I trial began in late 2003 and has completed enrollment of the three formulation groups. In September 2004, we announced four-month follow-up data for one of the three formulation groups from the COSTAR I trial, and in January 2005, we presented four-month follow up data for a second formulation group. Our COSTAR I trial enrolled 87 patients at four sites and will serve as another supporting trial for our CoStar stent in more complex patient populations. Based on the results from the PISCES, EuroSTAR and COSTAR I clinical studies, we submitted an investigational device exemption, or IDE, application to the U.S. Food and Drug Administration, or FDA, in the first quarter of 2005 for our planned U.S. pivotal clinical trial, COSTAR II, and in March 2005, we received conditional approval of our IDE application. We have not yet received any government regulatory approvals necessary to commercialize our CoStar stent. If our clinical trials proceed as scheduled and the outcomes of these clinical trials are favorable, we anticipate receiving regulatory approval for our CoStar stent in the European Community in late 2005 and in the United States in 2007. We could be delayed by adverse results or regulatory complications, and we may never achieve regulatory approval. No regulatory approval is currently required to market our CoStar stent in India.

We have entered into agreements with Biotronik AG, Interventional Technologies, Pvt., Ltd., or IVT, and affiliates of St. Jude Medical, Inc. to distribute our CoStar stent outside of the United States. We recently began a limited market release of our CoStar stent in India pursuant to our distribution agreement with IVT. We expect to pursue commercialization in the United States with our own sales force.

Industry Background

Coronary Artery Disease

Coronary artery disease is a progressive, pathological condition that leads to the obstruction of the blood vessels providing blood flow to the heart muscle. According to the National Institutes of Health, coronary artery disease affects about 13 million people in the United States and is the leading cause of death in both men and women. The disease is caused by the accumulation of fat-laden cells in the inner lining of the coronary arteries, leading to a localized patchy thickening, called an atherosclerotic plaque. As the plaque expands into the lumen,

or the inner channel of the artery through which blood flows, the diameter of the lumen narrows. The portion of the heart muscle normally nourished by the affected artery can become starved for oxygen, or ischemic, causing chest pains. Moreover, plaques tend to attract platelets, which can cause clots and lead to the further obstruction of blood flow to the heart, potentially causing an AMI.

The Development of Treatments for Coronary Artery Disease

Treatments for patients with life-threatening coronary artery disease have advanced dramatically over the last 20 years, from highly invasive, open-chest bypass surgery to minimally invasive angioplasty procedures.

Coronary Artery Bypass Grafting

Coronary artery bypass grafting, or CABG, is an invasive surgical procedure developed in late 1960s that requires an incision in a patient's chest to gain access to the heart. In this procedure, the cardiac surgeon uses a graft from another blood vessel of the patient to "bypass" the obstructed artery. CABG is an expensive procedure involving hospital stays of several days to a week or longer, and recovery periods of several weeks.

Angioplasty

In the late 1970s, percutaneous transluminal coronary angioplasty, commonly referred to as balloon angioplasty, was developed as a less invasive treatment method to open a narrowed or blocked blood vessel. In an angioplasty procedure, an interventional cardiologist inserts a flexible catheter with a balloon tip through the femoral artery in the groin and maneuvers the catheter through the vasculature into the coronary arteries. At the site of the blockage, the balloon is inflated, compressing the plaque and stretching the artery wall to create a larger channel for blood flow. The balloon is then deflated, and the catheter is removed. A patient can generally be released from the hospital within one to two days following the procedure. The introduction of balloon angioplasty significantly improved recovery times, resulted in less patient discomfort and reduced cost per procedure as compared to CABG.

While less invasive and expensive than CABG surgery, the ultimate clinical effectiveness of balloon angioplasty has been hampered by restenosis, or the re-narrowing of the artery lumen following balloon angioplasty. Restenosis has at least two mechanisms, either or both of which can occur following an angioplasty procedure:

- a re-narrowing of the artery lumen after balloon angioplasty due to an elastic recoil of the artery wall; and
- a re-narrowing of the artery lumen over a period of months after balloon angioplasty due to the proliferation or growth of cellular and extra-cellular material, or neointima, within the artery wall, which is believed to be caused by injury to the artery wall.

Evolution of Stents to Address Restenosis

The Development of Bare Metal Stents

To address the elastic recoil component of restenosis, medical devices known as stents were developed. Stents are tubular mesh devices consisting of interconnected metal struts that are inserted inside the artery to act as scaffolding, propping open the narrowed blood vessel. During an angioplasty procedure, a stent mounted on a balloon catheter is delivered to the affected segment of the artery and expanded inside the artery by inflating the balloon. The balloon catheter is then removed, leaving the stent in the artery. Bare metal stents became widely used in the mid-1990s in combination with balloon angioplasty and quickly became used in the majority of angioplasty procedures. We believe that the use of bare metal stents reduces the rate of restenosis by approximately one-third when compared to balloon angioplasty alone. While the use of bare metal stents addresses the elastic recoil component of restenosis, bare metal stents are not designed to reduce, and may in fact

exacerbate, restenosis caused by the proliferation or growth of cells and extra cellular matrix materials. As a result, we estimate that restenosis after bare metal stent implantation still occurs in approximately 10% to 35% of procedures within six months of treatment, which typically necessitates repeat angioplasty, re-stenting or bypass surgery.

The Development of Drug Eluting Stents

Drug eluting stents were developed to address restenosis caused by the growth and proliferation of neointima. We believe that drug eluting stents represent the most advanced and sophisticated treatment currently available to address restenosis. Currently marketed drug eluting stents are conventional bare metal stents that are coated on the surface with a drug that is designed to reduce restenosis by inhibiting the growth or proliferation of neointima. According to published studies, currently marketed drug eluting stents have been shown in clinical trials to reduce the rate of restenosis to less than 10%.

The first two marketed drug eluting stents only recently gained regulatory approval. Johnson & Johnson's CYPHER™ stent was commercially launched in Europe in April 2002 and in the United States in April 2003. Boston Scientific Corporation's TAXUS™ Express^{2}™ stent was commercially launched in Europe in February 2003 and in the United States in March 2004. Market adoption of drug eluting stents has been rapid, and we believe that drug eluting stents will capture approximately 90% of the stent market within three years. In addition to premium pricing of drug eluting stents at two to three times that of bare metal stents, we expect that market growth in the drug eluting stent industry will also be driven by procedure growth since the low restenosis rates of drug eluting stents are likely to cause cardiologists to opt for angioplasty for complex, high-risk cases rather than resorting to the more invasive CABG surgery alternative.

Factors Impacting the Effectiveness of Drug Eluting Stents

The effectiveness of drug eluting stents depends on the following principal components:

- stent design;
- drug delivery mechanism; and
- drug.

Stent Design

Drug eluting stents require an appropriate balance of several design parameters to enable effective treatment of restenosis. These design characteristics include:

- *Profile:* diameter of the stent when crimped, or mounted, on the delivery catheter.
- *Deliverability*: ability to reach blockages in the coronary arteries during stent deployment.
- *Flexibility*: properties of the stent that allow it to bend along the stent axis and conform to the artery after deployment.
- *Choice of Metal*: most commonly stainless steel or cobalt based alloys.
- *Axial Stability*: consistent vessel support along the length of the stent.
- *Vessel Wall Apposition*: absence of gaps between the drug eluting stent struts and the vessel wall.
- *Radiopacity*: ability of the physician to view the stent in the coronary anatomy under x-ray imaging guidance.

The profile of the stent, in combination with the stent's flexibility and radiopacity, affect the stent's deliverability. Stents with a lower profile, or smaller diameter when crimped, may be more easily navigated through the coronary arteries and delivered to the site of the blockage as compared to those with a higher profile.

Conversely, stents with a higher profile and less flexibility are more difficult to deliver, especially to coronary blockages in narrow, tortuous vessels in the coronary anatomy. The stent's radiopacity also aids in delivering the stent to the site of the blockage by allowing the physician to more clearly view the stent in the coronary anatomy under x-ray imaging guidance.

Stents have traditionally been made from a stainless steel alloy, although more recently, cobalt chromium stents have been introduced. Stents made of cobalt chromium have greater tensile strength than stents made of stainless steel. The enhanced tensile strength allows the stent struts to be thinner and narrower, leading to increased flexibility, a lower profile and improved axial stability. Stents made from certain cobalt chromium alloys also provide for improved radiopacity as compared to thin strut stainless steel stents.

The Drug Delivery Mechanism

Conventional drug eluting stents are coated on the surface with a drug incorporated into a polymer matrix. The polymer is necessary to fix the drug on the surface of the stent and to modulate its release. The stent is typically sprayed with or dipped into a drug-polymer composition. Current spraying and dipping processes can result in non-uniform distribution of the drug on the stent. When these non-uniformities exceed limits specified by regulatory bodies, lower manufacturing yields can result. The coating depth of a conventional surface-coated stent is usually very thin, limiting the drug volume on the stent. Certain inherent limitations of conventional surface-coated stents include:

- *Limited class of available polymers.* The choice of polymers for surface-coated stents is limited by certain properties, such as elasticity and adhesion, needed to withstand the stresses of stent deployment and expansion. We believe that many types of therapeutic agents cannot be delivered for an extended period when combined with polymers suitable for surface-coated stents. These include water-soluble drugs, proteins, peptides and oligonucleotides, or short strands of DNA.
- *Limited control over drug release kinetics and direction of drug delivery.* Following implantation, surface-coated stents generally release their drug at a rapid rate for a short period, after which the rate of drug release slows. Since the efficacy of drugs may depend on how they are released in the body (some drugs may work best when concentration levels are reached quickly, while others may require sustained delivery over an extended time period), conventional surface-coated stents do not necessarily provide for optimized release kinetics. For example, the DELIVER clinical trial conducted by Guidant Corporation and Cook Incorporated failed to meet its clinical endpoints. The ACHIEVE™ stent used in the DELIVER trial was loaded with a paclitaxel dose at least as great as Boston Scientific's Taxus™ Express²™ stent, but the stent did not provide for sustained release of the drug. The DELIVER trial investigators suggested that the greater late loss observed in the ACHIEVE stent compared with the TAXUS™ Express²™ stent may be explained by the sustained release kinetics of the TAXUS™ Express²™ stent. Conventional surface-coated stents also lack a mechanism for controlling the directional release of the therapeutic agent, resulting in the release of the drug into both the arterial wall and bloodstream. We believe that the thin layer of polymer used in conventional surface-coated stents, with the required properties of elasticity and adhesion, cannot achieve the controlled drug release kinetics that can be obtained with deeper inlays, and that this reduced control of drug kinetics limits the applications for conventional surface-coated stents. The four-month and twelve-month follow-up data from our PISCES study showed significant variation in clinical effect in identical doses of paclitaxel with different release kinetics. Published clinical data on alternative release kinetics for sirolimus are limited.
- *Residual drug or polymers.* Currently marketed stents use non-bioresorbable polymers and some polymers used on surface-coated stents do not completely release the drug incorporated in the stent coating. While bare metal stents are known to be well tolerated after implantation in coronary arteries, some polymeric stent coatings (not necessarily those on current commercial products) have been associated with acute and chronic inflammatory responses in arterial tissue. The existence of residual drugs or polymers left in contact with the artery wall may be viewed as undesirable as the long-term results are unknown.

- *Peeling, mechanical damage and sticking.* Surface-coated stents are vulnerable to peeling, mechanical damage and sticking during the course of manufacturing, handling or deployment. Polymer sticking may also be implicated in balloon retraction problems during the course of implanting the stent.

The Drug

The success of a drug eluting stent depends partly on the ability of the active drug to interfere with the process of restenosis. The first drug widely studied and approved for use in a drug eluting stent for the treatment of restenosis was sirolimus, also known as rapamycin, which is an immunosuppressant agent with anti-inflammatory properties. One of a new line of immunosuppressants, sirolimus inhibits the activation of key cellular regulators, thus inhibiting cellular proliferation and growth. Paclitaxel, which is used in a recently approved drug eluting stent, also interferes with cellular proliferation and growth, but works in a different way than sirolimus. Paclitaxel interferes with the structure and function of cellular elements called microtubules, which leads to the inhibition of cell division and growth, and can lead to cell death.

In addition to sirolimus and paclitaxel, there may be other drugs that, alone or in combination, offer therapeutic benefits. These therapeutic benefits may in some circumstances be dependent upon control of release kinetics. Other sirolimus derivatives are being evaluated for the treatment of restenosis and a broad variety of immunosuppressive, anti-leukocyte or anti-proliferative agents may also be useful, although limited testing and data are available. A stent with the ability to deliver a broad range of drugs, including multiple drugs, and to control release kinetics may have potential advantages in exploiting applications of new drug candidates.

Limitations of Conventional Drug Eluting Stents

The limitations of conventional surface-coated drug eluting stents include:

- limited control over drug release kinetics and direction of drug delivery;
- limited universe of available drugs;
- limited class of available polymers;
- surface coatings are prone to peeling, mechanical damage and sticking during manufacturing and implantation;
- lack of uniformity in coating thickness and uneven or incomplete drug delivery, including the occurrence of residual polymer on the stent; and
- difficulty in loading and delivering multiple drugs with independent release kinetics.

Our Solution

We are seeking to capitalize on the full therapeutic potential of drug eluting stents through the development of a stent specifically designed for drug delivery. Rather than retrofitting a bare metal stent with a drug coating, our stent design incorporates hundreds of small holes, each acting as a reservoir into which we can load drug-polymer compositions. Through this proprietary design, we believe that we can greatly enhance control of drug release kinetics and direction of drug delivery, enable a wider range of drug therapies and potentially increase the effectiveness and range of clinical applications of drug eluting stents. Based on the data from our PISCES clinical study, we believe that control of drug delivery can have a direct impact on clinical outcomes.

Our stents incorporate special, proprietary structural elements called "ductile hinges," which enable us to create drug reservoirs in our stent struts. Ductile hinges are specially contoured features that absorb virtually all of the metal deformation that occurs as a stent is expanded inside the coronary artery. The other structural elements of the stent thus remain relatively deformation-free. This has two important consequences. First, we can incorporate our reservoirs into the stent struts without compromising strength, scaffolding or flexibility. Second,

since the reservoirs are largely non-deforming during stent expansion, the drug-polymer composition in the reservoirs will not be extruded, fractured or otherwise disrupted upon stent expansion. This in turn allows us to use polymers in our reservoirs which do not have the level of flexibility, adhesion and other properties required in surface coatings.

We believe that it would be difficult to duplicate our high volume drug reservoirs in conventional stent designs without incorporating our proprietary ductile hinges. Conventional stents generally attempt to spread deformation as evenly as possible throughout the stent structure. When large reservoirs are formed in such a structure, engineering structural analysis shows severe deformation of the reservoirs as the stent expands. Material contained in the reservoirs would likely be fractured or extruded, which we believe would be unacceptable from both a clinical and regulatory standpoint.

We believe that our stents possess the following key advantages compared to conventional surface-coated drug eluting stents:

- ***Enhanced control of drug delivery.***
  - *Controllable release kinetics.* While conventional surface-coated drug eluting stents provide limited control over the rate of drug release and generally release their drug at a rapid rate for a short period, after which the rate of drug release slows, the drug inlay design of our stents allows for greater control of release kinetics. Since drug release kinetics are controllable by selecting the pattern in which polymers and drugs are loaded into the holes, a range of release kinetics can be created. As the efficacy of drugs may depend on how they are released in the body, our stents are designed to allow release kinetics to be better matched to the requirements of a drug.
  - *Directional drug control.* Our stent reservoirs can include a polymer barrier on the side of the stent facing the bloodstream, which is called the luminal side, ensuring that substantially all of the drug releases into the arterial wall. Alternatively, the stent can be designed to release drug primarily into the bloodstream if the intent is to deliver drug to tissue downstream from the site of the stent, or the stent can be designed to release drug in both directions.
  - *Control over manufacturing consistency.* Because the drug formulation is loaded into our drug reservoirs using a precision-guided jetting technology, we believe that we can effectively control the drug loading process, allowing us to reach a level of uniformity across the stent that we believe compares favorably to that of conventional surface-coated stents.
- ***Enhanced flexibility in drug therapies.***
  - *Capability to deliver a wider range of drugs.* Because of our ability to vary the structure of the drug inlay within the reservoirs, we believe that our stents are capable of delivering a broader range of compounds than conventional surface-coated stents. In addition to fat-soluble drugs deliverable by conventional surface-coated stents, our stents can deliver water-soluble drugs, proteins, peptides and oligonucleotides.
  - *Controlled delivery of multiple drugs.* Our stent design permits controlled delivery of multiple drugs from a single stent. For example, a stent could be designed to release both an anti-proliferative agent and an anti-inflammatory drug to prevent restenosis in high risk patients. Two drugs can be deposited into the same reservoir or different reservoirs, and the drugs can be released independently.
  - *Expanded drug capacity.* The coating depth of a conventional surface-coated stent is usually very thin, limiting the drug volume that can be applied. Our reservoirs provide the potential for greater dose capacity than thin surface coatings, allowing our stents to deliver more drug for an extended period of time, if required.

- ***Enhanced polymer capabilities.***
  - *Low exposure of polymer to the body.* Because of the reservoir design of our stents, we provide lower surface area contact of the polymer to the artery wall than a conventional surface-coated stent. Our stent has less than 15% of the polymer surface area of conventional surface-coated stents.
  - *Bioresorbable polymers.* The polymers that are available for use in our stents include polymers that are absorbed by the body after the drug is released, leaving no permanent residual polymers at the target site.
  - *Wider range of available polymers.* Because our stent platform provides a non-deforming drug reservoir that is not affected by the expansion of the stent, a wider range of polymers can be used in our stents compared to the polymers available for conventional surface-coated stents, which need to be elastic and adhesive to accommodate stent expansion.
- ***Superior manufacturability.*** We believe that our proprietary manufacturing technologies, coupled with our stent design, allow us to benefit from relatively high throughput, high uniformity and high manufacturing yield. Our automated drug loading technology, in which individual stent holes are mapped and then loaded with a computer guided system, produces a uniform distribution of drug across the stent. We believe that our manufacturing process permits efficient scale-up for commercial manufacturing.

Our Strategy

Our goal is to become a leading innovator in the emerging field of vascular drug delivery through medical devices. Key elements of our strategy include:

- *Continue to demonstrate that drug release kinetics affect treatment outcomes.* An important part of our clinical strategy is to continue to demonstrate that the drug inlay design of our stents provides greater control of drug release kinetics. The data from our PISCES trial indicate that drug release kinetics can have an effect on treatment outcomes, and we intend to use the results of our PISCES trial as well as the results from our COSTAR I and EuroSTAR clinical trials to continue to demonstrate that drug release kinetics can affect outcomes. In September 2004, we announced four-month follow-up data for one of the three formulation groups from the COSTAR I trial, and in January 2005, we presented four-month follow-up data for a second formulation group from the COSTAR I trial. In March 2005, we announced six-month follow-up data from the EuroSTAR trial and twelve-month follow-up data from the PISCES trial. We intend to expand on these trials to investigate whether the design of our stents can improve treatment outcomes for other indications. We believe that by continuing to demonstrate that drug release kinetics affect outcomes, we will ultimately establish that drug release kinetics are important factors in assessing the efficacy of drug eluting stents.
- *Commercialize CoStar for the treatment of restenosis.* We plan to commercialize one of the first cobalt chromium drug eluting stents. As a result of its low profile and superior deliverability, we have focused on the development and commercialization of our CoStar stent, our cobalt chromium paclitaxel eluting stent, for the treatment of restenosis. We plan to initially commercialize the CoStar stent outside of the United States, and we have entered into distribution agreements with third parties to do so. We plan to expand our manufacturing capacity to meet anticipated demand upon commercialization, and we intend to manufacture the CoStar stent in Ireland for commercialization outside of the United States. In March 2005, we received conditional approval of our IDE application from the FDA to permit commencement of our planned U.S. pivotal clinical trial of the CoStar stent for the treatment of restenosis. Our goal is to directly commercialize the CoStar stent, and potentially other products, in the United States, where we plan to build a highly-focused sales and marketing infrastructure to market the CoStar stent to interventional cardiologists.
- *Develop and commercialize new drug eluting stents for the treatment of restenosis.* We believe that our ability to control drug release kinetics offers the potential to make us a technology leader in the

development of next generation stents. We intend to penetrate this evolving market by developing additional products for the treatment of restenosis, including products with drugs other than paclitaxel, or products that deliver a combination of drugs. We also intend to segment the current restenosis market by developing and marketing stents with specialized applications, such as stents targeting diabetics, a patient population which tends to suffer from more complex forms of cardiovascular disease.

- *Leverage our technology platform for other indications.* We believe that there are applications of our technology beyond the treatment of restenosis. We are seeking to develop drug eluting stents for unmet medical needs in cardiology, such as AMI, and vascular diseases that we believe can be addressed with our technology.
- *Explore strategic partnerships.* We intend to seek partnerships with medical device, biotechnology and pharmaceutical companies for the development of new products utilizing our stent technology. These partnerships could include in-licensing of drugs from biotechnology or pharmaceutical companies, and out-licensing our stent design and drug delivery technology to medical device, biotechnology or pharmaceutical companies for selected indications or product development collaborations. In March 2005, we entered into an agreement with Novartis Pharma AG granting us the right to evaluate three Novartis pharmaceutical compounds for the potential development of a product combining a Novartis compound with our stents for the treatment of vascular diseases.

Clinical Development Program

We have developed three stents that have been or are being evaluated in clinical trials: a bare stainless steel stent, a stainless steel stent with paclitaxel and a cobalt chromium stent with paclitaxel, our CoStar stent. We do not intend to commercialize either our bare stainless steel stent or our stainless steel stent with paclitaxel. We have pursued a clinical development strategy of using these stents to demonstrate that the drug inlay design of our stents permits us to control drug release kinetics, to establish the safety of our stent design, to demonstrate that drug release kinetics can have a direct impact on clinical outcomes and to establish the basis for regulatory approval of our CoStar stent in Europe and the United States.

The four- and twelve-month follow-up data from our PISCES trial indicate that drug release kinetics have an effect on treatment outcomes, and an important part of our clinical strategy is to continue to demonstrate that drug release kinetics affect outcomes. We believe that the results of the clinical trials of our bare stainless steel stent and stainless steel stent with paclitaxel, including the PISCES trial, will provide supporting data for our applications for regulatory approval in Europe and the United States. We expect that the pivotal EuroSTAR trial will form the basis for marketing approval of the CoStar stent in the European Community, and we have received conditional approval of our IDE application from the FDA to permit commencement of our U.S. pivotal clinical trial, which we expect will form the basis for regulatory approval of the CoStar stent in the United States. We plan to conduct a trial specifically designed for Japanese marketing approval.

Our PISCES, SCEPTER, COSTAR I and EuroSTAR trials were designed to evaluate varying doses of paclitaxel eluted in one or two directions over different time periods. Because the duration of drug release *in vivo* is very difficult to measure, the descriptions we use for duration (*i.e.*, "five days," "ten days" and "30 days") are approximations that are based on *in vitro* measurements.

The performance of drug eluting stents is assessed using a number of metrics, which compare data collected at the time of stent implantation to data collected when a patient is re-assessed at follow-up. The time periods for follow-up are usually four months for pilot trials, six months for pivotal trials for marketing approval in the European Community and eight to nine months for pivotal trials for FDA approval. The common metrics used to evaluate the efficacy of drug eluting stents, and the ranges for the reported results from U.S. pivotal trials of FDA-approved conventional drug eluting stents for these metrics, include:

Metric	Description	Results from U.S. pivotal trials of FDA-approved conventional drug eluting stents
Binary restenosis rate	Binary restenosis rate is the percentage of patients at follow-up that have a greater than 50% reduction in the lumen diameter. The metric may either be in-stent, analyzing only the lumen within the stent, or in-segment, analyzing the lumen within the stent plus 5mm on either side of the stent.	In-stent: 3.2% to 5.5% In-segment: 7.9% to 8.9%
Target lesion revascularization rate	Target lesion revascularization rate, or TLR rate, is the percentage of patients at follow-up who have another coronary intervention, such as an angioplasty or a CABG procedure, to treat a lesion, or blockage in the artery, within the stent or within 5mm on either side of the stent.	3.0% to 4.1%
Late loss	Late loss is the decrease in the minimum lumen diameter of the artery measured in millimeters at follow-up as compared to the minimum lumen diameter at the time of the stent implantation. Late loss may be either in-stent or in-segment.	In-stent: 0.17mm to 0.39mm In-segment: 0.23mm to 0.24mm
Percent volume obstruction	Percent volume obstruction by intravascular ultrasound, or IVUS, is the volume of the lumen in the stent occupied by restenotic tissue.	2.6% to 12.2%
Major Adverse Cardiac Event Rate	Major adverse cardiac event, or MACE, rate is the percentage of patients at follow-up that have experienced another coronary intervention, an AMI, or cardiac death.	7.1% to 8.5%

DepoStent

The DepoStent trial was designed to evaluate the safety and performance of our basic stainless steel stent design without drugs or polymer. The intent of the DepoStent pilot study was to assess whether a stent with drug reservoirs would perform differently than a conventional bare metal stent. The trial, which included 53 patients at two sites in the Netherlands, was conducted in 2003. In December 2003, we completed six-month follow-up of patients in the trial. The results from the DepoStent trial indicated that the clinical outcomes of patients receiving this stent were similar to patients receiving conventional bare metal stents, and that holes in stent struts did not lead to a higher incidence of adverse effects. We obtained marketing approval in the European Community for our bare stainless steel stent, although we do not intend to commercialize this stent. Data from this trial was used to support our IDE submission for our planned U.S. pivotal clinical trial.

PISCES

The Paclitaxel In-Stent Controlled Elution Study, or PISCES study, was designed to evaluate the safety and performance of paclitaxel delivered at different rates, doses and directions of delivery using our stainless steel stent. Enrollment for this pilot study, which consisted of 191 patients at ten sites in South America, Europe and New Zealand, was conducted in 2003. Of the 191 patients participating in the PISCES study, 187 received one of six different formulations of paclitaxel that varied by dose, estimated duration of drug release rate and directionality (drug release to only the arterial wall, or mural release, and release to both the arterial wall and the lumen, or bidirectional release). The last patient was treated in December 2003. Data from this trial was used to support our IDE submission for our planned U.S. pivotal clinical trial. The table below summarizes the formulations evaluated in the PISCES study.

Formulation	F1	F2	F3	F4	F5	F6
Paclitaxel dose (mcg/17mm stent)	10	10	10	10	30	30
Estimated duration of elution (days)	5	10	10	30	30	10
Direction of elution	bidirectional	mural	bidirectional	mural	mural	bidirectional

In May 2004, we released four-month follow-up data, and in March 2005, we released twelve-month follow-up data from the PISCES trial.

At four-month follow-up, all six formulations were determined to be safe, with no deaths from discharge to 30 days. Two groups with the longest duration formulations, formulations F4 and F5, had particularly favorable outcomes. For formulation F4, the in-stent binary restenosis rate and TLR rate were both 0 percent, the in-stent late loss was 0.38mm, the in-segment restenosis rate was 2.6 percent, the in-segment late-loss was 0.20mm, the percent volume obstruction was 7.7 percent, and the MACE rate was 2.6 percent. For formulation F5, the in-stent binary restenosis rate was 3.8 percent, the TLR rate was 3.4 percent, the in-stent late loss was 0.30mm, the in-segment restenosis rate was 3.8 percent, the in-segment late-loss was 0.21mm, the percent volume obstruction was 5.1 percent, and the MACE rate was 3.4 percent. By comparison, the remaining four groups with shorter duration of drug elution, ranging from approximately five to ten days for either 10mcg or 30mcg of paclitaxel per 17mm stent and indicated as formulations F1, F2, F3 and F6 above, generally had less efficacy with respect to these endpoints. The results indicate, for what we believe to be the first time, that drug release kinetics and direction of delivery have an effect on treatment outcomes.

At twelve-month follow-up, all six formulations were determined to be safe. There were no reported cases of delayed stent thrombosis between six months, when patients ceased antiplatelet therapy, and twelve-month follow-up. For formulation F4 the in-stent binary restenosis rate and TLR rate were both 0 percent, the in-stent late loss was 0.52mm, the in-segment restenosis rate was 3.1 percent, the in-segment late-loss was 0.30mm, the percent volume obstruction was 12.0 percent, and the MACE rate was 5.1 percent. For formulation F5, the in-stent binary restenosis rate was 5.6 percent, the TLR rate was 6.9 percent, the in-segment restenosis rate was 5.6 percent, the in-segment late-loss was 0.24mm, the percent volume obstruction was 10.1 percent, and the MACE rate was 6.9 percent. We are currently in the process of evaluating the data from the remaining four groups.

Based on the data from the PISCES trial, we believe that PISCES formulations F4 and F5 represent the superior formulations for evaluation in future clinical trials. We intend to pursue formulation F4 in our planned U.S. pivotal clinical trial of our CoStar stent, COSTAR II.

SCEPTER

The Study of Controlled Elution of Paclitaxel for The Elimination of Restenosis, or SCEPTER study, was designed to evaluate our paclitaxel eluting stainless steel stent for safety and performance, measuring late loss versus our bare metal stent used in the DepoStent study and clinical safety at six months. We undertook this study, without waiting for the results from the PISCES study, with the initial objective of it serving as the basis for marketing approval in the European Community. Enrollment for this study, which included 271 patients at 15 sites in Europe and one site in New Zealand, was completed in 2003. Each patient participating in the SCEPTER study received stents with formulations equivalent to formulations F1 or F2 of the PISCES study. After analyzing the four-month follow-up data from the PISCES trial, we know that formulations F1 and F2 of the PISCES trial were not ideal. Moreover, our commercialization strategy is focused on our CoStar cobalt chromium stent platform rather than our initial stainless steel stent platform. We do not yet have final results for this trial. We are continuing to monitor patients for twelve-month safety. Data from this trial was used to support our IDE submission for our planned U.S. pivotal clinical trial.

COSTAR I

The COSTAR I study is designed to evaluate the safety and performance of three formulations of paclitaxel loaded on our CoStar stent with two formulations delivered over approximately 30 days and one formulation delivered over approximately ten days. A previously contemplated 30mcg 30-day release formulation was ultimately not enrolled since it was the subject of the second arm of the EuroSTAR trial. The pilot study enrolled a total of 87 patients at four sites in India and follow-up is ongoing. We intend to analyze four-month results and then continue to monitor the patients through a twelve-month follow-up period. Data from this trial was used to support our IDE submission for our planned U.S. pivotal clinical trial.

We have completed enrollment of an aggregate of 77 patients in the two 30-day formulations, one of which is similar to formulation F4 of the PISCES trial (formulation group 2 below), and the other of which is a low dose, 3mcg formulation to evaluate the lower boundary of efficacy (formulation group 1 below). We had started enrolling patients in a third group (formulation group 3 below) using a stent formulation similar to the PISCES formulation F6, but we elected to cease enrollment in this group after ten patients had been enrolled as a result of our evaluation of additional data, which indicate that the longer release formulations would be more efficacious.

In September 2004, we released four-month follow-up data for formulation group 2 and in January 2005, we presented four-month follow-up data for formulation group 3. These data are summarized below. Although enrollment is complete for formulation group 1, the results for formulation group 1 are not yet available.

Group	1	2	3
Paclitaxel dose (mcg/17mm stent)	3	10	30
Estimated duration of elution (days)	30	30	10
Direction of elution	mural	mural	bidirectional
Number of patients	37	40	10
Corresponding PISCES formulation	N/A	F4	F6
In-stent restenosis rate (%)		1.9	14.3
In-segment restenosis rate (%)		3.8	14.3
TLR rate (%)		1.8	0.0
In-stent late loss (mm)—lesions with multiple stents		0.43	0.51*
In-stent late loss (mm)—lesions with single stent		0.40	
In-segment late loss (mm)—lesions with multiple stents		0.24	0.52*
In-segment late loss (mm)—lesions with single stent		0.21	
Volume obstruction (%)		7.1	7.1
MACE rate (%)		5.0	10.0

* For lesions treated with a single or multiple stents.

The results for formulation group 2 are for a 10mcg dose per 17mm stent released over approximately 30 days. A total of 57 lesions were treated in 40 individuals from a complex patient population. More than 50% of the patients had a prior myocardial infarction, or heart attack, and 28% were diabetic. Other complex characteristics of the patient group included small diameter coronary vessels and long lesions.

At four-month follow-up, we believe that the results for formulation group 2 compare favorably with, and the binary restenosis rate, TLR rate, late loss, percent volume obstruction and MACE rate were not significantly different from, the outcomes for formulation F4 from the PISCES trial.

EuroSTAR

Our EuroSTAR clinical study is a pivotal trial designed to evaluate our CoStar stent for safety and performance, measuring late loss versus a historical bare metal stent control and clinical safety at six months. The pivotal study, which is planned to include up to 320 patients at 17 sites in Europe and two sites in New Zealand, is currently being conducted. We will continue to monitor the patients through twelve-month follow-up. Data from this trial was used to support our IDE submission for our planned U.S. pivotal clinical trial.

In this trial, we enrolled two groups of patients to further evaluate the two leading formulations from the PISCES clinical study—the 10mcg dose over 30 days, formulation F4 of the PISCES trial, and the 30mcg dose over 30 days, formulation F5 of the PISCES trial. In March 2005, we announced six-month follow-up data from the first group of patients in the trial. A total of 176 lesions were treated in 145 patients using formulation F4 of the PISCES trial. At six-month follow-up, the in-stent binary restenosis rate was 3.4 percent, and the in-stent late loss was 0.26mm. The in-segment binary restenosis rate was 4.7 percent, and the in-segment late loss was 0.07mm. The TLR rate was 1.7 percent, and the MACE rate was 4.8 percent. Enrollment in the second group was completed in March 2005.

Based on the data from the first group of patients in the EuroSTAR trial, we submitted an application to a designated European Notified Body in the first quarter of 2005 to commercialize the CoStar stent in the European Community. If we receive the Notified Body's certification of conformity with applicable regulatory requirements and we complete our own conformity assessment, our stent will be entitled to bear CE marking, which is required prior to marketing devices in the European Community.

COSTAR II

Based on the results from the DepoStent, PISCES, SCEPTER, COSTAR I and EuroSTAR clinical studies, we submitted an IDE application to the FDA in the first quarter of 2005 for our planned U.S. pivotal clinical trial, COSTAR II, evaluating our CoStar stent, controlled against a conventional drug eluting stent, for the treatment of restenosis. In March 2005, we received conditional approval of our IDE application from the FDA to commence limited enrollment in the COSTAR II trial. We are required to provide additional information to the FDA prior to the FDA granting full approval of the IDE application, including information that will be reviewed prior to the FDA approving full enrollment in the COSTAR II trial. We anticipate commencing the study by mid-2005. Our COSTAR II trial will be based on formulation F4 from the PISCES trial. If this clinical trial proceeds with the currently planned protocol and the data from this clinical trial is favorable, we could submit a premarket approval application, or PMA, to the FDA in late 2006.

Pre-clinical Programs

AMI

We are investigating the potential applicability of our stent technology to the treatment of AMI. We commenced pre-clinical studies of our AMI stent in November 2004. In treating AMI, the goal is to restore blood flow to the heart muscle as soon as possible. The methods currently used to treat AMI include the administration of drugs, such as thrombolytic agents, which work by breaking up the clot blocking the artery, as well as performing angioplasty and stent implantation at the site of the blockage to restore blood flow. However, the heart muscle is often permanently damaged even if these treatments are provided soon after an AMI occurs. During the last few decades, a number of clinical studies were performed that demonstrated that a combination of glucose, insulin and potassium delivered to a patient intravenously for twelve to 24 hours after an AMI could reduce the damage to the heart muscle.

We are developing a stent designed to be placed at the site of a blocked artery during balloon angioplasty following an AMI. Our AMI stent is designed to release insulin into the lumen such that the insulin would travel downstream from the site of the blockage, providing targeted delivery of insulin to the damaged muscle cells with the intent of reducing the damage caused by the AMI and preserving heart function.

New Compounds for the Treatment of Restenosis

We are developing more complex systems that may provide the opportunity to deliver from our stent a wide range of compounds that are difficult to deliver from conventional surface-coated stents, including water-soluble compounds.

Other Product Development Initiatives

In May 2004, we signed a non-binding letter of intent with Biotronik AG that sets forth the terms of broad collaboration under which the parties would explore the feasibility of generating new products and/or new product applications using each party's technology and expertise. In particular, we and Biotronik are currently in discussions to potentially work together to combine Biotronik's absorbable metal stent with our vascular drug delivery stent platform, enabling tailored drug release kinetics from a bioresorbable stent for the treatment of restenosis and other vascular disorders. The magnesium alloy stent developed by Biotronik was designed to enable re-intervention on stented vessels, a procedure that is not possible in the majority of cases. In addition, unlike the metal found in

conventional stents, the magnesium alloy used in Biotronik's bioresorbable stents does not interfere with magnetic resonance imaging, an increasingly important alternative to standard angiography, which employs x-rays. Biotronik's bioresorbable stent is currently in clinical evaluation for peripheral arterial disease. The non-binding letter of intent contemplates that any collaboration with Biotronik will be organized around multiple discrete projects, each targeting a specific goal and governed by a mutually agreed upon work plan. This letter of intent also contemplates a collaborative relationship that would extend for a minimum of two years.

In March 2005, we signed an agreement with Novartis Pharma AG granting us the right to evaluate three Novartis pharmaceutical compounds—imatinib mesylate, pimecrolimus and a pre-commercial compound, midostaurin—for the potential development of a product combining a Novartis compound with our stents for the treatment of vascular diseases. Based on the terms of the agreement, we will initially evaluate all three compounds and, based on results, will have the option to obtain a world-wide, non-exclusive license to develop, manufacture and commercialize our stents with one of the three compounds evaluated. If we exercise our option to license one of the compounds, we will be responsible for product development, including clinical testing, manufacturing and regulatory filings, and will pay Novartis licensing fees, milestone payments and royalties on product sales. Novartis will supply us with all three compounds and once we have exercised our option to obtain a license to one of the three compounds, Novartis will supply us with the selected compound and will collaborate with us on certain regulatory and technical issues. Each of the Novartis compounds will be tested in combination with our cobalt chromium stent platform to evaluate their potential in treating restenosis and related vascular diseases. Imatinib mesylate belongs to a class of drugs collectively known as signal transduction inhibitors. It is an inhibitor of several protein-tyrosine kinases including platelet derived growth factor (PDGF) that are believed to play a role in reducing cell proliferation and therefore may have applications in the treatment of restenosis. Pimecrolimus is a cell-selective inhibitor of the production and release of pro-inflammatory cytokines. It is believed that inflammation is one of the key mechanisms in restenosis as well as other vascular inflammatory diseases such as unstable plaques. Midostaurin is an inhibitor of both fibroblast growth factor (FGF) protein kinases and extracellular matrix synthesis associated with vascular endothelial dysfunction such as in the restenosis process in diabetic patients.

In the ordinary course of our business, we negotiate with biotechnology and pharmaceutical companies to in-license additional compounds for use in the treatment of restenosis and for other indications.

Sales and Marketing

In the United States, we plan to build a highly-focused sales and marketing infrastructure to market our CoStar stent to interventional cardiologists. We believe that the interventional cardiology market in the United States is readily accessible by a limited sales and marketing presence. To penetrate interventional cardiology markets outside the United States, as appropriate, we have entered into the following distribution agreements with respect to the commercialization of our products. These agreements primarily encompass distribution of our CoStar stent, although the distributors also have the right to distribute our bare cobalt chromium stent. We do not anticipate that sales of our bare cobalt chromium stent will be significant, and we do not plan to market our bare cobalt chromium stent in the United States.

Biotronik AG

In May 2004, we entered into an agreement with Biotronik under which Biotronik is the exclusive distributor of the CoStar stent in a territory covering all countries of the world except the United States, Japan, Australia, New Zealand, Korea, Pakistan, Kenya, Sri Lanka, Bangladesh, Tanzania and India. Within this territory, Biotronik will be responsible for promoting, marketing and selling our CoStar stent. However, we will continue to be responsible for obtaining and maintaining marketing approvals throughout the territory described above. We are currently conducting the EuroSTAR clinical trial that, if successful, we anticipate will provide the basis for marketing approval for our CoStar stent in Europe. Biotronik can require us to use best efforts to seek regulatory approval in additional countries in Biotronik's territory. We will pay a portion of the costs associated

with securing such additional regulatory approvals, and the remainder will be paid by Biotronik. Under the agreement, Biotronik will purchase stents from us at a transfer price equal to a fixed percentage of Biotronik's average invoiced selling price less certain amounts. Absent early termination for the reasons set forth below, the agreement with Biotronik will continue in force until December 31, 2007, at which point it will automatically renew for an additional year unless one of the parties objects. Either party may terminate the agreement if:

- the other party commits an uncured material breach of the agreement;
- the other party becomes insolvent or files for bankruptcy;
- the other party engages in unethical business conduct;
- a law or regulation renders performance of the contract unduly onerous;
- a product distributed under the agreement infringes the intellectual property of a third party and curing such infringement is not commercially or technically feasible; or
- either party undergoes a change of control event.

In addition, Biotronik can terminate the agreement if we discontinue manufacturing our CoStar stent, and we can terminate the agreement if Biotronik fails to satisfy certain obligations to diligently seek to commercialize our CoStar stent. In addition, we agreed to indemnify Biotronik in certain circumstances if our products infringe the proprietary rights of others.

St. Jude Medical

In November 2004, we entered into three related agreements with affiliates of St. Jude Medical, Inc. under which these entities agreed to be the exclusive distributors of our CoStar stent in Japan, Korea, New Zealand and Australia. Specifically, Getz Bros. Co., Ltd. agreed to be our exclusive distributor in Japan, St. Jude Medical Australia Pty. Ltd. agreed to be our exclusive distributor in Australia and New Zealand and St. Jude Medical (Hong Kong) Limited agreed to be our exclusive distributor in Korea. Within their respective territories, the St. Jude affiliates will be responsible for promoting, marketing and selling our CoStar stent. In addition, the St. Jude affiliates will be responsible for obtaining and maintaining any regulatory approvals in their respective territories, and these regulatory approvals will be owned by the applicable affiliate. However, we will continue to be responsible for obtaining and maintaining marketing approvals in the United States and Europe, and we anticipate that fulfilling European approval requirements for CE marking will be sufficient to permit marketing of our CoStar stent in Australia, New Zealand and Korea after local requirements of labeling and import are met. Under certain circumstances, including early termination of the agreements, we have the right to require that all regulatory approvals owned by the St. Jude affiliates be transferred to us in exchange for a one-time fee. With respect to CoStar stents to be sold in Japan, Getz will purchase the stents from us at a transfer price equal to a fixed percentage of the reimbursement rate for drug eluting stents that is published by the Japanese government. The transfer price for CoStar stents to be sold by the two other St. Jude affiliates will be equal to a fixed percentage of the average selling price of our CoStar stent in the relevant territory. Absent early termination for the reasons described below, all three agreements will continue in force for four years following the date on which the Japanese government approves our CoStar stent for reimbursement, at which point each agreement will automatically renew for an additional three years unless the respective affiliate has not met certain minimum purchase obligations under the agreement. Either party may terminate the agreement if the other party commits an uncured material breach of the agreement, or if the other party becomes insolvent or files for bankruptcy. We may terminate all of the agreements if we or St. Jude undergo a change of control. In addition, if one of the St. Jude affiliates undergoes a change of control, we may terminate the agreement with that affiliate, unless the affiliate is Getz, in which case we may terminate all of the agreements. In order to exercise our termination rights under any of these change of control scenarios, we will need to pay a one-time fee. We have agreed to indemnify each of the St. Jude affiliates under certain circumstances if our products infringe the proprietary rights of others.

Interventional Technologies

In July 2004, we entered into an agreement with Interventional Technologies, Pvt., Ltd., or IVT, under which IVT will be the exclusive distributor of our bare cobalt chromium stent and the CoStar stent in India, Pakistan, Bangladesh, Sri Lanka, Kenya and Tanzania. Within this territory, IVT will be responsible for promoting, marketing and selling these stents. Under the agreement, IVT will purchase stents from us at a fixed, per-unit price. Absent early termination for the reasons set forth below, the agreement with IVT will continue in force for three years and can be renewed for additional one year terms, subject to the mutual written agreement of the parties. Either party may terminate the agreement if the other party commits an uncured material breach of the agreement, or if the other party becomes insolvent or files for bankruptcy. In addition, we can terminate the agreement at any time, subject to advance written notice to IVT, and we can terminate the agreement immediately if IVT undergoes a change of control event. In March 2005, IVT began limited commercial sales of our CoStar stent in India.

Manufacturing and Raw Materials

We have a 29,000 square foot manufacturing facility in Menlo Park, California. We plan to use this facility to manufacture the CoStar stents for our planned U.S. pivotal clinical trial. We have recently established limited manufacturing capacity in Athlone, Ireland to manufacture commercial quantities of our CoStar stent, initially for sale outside of the United States. Our 27,000 square foot manufacturing facility in Ireland became operational in the first quarter of 2005 and we are currently in the process of preparing the facility for full production in anticipation of our planned commercial launch in the European Community. Our facilities are required to meet regulatory standards applicable to the manufacture of products for clinical use and commercial sale.

We have developed proprietary automated drug-loading systems that allow therapeutic agents to be loaded into stents quickly and precisely. In this system, a number of stents are placed in an automated loading machine, and the precise locations of the individual holes on each stent are mapped by a high-speed computer vision system. The drug-polymer composition is then loaded into the drug reservoirs using a precision-guided jetting technology. Stents manufactured using this process reach a level of uniformity that we believe to be unmatched by conventional surface-coated stents.

We purchase many of the materials and components used in manufacturing our CoStar stent, some of which are custom made. Certain supplies are purchased from single sources due to quality considerations, costs or constraints resulting from regulatory requirements. Agreements with certain of our suppliers can be terminated by either party upon short notice, and only our supplier of laser-cut stents and our supplier of catheters have agreed to maintain a guaranteed level of production capacity based on our demand forecasts. Our agreement with our supplier of laser-cut stents terminates in July 2007, and our agreement with our supplier of catheters terminates in November 2006. Both agreements will terminate earlier in the event of our material breach that remains uncured. We cannot quickly establish additional or replacement suppliers for certain components or materials, largely due to the FDA approval process and the complex nature of the manufacturing processes employed by our suppliers, including in particular the laser-precision cutting process required to produce our CoStar stent. Production issues, including capacity constraints affecting our facilities or those of our suppliers can affect our ability to bring new or existing products to market.

In April 2003, we entered into a license and supply agreement with Phytogen International LLC. Under the agreement, Phytogen manufactures and supplies to us paclitaxel in bulk form, which we then incorporate into the CoStar stent. In return, we are obligated to pay Phytogen a royalty on sales of our paclitaxel eluting stents and a percentage share of fees received for licensing these stents to others. We agreed to indemnify Phytogen in certain circumstances if our products infringe the proprietary rights of others. The agreement continues until the tenth anniversary of the initial commercial launch of the CoStar stent. If we commit a material breach of the agreement, we could lose our sole supply of paclitaxel.

Competition

The medical device, biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products, designs and processes. We face competition from many different sources, including commercial medical device, pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Due to the high demand for new stent technology, research is intense and new treatments are being sought out and developed continuously by our competitors.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

There are a number of companies developing or marketing treatments for restenosis that are directly competitive with our technology. In particular, Boston Scientific Corporation has developed a paclitaxel eluting stent, the TAXUS™ Express²™ stent, which is marketed in the United States, Europe and other international markets. Johnson & Johnson has developed a stent coated with rapamycin, the CYPHER™ stent, which is marketed in the United States and Europe. The TAXUS™ Express²™ stent and the CYPHER™ stent are currently the only FDA approved drug eluting stents in the United States. In addition, Guidant Corporation, Abbott Laboratories, Biocompatibles International plc and Medtronic, Inc. are all developing drug eluting stents. All of the drug eluting stents that have been publicly disclosed as being under development by other companies are surface-coated stents. Many of these companies claim that their drug eluting stents provide the ability to control release kinetics.

In August 2004, Boston Scientific announced that it had begun patient enrollment in a pivotal study to collect data to support regulatory filings required to commercialize its new TAXUS™ Liberte™ paclitaxel-coated coronary stent as a platform for its next-generation drug eluting coronary stent system. Boston Scientific has stated that the trial is designed to assess the safety and efficacy of a slow-release dose formulation for the treatment of coronary disease and that the TAXUS™ Liberte™ stent system is designed to further enhance the stent's deliverability and conformability, particularly in challenging lesions.

Successful clinical results, regulatory review and commercialization of any of these competing technologies could have a material adverse impact on our business. In addition, other companies are developing various other technologies for the reduction or treatment of restenosis, as well as other technologies for treating cardiovascular disease in general, which will compete with our stent platform should these products be approved for commercialization.

Patents and Proprietary Rights

Overview

Intellectual property rights, including in particular patent rights, play a critical role in the drug eluting stent sector of the medical device industry, and therefore in our business. Patents represent rights granted to the patent owner by the government of a particular country to exclude third parties from practicing an invention in that country. The invention may be a particular product, for example a stent, or a method for accomplishing an objective, such as a method to use a stent to treat restenosis, or a method to manufacture a stent. A patent typically consists of several "claims" that set out the boundaries of the inventive subject matter that a patent holder can prevent others from making, using, selling or offering to sell for the lifetime of the patent.

A patent owner generally may exclude third parties from commercializing a product that infringes at least one claim of the patent. Whether a product or its use infringes a patent claim is highly fact-specific and sometimes not apparent from the literal words of the claim. Parties involved in a patent dispute may not be able to predict with certainty whether a court will conclude that a product infringes a patent claim until the court interprets the claim. This uncertainty can be heightened in the United States by the doctrine of equivalence. Under this doctrine, a product that does not infringe the literal words of a patent claim may nevertheless be found to infringe the patent if, for example, it performs substantially the same function in substantially the same way to achieve substantially the same result as the invention to which the claim is directed.

In order for a patent to be enforceable by its owner, it must be valid. To be valid, the claims must satisfy the criteria established by the issuing government for granting a patent. The patent claim must describe something that is new, or "novel." In addition, in the United States and some other countries, a claim for an invention is not patentable if, at the time the invention arose, it would have been "obvious" to an ordinary worker in that field. Whether a patent claim is novel and nonobvious is tested by comparison to the "prior art," which is a term that refers to the total state of technology at the time of filing the patent application, which in general includes, among other things, publications in any language in any country, publicly available patent filings, public use in the United States, and offers for sale or sales. The prior art date of a U.S. patent publication, or an international Patent Cooperation Treaty, or PCT, application that designates the United States and is published in English, is the date of filing. The prior art date of an international application that does not designate the United States or is published in a language other than English is its publication date. The patent claim must also be sufficiently clear and definite so as to allow the public to know whether it is infringing the claim, that is, it must give proper notice of infringement.

In the United States, patents are issued by the U.S. Patent Office. In the United States, federal courts or the U.S. Patent Office may subsequently decide that one or more claims contained in a patent are invalid, rendering those claims unenforceable against third parties. Establishing invalidity of even one patent claim, however, can be difficult. In the United States, issued patents enjoy a presumption of validity as a matter of law, and the party challenging the validity of a patent claim has the burden of proof, which can only be satisfied by clear and convincing evidence. By contrast, in a patent litigation the patent owner need only prove infringement by the "preponderance of the evidence" standard that is generally applicable in civil litigation.

If an issued patent is infringed by a third party and the relevant claims are found to be valid and enforceable, the patent owner can seek damages for infringement that has occurred up to the time of such a finding. In the United States, if the infringing third party is determined to have infringed the patent willfully, the patent owner may also be entitled to increased damages (up to three times actual damages) and, potentially, attorneys' fees. Whether or not infringement is determined to be willful, the court may enjoin, or prohibit, the infringer from engaging in further infringing activity or otherwise set forth the conditions for the continued use of the patented technology. The patent owner in general has no obligation to make a license available on reasonable terms or at all. However, upon finding a claim valid and infringed, a court, in its discretion based on the evidence presented, may determine that the infringing product is so important to the public that the public's interest is not served by excluding the product from the market. In such a case, the court will allow the product to remain on the market and require that the infringer pay equitable compensation to the patent owner. This discretion of the court is rarely invoked outside of the medical area and, even in the medical area, is not typically invoked unless there is no reasonable substitute for the product and the human health would be impaired absent continued access to the product. Where this discretion is invoked to permit continued presence in the market, the court may place constraints on such presence, for example, limiting the duration or other circumstances under which the product can remain available.

The third party, whether faced with litigation or not, may seek to obtain from the patent owner a license that would enable the third party to continue commercializing the patented technology.

Patents are issued and enforced on a country-by-country basis. In the European Union, there is a centralized process for seeking patents at the European Patent Office, or the EPO, although patents, once issued, are enforced on a country-by-country basis. In addition, unlike in the United States, once a patent is issued through the EPO

centralized process, it can be challenged at the EPO by third parties in a proceeding known as an opposition. During the pendency of an opposition proceeding, the owner of the patent can still seek to enforce the patent on a country-by-country basis against purported infringers, although the courts of a given country may choose to stay, or suspend, the enforcement action pending resolution of the EPO opposition proceeding. As an alternative, parties affected by patents can file invalidation proceedings directly in a selected country, and the country will thereafter independently determine whether to wait for a decision on the EPO opposition (including any appeals that may be taken) or commence deciding the validity of the patent claims under the law of that country notwithstanding the EPO opposition process.

In a patent litigation, both parties are at risk. The purported infringer is at risk of being held to infringe and therefore liable for damages (including possibly increased damages and attorneys' fees), which can be substantial. Also, an infringer may be enjoined by the court from further activities relating to the infringing product. At the same time, however, the purported infringer may assert that the patent claims at issue are invalid or otherwise unenforceable. If the accused infringer prevails in its assertions, the patent owner may permanently lose its patent rights or have those rights curtailed.

Our Patents and Proprietary Rights

We rely on intellectual property rights for the protection of our CoStar stent and plan to rely on these rights to protect any other products that we may develop. We own a number of issued patents and pending patent applications in the United States and foreign countries and plan to file additional patent applications on inventions that are important to our business and that we believe are patentable. We intend to aggressively pursue and defend patent protection on our proprietary technologies.

As of March 3, 2005, we held 8 U.S. patents and had 47 pending U.S. patent applications and 50 pending foreign patent applications (which include 14 international PCT applications and 36 foreign national applications). The U.S. patents that cover our CoStar stent are:

- U.S. Patent No. 6,241,762, entitled "Expandable Medical Device with Ductile Hinges," which expires in 2018;
- U.S. Patent No. 6,562,065, entitled "Expandable Medical Device with Beneficial Agent Delivery Mechanism," which expires in 2018; and
- U.S. Patent No. 6,764,507, entitled "Expandable Medical Device with Improved Spatial Distribution," which expires in 2020.

Applications for patents corresponding to the subject matter of U.S. Patent No. 6,241,762 have been filed in Europe, Israel, Japan, Korea, Australia and Canada. Patents, if issued on these pending foreign applications, will expire in 2018. In addition, 22 of our pending U.S. applications and 25 of our international applications (including four PCT and 21 foreign national applications) have claims or subject matter directed to our CoStar stent. Patents relating to these applications, if issued, will expire between 2018 and 2025.

We have four U.S. patent applications and two international PCT applications covering stents for the treatment of AMI. Patents, if issued on these applications, will expire between 2023 and 2024.

The other U.S. and foreign patent applications in our patent portfolio are directed generally to inventions relating to stent structures, drug delivery technologies, methods of manufacturing our CoStar stent and other products that we may develop.

To date, our patents have not been challenged by a third party, and we do not know whether, if challenged, they will be found to be valid and enforceable or how broadly the claims would be interpreted. As a result, we do not know how much practical protection our patent rights will afford us.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information by generally requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement, through which we seek to protect our intellectual property. Agreements with our employees also prevent them from bringing the proprietary rights of third parties to us. We also generally require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

Third-Party Patent Rights

The medical device industry in general, and the stent sector of this industry in particular, are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. We are aware of numerous patents issued to third parties that relate to aspects of our business, including the design and manufacture of drug eluting stents as well as the use of catheters to place stents. The owners of each of these patents could assert that the manufacture, use or sale of our CoStar stent infringes one or more claims of their patents. Each of these patents contains multiple claims, any one of which may be independently asserted against us on commercialization of our product. The following summary discusses certain patents that we believe, as a result of the claims these patents contain in relation to our CoStar stent, may represent a material litigation risk to us. There may be additional patents that relate to aspects of our technology that will materially and adversely affect our business. Moreover, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, or patents that we are not aware of, which may later result in issued patents that materially and adversely affect our business.

The patent expiration dates indicated below assume that the indicated patents are not invalidated or extended prior to their scheduled expiration dates. Many of the patents discussed below have one or more equivalent foreign issued patents or related pending applications (in addition to any described in the summary below).

The fact that we list a patent below as a potential risk to us does not mean that we necessarily consider the patent either valid or enforceable or that a court would necessarily conclude that we infringe the patent. However, it may be determined by a court or otherwise that patents that have been issued or are issued in the future to third parties contain one or more valid claims that we infringe.

Use of Paclitaxel to Treat Restenosis

Our CoStar stent incorporates the antiproliferative drug paclitaxel as a therapeutic for restenosis. Angiotech has asserted during patent prosecution that the treatment of restenosis can also be categorized as the treatment of stenosis or angiogenesis. We do not believe that restenosis is an angiogenesis driven disease. We are aware of a number of U.S. patents with claims that are directed to either (i) the use of paclitaxel to treat angiogenesis, stenosis or restenosis generally, regardless of how the paclitaxel is administered or (ii) a stent that includes paclitaxel in a polymer or the use of such a stent to treat angiogenesis, stenosis or restenosis.

Boston Scientific purchased from NeoRx Corporation a series of patents, referred to as the "Kunz" patents, which cover the use of paclitaxel to treat restenosis generally and also via a stent, including, without limitation, U.S. Patent Nos. 5,733,925, 5,811,447, 6,074,659, 6,171,609, 6,268,390, 6,306,421, 6,515,009, 6,599,928 and 6,663,881. There are other Kunz U.S. and foreign patent applications pending. Three Kunz patents, U.S. Patent No. 6,171,609, with a claim directed to a stent with a cell growth inhibitor effective to inhibit stenosis or reduce restenosis following the placement of a stent, U.S. Patent No. 6,599,928, with claims directed to a method for maintaining vessel luminal area that includes inserting a stent that has a cytostatic agent that does not exhibit substantial cytotoxicity to treat restenosis, and U.S. Patent No. 6,515,009 with claims directed to methods for maintaining vessel luminal area by administering dosage forms of a cytostatic amount of a cytoskeletal inhibitor which does not exhibit substantial cytotoxicity, have been asserted by Boston Scientific and SciMed Life

Systems, Inc., a subsidiary of Boston Scientific, against Johnson & Johnson and Cordis in Federal District Court in Delaware. On March 11, 2005, the Federal District Court in Delaware dismissed all claims relating to the patents without the right to bring the claims in the future, and dismissing all counterclaims by Johnson & Johnson, Cordis and Guidant with the right to assert the counterclaims in the future. The Kunz patents expire between 2011 and 2020.

Angiotech Pharmaceuticals, Inc. is the owner of a family of patents, sometimes referred to as the "Hunter" patents, U.S. Patent Nos. 6,544,544 and 5,716,981 and EP 0 706 376 (the "EP" designation indicates a patent issued by the European Patent Office), and has licensed from the U.S. government a family of other patents, sometimes referred to as the "Kinsella" patents, U.S. Patent Nos. 6,429,232, 5,616,608 and 6,403,635 and EP 0 711 158, that cover the use of paclitaxel-coated stents to treat angiogenesis and restenosis (together referred to as the "Angiotech" patents). There are other Hunter and Kinsella patents and patent applications pending in the United States and in foreign countries. We understand that, in 1997, Angiotech granted co-exclusive sublicenses to Boston Scientific Corporation and Cook Inc. in the Angiotech patents. We also understand that this license has been converted to an exclusive license in the coronary vascular field of use to Boston Scientific and that Boston Scientific has obtained the right to sublicense the Angiotech patents. The Angiotech patents expire between 2013 and 2015.

EP 0 706 376 B1 to Hunter was granted in May 1997 to Angiotech and was initially opposed at the EPO by five parties in a proceeding that commenced in March 1998. The Opposition Division of the EPO issued a decision in August 2000 that revoked the patent based on the unpatentability of a claim directed to the use of paclitaxel generally (without the reference to administration via a stent) to treat angiogenesis over certain prior art references, most notably PCT publication WO 93/11120 filed by Kopia, that generally described in June 1993 that paclitaxel is an antiproliferative that is useful in the treatment of restenosis. Angiotech appealed the decision of the Opposition Division to the European Technical Boards of Appeal. In a decision dated April 25, 2003, the European Technical Boards of Appeal sent the proceeding back to the Opposition Division for further consideration of the claims directed to a stent coated with a polymeric material that includes paclitaxel. In a hearing on January 24, 2005, the Opposition Division rendered a decision allowing certain claims to a stent coated with paclitaxel or its analog or derivative and a polymer. This decision can be appealed by the two remaining opposition parties to the European Technical Boards of Appeal. If neither of the two remaining opposition parties appeal the decision of the Opposition Division, the decision will become final after the time period for appeals expires. This time period has not yet been set by the European Patent Office. If these proceedings are considered final, we may be required to challenge the validity in each European country designated as covered by EP 0 706 376 B1 in which we seek to commercialize our CoStar stent.

On February 1, 2005, Angiotech Pharmaceuticals, Inc. and Boston Scientific Corporation (as Angiotech's licensee) initiated legal proceedings against us in the District Court in the Hague, Netherlands, seeking: a declaration that our CoStar stent infringes EP 0 706 376 B1 in the Netherlands and other countries designated in EP 0 706 376 B1; an order that we and our affiliates cease any infringement of EP 0 706 376 B1 in the Netherlands and other designated European countries; an order that we not use our CE marketing approval, if obtained by us, for three years or for a period of time which the District Court deems appropriate and/or at the choice of Boston Scientific and Angiotech; an order requiring us to withdraw all information and documentation concerning the clinical trials we have conducted in the Netherlands from all relevant regulatory authorities worldwide; an order requiring us to pay 2,460 euros per sale of our CoStar stent in Europe or, at the choice of Boston Scientific and Angiotech, 2,460 euros per day that we do not comply; an order that we indemnify Boston Scientific and Angiotech or surrender our profit on sales of our CoStar stent in countries covered by EP 0 706 376 B1; and an order that we pay the costs of the proceedings. We intend to defend ourselves in this proceeding, including the filing of counterclaims where appropriate. If we do not succeed in either invalidating EP 0 706 376 B1 or in establishing that the patent is not infringed by our CoStar stent, we will not be able to commercialize our CoStar stent in the Netherlands and we may not be able to commercialize our CoStar stent in other European countries designated in EP 0 706 376 B1 without a license from Boston Scientific, which may not be available to us on acceptable terms, or at all.

On February 18, 2005, we initiated proceedings against Angiotech and the University of British Columbia in the High Court of Justice in the United Kingdom requesting that the court invalidate EP 0 706 376 B1 based on the grounds that all claims of the patent either lack novelty or are obvious in light of the state of scientific knowledge at the priority date of the patent. A trial date for this proceeding has been set for October 4, 2005. If the High Court of the United Kingdom rules that EP 0 706 376 B1 is valid in the United Kingdom, then we may in the future need to litigate whether we infringe any of the valid claims. If we are found to infringe one or more valid claims, then we may not be able to commercialize our CoStar stent in the United Kingdom without a license from Boston Scientific, which may not be available to us on acceptable terms, or at all.

On March 31, 2005, we filed an Application to Revoke Australian Patent Nos. 728873, 771815 and 693797 owned by Angiotech Pharmaceuticals and University of British Columbia in the Federal Court of Australia (Victoria District Registry), on the bases, among others, that the patents are invalid in light of the state of scientific knowledge as of the priority date of the patents and that they are not enabled for the claimed subject matter. We are not currently conducting clinical trials in Australia on our CoStar stent, but we may seek to commercialize our CoStar stent in Australia in the future. However, if the Federal Court of Australia rules that these Australian patents are valid, then we may in the future need to litigate whether we infringe any of the valid claims. If we are found to infringe one or more valid claims, then we may not be able to commercialize our CoStar stent in Australia without a license from Boston Scientific, which may not be available to us on acceptable terms, or at all.

EP 0 711 158 B1 to Kinsella et al. was granted in October 2003 to the U.S. government (and also licensed to Angiotech) with claims to a drug delivery system for local delivery of paclitaxel, which can be via a stent, as well as claims to the use of paclitaxel to reduce or prevent the development of atherosclerosis. Prior to the expiration of the opposition period, we filed an opposition against these Kinsella claims based in part on prior disclosure of local delivery of paclitaxel and/or use of paclitaxel in treatment of atherosclerosis in multiple prior art references. The Opposition Division has not yet set a time limit for filing amendments and arguments.

Stent Structure

We are aware of a large number of U.S. patents issued to third parties relating to stent design. Because of the large number of patents in this field, it is particularly difficult to identify those patents that could materially and adversely affect our business.

U.S. Patent No. 6,783,543 was recently issued to SciMed Life Systems, a subsidiary of Boston Scientific, with claims covering an expandable stent with a plurality of cavities which are micro-holes or micro-slits that extend from the outer surface through the inner surface and which act as reservoirs for a substance. The patent expires in 2021.

Advanced Cardiovascular Systems, Inc., a subsidiary of Guidant, owns a series of patents, the "Lau" patents, including, but not limited to, U.S. Patent Nos. 5,421,955, 5,514,154, 6,066,167, 6,309,412, 6,432,133, 6,485,511, 6,596,022 and 6,689,159. The Lau patents claim stent structures including cylindrical elements and interconnecting elements. The Lau patents expire between 2011 and 2013.

Medinol, Ltd. owns a large number of U.S. patents and patent applications directed to stent designs and manufacture. Medinol sued Johnson and Johnson in a patent infringement action involving some but not all of the claims of U.S. Patent Nos. 5,733,303, 5,843,120 and 5,972,018. In January 2004, the U.S. Court of Appeals for the Federal Circuit held that most of the asserted claims were invalid as obvious, but that claim 13 of the '120 patent directed to a particular stent design was valid and infringed.

Medinol, Ltd. is also in current litigation with Guidant and Advanced Cardiovascular Systems in the Southern District of New York over alleged infringement of U.S. Patent Nos.: 5,733,303, 5,843,120, 5,972,018, 6,443,982 and 6,461,381 by the manufacture and sale of the MULTI LINK PENTA® and MULTI LINK ZETA™

systems. A recent ruling was entered granting Guidant and ACS partial summary judgment with respect to claims 24 of the '303 patent and 64 of the '018 patent. Guidant's motion was denied as to the following claims: 28 of the '303 patent; 13, 16, 18, and 27 and 28 of the '120 patent; 51 of the '018 patent; 1, 2-15 and 17 of the '982 patent; and 56-58, 61, 63, 65-66 and 68-70 of the '381 patent.

Boston Scientific and others asserted oppositions to granted Medinol patents in Europe. In April 2004, the European Technical Boards of Appeal held a Medinol patent invalid in the appeal of a prior decision maintaining the patent by the European Opposition Division based on an opposition by Boston Scientific and others. In an earlier European Opposition proceeding, Medinol stent claims in another European Patent were upheld as valid over oppositions filed by SciMed, Cordis and others, and this opposition is currently on appeal to the European Technical Boards of Appeal.

Two patents issued to Sorin Biomedica Cardio S.p.A., U.S. Patent Nos. 6,309,414 and 6,616,690, generally cover expandable stents for supporting the wall of the lumen of a vessel. The Sorin patents expire in 2017.

We are aware of U.S. Patent Nos. 6,656,162 and 5,797,898 and U.S. Patent Application Publication No. 2004/0166140 A1, to Santini, Jr., et al., owned by MicroCHIPS, Inc., with claims directed to a device for the controlled release of one or more drugs that include an implantable stent; at least two reservoirs in the stent and a release system contained in each of the at least two reservoirs, wherein the release system includes one or more drugs for release. The patent expires in 2020.

We are also aware of a number of patents issued to Palmaz, which are owned by Cordis including, without limitation, U.S. Patent Nos. 4,733,665, 4,776,337 and 4,739,762, related to balloon expandable stents. These patents expire in 2005, prior to our planned U.S. market launch.

Stent Delivery Catheters

In order to deliver a stent, a physician must use a catheter designed for stent delivery. Consequently, we plan to commercialize our CoStar stent in combination with a delivery catheter of our design. In particular, we are currently in clinical trials with a delivery catheter of a type referred to as a "rapid exchange" catheter, and are conducting research on the use of a number of other types of delivery catheter designs. We are aware of a number of patents relating to the design and use of catheters, including rapid exchange catheters, that have been issued to third parties.

One family of patents, termed the "Lau" patents, U.S. Patent Nos. 6,527,789 and 6,488,694, directed to a rapid exchange catheter to deliver a stent, is owned by Advanced Cardiovascular Systems. The Lau patents expire between 2011 and 2013.

Another family of patents, termed the "Yock" patents, including, without limitation, U.S. Patent Nos. 6,036,715, 5,061,273, 5,451,233, 5,040,548, 5,749,888 and 6,575,993, directed to a type of design of a rapid exchange catheter, is also owned by Advanced Cardiovascular Systems. The Yock patents expire between 2006 and 2008. Another family of patents, termed the "Horzewski" patents, include U.S. Patent Nos. 4,748,982, 5,496,346 and 5,626,600, directed to another type of catheter design, is also owned by Advanced Cardiovascular Systems. These patents expire in 2005.

Another family of patents that cover rapid exchange catheters, termed the "Bonzel" patents, U.S. Patent Nos. 4,762,129 and 5,002,531, are owned by Boston Scientific. The Bonzel patents expire in 2005, prior to our planned U.S. market launch.

Method of Manufacturing Coated Stents

We are aware of two patents, U.S. Patent Nos. 6,395,326 and 6,616,765, that are owned by Advanced Cardiovascular Systems, directed to the application of a material to a stent, and which are referred to as the "Castro" patents. The Castro patents expire in 2020.

Consequences of Infringement

All of the major companies in the stent and related markets, including Boston Scientific Corporation, Johnson & Johnson, Guidant Corporation and Medtronic, have been repeatedly involved in patent litigation relating to stents since at least 1997. As described above, Angiotech and Boston Scientific have initiated legal proceedings against us seeking a declaration that our CoStar stent infringes Angiotech's EP 0 706 376 B1 and seeking various orders preventing us from commercializing our CoStar stent in certain European countries, and requiring us, among other things, to pay damages. In addition, we have initiated legal proceedings in the United Kingdom and in Australia seeking to revoke or invalidate certain of Angiotech's Hunter patents. Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to other large and well-capitalized companies who own or control patents relating to stents and their use, manufacture and delivery, we believe that it is highly likely that additional third parties will assert patent infringement claims against the manufacture, use or sale of our CoStar stent based on one or more of these or other patents. Any lawsuit could seek to enjoin, or prevent, us from commercializing our CoStar stent and may seek damages from us, and would likely be expensive for us to defend against. We have also received correspondence from third parties who have intellectual property rights in, or who have been actively involved in litigation or oppositions relating to, coronary stents, asserting that they may have rights to patents that are relevant to our operations or our stent platform and requesting initiation of discussions.

If any patents are ultimately determined to contain one or more valid claims that we infringe, we may, among other things, 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 CoStar stent, through a court-imposed sanction called an injunction;
- expend significant resources to redesign our technology so that it does not infringe others' patent rights, or to develop or acquire non-infringing intellectual property, which may not be possible;
- discontinue manufacturing or other processes incorporating infringing technology; and/or
- obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

In addition, litigation with any of these patent owners, even if their allegations are without merit, would likely be expensive and time-consuming and divert management's attention from our core business.

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 approval.

Our conclusions regarding non-infringement and invalidity are based in part on a review of publicly available databases and other information. There may be information not available to, or otherwise not reviewed by, us that might change our conclusions. Moreover, as described above, the scope and validity of patent claims are determined based on many facts and circumstances, and in a litigation a court may reach a different conclusion on any given patent claim than the conclusions that we have reached.

While our products are in clinical trials, and prior to commercialization, we believe that our activities in the United States related to the submission of data to the FDA fall within the scope of the exemptions that cover activities related to developing information for submission to the FDA and fall under general investigational use or similar laws in other countries. However, the U.S. exemptions would not cover our stent manufacturing or other activities in the United States that support overseas clinical trials if those activities are not also reasonably related to developing information for submission to the FDA.

See "Risk Factors—Risks Related to Our Intellectual Property—If any patent infringement or other intellectual property claims asserted against us are successful, we could be enjoined, or prevented, from developing and commercializing our CoStar stent or other product candidates," "—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 market share, and, therefore, our revenues" and "—We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights."

Government Regulation

United States

Our product candidates are combination products because they are comprised of two or more regulated components (i.e., a drug and a device) that are physically combined and produced as a single entity. Because the primary mode of action is that of a medical device, our products are regulated primarily as devices by the FDA under the Federal Food, Drug, and Cosmetic Act. Some aspects of our product candidates (e.g., release kinetics) will be reviewed by FDA's drug review center. FDA regulations govern:

- product design and development;
- product testing;
- product manufacturing;
- product safety;
- product labeling;
- product storage;
- record keeping;
- pre-market clearance or approval;
- advertising and promotion;
- production; and
- product sales and distribution.

Unless an exemption applies, each product that we currently plan to commercially distribute in the United States will require either prior 510(k) clearance by, or prior premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk are placed in either class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission for commercial distribution. This process is known as 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or a device deemed to be not substantially equivalent to a previously cleared 510(k) device, are placed in class III. In general, a class III device cannot be marketed in the United States unless the FDA approves the device after submission of a premarket approval application. The FDA can also impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

Premarket Approval

Our CoStar stent is a combination product that will be regulated primarily as a class III medical device. FDA approval of a premarket approval application, or PMA, is required before marketing of a class III medical device in the United States can precede. The process of obtaining premarket approval is much more costly, lengthy and uncertain than 510(k) clearance. A PMA must be supported by extensive data including, but not limited to, technical, pre-clinical and clinical studies, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling.

After the FDA determines that a PMA is complete, the FDA accepts the application and begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted premarket approval application, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the quality system regulations. Under the Medical Device User Fee and Modernization Act of 2002, the fee to submit a PMA can be up to $240,000 per PMA, but certain companies may qualify for a small business exemption. New PMAs or supplemental PMAs are required for significant modifications to the manufacturing process, labeling, use and design of a device that is approved through the premarket approval process. Premarket approval supplements often require submission of the same type of information as a PMA except that the supplement is limited to information needed to support any changes from the device covered by the original PMA, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Studies

A clinical study is almost always required to support a PMA and is sometimes required for 510(k) clearance. Clinical trials for a "significant risk" device require 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. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the institutional review board overseeing the clinical trial. If the product is deemed a "non-significant risk" device under FDA regulations, only informed consent and approval from the institutional review board overseeing the clinical trial is required. We have received conditional approval of our IDE application from the FDA to permit commencement of our COSTAR II pivotal clinical trial. The FDA's conditional approval of our IDE application allows us to begin a limited enrollment in our COSTAR II trial. We are required to provide additional information to the FDA prior to the FDA granting full approval of the IDE application, including information that will be reviewed prior to the FDA approving full enrollment in our COSTAR II trial. While we anticipate that we will be able to provide the additional information that the FDA has requested, there can be no assurance that we will receive full approval of our IDE application on a timely basis, if at all. If we are unable to provide the additional information to the FDA, or if the FDA does not believe that the additional information we provide is sufficient, the FDA may require us to cease enrollment in the trial until adequate information is provided. 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, requirements. 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 study subjects outweigh the anticipated benefits. The results of clinical testing may not be sufficient to obtain approval of the product.

Pervasive and Continuing FDA Regulation

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

- quality system regulation, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- labeling regulations, which govern product labels and labeling, prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling and promotional activities;
- 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 it were to recur; and
- notices of correction or removal and recall regulations.

Advertising and promotion of medical devices are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, some promotional activities for FDA-regulated products have been the subject of enforcement actions brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act, competitors and others can initiate litigation relating to advertising claims.

Compliance with regulatory requirements is enforced through periodic, unannounced facility inspections by the FDA and the Food and Drug Branch of the California Department of Health Services. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters or untitled letters;
- fines, injunction and civil penalties;
- recall or seizure of our products;
- customer notification, or orders for repair, replacement or refund;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for premarket approval of new products;
- withdrawing premarket approvals that are already granted; and
- criminal prosecution.

International

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

The primary regulatory environment in Europe is that of the European Community, which consists of 26 countries encompassing nearly all the major countries in Europe. Other countries which are not part of the European Community, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Community with respect to medical devices. The European Community has adopted Directive 93/42/EEC on medical devices and numerous standards that govern and harmonize the national laws and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices that are marketed in member states. Medical devices that comply with the requirements of the national law of the member state in which they are first marketed will be entitled to bear CE marking, indicating that the device conforms with applicable regulatory requirements, and, accordingly, can be commercially marketed within European Community states. The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for an implantable stent that incorporates a drug (which falls into class III), the method involves a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third party assessment by a Notified Body, usually of the design of the device and of the manufacturer's quality system. A Notified Body is a private commercial entity that is designated by the national government of a member state as being competent to make independent judgments about whether a product complies with applicable regulatory requirements. The manufacturer's assessment will include a clinical evaluation of the conformity of the device with applicable regulatory requirements, which for a new drug eluting stent will include the results of clinical studies.

The approval of a regulatory authority and of an ethics committee is required in order to undertake a clinical study in a European Community state. Where a medical device incorporates a drug, the requirements for safety, efficacy and quality of that drug as set out in the legislation governing pharmaceutical products must be satisfied, which requires approval of such aspects by a regulatory authority. National laws and guidelines regulate other aspects such as labeling and post-marketing due diligence requirements. Continued regular auditing and re-certification by a Notified Body is generally required for a class III device.

We are not subject to any regulatory approval process in order to commercialize our CoStar stent in India. We have received export approval from the FDA that enables us to ship product to India that has not been approved for commercial distribution in the United States. We may also manufacture our products in Ireland for export outside of the European Community before we are entitled to bear CE marking.

Outside of the European Community, the requirements to commercialize a medical device vary country by country. Some countries, such as Japan, have their own governmental approval process through which clinical trial data and other information are submitted to a regulatory authority. In other countries, a medical device may be commercialized if the product has been approved in the United States or is entitled to bear CE marking.

State of California

The State of California requires that we obtain two separate licenses, one to manufacture medical devices and the other to manufacture drugs, and subjects us to periodic inspection. Our facilities and manufacturing processes were inspected in March 2004. We passed the inspection and received both licenses from the Food and Drug Branch, or FDB, of the California Department of Health Services in June 2004. Both of these licenses expire and must be renewed in May 2005.

Research and Development

Since inception, we have devoted a significant amount of resources to develop our stent platform. During 2002, 2003 and 2004, we recorded $3.6 million, $9.2 million and $18.8 million, respectively, in research and development expenses.

Employees

As of December 31, 2004, we had 75 full time employees, five of whom hold Ph.D., M.D. or comparable degrees and 16 of whom hold other advanced degrees. Approximately 61 employees are engaged in research and development and 14 in business development, finance and other administrative functions. None of our employees are represented by a labor union or are covered by a collective bargaining agreement. We believe that we maintain good relations with our employees.

Executive Officers of the Registrant

The following sets forth certain information regarding our executive officers as of March 15, 2005.

Name	Age	Position
Frank Litvack, M.D.	49	Chief Executive Officer and Chairman of the Board
John F. Shanley	55	Founder, Chief Technology Officer and Director
Azin Parhizgar, Ph.D.	45	Vice President, Chief Operating Officer
Michael Boennighausen	44	Vice President, Finance and Administration and Chief Financial Officer
Earle L. Canty	52	Vice President, Regulatory Affairs and Quality Assurance
Stephan H. Diaz	62	Vice President, Engineering and Pilot Production
Cindy A. Lynch	36	Vice President, Intellectual Property
Jeff Tillack	40	Vice President, Operations

Frank Litvack, M.D. has been chairman of our board of directors since 2002. In 2003, Dr. Litvack was appointed Chief Executive Officer. From 1999 to 2001, Dr. Litvack was Chairman and Chief Executive Officer of Fasturn Inc., a software company. Since 2001, Dr. Litvack has been a managing director of the general partner of Calmedica Capital, L.P. Since 2000, Dr. Litvack has been a Professor of Medicine at University of California, Los Angeles. From 1989 until 1997, Dr. Litvack was a founder and director of Progressive Angioplasty Systems Inc., which was acquired by United States Surgical Corporation. Since 1996, Dr. Litvack has been a member of

Calmedica International, LLC. Dr. Litvack currently holds the rank of Attending Physician at Cedars-Sinai Medical Center. Since 1985, Dr. Litvack has been an attending cardiologist at Cedars-Sinai Medical Center. Dr. Litvack co-directed the Cardiovascular Intervention Center at Cedars-Sinai Medical Center from 1986 to 2000. Dr. Litvack holds an M.D. from McGill University.

John F. Shanley founded Conor Technologies, our predecessor company, in 1996, and founded Conor Medsystems in 1999. Mr. Shanley has been our Chief Technology Officer since 2002 and a member of our board since 1999. From 1999 to 2002, Mr. Shanley was our Chief Executive Officer. From 1992 to 1995, Mr. Shanley served as Vice President, Operations and Engineering for Purus, Inc., a start-up technology company. Mr. Shanley holds a B.S. in Engineering Science and a M.S. in Materials Science from the University of Notre Dame.

Azin Parhizgar, Ph.D. has been our Vice President, Chief Operating Officer, since September 2004. From 2002 to 2004, Dr. Parhizgar was an independent consultant advising companies involved in the development of device/drug/biologics technologies and other emerging cardiovascular technology sectors. From 1996 to 2002, Dr. Parhizgar held various positions with Medtronic, Inc., a medical device company, including Executive Vice President of Emerging Ventures and Regulatory Science at Medtronic AVE and Executive Vice President of Global Regulatory, Quality and Clinical Affairs at Medtronic Vascular. Dr. Parhizgar holds a dual B.Sc. in Biology and Chemistry from Boston College, a M.Sc. in Biomechanical Engineering and a Ph.D. in Tissue Engineering both from Brown University.

Michael Boennighausen has been our Vice President, Finance and Administration, since July 2002 and was appointed our Chief Financial Officer in April 2004. From 1994 to 2002, Mr. Boennighausen served in various positions at ALZA Corporation, a pharmaceutical company, including Group Controller and Director of Investor Relations. Prior to ALZA, Mr. Boennighausen served as a health care policy analyst and also was a volunteer with the U.S. Peace Corps in Africa. Mr. Boennighausen holds a B.A. in Political Science from Stanford University and an M.B.A. from University of California, Los Angeles.

Earle L. Canty has been our Vice President of Regulatory Affairs and Quality Assurance since January 2004. From 2001 to 2003, Mr. Canty was Vice President for Regulatory Affairs, Clinical Affairs and Quality Assurance at TriVascular, Inc., a medical equipment company. From 1998 to 2001, Mr. Canty was a regulatory affairs and quality assurance consultant for various clients. From 1996 to 1998, Mr. Canty was Vice President for Regulatory Affairs and Quality Assurance at Cardiac Pathways Corporation, a medical device company. From 1995 to 1996, Mr. Canty was Vice President for Regulatory Affairs and Quality Assurance at Symphonix Devices, a medical device company. From 1987 to 1994, Mr. Canty was Vice President for Regulatory Affairs and Quality Assurance at Ventritex Inc., a medical device company. Mr. Canty holds a B.S. and an M.A. in Biological Sciences from Stanford University.

Stephen H. Diaz has been our Vice President of Engineering and Pilot Production since 2003. From 2001 to 2003, Mr. Diaz was our director of engineering. From 1999 to 2001, Mr. Diaz was retired. From 1970 to 1999, Mr. Diaz held a number of senior management positions at Raychem Corporation, an electronics company, including Design Engineer and Technical Director. Mr. Diaz holds a B.S. in Mechanical Engineering from Louisiana State University.

Cindy A. Lynch has been our Vice President of Intellectual Property since 2003. From 1997 to 2003, Ms. Lynch was a partner and an associate with Burns, Doane, Swecker & Mathis, LLP, a law firm specializing in intellectual property law. Ms. Lynch is a former patent examiner at the U.S. Patent and Trademark Office in the medical device group. Ms. Lynch holds a B.S. in Mechanical Engineering from Tufts University and a J.D. from George Mason University School of Law.

Jeff Tillack has been our Vice President of Operations since 2003. From 2000 to 2003, Mr. Tillack was Vice President and General Manager at Medsource Technologies, Inc., a medical device company. From 1998 to 2000, Mr. Tillack was Director of Operations at Medtronic, Inc., a medical device manufacturer. Mr. Tillack holds a B.S. in Mechanical Engineering from North Carolina State University and an M.B.A. from the University of North Carolina.

About Conor Medsystems

We were incorporated in Delaware in October 1999. Our principal executive offices are located at 1003 Hamilton Court, Menlo Park, California 94025, and our telephone number is (650) 614-4100. Our website address is *http://www.conormed.com.* The information contained in, or that can be accessed through, our website is not part of this report.

Available Information

We file electronically with the United States Securities and Exchange Commission our annual reports 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. We make available on our website at http:/www.conormed.com, free of charge, copies of these reports as soon as reasonably practical after filing these reports with, or furnishing them to, the SEC.

Risk Factors

We have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment.

Risks Related to Our Intellectual Property

Intellectual property rights, including in particular patent rights, play a critical role in the drug eluting stent sector of 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. These risks are summarized below. We describe in greater detail our patent position, and patents held by third parties that could impact our business, under "Item 1. Business—Patents and Proprietary Rights." You should consider carefully the matters discussed under that caption and in the risk factors below in considering an investment in our common stock.

If any patent infringement or other intellectual property claims asserted against us are successful, we could be enjoined, or prevented, from commercializing our CoStar stent or other product candidates.

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 paclitaxel (in general or on a stent) to treat restenosis;
- stent structure;
- catheters used to deliver stents; and
- stent manufacturing processes.

A number of these patents are owned by very large and well-capitalized companies that are active participants in the stent market, such as Boston Scientific Corporation and Guidant Corporation. Several of these third party patents have been or are being asserted in litigation against purported infringers, including against us, demonstrating a willingness by the patent owners to litigate their claims. On February 1, 2005, Angiotech Pharmaceuticals and Boston Scientific (as Angiotech's licensee) initiated legal proceedings against us in the District Court in the Hague, Netherlands seeking a declaration that our CoStar stent infringes European Patent No. 0 706 376 B1, one of the Hunter patents owned by Angiotech and licensed to Boston Scientific. In the suit, Angiotech and Boston Scientific

are also seeking orders, among other things, preventing us from commercializing our CoStar stent in certain European countries and requiring us to pay damages. Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to other large and well-capitalized companies who own or control patents relating to stents and their use, manufacture and delivery, we believe that it is highly likely that additional third parties will assert patent infringement claims against the manufacture, use or sale of our CoStar stent based on one or more of these or other patents. We have also received letters from third parties who have intellectual property rights in, or who have been actively involved in litigation or oppositions relating to, coronary stents, asserting that they may have rights to patents that are relevant to our operations or our stent platform and requesting the initiation of discussions. Any lawsuit could seek to enjoin, or prevent, us from commercializing our CoStar stent and may seek damages from us, and would likely be expensive for us to defend against. A court may determine that these patents are valid and infringed by us. For a description of patents that we consider to pose a material litigation risk to us, see the discussion under the caption "Business-Patents and Proprietary Rights-Third-Party Patent Rights." There may be patents in addition to those described under that caption that relate to aspects of our technology and that may materially and adversely affect our business. Moreover, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that pose a material risk to us.

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. Some of the companies in these markets, such as Boston Scientific and Guidant Corporation, have been able to capture significant market share by introducing new technologies. 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 potential new entrants into the market. All of the major companies in the stent and related markets, including Boston Scientific Corporation, Johnson & Johnson, Guidant Corporation and Medtronic, have been repeatedly involved in patent litigation relating to stents since at least 1997. Recently filed patent litigation includes litigation between Boston Scientific and Johnson & Johnson relating to Boston Scientific's drug eluting and bare metal stents and Johnson & Johnson's drug eluting stent, as well as patent litigation by Advanced Cardiovascular Systems, a subsidiary of Guidant, against Boston Scientific relating to stent structure. Each company is claiming that the other company infringes its intellectual property. We may pose a competitive threat to many of the companies in the stent and related markets. Accordingly, many of these companies, especially Boston Scientific and others against which we would compete directly, have a strong incentive to take steps, through patent litigation or otherwise, to prevent us from commercializing our CoStar stent and as indicated above, Angiotech and Boston Scientific have initiated legal proceedings in the Netherlands against us seeking to prevent us from commercializing our CoStar stent in certain European countries. Boston Scientific also owns a series of patents, known as the "Kunz" patents, which cover the use of paclitaxel to treat restenosis generally and also to treat restenosis via a stent. Boston Scientific is currently asserting two of the Kunz patents in a patent infringement lawsuit in the Federal District Court in Delaware against Johnson & Johnson and Cordis Corporation, a subsidiary of Johnson & Johnson, and it is possible that Boston Scientific could assert a patent infringement claim against us based on these patents.

Angiotech is the owner of a number of patents, sometimes referred to as the "Hunter" patents, and has licensed from the U.S. government a number of other patents, sometimes referred to as the "Kinsella" patents, that also cover the use of paclitaxel coated stents to treat angiogenesis and restenosis. The legal proceedings initiated by Angiotech and Boston Scientific against us in the Netherlands allege that the CoStar stent infringes one of the Hunter patents. We understand that, in a 1997 license agreement, Angiotech granted co-exclusive sublicenses to Boston Scientific and Cook Inc. under these patents. On September 24, 2004, Angiotech announced that Cook elected to exit the coronary vascular field and focus on the development of paclitaxel-eluting peripheral vascular and gastrointestinal stents. Angiotech also announced that Cook returned all of its rights in the coronary vascular field under the 1997 license agreement to Angiotech. On November 23, 2004, Boston Scientific announced that they had become the only license holder of these rights in the coronary vascular field of use and had obtained the right to sublicense these rights. Angiotech announced that Cook will maintain its rights in the Angiotech patents in the field of paclitaxel-eluting peripheral vascular and gastrointestinal stents.

Boston Scientific owns other patents that may have a material adverse affect on us. These include a stent structure patent with claims covering an expanded stent with a plurality of cavities which are micro-holes or micro-slits that extend from the outer surface through the inner surface and which act as reservoirs for a substance.

In addition, Guidant owns a number of patents that could have a material adverse effect on us. These include the "Yock" family of patents that are directed to rapid exchange catheters, the "Lau" family of patents which claim rapid exchange catheters for stent delivery, another "Lau" family of patents directed to stent structures and the "Castro" patents, which are directed to a manufacturing process involving the application of a material to a stent.

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 fall within the scope of the exemptions that cover activities related to developing information for submission to the FDA and fall under general investigational use or similar laws in other countries. However, the U.S. exemptions would not cover our stent manufacturing or other activities in the United States that support overseas clinical trials if those activities are not also reasonably related to developing information for submission to the FDA.

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/or to allege non-infringement of the asserted patent claim. In February 2005, we initiated legal proceedings in the High Court of Justice in the United Kingdom requesting that the court invalidate EP 0 706 376, which is one of the Hunter patents owned by Angiotech and licensed to Boston Scientific that is the subject of the legal proceedings asserted against us in the Netherlands. In Europe, individual country laws control the standard for patent invalidation, and the burden of proof to invalidate a particular claim can vary among countries. 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.

In the event that we are found to infringe any valid claim in a patent held by a third party, we may, among other things, 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 CoStar stent, through a court-imposed sanction called an injunction;
- expend significant resources to redesign our technology so that it does not infringe others' patent rights, or to develop or acquire non-infringing intellectual property, which may not be possible;
- discontinue manufacturing or other processes incorporating infringing technology; and/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, like Boston Scientific, against which we would compete directly. This would include, for example, a license to the Kunz, Hunter or Kinsella patents. 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 approval.

In addition, some of our agreements, including our agreement with Phytogen International LLC for the supply of paclitaxel, our distribution agreements with Biotronik AG and the St. Jude Medical affiliates and our supply agreements for laser-cut stents and catheters, 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 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 market share, and, therefore, our revenues.

Our ability to protect our drug eluting stent technology from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. 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 drug eluting stents 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 stents like ours, despite our patent rights.

The validity of our patent claims depends, in part, on whether prior art references described or rendered 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 U.S. Patent and Trademark Office, which we refer to as the U.S. Patent Office, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent Office 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 U.S. position. 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 inventions.

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 may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

There has been substantial litigation and other proceedings regarding patent and intellectual property rights in the medical device industry generally and the drug eluting stent industry in particular. We are currently defending, and may in the future be forced to defend, claims of infringement brought by our competitors and others, and we may institute litigation against others who we believe are infringing our intellectual property rights. The outcome of patent litigation is subject to substantial uncertainties, especially in medical device-related patent cases that may, for example, turn on the interpretation of claim language by the court which may not be to our advantage, and also the testimony of experts as to technical facts upon which experts may reasonably disagree. Our involvement in intellectual property litigation could result in significant expense. Some of our competitors, such as Boston Scientific and Guidant, have considerable resources available to them and a strong economic incentive to undertake substantial efforts to stop or delay us from bringing our CoStar stent 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. Moreover, regardless of the outcome, intellectual property litigation against or by us could significantly disrupt our development and commercialization efforts, divert our management's attention and quickly consume our financial resources.

If third parties file patent applications or are issued patents claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings with the U.S. Patent Office or in other proceedings outside the United States, including oppositions, to determine priority of invention or patentability. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel will be diverted in pursuit of these proceedings.

Risks Related to Our Business

We will depend heavily on the success of our lead product candidate, our CoStar stent, which is still in development. If we are unable to commercialize our CoStar stent or experience significant delays in doing so, our ability to generate revenue will be significantly delayed and our business will be harmed.

We have invested all of our product development time and resources in our drug eluting stent technology, which we intend to commercialize initially in the form of our CoStar stent. We anticipate that in the near term our ability to generate revenues will depend solely on the successful development, regulatory approval and commercialization of our CoStar stent. If we are not successful in the completion of clinical trials for the development, approval and commercialization of our CoStar stent, we may never generate any revenues and may be forced to cease operations. Although we are investigating the potential applicability of our stent technology to the treatment of an acute myocardial infarction, or AMI, we do not expect to seek regulatory approval of this product candidate for many years, if at all.

The commercial success of our CoStar stent will depend upon successful completion of clinical trials, manufacturing commercial supplies, obtaining marketing approval, successfully launching the product and acceptance of the product by the medical community and third party payors as clinically useful, cost-effective and safe. If the data from our clinical trials is not satisfactory, we may not proceed with our planned filing of applications for regulatory approvals or we may be forced to delay the filings. Even if we file an application for approval with satisfactory clinical data, the FDA or foreign regulatory authorities may not accept our filing, or may request additional information, including data from additional clinical trials. The FDA or foreign regulatory authorities may also approve our CoStar stent for very limited purposes with many restrictions on its use, may delay approval, or ultimately, may not grant marketing approval for our CoStar stent. Even if we do receive FDA or foreign regulatory approval, we may be unable to gain market acceptance by the medical community and third party payors.

We do not have the necessary regulatory approvals to market our CoStar stent or any other product candidates, and we may never obtain regulatory approval.

We do not have the necessary regulatory approvals to market our CoStar stent or any other product in the United States or in any foreign market. The regulatory approval process for our CoStar stent involves, among other things, successfully completing clinical trials and obtaining FDA approval of a premarket approval application, or PMA, and obtaining equivalent foreign market approvals, including taking the steps necessary for our CoStar stent to bear CE marking in the European Community. We cannot assure you that we will obtain the necessary regulatory approvals to market our CoStar stent in the United States or abroad.

Our CoStar stent is a combination product that will be regulated primarily as a class III medical device in the United States, which cannot be commercially distributed until the FDA approves our PMA. The premarket approval process can be expensive and uncertain, requires detailed and comprehensive scientific and other data, generally takes several years and may never result in the FDA granting premarket approval. We will also have to obtain similar, or in some cases more stringent, foreign marketing approval in order to commercialize our product candidates outside of the United States. If we do not obtain the requisite regulatory or marketing approvals, we will be unable to market our CoStar stent and may never recover any of the substantial costs we have invested in the development of our CoStar stent.

If our pre-clinical tests or clinical trials for our CoStar stent or other product candidates do not meet safety or efficacy endpoints, or if we experience significant delays in these tests or trials, our ability to commercialize our CoStar stent or other product candidates and our financial position will be impaired.

Before marketing our CoStar stent or any other product candidate, we must successfully complete pre-clinical studies and clinical trials that demonstrate that the product is safe and effective. Product development, including pre-clinical studies and clinical testing, is a long, expensive and uncertain process and is subject to delays. It may take us several years to complete our testing, if at all, and a trial may fail at any stage. For example, we discovered that the dosage formulations for our SCEPTER trial were not ideal.

The results of pre-clinical or clinical studies do not necessarily predict future clinical trial results, and acceptable results in early studies might not be seen in later studies. For example, the four- and six-month follow-up data from our COSTAR I and EuroSTAR studies, respectively, may not be sustained in later follow-up of patients in the trials, and we may discover unanticipated side effects. Any pre-clinical or clinical tests may fail to produce results satisfactory to the FDA or foreign regulatory authorities. Pre-clinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval.

We intend to design the protocol of our planned pivotal U.S. clinical trial for our CoStar stent based in part on prior clinical trials that used different stents. The results of these prior clinical trials may not be indicative of the clinical results we would obtain for our U.S. pivotal clinical trial.

We intend to commercialize our drug eluting stent technology in the form of our CoStar stent, which is a cobalt chromium, paclitaxel eluting stent. We have only limited clinical data on our CoStar stent, which we derived from the EuroSTAR and COSTAR I studies. Our other prior clinical trials used either a bare metal stainless steel stent or a stainless steel, paclitaxel eluting stent. In addition to using a different metal than used in our CoStar stent, the stainless steel stent had slightly different dimensions than our CoStar stent. We intend to design the protocol, including the dosage formulations, for our planned U.S. pivotal clinical trial based on the results of these prior clinical trials. This trial is being designed in large part based on the results of our PISCES study, which used a stainless steel, paclitaxel eluting form of our stent technology, as well as on the results of our COSTAR I study. Although we have twelve-month follow-up data from the PISCES study, we have only four-month follow-up data from the COSTAR I study.

The results of these prior trials may not be indicative of the behavior of, and therefore the clinical results we will obtain with, our CoStar stent. If results at least as favorable as the four- and twelve-month results in our PISCES study and the four-month results in our COSTAR I study are not observed in our planned U.S. pivotal clinical trial, our development efforts will be delayed or halted and our business may be harmed.

The clinical results we have reported to date may not be indicative of future clinical results.

The clinical results that we have reported to date are limited to four- and twelve-month follow-up data from our PISCES study, six-month follow-up data from our EuroSTAR study, and four-month follow-up data from our COSTAR I study. Our planned U.S. pivotal clinical trial, COSTAR II, will require at least eight-month follow-up data. The four-and six-month results from our COSTAR I and EuroSTAR studies, respectively, may not be indicative of the clinical results obtained when we examine the patients at a later date. While the stainless steel, paclitaxel eluting stent has shown favorable results after twelve months in our PISCES study, it is possible that the long-term results we obtain with our CoStar stent may not show similar effectiveness.

Our current and planned clinical trials may not begin on time, or at all, and may not be completed on schedule, or at all.

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:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate we expect;
- patients are not followed-up at the rate we expect;
- patients experience adverse side effects or events 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 not be related to our product candidates;
- third party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices, 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 not to be in compliance with regulatory requirements;
- third party suppliers fail to provide us with critical components, including stent delivery catheters, cobalt chromium tubing and precision laser-cut stents, which conform to design and performance specifications;
- the failure of our manufacturing process to produce finished products which conform to design and performance specifications;
- changes in governmental regulations or administrative actions;
- the interim results of the clinical trial are inconclusive or negative; or
- our trial design, although approved, is inadequate to demonstrate safety and/or efficacy.

Before we can commence our planned U.S. pivotal clinical trial for our CoStar stent, an investigational device exemption, or IDE, application must be approved by the FDA. Although we have received conditional approval of our IDE application from the FDA, the FDA's conditional approval of our IDE application allows us to begin only a limited enrollment in our COSTAR II trial. We are required to provide additional information to the FDA prior to the FDA granting full approval of our IDE application, including information that will be reviewed prior to the FDA approving full enrollment in our COSTAR II trial. While we anticipate that we will be able to provide the additional information that the FDA has requested, there can be no assurance that we will receive full approval of our IDE application on a timely basis, if at all. If we are unable to provide the additional information to the FDA, or if the FDA does not believe that the additional information we provide is sufficient, the FDA may require us to cease enrollment in the trial until adequate information is provided.

Clinical trials may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. For example, our planned U.S. pivotal clinical trial for our CoStar stent is designed to enroll approximately 1,700 patients at up to 70 U.S. sites and 15 international sites. Patient enrollment in clinical trials and completion of patient follow-up in clinical trials 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 study 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 to assess the safety and effectiveness of our CoStar stent, or they may be persuaded to participate in contemporaneous trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical effects unrelated to our CoStar stent. Delays in patient enrollment or failure of patients to continue to participate in a study may cause an increase in costs and delays or result in the failure of the trial.

Our development costs will increase if we have material delays in our clinical trials or if we need to perform more or larger clinical trials than planned. Adverse events during a clinical trial could cause us to repeat a trial, terminate a trial or cancel the entire program.

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

Our planned U.S. pivotal clinical trial of our CoStar stent could be significantly delayed or harmed if we experience problems with the stent to be used in the control group for this trial. We plan to use Boston Scientific's TAXUS™ Express²™ stent as the control stent in our planned U.S. pivotal clinical trial. In July 2004, Boston Scientific announced the recall of approximately 85,000 TAXUS™ Express²™ stent systems and approximately 11,000 Express²™ stent systems due to characteristics in the delivery catheters that have the potential to impede balloon deflation during a coronary angioplasty procedure. In August 2004, Boston Scientific announced that it would recall an additional 3,000 TAXUS™ Express²™ stents. If prior to or during the enrollment and treatment period for our planned U.S. 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 trial based on an alternative control stent. Any significant delay or redesign would significantly delay and potentially impair our ability to commercialize our CoStar stent.

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

A key element of our strategy is to discover, develop and commercialize a portfolio of new products in addition to our CoStar stent. We are seeking to do so through our internal research programs and intend to explore strategic collaborations for the development of new products utilizing our stent technology. Research programs to identify new disease targets, product candidates and delivery techniques require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- our delivery technologies may not safely or efficiently deliver the drugs; and
- product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective.

Our strategy also includes exploring the use of compounds and drugs other than paclitaxel for the treatment of restenosis and other indications. We may not be able obtain any necessary licenses to promising compounds or

drugs on reasonable terms, if at all. In addition, our strategy includes substantial reliance on strategic collaborations with others to develop new products. If these collaborators do not prioritize and commit substantial resources to these collaborations, or if we are unable to secure successful collaborations on acceptable business terms, we may be unable to discover suitable potential product candidates or develop additional delivery technologies and our business prospects will suffer.

Pre-clinical development is a long, expensive and uncertain process, and we may terminate one or more of our pre-clinical development programs.

We may determine that certain pre-clinical product candidates or programs do not have sufficient potential to warrant the allocation of resources, such as the potential development of our stent technology for the treatment of AMI. Accordingly, we may elect to terminate our programs for such product candidates. If we terminate a pre clinical program in which we have invested significant resources, our prospects will suffer, as we will have expended resources on a program that will not provide a return on our investment and will have missed the opportunity to have allocated those resources to potentially more productive uses.

We depend on single source suppliers for our CoStar stent components, manufacturing components and the active drug used in our CoStar stent. The loss of these suppliers could delay our clinical trials or prevent or delay commercialization of our CoStar stent.

We rely on third parties to supply us with the critical components and the active drug, paclitaxel, used in our CoStar stent. Phytogen International LLC is our sole supplier of paclitaxel. Our agreement with Phytogen restricts our ability to commercialize products that incorporate paclitaxel we purchase from third parties, and there is a limited number of alternative suppliers that are capable of manufacturing paclitaxel and are willing, or legally able, to do so. In addition, the agreement permits Phytogen to manufacture and supply paclitaxel to others. If Phytogen is unable or refuses to meet our demand for paclitaxel, if Phytogen terminates its agreement with us or if Phytogen's supplies do not meet quality and other specifications, the development and commercialization of our CoStar stent could be prevented or delayed. To date, our paclitaxel requirements have consisted of quantities that we need to conduct our pre-clinical and clinical trials. If we obtain market approval for our CoStar stent, we anticipate that we will require substantially larger quantities of paclitaxel. Phytogen may not provide us with sufficient quantities of paclitaxel that meet quality and other specifications, and we may not be able to locate an alternative supplier of paclitaxel in a timely manner or on commercially reasonable terms, if at all.

We do not have long-term contracts with our third party suppliers of stent delivery catheters or the cobalt chromium tubing and laser-precision cutting process required to produce our CoStar stent. In addition, we do not have long-term contracts with our third party suppliers of some of the equipment and components that are used in our manufacturing process. Except for the suppliers of our laser-cut stents and stent delivery catheters, none of our suppliers have agreed to maintain a guaranteed level of production capacity. Furthermore, suppliers that have guaranteed a level of production capacity may still be unable to satisfy our supply needs. Establishing additional or replacement suppliers for these components may 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 the manufacturers of stent components 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 may face additional regulatory delays and the manufacture and delivery of our CoStar stent could be interrupted for an extended period of time, which may delay completion of our clinical trials or commercialization of our CoStar stent. In addition, we will be required to obtain regulatory clearance 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 CoStar stent may not be received on a timely basis or at all.

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

We currently manufacture our CoStar stent at our facilities in Menlo Park, California, and in our manufacturing facility in Athlone, Ireland. If there were a disruption to our existing manufacturing facilities, we would have no other means of manufacturing our CoStar stent until we were able to restore the manufacturing capability at our current facilities or develop alternative manufacturing facilities. If we were unable to produce sufficient quantities of our CoStar stent for use in our current and planned clinical trials, or if our manufacturing process yields substandard stents, our development and commercialization efforts would be delayed.

We currently have limited resources, facilities and experience to commercially manufacture our product candidates. In order to produce our CoStar stent 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 the current level of production. There are technical challenges to scaling-up manufacturing capacity, and developing commercial-scale manufacturing facilities would require the investment of substantial additional funds and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required scale-up in a timely manner or at all. If we are unable to do so, we may not be able to produce our CoStar stent 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 CoStar stent and are unable to manufacture a sufficient supply of our CoStar stent, our revenues, 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.

In addition, while we have validated our manufacturing process for consistency, we have experienced drug release kinetic variability within and between manufacturing lots, and we may experience similar issues in the future. Manufacturing lot variability may result in unfavorable clinical trial results.

Additionally, any damage to or destruction of our Menlo Park facilities or our equipment, prolonged power outage or contamination at our facility would significantly impair our ability to produce our CoStar stents. For example, 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.

Our manufacturing facilities and the manufacturing facilities of our suppliers must comply with applicable 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 product candidates require access to, or the development of, manufacturing facilities that meet applicable regulatory standards to manufacture a sufficient supply of our products. Although we are currently manufacturing product in our facility in Ireland on a limited basis, and are in the process of preparing the facility for full production in anticipation of our planned commercial launch in the European Community, our manufacturing facility may not meet applicable foreign regulatory requirements or standards at acceptable cost and on a timely basis. In addition, the FDA must approve facilities that manufacture our products for U.S. commercial purposes, as well as the manufacturing processes and specifications for the product. 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. Our suppliers may not satisfy these 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.

Quality issues in our manufacturing processes could delay our clinical development and commercialization efforts.

The production of our CoStar stent must occur in a highly controlled, clean environment to minimize particles and other yield- and quality-limiting contaminants. In spite of stringent quality controls, weaknesses in process control or minute impurities in materials may cause a substantial percentage of defective products in a lot. If we are not able to maintain stringent quality controls, or if contamination problems arise, our clinical development and commercialization efforts could be delayed, which would harm our business and our results of operations.

Our CoStar stent may never achieve market acceptance even if we obtain regulatory approvals.

Even if we obtain regulatory approval, our CoStar stent, or any other drug delivery device that we may develop, may not gain market acceptance among physicians, patients, health care payors and the medical community. The degree of market acceptance of any of our drug delivery devices that we may develop will depend on a number of factors, including:

- the perceived effectiveness of the product;
- the prevalence and severity of any side effects;
- potential advantages over alternative treatments;
- the strength of marketing and distribution support; and
- sufficient third party coverage or reimbursement.

If our CoStar stent, or any other drug delivery device that we may develop, is approved but does not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate product revenue and we may not become profitable.

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

The availability and levels of reimbursement by governmental and other third party payors affect the market for our product candidates. The efficacy, safety, performance and cost-effectiveness of our product candidates and of any competing products will determine the availability and level of reimbursement. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought. Although we recently launched our CoStar stent in India, India does not currently have a reimbursement infrastructure, and we do not anticipate that the initial commercialization of our CoStar stent in India will provide us with any significant revenues.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third party payors may adversely affect the demand for our products currently under development and limit our ability to sell our product candidates on a profitable basis. In addition, third party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our products is unavailable 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.

If we are unable to establish sales and marketing capabilities or enter into and maintain arrangements with third parties to sell and market our CoStar stent, 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 drug eluting stents or other medical devices. To market and sell our CoStar stent internationally, we have entered into distribution agreements with third parties and anticipate that we will have to enter into additional distribution arrangements. Our existing distribution agreements are generally short-term in duration, and we will have to pursue alternative distributors if the other parties to these distribution agreements terminate or elect not to renew their agreements with us. If our relationships with our distributors do not progress as anticipated, or if their sales and marketing strategies fail to generate sales of our products in the future, our business, financial condition and results of operations would be harmed.

If our CoStar stent is approved for commercial sale in the United States, we currently plan to establish our own sales force to market it in the United States. 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 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 CoStar stent 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, our product revenues could be lower than if we directly marketed and sold our CoStar stent, or any other drug delivery 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 revenues received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. Some of our existing or future distributors may have products or product candidates that compete with ours, and they may have an incentive not to devote sufficient efforts to marketing our products. For example, Biotronik AG, with whom we have an agreement that primarily covers European distribution, is developing an absorbable magnesium alloy stent. 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.

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 and more effective 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 in the drug delivery field.

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. Our principal competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. For example, Johnson & Johnson and Boston Scientific, two companies with far greater financial and marketing resources than we possess, have both developed, and are actively marketing, drug eluting stents which have been approved by the FDA. We may be unable to demonstrate that our CoStar stent offers any advantages over Johnson & Johnson's CYPHER™ stent or Boston Scientific's TAXUS™ Express²™ stent. In addition, in August 2004, Boston Scientific announced that it had begun enrolling patients in a pivotal study to support commercialization of its new TAXUS™ Liberte™ coronary stent as a platform for its paclitaxel eluting coronary stent system. Boston Scientific has stated that the trial is designed to assess the safety and efficacy of a slow-release dose formulation for the treatment of coronary disease and that the TAXUS™ Liberte™ stent system is designed to further enhance deliverability and conformability, particularly in challenging lesions. Many other large companies, including Guidant Corporation, Medtronic Inc. and Abbott

Laboratories, among others, are reportedly developing drug eluting stents. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with, or mergers with or acquisitions by, large and established companies or through the development of novel products and technologies.

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 product candidates obsolete or non-competitive.

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 commercialize stents or other medical device or pharmaceutical products that are safer or more effective, have fewer side effects or are less expensive than any products that we may develop. For example, we are aware of companies that are developing various other less-invasive technologies for treating cardiovascular disease, 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 the third parties on whom 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 product candidates.

We do not have the ability to independently conduct clinical trials for our product candidates, 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 our pre-clinical development of product candidates. 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 product candidates 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. For instance, one of our competitors is a major supplier of the intravascular ultrasound, or IVUS, catheters used in our clinical trials to measure percent volume obstruction, or the volume of the lumen, or the inner channel of the artery through which blood flows, in the stent occupied by restenotic tissue. If the supply of IVUS catheters to our clinical trial sites is interrupted, our clinical trials may be delayed or terminated.

Our product candidates 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 U.S. marketplace in 2003. To date, the FDA has approved only Boston Scientific's TAXUS™ Express²™ and Johnson & Johnson's CYPHER™ drug eluting stents for commercial sale. Because drug eluting stents are relatively new, regulatory agencies, including the FDA, may be slower in evaluating product candidates. For example, there are currently several measures of restenosis, including binary restenosis rate, in-stent late loss, in-segment late loss, percentage volume obstruction and percentage diameter loss. Treatments may exhibit a favorable measure using one of these metrics and an unfavorable measure using another metric. It has not been settled which of these metrics, or another metric, is the ideal measure for evaluating the clinical effectiveness of stents. It is possible that a change in the accepted metrics may result in reconfiguration and delays in our clinical trials or our CoStar stent being considered not to be clinically effective.

Furthermore, unlike surface-coated stents, our product candidates are based on drug delivery polymer reservoirs. Because there are currently no approved products based on this technology, the regulatory requirements governing this type of product may be more rigorous or less clearly established than those for already approved surface-coated stents or other vascular drug delivery devices. In addition, our CoStar stent has not been approved for use as a bare stent, and we do not expect to obtain FDA approval for this stent as a bare stent prior to filing our PMA with the FDA. We must provide the FDA and foreign regulatory authorities with pre-clinical and clinical data that demonstrate that our product candidates are safe and effective before they can be approved for commercial sale. We have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals, and our clinical staff is currently composed of only six employees. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals for our product candidates.

Even if our products are approved by regulatory authorities, if we 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. 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 or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturer or manufacturing problems or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

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

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

We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future.

We are a development stage company with a limited operating history. As of December 31, 2004, we had a deficit accumulated during the development stage of $44.5 million. We have incurred net losses in each year since our inception in 1999, including net losses of $11.0 million for the year ended December 31, 2003 and $25.9 million for the year ended December 31, 2004. We expect to continue to incur significant and increasing operating losses, in the aggregate and on a per share basis, for the next several years. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, net current assets and working capital.

Because of the numerous risks and uncertainties associated with developing medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Currently, we have no

products available for commercial sale, and, to date, we have not generated any product revenue. We have financed our operations and internal growth primarily through private placements of equity securities and convertible promissory notes, as well as our initial public offering of our common stock. We have devoted substantially all of our efforts to research and development, including clinical trials.

We expect our research and development expenses to increase in connection with the conduct of our clinical trials. As a public company, our general and administrative and legal costs have increased due to the additional operational and regulatory burdens applicable to public companies. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 and related regulations implemented by the Securities and Exchange Commission and the National Association of Securities Dealers, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. We are currently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from product development activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Moreover, subject to regulatory approval of any of our product candidates, we expect to incur sales and marketing and increased manufacturing expenses.

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

We may 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; and
- commercialize our product candidates, if any such product candidates receive regulatory approval for commercial sale.

We believe that our existing cash and cash equivalent balances, as well as the interest we earn on these balances, and future limited product sales will be sufficient to meet our anticipated cash requirements through at least the first half of 2006. However, our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- 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 product candidates 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.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it will be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs.

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

We are highly dependent on our Chairman and Chief Executive Officer, Dr. Frank Litvack, and our Chief Technology Officer, John F. Shanley, and our other officers. Due to the specialized knowledge each of our officers possesses with respect to interventional cardiology and our operations, the loss of service of any of our officers could delay or prevent the successful completion of our clinical trials and the commercialization of our CoStar stent. Each of our officers may terminate their employment without notice and without cause or good reason. We do not carry key person life insurance on our officers.

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

If we are unable to manage our expected growth, we may not be able to commercialize our product candidates, including our CoStar stent.

We expect to rapidly expand our operations and grow our research and development, product development and administrative operations, including the establishment of a manufacturing facility in Ireland. This expansion has placed, and is expected to continue to place, a significant strain on our management and operational and financial resources. In particular, the commencement of our planned U.S. pivotal clinical trial will consume a significant portion of management's time and our financial resources. To manage any further growth and to commercialize our CoStar stent, we will be required to improve existing and implement new operational and financial systems, procedures and controls and expand, train and manage our growing employee base. Our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth. If we are unable to manage our growth effectively, our business could be harmed.

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

From time to time, we estimate and publicly announce (including in this Annual Report on Form 10-K) the timing of the accomplishment of various clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones include the enrollment of patients in our clinical trials, the release of data from our clinical trials and other clinical and regulatory events, including the submission to the FDA of a PMA for our CoStar stent. These estimates are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. 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.

Changes in foreign currency exchange rates may increase our expenses or reduce our revenues.

If we obtain regulatory approval, we intend to market our CoStar stent in foreign markets by contracting with distributors. The related distribution agreements may provide for payments in a foreign currency. For example, our current distribution agreement with Biotronik AG provides for payments to us in euros. In addition, we are currently developing a manufacturing facility in Ireland, for which we expect to incur expenses, including construction expenses, rental payments and employee salaries, denominated in euros. Our contracts for conducting certain of our clinical trials in Europe are also denominated in euros. Accordingly, if the euro strengthens against the U.S. dollar, our expenses related to our foreign clinical trials and Ireland facilities will increase, and if the U.S. dollar strengthens against the euro, our payments from Biotronik, if any, will decrease.

We may become exposed to fluctuations in other foreign currencies in the future, and our exposure to foreign currency exchange rates may adversely affect our results of operations.

Risks Related to Our Industry

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

In both the United States and 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. For example, the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, has announced that during the 2005 fiscal year, it will review in-patient and out-patient claims involving arterial stent implantation to determine whether Medicare payments for these services were appropriate. A determination by the OIG that inappropriate billing of arterial stents to Medicare is widespread could lead to increased enforcement of Medicare requirements regarding their use. The potential for adoption of these proposals affects or will affect our ability to raise capital, obtain additional collaborators and market our products. We 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 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 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 coverage may not be adequate to protect us against any future product liability claims. In addition, if any of our product candidates are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain insurance at acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

Our research and development activities involve the controlled use of hazardous chemicals. Our operations also produce hazardous waste products. We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of these materials. We generally contract with third parties for the disposal of such substances. We cannot eliminate the risk of accidental contamination or injury from these materials. We may be required to incur substantial costs to comply with current or future environmental and safety regulations. If an accident or contamination occurred, we would likely incur significant costs associated with civil penalties or criminal fines and in complying with environmental laws and regulations. We do not have any insurance for liabilities arising from hazardous materials. Compliance with environmental laws and regulations is expensive, and current or future environmental regulation may impair our research, development or production efforts.

Risks Related to Our Common Stock

Our internal control over financial reporting may not be effective, and our independent registered public accounting firm may not be able to certify as to the effectiveness of our internal control over financial reporting, which could have a material adverse effect on our stock price.

We are evaluating our internal control over financial reporting in order to allow management to report on, and our independent registered public accounting firm to attest to, our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002 and the rules and regulations of the SEC, which we collectively refer to as Section 404. We are currently in the process of analyzing our systems and processes in an effort to comply with the management assessment and auditor certification requirements of Section 404, which we expect will initially apply to us as of December 31, 2005. If we determine that we do not have adequate internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. If we cannot favorably assess, or our independent registered public accountants are unable to provide an unqualified attestation report on our assessment of, and on the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

Anti-takeover defenses that we have in place could prevent or frustrate attempts to change our direction or management.

Provisions of our certificate of incorporation and bylaws and applicable provisions of Delaware law may make it more difficult for or prevent a third party from acquiring control of us without the approval of our board of directors. These provisions:

- establish a classified board of directors, so that not all members of our board may be elected at one time;
- set limitations on the removal of directors;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit cumulative voting in the election of our directors, which would otherwise permit less than a majority of stockholders to elect directors;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- provide our board of directors the ability to designate the terms of and issue a new series of preferred stock without stockholder approval.

In addition, Section 203 of the Delaware General Corporation Law generally prohibits us from engaging in any business combination with certain persons who own 15% or more of our outstanding voting stock or any of our associates or affiliates who at any time in the past three years have owned 15% or more of our outstanding voting stock. These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Our principal stockholders and management own a significant percentage of our stock and are able to exercise significant influence over our affairs.

Our executive officers, current directors and holders of five percent or more of our common stock, as of December 31, 2004, beneficially owned approximately 31.6% of our common stock. The interests of these stockholders may be different than the interests of other stockholders on these matters. This concentration of ownership could also have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock.

If our stock price is volatile, purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for small healthcare companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price they paid for our common stock. The market price for our common stock may be influenced by many factors, including:

- results of our clinical trials;
- developments or disputes concerning patents or other proprietary rights;
- failure of any of our product candidates, if approved for commercial sale, to achieve commercial success;
- regulatory developments in the United States and foreign countries;
- ability to manufacture our products to commercial standards;

- public concern over our products;
- litigation;
- the departure of key personnel;
- future sales of our common stock;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- investors' perceptions of us; and
- general economic, industry and market conditions.

A decline in the market price of our common stock could cause you to lose some or all of your investment and may adversely impact our ability to attract and retain employees and raise capital. In addition, stockholders may initiate securities class action lawsuits if the market price of our stock drops significantly, which may cause us to incur substantial costs and could divert the time and attention of our management.

If there are substantial sales of our common stock, our stock price could decline.

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that existing stockholders might sell shares of our common stock, the market price of our common stock could decline significantly. As of March 15, 2005, we had 33,100,130 outstanding shares of common stock. Of these shares, the 6,900,000 shares sold in our initial public offering that were outstanding as of March 15, 2005 were freely tradable without restriction or further registration, unless purchased by our affiliates. The remaining 26,200,130 shares were restricted as a result of securities laws or the lock-up agreements the holders of these shares entered into with the underwriters in connection with our initial public offering. Beginning on June 13, 2005, the date of the expiration of the lock-up agreements referred to above, the remaining 26,200,130 shares will be available for sale as follows:

- 1,967,326 shares of common stock will be immediately eligible for sale in the public market without restriction;
- 16,717,687 shares of common stock will be eligible for sale in the public market under Rule 144 or Rule 701, subject to the volume, manner of sale and other limitations under those rules; and
- the remaining 7,515,117 shares of common stock will become eligible under Rule 144 for sale in the public market from time to time upon exercise of their respective holding periods.

Existing stockholders holding an aggregate of 22,496,427 shares of common stock, based on shares outstanding as of March 15, 2005, including 483,816 shares underlying outstanding warrants, have rights with respect to the registration of these shares of common stock with the Securities and Exchange Commission. If we register their shares of common stock following the expiration of the lock-up agreements referred to above, they can immediately sell those shares in the public market.

We have filed a registration statement covering 7,779,014 shares of common stock that are authorized for issuance under our stock option plans and employee stock purchase plan, which can be freely sold in the public market upon issuance, subject to the lock-up agreements referred to above and restrictions on our affiliates.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more

of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never declared or paid any cash dividends on our common stock or other securities, and we currently do not anticipate paying any cash dividends in the foreseeable future. Accordingly, our stockholders will not realize a return on their investment unless the trading price of our common stock appreciates.

Item 2. Properties.

As of December 31, 2004, we leased an approximately 29,000 square foot facility in Menlo Park, California for our headquarters and as the base for research and development activities. This lease expires in April 2007. We have also leased an approximately 2,800 square foot temporary manufacturing facility in Athlone, Ireland, on a month-to-month basis. In February 2005, we entered into a ten-year lease, which has an option for an additional ten year term, for an approximately 27,000 square foot permanent manufacturing facility in Athlone, Ireland. This facility includes an approximately 5,000 square foot clean room. We are currently negotiating an amended lease with the current landlord of our facility in Menlo Park, California to lease an additional 26,000 square feet of space. We believe that with the lease of the additional space in Menlo Park, California, our facilities will be sufficient to meet our needs through early 2006.

Item 3. Legal Proceedings.

On February 1, 2005, Angiotech Pharmaceuticals, Inc. and Boston Scientific Corporation (as Angiotech's licensee) initiated legal proceedings against us in the District Court in the Hague, Netherlands, seeking: a declaration that our CoStar stent infringes European Patent No. (EP) 0 706 376 B1 in the Netherlands and other countries designated in EP 0 706 376 B1; an order that we and our affiliates cease any infringement of EP 0 706 376 B1 in the Netherlands and other designated European countries; an order that we not use our CE marketing approval, if obtained by us, for three years or for a period of time which the District Court deems appropriate and/or at the choice of Boston Scientific and Angiotech; an order requiring us to withdraw all information and documentation concerning the clinical trials we have conducted in the Netherlands from all relevant regulatory authorities worldwide; an order requiring us to pay 2,460 euros per sale of our CoStar stent in Europe or, at the choice of Boston Scientific and Angiotech, 2,460 euros per day that we do not comply; an order that we indemnify Boston Scientific and Angiotech or surrender our profit on sales of our CoStar stent in countries covered by EP 0 706 376 B1; and an order that we pay the costs of the proceedings. We intend to defend ourselves in this proceeding, including the filing of counterclaims where appropriate. If we do not succeed in either invalidating EP 0 706 376 B1 or in establishing that the patent is not infringed by our CoStar stent, we will not be able to commercialize our CoStar stent in the Netherlands and we may not be able to commercialize our CoStar stent in other European countries designated in EP 0 706 376 B1 without a license from Boston Scientific, which may not be available to us on acceptable terms, or at all.

On February 18, 2005, we initiated proceedings against Angiotech and the University of British Columbia in the High Court of Justice in the United Kingdom requesting that the court invalidate EP 0 706 376 B1 based on the grounds that all claims of the patent either lack novelty or are obvious in light of the state of scientific knowledge at the priority date of the patent. A trial date for this proceeding has been set for October 4, 2005. If the High Court of the United Kingdom rules that EP 0 706 376 B1 is valid in the United Kingdom, then we may in the future need to litigate whether we infringe any of the valid claims. If we are found to infringe one or more valid claims, then we may not be able to commercialize our CoStar stent in the United Kingdom without a license from Boston Scientific, which may not be available to us on acceptable terms, or at all.

On March 31, 2005, we filed an Application to Revoke Australian Patent Nos. 728873, 771815 and 693797 owned by Angiotech and University of British Columbia in the Federal Court of Australia (Victoria District

Registry), on the bases, among others, that the patents are invalid in light of the state of scientific knowledge as of the priority date of the patents and that they are not enabled for the claimed subject matter. We are not currently conducting clinical trials in Australia on our CoStar stent, but we may seek to commercialize our CoStar stent in Australia in the future. However, if the Federal Court of Australia rules that these Australian patents are valid, then we may in the future need to litigate whether we infringe any of the valid claims. If we are found to infringe one or more valid claims, then we may not be able to commercialize our CoStar stent in Australia without a license from Boston Scientific, which may not be available to us on acceptable terms, or at all.

We cannot predict the outcome of the legal proceedings we initiated against Angiotech and the University of British Columbia in the United Kingdom and Australia, nor can we predict the outcome of the legal proceedings initiated against us by Boston Scientific and Angiotech in the Netherlands. Moreover, we cannot predict the cost of such litigation, which may require a substantial diversion of our financial assets and other resources and consequently prevent us from allocating sufficient resources to the development of our CoStar stent. In the event that we are found to infringe any valid patent claim held by Angiotech or Boston Scientific (as Angiotech's licensee) we may, among other things, be required to:

- pay damages, including up to treble damages in the United States and the other party's attorneys' fees, which may be substantial; and outside of the United states, all or a portion of the other party's attorneys' fees, which may be substantial;
- cease the development, manufacture, use, marketing and sale of our CoStar stent;
- 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; and/or
- obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

In addition, if the outcomes of the legal proceedings we initiated against Angiotech and the University of British Columbia in the United Kingdom and Australia are not favorable to us, we are likely to be found liable for the opposing parties' costs incurred in connection with the legal proceedings, and we could be found liable for an award of additional damages to the opposing parties if the court decides that our requests to invalidate patents are without sufficient merit or not pursued in good faith. Further, it is not uncommon in cases of this kind for a defendant to assert counterclaims, which could significantly increase our costs, potential liability for damages, and other risks arising from these legal proceedings.

Item 4. Submission of Matters to a Vote of Security Holders.

In November 2004, we submitted certain matters to our stockholders for their approval in connection with our initial public offering. On November 22, 2004, our stockholders approved each of these matters, as set forth below. We did not receive written consents from each stockholder. On November 22, 2004, there were 61,395,790 shares of common stock outstanding (on an as-if converted basis and without giving effect to the 0.42-for-1 reverse split of our common stock and preferred stock effected on November 23, 2004). The results of the voting (on an as-if-converted basis and without giving effect to the 0.42-for-1 reverse split of our common stock and preferred stock effected on November 23, 2004) from the stockholders that returned written consents to us is as follows:

1. An amendment to our 1999 Stock Plan to increase the aggregate number of shares of our common stock authorized thereunder by 1,000,000 shares;

For: 48,569,451
Against: 0

2. The amendment and restatement of our Amended and Restated Certificate of Incorporation to effect a 0.42-for-1 reverse split of our common stock and preferred stock, and in connection therewith, to reduce the number of outstanding shares of our capital stock;

For: 48,569,451
Against: 0

3. The amendment and restatement of our Amended and Restated Certificate of Incorporation following our initial public offering;

For: 48,569,451
Against: 0

4. The amendment and restatement of our Bylaws following our initial public offering;

For: 48,569,451
Against: 0

5. The amendment and restatement of our 1999 Stock Plan as the 2004 Equity Incentive Plan;

For: 48,569,451
Against: 0

6. The approval of our 2004 Non-Employee Directors' Stock Option Plan;

For: 48,569,451
Against: 0

7. The approval of our 2004 Employee Stock Purchase Plan; and

For: 48,569,451
Against: 0

8. The approval of our form of Indemnity Agreement.

For: 48,569,451
Against: 0

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been traded on the Nasdaq National Market under the symbol "CONR" since December 14, 2004. The following table sets forth the high and low closing prices of our common stock for the periods indicated as reported by Nasdaq.

	High	Low
2004		
Fourth Quarter (from December 14, 2004)	$13.90	$12.90

The closing price for our common stock as reported by the Nasdaq National Market on March 15, 2005 was $17.59 per share.

As of March 15, 2005, there were approximately 198 stockholders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends. We currently expect to retain earnings for use in the operation and expansion of our business, and therefore do not anticipate paying any cash dividends for the next several years, if at all.

Use of Proceeds from the Sale of Registered Securities

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-119174), that was declared effective by the Securities and Exchange Commission on December 13, 2004, and a Registration Statement on Form S-1 filed pursuant to Rule 462 (File No. 333-121224) on December 14, 2004, pursuant to which we and a selling stockholder sold all 6,900,000 shares of our common stock registered. The offering commenced on December 14, 2004 and was completed after all of the shares of common stock that were registered were sold. The managing underwriters in the offering were Citigroup Global Markets Inc., CIBC World Markets Corp., SG Cowen & Co., LLC and A.G. Edwards & Sons, Inc. The aggregate offering price of the 6,900,000 shares registered and sold was $89.7 million. Of this amount, $6.3 million was paid in underwriting discounts and commissions, and an additional $2.3 million of expenses was incurred. None of the expenses were paid, directly or indirectly, to directors, officers or persons owning 10% or more of our common stock, or to our affiliates.

As of March 15, 2005, we had invested the $78.1 million in net proceeds we received from the offering in liquid money market accounts. We did not receive any portion of the $3.1 million in net proceeds received by the selling stockholder in the offering. We expect to use the net proceeds from the offering as follows:

- to continue the development of our products, including clinical trials and research programs;
- to build sales and marketing capabilities; and
- working capital and other general corporate purposes.

The amounts we actually expend in these areas may vary significantly from our expectations and will depend on a number of factors, including operating costs, capital expenditures and any expenses related to defending claims of intellectual property infringement. A portion of the net proceeds may also be used to acquire or invest in complementary businesses, technologies, services or products. We have no current plans, agreements or commitments with respect to any such acquisition or investment, and we are not currently engaged in any negotiations with respect to any such transaction.

Recent Sales of Unregistered Securities

From January 1, 2004 to December 31, 2004, we issued and sold the following unregistered securities (as adjusted to give effect to the 0.42-for-1 reverse split of our common stock and preferred stock effected on November 23, 2004):

(1) From January 1, 2004 to December 31, 2004, we sold an aggregate of 768,769 shares of our common stock to 21 employees, four directors and seven consultants for cash consideration in the aggregate amount of $460,000 upon the exercise of stock options and stock awards granted under our 1999 Stock Plan, no shares of which have been repurchased. Our 1999 Stock Plan was amended and restated as our 2004 Equity Incentive Plan in connection with our initial public offering.

(2) From January 1, 2004 to December 31, 2004, we granted stock options and stock awards to 65 employees, six directors and 13 consultants under our 1999 Stock Plan covering an aggregate of 3,849,090 shares of common stock, at exercise prices ranging from $0.29 to $2.50 per share. Of these, options covering an aggregate of 263,208 shares were canceled without being exercised.

(3) In July and August 2004, we sold 6,711,431 shares of our Series E preferred stock to 65 accredited investors and one director, at $5.95 per share, for an aggregate purchase price of $39,949,000. The shares of our Series E preferred stock converted into shares of our common stock at the rate of one share of common stock for each share of Series E preferred stock in connection with the closing of our initial public offering.

(4) In September 2004, we sold 2,488 shares of our common stock and 1,826 shares of our Series C preferred stock to one accredited investor for cash consideration in the aggregate amount of $19,812 upon the exercise of warrants. The shares of our Series C preferred stock converted into shares of our common stock at the rate of one share of common stock for each share of Series C preferred stock in connection with the closing of our initial public offering.

(5) In November 2004, we sold 2,738 shares of our Series C preferred stock to two accredited investors for cash consideration in the aggregate amount of $7,497.93 upon the exercise of warrants.

(6) In November 2004, we issued a $5,000,000 convertible promissory note to an accredited investor which converted into shares of our common stock upon the completion of our initial public offering at a conversion price equal to $13.00, the initial public offering price of our common stock.

The issuances described in paragraphs (1) and (2) were deemed exempt from registration under the Securities Act in reliance on either (a) Rule 701 promulgated under the Securities Act as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701 or (b) Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and instruments issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

The sales and issuances of securities in the transactions described in paragraphs (3), (4), (5) and (6) were exempt from registration pursuant to the Securities Act by virtue of Section 4(2) and/or Regulation D promulgated thereunder as transactions not involving any public offering. All of the purchasers of securities for which we relied on Rule 506 of Regulation D and/or Section 4(2) represented that they were accredited investors as defined under the Securities Act or a person described under Rule 506(b)(2)(ii) under the Securities Act. We believe that the issuances are exempt from the registration requirements of the Securities Act on the basis that (a) the purchasers in each case represented to us that they intended to acquire the securities for investment only and not with a view to the distribution thereof and that they either received adequate information about the registrant or had access, through employment or other relationships, to such information and (b) appropriate legends were affixed to the stock certificates issued in such transactions.

Item 6. Selected Consolidated Financial Data.

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and the accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K. The consolidated statements of operations data for the period from inception (October 25, 1999) through December 31, 2004 and for the years ended December 31, 2002, 2003 and 2004, and the consolidated balance sheet data at December 31, 2003 and 2004, are derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The consolidated statements of operations data for the period from inception (October 25, 1999) through December 31, 2000, and for the year ended December 31, 2001, and the consolidated balance sheet data at December 31, 2000, 2001 and 2002 are derived from our audited consolidated financial statements that are not included in this Annual Report on Form 10-K. Historical results are not indicative of the results to be expected in the future.

	Period From Inception (October 25, 1999) through December 31, 2000	Years ended December 31, 2001	2002	2003	2004	Period From Inception (October 25, 1999) through December 31, 2004
		(In thousands, except per share data)				
Consolidated Statement of Operations Data:						
Contract revenue	$ —	$ —	$ 67	$ —	$ —	$ 67
Operating expenses:						
Research and development (1)	424	1,432	3,623	9,193	18,781	33,453
General and administrative (1)	211	548	1,415	1,848	7,607	11,629
Total operating expenses	635	1,980	5,038	11,041	26,388	45,082
Loss from operations	(635)	(1,980)	(4,971)	(11,041)	(26,388)	(45,015)
Interest and other income	8	4	66	72	538	688
Interest expense	—	—	(165)	—	(19)	(184)
Net loss	(627)	(1,976)	(5,070)	(10,969)	(25,869)	(44,511)
Accretion to redemption value of redeemable convertible preferred stock	—	—	(434)	(1,480)	(3,125)	(5,039)
Deemed dividend upon issuance of Series E convertible preferred stock	—	—	—	—	(23,435)	(23,435)
Net loss attributable to common stockholders	$ (627)	$(1,976)	$(5,504)	$(12,449)	$(52,429)	$(72,985)
Basic and diluted net loss per share attributable to common stockholders	$ (0.32)	$ (0.95)	$ (1.78)	$ (3.72)	$ (10.87)	
Shares used to compute basic and diluted net loss per share attributable to common	1,930	2,082	3,094	3,345	4,823	
(1) Includes non-cash stock-based compensation expense as follows:						
Research and development	$ —	$ —	$ —	$ 104	$ 2,500	$ 2,604
General and administration	—	—	—	70	3,855	3,925
Total	$ —	$ —	$ —	$ 174	$ 6,355	$ 6,529

	December 31,				
	2000	2001	2002	2003	2004
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 362	$ 284	$ 4,459	$ 22,389	$117,676
Working capital	271	(425)	4,001	20,398	114,521
Total assets	477	464	5,120	23,374	120,889
Long-term liabilities	—	—	14	25	251
Redeemable convertible preferred stock	1,000	1,790	12,104	40,934	—
Deficit accumulated during the development stage	(627)	(2,603)	(7,673)	(18,642)	(44,511)
Total stockholders' equity (deficit)	(614)	(2,036)	(7,472)	(19,692)	116,391

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes under "Item 8. Financial Statements and Supplementary Data." This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

We develop innovative controlled vascular drug delivery technologies. We have initially focused on the development of drug eluting stents to treat coronary artery disease. Our clinical efforts are currently focused on the development and commercialization of our CoStar stent, which is a cobalt chromium paclitaxel eluting stent, for the treatment of restenosis. To date, we have conducted clinical trials involving over 800 patients using our drug eluting stents, including more than 300 patients with our CoStar stent.

Since inception, we have devoted substantially all of our resources to developing our stent platform, raising capital and preparing for the planned commercialization of our CoStar stent. We have pursued a clinical development strategy of using our stents to demonstrate that the drug inlay design of our stents permits us to control drug release kinetics, to establish the safety of our stent design, to demonstrate that drug release kinetics can have a direct impact on clinical outcomes and to establish the basis for regulatory approval of our CoStar stent in Europe and the United States.

In early 2003, we initiated our PISCES study to evaluate the safety and performance of paclitaxel delivered with different release kinetics and doses using our stainless steel stent. We completed enrollment of 191 patients in late 2003 and announced twelve-month follow-up data in March 2005. The two formulations from our PISCES study that demonstrated the most favorable clinical outcomes are the focus of our subsequent EuroSTAR and COSTAR I trials, as well as our planned U.S. pivotal clinical trial, which are designed to evaluate our CoStar stent. The COSTAR I trial began in late 2003 and has completed enrollment of the three formulation groups. In September 2004, we announced four-month follow-up data for one of the three formulation groups from the COSTAR I trial, and in January 2005, we presented four-month follow-up data for a second formulation group. The EuroSTAR trial began in early 2004 and in March 2005, we announced six-month follow-up data from the first arm of our EuroSTAR trial. The EuroSTAR trial served as our pivotal trial to support our submission in February 2005 of an application to a designated Notified Body in the European Community, which is one of the steps we must undertake prior to marketing our CoStar stent in the European Community. In March 2005, we received conditional approval of our IDE application from the FDA to permit commencement of our planned U.S. pivotal clinical trial, COSTAR II, which will evaluate our CoStar stent controlled against a conventional drug eluting stent. We have not yet received any government regulatory approvals necessary to commercialize our CoStar stent. If our clinical trials proceed as scheduled and the outcomes of these clinical trials are favorable, we anticipate receiving regulatory

approval for our CoStar stent in the European Community in late 2005 and in the United States in 2007. We could be delayed by adverse results or regulatory complications, and we may never achieve regulatory approval. No regulatory approval is currently required to market our CoStar stent in India.

If we obtain the necessary regulatory approval, we plan to pursue commercialization in the United States with our own sales force and commercialize our CoStar stent internationally through distribution arrangements. We entered into agreements with Biotronik AG in May 2004 and Interventional Technologies, Pvt., Ltd., or IVT, in July 2004 to distribute our products outside of the United States, Japan, Australia, New Zealand and Korea. In November 2004, we entered into agreements with affiliates of St. Jude Medical, Inc. to distribute our CoStar stent in Japan, Korea, New Zealand and Australia. We recently began selling commercial units of our CoStar stent in India pursuant to our distribution agreement with IVT. We have recently established limited manufacturing capacity in Athlone, Ireland to manufacture commercial quantities of our CoStar stent, initially for sale outside of the United States, and we are currently in the process of preparing the facility for full production.

We were incorporated in Delaware in October 1999 and are a development stage company with a limited operating history. To date, we have not generated any significant revenues, and we have incurred net losses in each year since our inception. We expect these losses to continue and increase as we expand our clinical trial activities. We have financed our operations primarily through private placements of preferred stock and convertible promissory notes, as well as through our initial public offering of our common stock. In July and August 2004, we raised aggregate net cash proceeds of $38.9 million in a private placement of 6,711,431 shares of our Series E convertible preferred stock. In December 2004 and January 2005, we raised net proceeds of $78.1 million in our initial public offering of our common stock. We currently have no products approved for sale in the United States.

Financial Operations

Revenues

As of December 31, 2004, we had not generated any revenues from the sale of our stents. In March 2005, we began limited commercialization of our CoStar stent in India. We do not expect initial revenues from any sales of our CoStar stent in India to be significant. We recorded revenue in 2002 related to two collaborative research and development agreements. Both of these agreements were completed in 2002. We expect that any revenues we generate from sales of our CoStar stent will fluctuate from quarter to quarter.

Research and Development Expenses

Our research and development expenses primarily consist of clinical and regulatory expenses, including preclinical and clinical trial costs and the cost of manufacturing clinical supplies. Research and development costs also consist of employee compensation, supplies and materials, consultant services, facilities, and non-cash stock-based compensation. Our research and development expenses also included costs under our collaborative research and development agreements which were completed in 2002. We expense research and development costs as they are incurred. For the period from inception through December 31, 2004, we have incurred $33.5 million in research and development expenses, with nearly all of these expenses related to engineering, preclinical and clinical trials related to our planned commercialization of our CoStar stent. We expect our research and development expenses to increase significantly as we complete the development of our CoStar stent, research new product opportunities, conduct additional clinical trials and hire additional employees. We anticipate that the cost of completing our EuroSTAR trial will be approximately $2.0 million. If our COSTAR II trial proceeds as currently planned, we anticipate that it will cost at least $15.0 million to complete.

General and Administrative Expenses

Our general and administrative expenses consist primarily of compensation for executive, finance and administrative personnel and non-cash stock-based compensation. Other significant costs include professional fees for accounting and legal services, including legal services associated with our efforts to obtain and maintain

protection for the intellectual property related to our stent platform. For the period from inception through December 31, 2004, we have incurred $11.6 million in general and administrative expenses. We expect our general and administrative expenses to increase substantially due to the costs associated with operating as a publicly-traded company, costs associated with defending patent infringement claims asserted against us, and the costs associated with the infrastructure necessary to support the potential commercialization of our product candidates.

Results of Operations

Years Ended December 31, 2002, 2003 and 2004

Revenues

Revenues were $67,000 in 2002, $0 in 2003 and $0 in 2004. Revenues in 2002 were earned under two collaborative research and development agreements which were completed in 2002.

Research and Development Expenses

Research and development expenses were $3.6 million in 2002, $9.2 million in 2003 and $18.8 million in 2004. The $5.6 million increase from 2002 to 2003 was primarily due to higher non-payroll related clinical trial costs of $4.1 million for such items as tooling, consulting and outside services, and $1.5 million of higher payroll and non-cash stock-based compensation expenses as we added 17 research and development personnel to support our product development program during 2003. The $9.6 million increase from 2003 to 2004 was primarily due to $2.5 million of higher payroll and related expenses as we increased research and development personnel by 29 professionals, $2.7 million of higher non-payroll related expenditures for supplies, outside services, and consultants on our PISCES, COSTAR I and EuroSTAR clinical trials, $1.5 million of non-cash stock-based compensation expense increases, $926,000 of non-employee stock-based compensation increases, $1.3 million in increases for the manufacturing of our stents for clinical trials, and an increase of $674,000 on facilities expenses related to research and development.

General and Administrative Expenses

General and administrative expenses were $1.4 million in 2002, $1.8 million in 2003 and $7.6 million in 2004 The $433,000 increase from 2002 to 2003 was primarily attributable to the higher payroll and non-cash stock-based compensation expenses as we added finance and administrative personnel, as well as higher legal and accounting fees of $139,000. The $5.8 million increase from 2003 to 2004 was primarily due to $860,000 of higher payroll expenses as we added eight management and administrative personnel, an increase of $3.4 million of non-cash employee stock-based compensation expenses, an increase of $359,000 of non-employee stock-based compensation, an increase of $569,000 of professional services for legal, audit and other consulting services, and an increase of $389,000 in trade show and promotional expenses.

Interest and Other Income

Interest and other income was $66,000 in 2002, $72,000 in 2003 and $538,000 in 2004. The increase of $6,000 from 2002 to 2003 was due to higher cash balances resulting from our Series D convertible preferred stock financing in August and October 2003. The increase of $466,000 from 2003 to 2004 was due to higher cash balances from the completion of our Series D convertible preferred stock financing in August and October 2003, our Series E convertible preferred stock financing in July and August 2004, and to a lesser extent, our initial public offering in December 2004.

Interest Expense

Interest expense was $165,000 in 2002, $0 in 2003 and $19,000 in 2004. The interest expense in 2002 was primarily due to the issuance of $2.5 million of convertible promissory notes and related warrants. The promissory notes were converted into shares of our preferred stock in May 2002. The interest expense in 2004 was primarily due to the $5.0 million convertible note we issued in November of 2004, which was converted into shares of our common stock upon the completion of our initial public offering in December 2004.

Liquidity and Capital Resources

We have incurred losses since our inception in October 1999, and, as of December 31, 2004, we had a deficit accumulated during the development stage of $44.5 million. We have funded our operations to date principally from our initial public offering in December 2004 and private placements of equity securities and convertible promissory notes, raising aggregate net proceeds of $154.2 million through December 31, 2004.

As of December 31, 2004, we did not have any outstanding or available debt financing arrangements, we had working capital of $114.5 million and our primary source of liquidity was $117.7 million in cash and cash equivalents. Pending their ultimate use, we currently invest our available funds in liquid money market accounts.

Net Cash Used in Operating Activities

Net cash used in operating activities was $4.7 million in 2002, $9.1 million in 2003 and $18.1 million in 2004. The net cash used in each of these periods primarily reflects the net loss for those periods of $5.1 million, $11.0 million, and $25.9 million, respectively, partially reduced by depreciation of $84,000, $153,000 and $245,000, non-cash stock-based compensation of $0, $130,000 and $5.0 million, the issuance of stock to consultants as stock-based compensation of $95,000, $44,000 and $1.3 million, and changes in operating assets and liabilities of $28,000, $1.5 million and $1.0 million for the years ended December 31, 2002, 2003 and 2004, respectively.

Net Cash Used in Investing Activities

Net cash used in investing activities was $345,000 in 2002, $365,000 in 2003 and $1.6 million in 2004,. Cash used in investing activities is primarily related to purchases of property and equipment for $248,000, $323,000 and $1.5 million for the years ended December 31, 2002, 2003 and 2004, respectively.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $9.2 million in 2002, $27.4 million in 2003 and $115.0 million in 2004. Net cash provided by financing activities was primarily attributable to our issuance of common stock, convertible preferred stock and convertible promissory notes.

Operating Capital and Capital Expenditure Requirements

As of December 31, 2004, we had not commercialized any products and we have not yet achieved profitability. We anticipate that we will continue to incur net losses for the next several years as we develop our products, expand our clinical development team and corporate infrastructure, and prepare for the potential commercial launch of our CoStar stent. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need to generate significant product revenues to achieve profitability.

We do not expect to generate significant product revenues until we successfully obtain marketing approval for and begin selling our CoStar stent in Europe. We believe that our cash and cash equivalent balances and interest we earn on these balances will be sufficient to meet our anticipated cash requirements through at least the first half of 2006. If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, or if we develop additional products, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

We anticipate spending at least $15.0 million over the next two years for clinical trials to complete the development of our CoStar stent. We estimate that the development of any new product candidates will cost between $15.0 million and $25.0 million per product candidate and will take up to four years to complete. We expect to fund the development of potential product candidates with our existing cash and cash equivalent balances.

Our forecasts of the period of time through which our financial resources will be adequate to support our operations and the costs to complete development of products are forward-looking statements and involve risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in the "Risk Factors" section under Item 1 of this Annual Report on Form 10-K. 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 drug eluting stents, such as our CoStar stent, we are unable to estimate the exact amounts of capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our clinical trials and other research and development activities;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the cost and timing of completion of a commercial scale manufacturing facility;
- the costs and timing of regulatory approval;
- the costs of establishing sales, marketing and distribution capabilities;
- the effect of competing products that are developed; and
- the terms and timing of any collaborative, licensing and other arrangements that we may establish.

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

On February 1, 2005, Angiotech Pharmaceuticals, Inc. and Boston Scientific Corporation (as Angiotech's licensee) initiated legal proceedings against us in the District Court in the Hague, Netherlands seeking a declaration that our CoStar stent infringes Angiotech's patent rights. In the suit, Angiotech and Boston Scientific are also seeking orders, among other things, preventing us from commercializing our CoStar stent in certain European countries and requiring us to pay damages. 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 who own or control patents relating to stents and their use, manufacture and delivery, we believe that it is highly likely that our competitors will continue to assert patent infringement claims against us. A number of these patents are owned by very large and well-capitalized companies that are active participants in the stent market, such as Boston Scientific and Guidant Corporation. Several of these third party patents have been or are being asserted in litigation against purported infringers, including against us, demonstrating a willingness by the patent owners to litigate their claims. Any lawsuit could seek to enjoin, or prevent, us from commercializing our CoStar stent and may seek damages from us, and would likely be expensive for us to defend against. We have also received letters from other third parties, some of whom have been actively involved in coronary stent litigation, asserting that they may have rights to patents that are relevant to our operations or our stent platform and requesting the initiation of discussions. A court may determine that these patents are valid and infringed by us. A finding that we infringe any valid claim in a patent held by a third party would have a material adverse effect on our results of operations, financial condition and liquidity, and we may, among other things, 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 CoStar stent, through a court-imposed sanction called an injunction;
- expend significant resources to redesign our technology so that it does not infringe others' patent rights, or to develop or acquire non-infringing intellectual property, which may not be possible;
- discontinue manufacturing or other processes incorporating infringing technology; and/or
- obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

An award of damages against us would adversely affect our results of operations and liquidity, and any delays or restrictions with respect to our commercialization plans resulting from such litigation would adversely affect our ability to generate revenues. In addition, our competitors have significant resources to devote to litigation against us, and we may need to expend significant resources to defend against such litigation. We could require significant additional funds to bear the costs of this litigation, regardless of whether we prevail. Our ability to continue to operate under our current operating plan could be impaired if such funds are not available. Since our costs in connection with any such litigation will vary greatly depending on the nature and timing of the litigation, it is not possible to estimate the effect of any such costs on our financial condition and results of operations. Amounts, if any, that may be incurred in connection with these matters cannot be reasonably estimated at this time.

Contractual Obligations

The following table summarizes our outstanding contractual obligations as of December 31, 2004 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

		Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating Leases	$1,098,000	$536,000	$546,000	$16,000	$—

The table above reflects only payment obligations that are fixed and determinable. Our commitments for operating leases relate to the lease for our headquarters in Menlo Park, California.

In February 2005, we entered into a ten-year operating lease, which has an option for an additional ten years, for manufacturing facilities in Athlone, Ireland. Total future minimum lease payments are $3.7 million. The lease payments for our manufacturing facilities in Ireland are denominated in euros and have been converted into U.S. dollars using the exchange rate in effect as of the date the Company entered into the lease.

We also have agreements with clinical sites and contract research organizations for the conduct of our clinical trials. We make payments to these sites and organizations based upon the number of patients enrolled and the period of follow-up in the trials. We are obligated to reimburse a contract research organization for approximately $1.5 million in fees and expenses through November 2005 in connection with our PISCES and SCEPTER clinical trials. As of December 31, 2004, all fees had been paid or accrued. We anticipate that the cost of completing our EuroSTAR trial will be approximately $2.0 million. If our U.S. pivotal clinical trial for our CoStar stent proceeds as currently planned, we anticipate that it will cost at least $15.0 million to complete.

As of December 31, 2004, we had also entered into letters of credit totaling $120,000 securing our operating leases.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated 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 revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included under "Item 8. Financial Statements and Supplementary Data," we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

Stock-Based Compensation

We account 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*, 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. We have adopted the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, *Accounting for Stock-Based Compensation*, as amended.

The information regarding net loss as required by SFAS No. 123, presented in Note 1 to our consolidated financial statements, has been determined as if we had accounted for our employee stock options under the fair value method. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the irregular impact of future years' vesting.

Stock compensation expense, which is a non-cash charge, results from 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. Given the absence of an active market for our common stock prior to our initial public offering in December 2004, our board of directors determined the estimated fair value of our common stock on the date of grant based on several factors, including progress and milestones achieved in our business, sales of convertible preferred stock and changes in valuation of existing comparable publicly-traded companies. In connection with the preparation of the financial statements necessary for the filing of our initial public offering in December 2004, we reassessed the estimated fair value of our common stock. Stock compensation expense per share equals the difference between the reassessed fair value per share of our common stock on the date of grant and the exercise price per share, and is amortized on a straight-line basis over the vesting period of the option, which is generally four years.

During the period from June 1, 2003 through December 31, 2004, we granted options to employees to purchase a total of 4,732,000 shares of common stock at exercise prices ranging from $0.29 to $2.50 per share. We did not obtain contemporaneous valuations from an unrelated valuation specialist during this period. Based upon the reassessment discussed above, we determined that the reassessed fair value of such options ranged from $0.38 to $13.00 per share during this period. In determining the reassessed fair value of the common stock as of each grant date, the factors identified in the preceding paragraph were taken into account. We also considered other material factors and business developments in reassessing fair value as of the respective option grant dates, including the following specific factors:

- the completion of enrollment in our SCEPTER clinical trial in October 2003;
- the initiation of enrollment in our COSTAR I clinical trial in November 2003;
- the completion of enrollment in our PISCES clinical trial in December 2003;
- the establishment of an expanded manufacturing and research development facility in March 2004;

- the completion of enrollment of the first formulation group in our EuroSTAR clinical trial in April 2004;
- the completion of enrollment in one formulation group of our COSTAR I clinical trial in January 2004;
- the announcement of results from our PISCES clinical trial in May 2004;
- the execution of our international distribution agreement with Biotronik AG in May 2004;
- the growth in the number of our employees and the recruitment of executive officers since June 2003;
- our Series E preferred stock financing in July and August 2004;
- our board of directors' authorization of management to initiate the process of preparing for an initial public offering late in the second quarter of 2004; and
- our initial public offering in December 2004.

From inception through December 31, 2004, we recorded deferred stock compensation of $30.5 million. At December 31, 2004, we had a total of $25.4 million remaining to be amortized. Total unamortized deferred stock compensation recorded for all option grants through December 31, 2004, is expected to be amortized as follows:

Year Ending December 31, 2005	Year Ending December 31, 2006	Year Ending December 31, 2007	Year Ending December 31, 2008	Year Ending December 31, 2009
$9,683,000	$6,121,000	$6,020,000	$3,410,000	$133,000

Stock compensation arrangements with non-employees are accounted for in accordance with SFAS No. 123, as amended by SFAS No. 148, and EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a fair value approach. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned. During the years ended December 31, 2002, 2003 and 2004, we granted options to purchase 135,282, 82,740 and 308,940 shares, respectively, of common stock to consultants. The weighted-average exercise price of these options was $0.26 per share for the years ended December 31, 2002 and 2003, and $0.75 per share for year ended December 31, 2004. These options generally vest over a four-year period. The related stock-based compensation expense, calculated in accordance with EITF 96-18 and using the Black Scholes option valuation model, was $37,000, $44,000 and $1.3 million during the years ended December 31, 2002, 2003 and 2004, respectively.

Recent Accounting Pronouncement

On December 16, 2004, the FASB issued an amendment to SFAS No. 123, *Share-Based Payment* ("SFAS No. 123R"), which is effective for public companies in periods beginning after June 15, 2005. We are required to implement the new standard no later than July 1, 2005. SFAS No. 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for equity instruments of the enterprise or liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. SFAS No. 123R eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, and requires instead that such transactions be accounted for using a fair-value-based method. Companies are required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. Under SFAS No. 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include modified prospective and modified retrospective adoption options. Under the modified prospective method, compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. The modified retrospective method includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures, either (a) all prior

periods presented or (b) prior interim periods of the year of adoption. We are currently evaluating option valuation methodologies and assumptions and therefore have not fully assessed the impact of adopting SFAS No. 123R. We have not yet determined the method of adoption or the effect of adopting SFAS 123R, and have not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123. Current estimates of option values using the Black-Scholes method may not be indicative of results from valuation methodologies ultimately adopted by us. We expect to continue to grant stock-based compensation to employees, and the adoption of the new standard may have a material impact on our results of operations.

Deemed Dividend upon Issuance of Series E Convertible Preferred Stock

In July and August 2004, we issued 6,711,431 shares of our Series E convertible preferred stock, for net proceeds of $38.9 million. The Series E convertible preferred stock is considered to have a beneficial conversion feature because the issuance prices were less than the reassessed fair values of our common stock on the issuance dates. We recorded a deemed dividend of $23.4 million during the three months ended September 30, 2004 due to this beneficial conversion feature. The Series E convertible preferred stock converted into shares of our common stock in connection with the closing of our initial public offering in December 2004.

Clinical Trial Accounting

We record accruals for estimated clinical study costs, comprising payments for work performed by contract research organizations and participating hospitals. These costs are a significant component of research and development expenses. We accrue costs for clinical studies performed by contract research organizations based on estimates of work performed under the contracts. Costs of setting up clinical trial sites are accrued immediately. Clinical costs related to patient enrollment are accrued as patients are enrolled in the trial.

Related Party Transactions

For a description of our related party transactions, see Note 9 to our consolidated financial statements included under "Item 8. Financial Statements and Supplementary Data."

Off-Balance Sheet Arrangements

Since inception, we have not engaged in material off-balance sheet activities, including the use of structured finance, special purpose entities or variable interest entities.

Item 7A. Qualitative and Quantitative Disclosures About Market Risk.

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, money market funds and corporate debt securities. Our cash and cash equivalents as of December 31, 2004 included liquid money market accounts. Due to the short-term nature of our investments, we believe that there is no material exposure to interest rate risk.

We have some obligations in foreign currencies, principally our contracts for conducting clinical trials and our lease payment obligations in Ireland, which are denominated in euros. We do not currently use derivative financial instruments to mitigate this exposure. However, we do not expect fluctuations in foreign exchange rates to have a material impact on our financial condition or results of operations.

Item 8. Financial Statements and Supplementary Data.

Conor Medsystems, Inc.
(a development stage company)

Financial Statements

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Conor Medsystems, Inc.

We have audited the accompanying consolidated balance sheets of Conor Medsystems, Inc. (a development stage company) as of December 31, 2003 and 2004, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2004, and for the period from inception (October 25, 1999) through December 31, 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also 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.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Conor Medsystems, Inc. (a development stage company) at December 31, 2003 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, and for the period from inception (October 25, 1999) through December 31, 2004, in conformity with U.S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 23, 2005

Conor Medsystems, Inc.
(a development stage company)

Consolidated Balance Sheets
(In thousands, except per share amounts)

	December 31, 2003	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 22,389	$117,676
Inventories	—	53
Prepaid expenses and other current assets	116	1,039
Total current assets	22,505	118,768
Property and equipment, net	453	1,716
Restricted cash	138	170
Officer loan receivable	108	—
Other assets	170	235
Total assets	$ 23,374	$120,889
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 983	$ 1,961
Accrued compensation	124	892
Accrued clinical development liabilities	566	729
Other accrued liabilities	314	434
Deferred rent	109	124
Liability for early exercise of stock options—current portion	11	107
Total current liabilities	2,107	4,247
Liability for early exercise of stock options	25	251
Commitments and contingencies (Notes 1, 5 and 10)		
Redeemable convertible preferred stock; $0.001 par value; 15,310 and no shares authorized at December 31, 2003 and 2004, respectively, issuable in series; 14,732 and no shares issued and outstanding at December 31, 2003 and 2004, respectively, aggregate liquidation preference of $42,789 at December 31, 2003	40,934	—
Stockholders' equity (deficit):		
Preferred stock; $0.001 par value; no shares and 5,000 shares authorized at December 31, 2003 and 2004, respectively; no shares issued or outstanding at December 31, 2003 and 2004	—	—
Common stock; $0.001 par value; 27,300 and 150,000 shares authorized at December 31, 2003 and 2004, respectively; 3,629 and 31,961 shares issued and outstanding at December 31, 2003 and 2004, respectively	4	32
Additional paid-in-capital	693	186,269
Note receivable from stockholder	(24)	—
Accumulated other comprehensive loss	—	(32)
Deferred stock compensation	(1,723)	(25,367)
Deficit accumulated during development stage	(18,642)	(44,511)
Total stockholders' equity (deficit)	(19,692)	116,391
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 23,374	$120,889

See accompanying notes

Conor Medsystems, Inc.
(a development stage company)

Consolidated Statements of Operations
(In thousands, except per share amounts)

	Years Ended December, 31			Period from Inception (October 25, 1999) Through December 31, 2004
	2002	2003	2004	
Contract revenue	$ 67	$ —	$ —	$ 67
Operating expenses:				
Research and development (1)	3,623	9,193	18,781	33,453
General and administrative (1)	1,415	1,848	7,607	11,629
Total operating expenses	5,038	11,041	26,388	45,082
Loss from operations	(4,971)	(11,041)	(26,388)	(45,015)
Interest and other income	66	72	538	688
Interest expense	(165)	—	(19)	(184)
Net loss	(5,070)	(10,969)	(25,869)	(44,511)
Accretion to redemption value of redeemable convertible preferred stock	(434)	(1,480)	(3,125)	(5,039)
Deemed dividend upon issuance of Series E convertible preferred stock	—	—	(23,435)	(23,435)
Net loss attributable to common stockholders	$(5,504)	$(12,449)	$(52,429)	$(72,985)
Basic and diluted net loss per share attributable to common stockholders	$ (1.78)	$ (3.72)	$ (10.87)	
Shares used to compute basic and diluted net loss per share attributable to common stockholders	3,094	3,345	4,823	
(1) Includes non-cash stock-based compensation expense as follows:				
Research and development	$ —	$ 104	$ 2,500	$ 2,604
General and administrative	—	70	3,855	3,925
Total	$ —	$ 174	$ 6,355	$ 6,529

See accompanying notes

Conor Medsystems, Inc.
(a development stage company)

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except per share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Note Receivable From Stockholder	Deferred Stock Compensation	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount						
Issuance of common stock in December 1999 to founder for services and technology at $0.002 per share	—	$ —	1,890	$ 2	$ 3	$—	$—	$—	$ —	$ 5
Balance at December 31, 1999	—	—	1,890	2	3	—	—	—	—	5
Issuance of common stock upon exercise of stock options in March 2000 for services at $0.02 per share	—	—	51	—	1	—	—	—	—	1
Issuance of common stock in August 2000 for services at $0.02 per share	—	—	42	—	1	—	—	—	—	1
Issuance of Series A preferred stock in February and April 2000 for cash of $1.19 per share, net of issuance costs of $7	273	318	—	—	—	—	—	—	—	—
Issuance of Series B preferred stock in November 2000 for cash of $2.38 per share, net of issuance costs of $19	294	682	—	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options at various times during the year for cash of $0.002 to $0.24 per share	—	—	300	—	5	—	—	—	—	5
Compensation related to stock options granted to non-employees	—	—	—	—	1	—	—	—	—	1
Net loss	—	—	—	—	—	—	—	—	(627)	(627)
Balance at December 31, 2000	567	1,000	2,283	2	11	—	—	—	(627)	(614)
Issuance of common stock upon exercise of stock options in April 2001 for services at $0.24 per share	—	—	21	—	5	—	—	—	—	5
Issuance of Series B preferred stock in March, April, May and August August 2001 for cash of $2.38 per share, net of issuance costs of $42	350	790	—	—	—	—	—	—	—	—
Issuance of common stock in October 2001 for cash of $0.60 per share	—	—	504	1	299	—	—	—	—	300
Issuance of common stock in November 2001 for licenses at $0.60 per share	—	—	357	—	213	—	—	—	—	213
Issuance of common stock at various times during the year upon exercise of stock options for cash and promissory note of $0.24 per share	—	—	93	—	22	(20)	—	—	—	2
Interest accrued on note receivable from stockholder	—	—	—	—	—	(1)	—	—	—	(1)
Compensation related to stock options granted to non-employees	—	—	—	—	35	—	—	—	—	35
Net loss	—	—	—	—	—	—	—	—	(1,976)	(1,976)
Balance at December 31, 2001 (carried forward)	917	1,790	3,258	3	585	(21)	—	—	(2,603)	(2,036)

See accompanying notes

Conor Medsystems, Inc.
(a development stage company)

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except per share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Note Receivable From Stockholder	Deferred Stock Compensation	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount						
Balance at December 31, 2001 (brought forward)	917	$ 1,790	3,258	$ 3	$ 585	$ (21)	$ —	$—	$ (2,603)	(2,036)
Issuance of Series C redeemable preferred stock in May and June 2002 for cash and promissory notes of $2.74 per share, net of issuance costs of $591	3,758	9,700	—	—	—	—	—	—	—	—
Issuance of Series C redeemable preferred stock warrants in May 2002 upon conversion of promissory notes	—	122	—	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options at various times during the year for cash of $0.02 to $0.29 per share	—	—	161	—	32	—	—	—	—	32
Accretion to redemption value of redeemable convertible preferred stock	—	434	—	—	(434)	—	—	—	—	(434)
Interest accrued on note receivable from stockholder	—	—	—	—	—	(2)	—	—	—	(2)
Compensation related to options to purchase preferred and common stock granted to non-employees	—	58	—	—	37	—	—	—	—	37
Net loss	—	—	—	—	—	—	—	—	(5,070)	(5,070)
Balance at December 31, 2002	4,675	12,104	3,419	3	220	(23)	—	—	(7,673)	(7,473)
Issuance of Series C redeemable preferred stock in January 2003 for cash of $2.74 per share	44	120	—	—	—	—	—	—	—	—
Issuance of Series D redeemable preferred stock in August and October 2003 for cash of $2.86 per share, net of issuance costs of $1,377	10,013	27,230	—	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options at various times during the year for cash of $0.02 to $0.29 per share	—	—	186	1	47	—	—	—	—	48
Accretion to redemption value of redeemable convertible preferred stock	—	1,480	—	—	(1,480)	—	—	—	—	(1,480)
Repurchase of common stock for cash of $0.02 per share	—	—	(7)	—	—	—	—	—	—	—
Vesting of common stock related to early exercises of stock options	—	—	31	—	9	—	—	—	—	9
Interest accrued on note receivable from stockholder	—	—	—	—	—	(1)	—	—	—	(1)
Deferred stock compensation related to employee stock option grants	—	—	—	—	1,853	—	(1,853)	—	—	—
Amortization of deferred stock compensation	—	—	—	—	—	—	130	—	—	130
Compensation related to stock options granted to non-employees	—	—	—	—	44	—	—	—	—	44
Net loss	—	—	—	—	—	—	—	—	(10,969)	(10,969)
Balance at December 31, 2003 (carried forward)	14,732	40,934	3,629	4	693	(24)	(1,723)	—	(18,642)	(19,692)

See accompanying notes

Conor Medsystems, Inc.
(a development stage company)

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except per share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Note Receivable From Stockholder	Deferred Stock Compensation	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount						
Balance at December 31, 2003 (brought forward)	14,732	$ 40,934	3,629	$ 4	$ 693	$ (24)	$ (1,723)	$—	$(18,642)	$ (19,692)
Issuance of Series E preferred stock in July and August 2004 for cash of of $5.95 per share, net of issuance costs of $1,036	6,711	38,894	—	—	—	—	—	—	—	—
Issuance of common stock at various times during the year upon exercise of stock options for cash of $0.02 to $1.19 per share	—	—	240	—	63	—	—	—	—	63
Issuance of common stock in September and December 2004 upon exercise of warrants in exchange for cash at $5.95 per share	—	—	9	—	52	—	—	—	—	52
Issuance of Series C redeemable preferred stock in September 2004 upon exercise of warrants in exchange for cash at $2.74 per share	91	250	—	—	—	—	—	—	—	—
Beneficial conversion feature of Series E preferred stock	—	—	—	—	23,435	—	—	—	—	23,435
Deemed dividend for Series E preferred stock	—	—	—	—	(23,435)	—	—	—	—	(23,435)
Accretion to redemption value of redeemable convertible preferred stock	—	3,125	—	—	(3,125)	—	—	—	—	(3,125)
Conversion of redeemable convertible preferred stock into common stock upon initial public offering in December 2004	(21,534)	(83,203)	21,534	22	83,181	—	—	—	—	83,203
Issuance of common stock in initial public offering in December 2004 for cash of $13.00 per share, net of issuance costs of $7,676	—	—	6,000	6	70,318	—	—	—	—	70,324
Issuance of common stock in December 2004 for promissory note of $13.00 per share			386	—	5,017	—	—	—	—	5,017
Vesting of common stock related to early exercises of stock options	—	—	163	—	71	—	—	—	—	71
Interest accrued on note receivable from stockholder	—	—	—	—	—	(2)	—	—	—	(2)
Repayment of note receivable from stockholder in December 2004	—	—	—	—	—	26	—		—	26
Deferred stock compensation related to employee stock option grants	—	—	—	—	28,670	—	(28,670)	—	—	—
Amortization of deferred stock compensation	—	—	—	—	—	—	5,026	—	—	5,026
Compensation related to stock options granted to non-employees	—	—	—	—	1,329	—	—	—	—	1,329
Comprehensive loss:										
Foreign currency exchange loss	—	—	—	—	—	—	—	(32)	—	(32)
Net loss	—	—	—	—	—	—	—	—	(25,869)	(25,869)
Comprehensive loss	—	—	—	—	—	—	—	—	—	(25,901)
Balance at December 31, 2004	—	$ —	31,961	$ 32	$186,269	$—	$(25,367)	$ (32)	$(44,511)	$116,391

See accompanying notes

Conor Medsystems, Inc.
(a development stage company)

Consolidated Statements of Cash Flows
(In thousands)

	Years Ended December 31,			Period from Inception (October 25, 1999) Through
	2002	2003	2004	December 31, 2004
Operating activities				
Net loss	$(5,070)	$(10,969)	$ (25,869)	$ (44,511)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	84	153	245	532
Amortization of deferred stock-based compensation	—	130	5,026	5,156
Loss on disposal of property and equipment	21	12	14	47
Issuance of common stock to consultants for services	—	—	—	220
Issuance of stock options to consultants for services	95	44	1,329	1,503
Accrued interest expense on notes payable	43	—	17	60
Interest expense related to issuance of warrants	122	—	—	122
Accrued interest income on notes receivable	(4)	(7)	—	(11)
Forgiveness of officer loan receivable	—	—	111	111
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	(17)	(99)	(923)	(1,038)
Other assets	(122)	(20)	(65)	(235)
Accounts payable	(31)	805	978	1,961
Accrued compensation	32	48	768	892
Inventories	—	—	(53)	(53)
Accrued clinical development liabilities	—	566	163	729
Other accrued liabilities	146	123	120	434
Deferred rent	20	89	15	124
Net cash used in operating activities	(4,681)	(9,125)	(18,124)	(33,957)
Cash flows from investing activities				
Transfers to restricted cash	(97)	(42)	(32)	(170)
Capital expenditures	(248)	(323)	(1,532)	(2,301)
Net cash used in investing activities	(345)	(365)	(1,564)	(2,471)
Financing activities				
Proceeds from issuance of common stock, including early exercise of stock options	55	70	70,854	71,285
Proceeds from issuance of redeemable convertible preferred stock, net	7,156	27,350	39,143	75,441
Proceeds from issuance of notes payable, net	2,090	—	5,000	7,500
Loans receivable from officer	(100)	—	—	(100)
Net cash provided by financing activities	9,201	27,420	114,997	154,126
Effect of exchange rate changes on cash and cash equivalents	—	—	(22)	(22)
Net increase in cash and cash equivalents	4,175	17,930	95,287	117,676
Cash and cash equivalents at beginning of period	284	4,459	22,389	—
Cash and cash equivalents at end of period	$ 4,459	$ 22,389	$117,676	$117,676
Supplemental schedule of noncash transactions				
Issuance of common stock for services, technology, and equipment	$ —	$ —	$ —	$ 224
Issuance of preferred stock to placement agent	$ 258	$ —	$ —	$ 258
Issuance of common stock for notes payable	$ —	$ —	$ 5,000	$ 5,020
Issuance of preferred stock to retire notes payable and accrued interest	$ 2,543	$ —	$ —	$ 2,543
Accretion to redemption value of redeemable convertible preferred stock	$ 434	$ 1,480	$ 3,125	$ 5,039
Deferred stock compensation	$ —	$ 1,854	$ 28,670	$ 30,524
Deemed dividend to redeemable convertible preferred stockholders	$ —	$ —	$ 23,435	$ 23,435
Conversion of redeemable convertible preferred stock into common stock	$ —	$ —	$ 83,203	$ 83,203

See accompanying notes

1. Organization and Summary of Significant Accounting Policies

Organization and Business

Conor Medsystems, Inc. (the "Company") was incorporated on October 25, 1999 and is developing innovative controlled vascular drug delivery technologies. Since inception, the Company's activities have consisted primarily of recruiting personnel, raising capital and performing product development. The Company is therefore considered to be in the development stage at December 31, 2004.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States and include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany transactions and balances have been eliminated.

Initial Public Offering

On December 14, 2004, the Company completed its initial public offering of 6,000,000 shares of its common stock at $13.00 per share. Net cash proceeds from the initial public offering were approximately $70.3 million, after deducting underwriting discounts, commissions and other offering expenses. In connection with the closing of the initial public offering, all of the Company's shares of Series A, B, C, D and E redeemable convertible preferred stock outstanding at the time of the offering were automatically converted into 21,534,150 shares of common stock.

On January 7, 2005, the underwriters of the Company's initial public offering exercised in full their over-allotment option for 642,000 shares of its common stock. On January 7, 2005, the Company received the net cash proceeds of approximately $7.8 million, after deducting underwriting discounts, commissions and other offering expenses.

Stock Split

In November 2004, the Board of Directors and stockholders approved a 0.42-for-1 reverse stock split of the Company's redeemable convertible preferred stock and common stock. The amended and restated certificate of incorporation of the Company was filed in November 2004 effecting the 0.42-for-1 reverse stock split and setting the authorized common stock and authorized preferred stock to 40,000,000 and 23,710,305 shares, respectively. All share and per share amounts for all periods presented in the accompanying consolidated financial statements have been retroactively adjusted to give effect to the stock split.

Risks and Uncertainties Related to Intellectual Property

The Company is aware of patents owned by third parties, to which it does not have licenses, which relate to, among other things, the use of paclitaxel to treat restenosis, stent structure, catheters used to deliver stents and stent manufacturing processes. For example, Boston Scientific Corporation owns a series of patents that cover the use of paclitaxel to treat restenosis generally and also to treat restenosis via a stent. In addition, Angiotech Pharmaceuticals, Inc. is the owner of a number of patents, and has licensed from the U.S. government a number of other patents, that also cover the use of paclitaxel coated stents to treat angiogenesis and restenosis. Boston Scientific, Guidant Corporation and other third parties also own other patents that may have a material adverse affect on the Company. On February 1, 2005, Angiotech Pharmaceuticals, Inc. and Boston Scientific Corporation (as Angiotech's licensee) initiated legal proceedings against the Company in the District Court in the Hague,

Netherlands seeking a declaration that the Company's CoStar stent infringes Angiotech's patent rights. In the suit, Angiotech and Boston Scientific are also seeking orders, among other things, preventing the Company from commercializing its CoStar stent in certain European countries and requiring the Company to pay damages. Based on the prolific litigation that has occurred in the stent industry and the fact that the Company may pose a competitive threat to other large and well-capitalized companies who own or control patents relating to stents and their use, manufacture and delivery, the Company believes that it is highly likely that additional third parties will assert patent infringement claims against the manufacture, use or sale of the Company's CoStar stent. Any lawsuit could seek to enjoin, or prevent, the Company from commercializing its CoStar stent and may seek damages from the Company, and will likely be expensive for the Company to defend against. The Company has also received letters from third parties, some of whom have been actively involved in coronary stent litigation, asserting that they may have rights to patents that are relevant to the Company's operations or its stent platform and requesting the initiation of discussions. In the event a court determines that the Company infringes any valid claim in a patent held by a third party, the Company expects that such a determination would have a material adverse effect on its results of operations, financial condition and liquidity, and that the Company may, among other things, be required to pay substantial damages, cease the development, manufacture, use and sale of products that infringe the patent rights of others, including its CoStar stent, expend significant resources to redesign the Company's technology so that it does not infringe others' patent rights, which may not be possible, and/or obtain licenses to the infringed intellectual property. The Company believes that it is unlikely that it would be able to obtain a license to any necessary patent rights controlled by companies, like Boston Scientific, against which it would compete directly. In addition, the Company's competitors have significant resources to devote to litigation against the Company, and the Company may need to expend significant resources to defend against such litigation. If these competitors pursue litigation against the Company, the Company could require significant additional funds to bear the costs of this litigation, regardless of whether the Company prevails. The Company's ability to continue to operate under its current operating plan could be impaired if such funds are not available. Since the Company's costs in connection with any such litigation will vary greatly depending on the nature and timing of the litigation, it is not possible for the Company to estimate the effect of such costs on its financial condition and results of operations. Amounts, ultimately payable, if any, resulting from an adverse outcome of any of these matters cannot be reasonably estimated at this time.

Foreign Currency Translation

The functional currency of the Company's subsidiaries in Ireland is the euro. Foreign assets and liabilities are translated into U.S. dollars at the year-end exchange rates, while components of the statement of operations are translated using average exchange rates in effect throughout the year. Gains and losses from foreign currency transactions are included in the consolidated statements of operations and were not material for any period presented. Foreign currency translation adjustments are included as a component of stockholders' equity (deficit).

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ from these estimates.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected

to result from the use of an asset and its eventual disposition are less than its carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. Impairment, if any, is assessed using discounted cash flows. Through December 31, 2004, there has been no such impairment.

Revenue Recognition

As of December 31, 2004, the Company has recognized no product sales. Contract revenue related to collaborative research and development arrangements is recognized as the related research and development services are performed over the period of each agreement. Payments received are not refundable and are generally based on reimbursement of qualified expenses, as defined in the agreements. Up-front payments received upon execution of collaborative agreements are recorded as deferred revenue and recognized as contract revenue on a systematic basis (on a straight-line basis or upon the timing and level of work performed) over the period that the related research and development services are performed. Milestone payments, if any, will be recognized as earned in accordance with the terms of the respective agreements. Deferred revenue may result when the Company does not expend the required level of effort during a specific period in comparison to funds received under the respective agreement.

Research and Development

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

Clinical Trial Expenses

Clinical trial costs are a component of research and development expenses. These expenses include fees paid to contract research organizations and participating hospitals and other service providers which conduct certain product development activities on behalf of the Company. Depending on the timing of payments to the service providers and the level of the service provided, the Company records prepayments or accruals relating to these costs. These accruals or prepayments are based on estimates of the work performed under service agreements, milestones achieved, patient enrollment and experience with similar contracts. The Company monitors each of these factors to the extent possible and adjusts its estimates accordingly.

Concentrations of Risk

Financial instruments which subject the Company to potential credit risk consist of its cash and cash equivalents to the extent of the amounts recorded on the balance sheet. The Company's cash and cash equivalents are placed with high credit quality financial institutions and issuers. The Company believes its established guidelines for the investment of its excess cash maintains safety and liquidity through its policies on diversification and investment maturities.

Cash and Cash Equivalents

The Company invests its excess cash in bank deposits and money market accounts. The Company considers all highly liquid investments with an original maturity of 90 days or less at the time of purchase to be cash equivalents. The Company currently has cash held in bank accounts and money market funds with a major banking corporation.

Letter of Credit

At December 31, 2004, the Company had an irrevocable letter of credit outstanding with a commercial bank for approximately $120,000, securing its facility leases. At December 31, 2004, the Company had deposited an aggregate of $170,000 in certificates of deposit securing the letter of credit and corporate credit cards. An equal amount of restricted cash has been separately disclosed in the accompanying consolidated balance sheets.

Inventories

Inventories are stated at the lower of cost (first in, first out) or market. At December 31, 2004, inventories consisted of raw materials. The Company provides for excess and obsolete inventories based on estimated forecasts of demand.

Property and Equipment

Property and equipment are stated at cost and are depreciated on a straight-line basis over the estimated useful lives of the assets, which generally range from three to five years. Leasehold improvements are amortized over the lesser of the useful life of the asset or the term of the lease.

Stock-Based Compensation

The Company accounts for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB Opinion No. 25"), Financial Accounting Standards Board ("FASB") Interpretation ("FIN") No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB No. 25*, and related interpretations and has adopted the disclosure-only provisions of Statement of Financial Accounting Standards ("SFAS") No. 123, *Accounting for Stock-Based Compensation* ("SFAS No. 123").

The information regarding net loss as required by SFAS No. 123, as amended, has been determined as if the Company had accounted for its employee stock options under the fair-value method. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the irregular impact of future years' vesting.

The following table illustrates the weighted-average assumptions for the Black-Scholes option pricing model used in determining the fair value of options granted to employees:

	Years Ended December 31,		
	2002	2003	2004
Dividend yield	0%	0%	0%
Risk-free interest rate	4.20%	3.31%	3.28%
Volatility	0.7	0.7	0.7
Expected life	5 years	5 years	5 years

In connection with the grant of certain stock options to employees during the year ended December 31, 2003, the Company recorded deferred stock compensation within stockholders' equity (deficit) of $1.9 million, which represents the difference between the reassessed fair value of the common stock and the option exercise price at the date of grant. Such amount will be amortized over the vesting period of the applicable options on a straight-line basis. The Company recorded stock-based compensation expense of $130,000 for the year ended December 31, 2003. For the year ended December 31, 2004, the Company recorded deferred stock compensation

within stockholders' equity (deficit) of $28.7 million. Such amount will be amortized over the vesting period of the applicable options on a straight-line basis. The Company recorded stock-based compensation expense of $5.0 million for the year ended December 31, 2004. The expected future amortization expense for deferred stock compensation for stock options granted through December 31, 2004, is as follows (in thousands):

Years Ending December 31,	
2005	$ 9,683
2006	6,121
2007	6,020
2008	3,410
2009	133
	$25,367

The table below illustrates the effect on net loss and net loss per share attributable to common stockholders had the Company applied the fair value provisions of SFAS No. 123 to employee stock compensation (in thousands, except per share amounts):

	Years Ended December 31,			Period from Inception (October 25, 1999 through December 31, 2004
	2002	2003	2004	
Net loss attributable to common stockholders—as reported	$(5,504)	$(12,449)	$(52,429)	$(72,985)
Add: Stock-based employee compensation expense included in reported net loss	—	130	5,026	5,156
Deduct: Stock-based employee compensation expense determined under the fair value method	(44)	(165)	(5,102)	(5,318)
Net loss attributable to common stockholders—proforma	$(5,548)	$(12,484)	$(52,505)	$(73,147)
Basic and diluted net loss per share attributable to common stockholders—as reported	$ (1.78)	$ (3.72)	$ (10.87)	
Basic and diluted net loss per share attributable to common stockholders—proforma	$ (1.79)	$ (3.73)	$ (10.89)	

Fair Value of Financial Instruments

Financial instruments, including cash and cash equivalents, accounts payable and accrued liabilities, are carried at cost, which management believes approximates fair value given their short-term nature.

Comprehensive Loss

Comprehensive loss is comprised of net loss and foreign currency translation adjustment in accordance with SFAS No. 130, *Reporting Comprehensive Income*. For the year ended December 31, 2004, comprehensive loss was $25.9 million. As the Company had no items of other comprehensive loss prior to the year ended December 31, 2004, the Company's net loss is the same as its comprehensive loss for such periods.

Income Taxes

The Company utilizes the liability method of accounting for income taxes as required by SFAS No. 109, *Accounting for Income Taxes*. Under the liability method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rules and rates that will be in effect in the years in which the differences are expected to reverse.

Recent Accounting Pronouncement

On December 16, 2004, the FASB issued an amendment to SFAS No. 123, *Share-Based Payment* ("SFAS No. 123R"), which is effective for public companies in periods beginning after June 15, 2005. The Company is required to implement the new standard no later than July 1, 2005. SFAS No. 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for equity instruments of the enterprise or liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. SFAS No. 123R eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, and requires instead that such transactions be accounted for using a fair-value-based method. Companies are required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. Under SFAS No. 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include modified prospective and modified retrospective adoption options. Under the modified prospective method, compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS No. 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date. The modified retrospective method includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures, either (a) all prior periods presented or (b) prior interim periods of the year of adoption. The Company is currently evaluating option valuation methodologies and assumptions and therefore has not fully assessed the impact of adopting SFAS No. 123R. The Company has not yet determined the method of adoption or the effect of adopting SFAS 123R, and has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS 123. Current estimates of option values using the Black-Scholes method may not be indicative of results from valuation methodologies ultimately adopted by the Company. The Company expects to continue to grant stock-based compensation to employees, and the adoption of the new standard may have a material impact on the Company's results of operations.

2. Net Loss Per Common Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration of common stock equivalents. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, redeemable convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following table presents the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except per share amounts):

	Years Ended December 31,		
	2002	2003	2004
Historical			
Numerator:			
Net loss attributable to common stockholders	$(5,504)	$(12,449)	$(52,429)
Denominator:			
Weighted average common shares outstanding	3,353	3,522	5,084
Less weighted average shares subject to repurchase	(259)	(177)	(261)
Denominator for basic and diluted net loss per share attributable to common stockholders	3,094	3,345	4,823
Basic and diluted net loss per share attributable to common stockholders	$ (1.78)	$ (3.72)	$ (10.87)
Historical outstanding anti-dilutive securities not included in the diluted net loss per share attributable to common stockholders calculation:			
Redeemable convertible preferred stock	4,675	14,731	—
Common shares subject to repurchase	244	176	493
Options to purchase common stock	893	1,924	4,741
Warrants to purchase common and preferred stock	595	595	495
	6,407	17,426	5,729

3. Property and Equipment

Property and equipment consists of the follows (in thousands):

	December 31,	
	2003	2004
Machinery and equipment	$ 621	$1,626
Office furniture and leasehold improvements	94	551
	715	2,177
Less accumulated depreciation and amortization	(262)	(461)
Property and equipment, net	$ 453	$1,716

4. Income Taxes

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2003	2004
Federal and state net operating loss carryforwards	$ 1,606	$ 2,431
Federal and state research and development tax credit carryforwards	559	1,282
Capitalized research and development costs	5,489	12,498
Other	105	2,409
Total deferred tax assets	7,759	18,620
Valuation allowance	(7,759)	(18,620)
Net deferred tax assets	$ —	$ —

Realization of deferred tax assets is dependent upon the Company generating taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately $4.7 million and $10.9 million during the years ended December 31, 2003 and 2004, respectively.

As of December 31, 2004, the Company had net operating loss carryforwards for federal income tax purposes of approximately $5.9 million, which will expire in the years 2020 through 2024, and federal research and development tax credit carryforwards of approximately $800,000, which will expire in the years 2022 through 2024. As of December 31, 2004, the Company had net operating loss carryforwards for state income tax purposes of approximately $6.1 million, which will expire in the years 2010 through 2014, and state research and development tax credit carryforwards of approximately $804,000 which will not expire.

Utilization of the Company's net operating loss carryforwards may be subject to substantial annual limitations due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss carryforwards before utilization.

5. Commitments and Contingencies

Operating Leases

The Company leases certain real and personal property under noncancelable operating leases. Future payments under these leases as of December 31, 2004 were as follows (in thousands):

Years ending December 31,	
2005	$ 536
2006	432
2007	114
2008	13
2009	3
	$1,098

In addition to these minimum lease payments, the Company is required to pay its share of operating expenses related to property taxes, insurance and routine maintenance in connection with its facility leases. Rent expense under the operating leases, including termination fees, was approximately $387,000, $551,000 and $420,000 for the years ended December 31, 2002, 2003 and 2004, respectively, and $1.7 million for the period from inception (October 25, 1999) through December 31, 2004.

In May 2003, the Company terminated a facility lease and paid $116,000 to the lessor as a termination fee. The termination fee is included in operating expenses in the accompanying consolidated statements of operations.

In February 2005, the Company entered into a ten-year lease, which has an option for an additional ten year term, for an approximately 27,000 square foot permanent manufacturing facility in Athlone, Ireland. This facility includes an approximately 5,000 square foot clean room. Lease payments are fixed for a period of five years, with provisions for annual adjustments for market changes, for the duration of the lease. Total future minimum lease payments are approximately $3.7 million. The estimated lease payments for the manufacturing facilities in Ireland are denominated in euros and have been converted into U.S. dollars using the exchange rate in effect as of the date the Company entered the lease.

Research Agreement

In March and November 2003, the Company entered into agreements with an independent contract research organization to conduct and manage certain of its European clinical trials. The Company is required to reimburse the research organization for approximately $1.5 million in fees and expenses through November 2005 as certain milestones are achieved. As of December 31, 2004, the Company had incurred all fees and expenses related to these agreements.

Guarantees and Indemnifications

In November 2002, the FASB issued FIN No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN No. 45 requires that upon issuance of a guarantee, the guarantor must recognize a liability for the fair value of the obligations it assumes under that guarantee.

The Company, as permitted under Delaware law and in accordance with its Bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is equal to the officer's or director's lifetime. The Company also intends to enter into additional indemnification agreements with its officers and directors upon the completion of this offering. The maximum amount of potential future indemnification is unlimited; however, the Company intends to obtain director and officer insurance that limits its exposure and may enable it to recover a portion of any future amounts paid. The Company believes the fair value for these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations as of December 31, 2004.

The Company has certain agreements with collaborators that contain indemnification provisions. In such provisions, the Company typically agrees to indemnify the collaborator against certain types of third-party claims. The Company accrues for known indemnification issues when a loss is probable and can be reasonably estimated. The Company also accrues for estimated incurred but unidentified indemnification issues based on historical activity. There were no accruals for or expenses related to indemnification issues for any period presented.

Legal Contingencies

The Company is subject to various claims and assessments in the normal course of its business. For a description of material legal proceedings currently affecting the Company, see Note 10.

6. License and Distribution Agreements

Phytogen International LLC

In April 2003, the Company entered into a license and supply agreement with Phytogen International LLC (Phytogen). Under the agreement, Phytogen manufacturers and supplies paclitaxel to the Company, which is incorporated into the CoStar stent. The Company is obligated to pay Phytogen royalties on sales of paclitaxel eluting stents and a percentage share of fees received by the Company for licensing such stents to other parties. The agreement continues until the tenth anniversary of the initial commercial launch of the CoStar stent.

Biotronik AG

In May 2004, the Company entered into an agreement with Biotronik AG ("Biotronik") under which Biotronik will be the exclusive distributor of CoStar stents in a territory covering all countries of the world except the United States, Japan, Australia, New Zealand, Korea, Pakistan, Kenya, Sri Lanka, Tanzania, Bangladesh and India. Within this territory, Biotronik will be responsible for promoting, marketing and selling the Company's CoStar stent. The Company will be responsible for obtaining and maintaining marketing approvals throughout the territory described above. Biotronik can require the Company to use best efforts to seek regulatory approval in additional countries in Biotronik's territory. The Company will pay a portion of the costs associated with securing such additional regulatory approvals, and the remainder will be paid by Biotronik. Under the agreement, Biotronik will purchase CoStar stents at a transfer price equal to a fixed percentage of Biotronik's average invoiced selling price, less certain amounts. Either party may terminate the agreement under the terms of the arrangement. Unless terminated earlier, the agreement will continue until December 31, 2007, at which point it will automatically renew for an additional year unless one of the parties objects.

In conjunction with the sale of the Company's Series E redeemable convertible preferred stock described below, an affiliate of Biotronik purchased an immaterial number of shares of Series E redeemable convertible preferred stock.

Interventional Technologies

In July 2004, the Company entered into an agreement with Interventional Technologies, Pvt., Ltd. ("IVT"), under which IVT will be the exclusive distributor of the Company's bare cobalt chromium stent and the CoStar stent in India, Pakistan, Bangladesh, Sri Lanka, Kenya, and Tanzania. Within this territory, IVT will be responsible for promoting, marketing and selling the licensed products. Under the agreement, IVT will purchase stents at a fixed, per-unit price. Either party may terminate the agreement under the terms of the arrangement. Unless terminated earlier, the agreement will continue for three years and can be renewed for additional one-year terms, subject to the mutual written agreement of the parties.

St. Jude Medical, Inc. Agreements

In November 2004, the Company entered into agreements with affiliates of St. Jude Medical, Inc. (the "Affiliates") under which the Affiliates agreed to be the exclusive distributor of COSTAR stents in Japan, Korea, New Zealand and Australia. Within these territories, the Affiliates will be responsible for promoting, marketing and selling the Company's COSTAR stent. The Affiliates will also be responsible for obtaining and maintaining regulatory approvals for the COSTAR stent in these territories, and these regulatory approvals will be owned by the Affiliates. The Company may require all regulatory approvals owned by the Affiliates to be transferred to the Company under certain circumstances for a one-time fee. Under the agreements, one of the Affiliates will purchase COSTAR stents for distribution in Japan at a transfer price equal to the fixed percentage of the reimbursement rate for drug eluting stents published by the Japanese government. The transfer price for stents to

be distributed in New Zealand, Korea and Australia will be equal to a fixed percentage of the average selling price of the COSTAR stent in each territory. Unless terminated earlier, the agreements will continue for four years following the date the Japanese government approves the COSTAR stent for reimbursement and will automatically renew for an additional three years provided the respective Affiliates have met certain minimum purchase obligations. The Company can pay a one-time fee to terminate any agreement upon a change of control of the Affiliate or all of the agreements upon a change of control of the Company, St. Jude Medical, Inc. or Getz Bros. Co., Ltd., which is one of the Affiliates. The Company has indemnified the Affiliates under certain circumstances if the Company's products infringe the proprietary rights of others. In conjunction with the agreements, the Company issued a convertible promissory note in the aggregate principal amount of $5 million to St. Jude Medical, Inc. as described in Note 7.

7. Notes Payable

From December 2001 to April 2002, the Company issued $2,500,000 of convertible promissory notes to existing stockholders that bear interest at 6%. In conjunction with the notes, the Company issued warrants to purchase the number of shares of convertible preferred stock equal to 10% of the note balance divided by the price per share of the next round of financing. In May 2002, all the outstanding notes, including accrued interest, were converted into 928,845 shares of Series C convertible preferred stock and warrants to purchase 91,291 shares of Series C convertible preferred stock at $2.74 per share. The warrants were immediately exercisable and expire three years from the date of issuance. The fair value of the warrants was determined to be $122,000 using the Black-Scholes option valuation method and the following assumptions: risk-free interest rate of 3.8%, a life of three years, volatility of 0.7, and no dividends. The fair value of the warrants was recorded as interest expense for the year ended December 31, 2002. All of the warrants to purchase shares of Series C redeemable convertible preferred stock were exercised prior to the Company's initial public offering as described in Note 8.

In November 2004, the Company issued a convertible promissory note to St. Jude Medical, Inc. in the amount of $5.0 million. The note was interest bearing at a rate of 5.0% per annum. On December 14, 2004, the note and accumulated interest automatically converted into 385,932 shares of common stock at the initial public offering price of $13.00 per share.

8. Redeemable Convertible Preferred Stock and Stockholder's Equity (Deficit)

Redeemable Convertible Preferred Stock

At December 31, 2003, the authorized, issued and outstanding shares of redeemable convertible preferred stock by series were as follows (in thousands):

	Shares Authorized	Shares Issued and Outstanding	Carrying Amount	Aggregate Liquidation Preference
Series A	273	273	$ 318	$ 325
Series B	644	644	1,472	1,533
Series C	3,893	3,802	11,300	11,711
Series D	10,500	10,012	27,844	29,220
	15,310	14,731	$40,934	$42,789

Redeemable convertible preferred stock was issuable in series, with rights and preferences designated for each series. Each outstanding share of the Series A, B, C, D and E redeemable convertible preferred stock was entitled to the number of votes equal to the number of shares of common stock into which such shares of

redeemable convertible preferred stock could be converted. Holders of Series A, B and E redeemable convertible preferred stock were entitled to non-cumulative dividends at a rate of 8% per share per annum based on the original per share issuance price when, as and if declared by the Board of Directors prior to and in preference to the payment of dividends to holders of common stock. Holders of Series C and D redeemable convertible preferred stock were entitled to cumulative dividends at a rate of 8% per annum, compounded annually from the date of issuance based on the original per share issuance price prior and in preference to the payment of dividends to holders of common stock upon the follow events: (i) when, as and if declared by the Board of Directors; (ii) upon redemption; or (iii) upon liquidation. No dividends were declared through the date of the Company's initial public offering on December 14, 2004, at which time all such shares were automatically converted into 21.5 million shares of the Company's common stock.

Series C and D redeemable convertible preferred stock were redeemable at any time on or after August 7, 2008 upon two-thirds vote of the holders of the outstanding Series C and D redeemable convertible preferred stock, voting together as a combined class. Series C and D redeemable convertible preferred stock were redeemable at the original issuance prices of $2.74 and $2.86 per share, plus any accrued but unpaid dividends. For the years ended December 31, 2002, 2003 and 2004, the Company accreted dividends on the Series C and D redeemable convertible preferred stock of $434,000, $1.5 million and $3.1 million, respectively.

Each share of Series A, B, C, D and E redeemable convertible preferred stock was convertible, at the option of the holder, into the number of shares of common stock that result from dividing $1.19, $2.38, $2.74, $2.86 and $5.95, respectively, by the conversion price in effect at the time of conversion. The initial conversion prices were subject to adjustment as specified in the Company's Amended and Restated Certificate of Incorporation, as amended.

Liquidation preference values of Series A, B, C, D and E redeemable convertible preferred stock were $1.19, $2.38, $2.74, $2.86 and $5.95 per share, respectively, plus any declared, accrued and unpaid dividends. After liquidation preference distributions to Series A, B, C, D and E redeemable convertible preferred stockholders were to have been paid, the remaining assets of the Company available for distribution to stockholders were to be distributed to the holders of common stock and holders of the Series C and Series D redeemable convertible preferred stock (determined on an as-converted basis with respect to Series C and Series D preferred stock).

The Company's Amended and Restated Certificate of Incorporation provided that a change in control was deemed to be a liquidation event and that any consideration paid in connection with such a transaction was allowed in accordance with the provisions about liquidation preferences and the order of distribution. As a result, a cash redemption of the Company's convertible preferred stock could have been triggered by a change in control, which was considered to be outside the control of the Company. Accordingly, convertible preferred stock is classified outside of permanent equity in the accompanying consolidated balance sheets prior to the Company's initial public offering.

In conjunction with the issuance of Series C redeemable convertible preferred stock in May 2002, the Company issued warrants to purchase 91,291 shares of Series C redeemable convertible preferred stock at $2.74 per share (see Note 7) and warrants to purchase 503,531 shares of common stock at $5.95 per share to the Series C investors. The estimated fair value of the warrants to purchase common stock was not material. Prior to the Company's initial public offering in December 2004, the warrant holders exercised warrants to purchase 91,291 shares of Series C redeemable convertible preferred stock for cash of $2.74 per share and 8,697 shares of common stock for cash of $5.95 per share.

In July 2002, the Company granted an option to purchase 105,000 shares of Series C redeemable convertible preferred stock at a purchase price of $2.74 per share in conjunction with a licensing agreement. The option expired 180 days from the execution date of the license agreement. The Company valued the option using the Black-Scholes valuation model and the following assumptions: volatility of 0.7, an expected life of 0.5 years, a risk-free interest rate of 1.5% and no dividend yield. The resulting estimated fair value of the option of $57,500 was recorded as research and development expense for the year ended December 31, 2002. In January 2003, the Company increased the number of authorized shares of Series C redeemable convertible preferred stock to 3,893,445 shares. The option holder exercised a portion of the option and purchased 43,827 shares of Series C redeemable convertible preferred stock. The remaining balance of the option expired unexercised.

Issuance of Series E Redeemable Convertible Preferred Stock and Deemed Dividend

In July and August 2004, the Company issued 6,711,431 shares of Series E redeemable convertible preferred stock at a price of $5.95 per share for net cash proceeds of $38.9 million. The rights and preferences of the Series E redeemable convertible preferred stock were similar to the Company's Series A and B redeemable convertible preferred stock. The Company recorded a deemed dividend of $23.4 million in the third quarter of 2004 to reflect the beneficial conversion feature embedded in the Series E redeemable convertible preferred stock based on the difference between the reassessed fair value of the Company's common stock on the closing dates of the financing and the issue price of the Series E redeemable convertible preferred stock.

Preferred Stock

As of December 31, 2004, the Company was authorized to issue 5,000,000 shares of preferred stock. The Company's Board of Directors has the authority, without action by the Company's stockholders, to designate and issue shares of preferred stock in one or more series. The Board of Directors may also designate the rights, preferences and powers of each series of preferred stock, any or all of which may be greater than the rights of the common stock including restrictions of dividends on the common stock, dilution of the voting power of the common stock, reduction of the liquidation rights of the common stock, and delaying or preventing a change in control of the Company without further action by the stockholders. To date, the Board of Directors has not designated any rights, preference or powers of any preferred stock and no shares have been issued.

1999 Stock Plan

In November 1999, the Company's Board of Directors and stockholders adopted the 1999 Stock Plan (the "1999 Plan"). The 1999 Plan, prior to its amendment and restatement as the Company's 2004 Equity Incentive Plan in December 2004, provided for the issuance of common stock and the granting of incentive stock options to employees, officers and directors and the granting of non-statutory stock options to consultants of the Company. The Company granted incentive stock options with exercise prices of not less than the estimated fair value of the stock on the date of grant (85% of the estimated fair value for non-statutory stock options). If, at the time the Company granted an option, the optionee directly owned stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, the option price was set to at least 110% of the estimated fair value and was not exercisable more than five years after the date of grant. Options granted under the 1999 Plan vest at varying rates determined on an individual basis by the Board of Directors, generally over four years. Except as noted above, options expire no more than 10 years after the date of grant or earlier if employment is terminated.

Options may be exercised prior to vesting, with the underlying shares subject to the Company's right of repurchase, which lapses over the vesting term. At December 31, 2003 and 2004, there were a total of 175,788 and 497,786 shares, respectively, of common stock outstanding subject to the Company's right of repurchase at prices ranging from of $0.24 to $1.19 per share, respectively. In accordance with Emerging Issues Task Force

("EITF") 00-23, *Issues Related to the Accounting for Stock Compensation Under APB Opinion No. 25*, and FIN No. 44, shares purchased after March 2002 under an early exercise of stock options are not deemed to be issued until those shares vest. Since March 2002, the Company has issued an aggregate of 686,700 shares of common stock pursuant to the early exercise of stock options. The amounts received in exchange for these shares have been recorded as a liability for early exercise of stock options in the accompanying consolidated balance sheets and will be transferred into common stock and additional paid-in capital as the shares vest.

During 2001, options to purchase 84,000 shares of common stock were exercised by the signing of a full recourse promissory note totaling $19,800 secured by certain shares of the Company's common stock. Principal and interest at 7% were due in September 2005. In December 2004, the note and interest was repaid in full.

2004 Equity Incentive Plan

In November 2004, the Company's Board of Directors and stockholders approved the 2004 Equity Incentive Plan (the "2004 Plan"), which amended and restated the 1999 Plan. The 2004 Plan became effective on December 14, 2004.

The terms of the 2004 Plan are similar to the terms of the 1999 Plan. Options are granted at fair market value on the date of grant, expire up to 10 years from the date of grant or up to three months following the termination of employment, whichever occurs earlier, and are exercisable at specific times prior to such expiration. Under the 2004 Plan, common stock may also be issued pursuant to stock purchase agreements that grant the Company the right to repurchase the shares at the original issue price in the event that the employment of the employee is terminated prior to certain pre-determined vesting dates.

2004 Non-Employee Directors' Stock Option Plan

In November 2004, the Company's Board of Directors and stockholders approved the 2004 Non-Employee Directors' Stock Option Plan (the "2004 Directors' Plan"). The 2004 Directors' Plan became effective on December 14, 2004. The 2004 Directors' Plan provides for the automatic grant of nonstatutory options to non-employee directors to purchase the Company's common stock. The exercise price of the options granted equals the fair market value of the common stock on the date of grant. Options granted under the 2004 Directors' Plan generally vest over three years and expire 10 years after the date of grant or earlier if the service relationship is terminated.

A summary of the activity under the Company's stock option plans is as follows (in thousands, except weighted average exercise prices):

		Options Outstanding and Exercisable	
	Shares Available	Number of Shares	Weighted Average Exercise Price
Authorized	630	—	—
Balance at December 31, 1999	630	—	—
Authorized	315	—	$ —
Granted	(393)	393	$ 0.02
Exercised	—	(351)	$ 0.02
Balance at December 31, 2000	552	42	$ 0.02
Authorized	630	—	—
Granted	(526)	526	$ 0.24
Exercised	—	(114)	$ 0.24
Canceled	—	—	—
Balance at December 31, 2001	656	454	$ 0.21
Authorized	109	—	—
Granted	(724)	724	$ 0.26
Exercised	—	(239)	$ 0.24
Canceled	46	(46)	$ 0.26
Balance at December 31, 2002	87	893	$ 0.24
Authorized	2,100	—	—
Granted	(1,352)	1,352	$ 0.29
Exercised	—	(265)	$ 0.26
Repurchased	6	—	$ 0.02
Canceled	56	(56)	$ 0.27
Balance at December 31, 2003	897	1,924	$ 0.26
Authorized	5,250	—	—
Granted	(3,849)	3,849	$ 1.02
Exercised	—	(769)	$ 0.60
Canceled	263	(263)	$ 0.40
Balance at December 31, 2004	2,561	4,741	$ 0.82

The weighted-average fair value of options granted during 2002, 2003 and 2004 was $0.17, $1.74 and $7.48 per share, respectively. At December 31, 2003 and 2004, the weighted-average remaining contractual life of outstanding options was 9.06 years and 9.13 years, respectively. At December 31, 2003 and 2004, the range of per share exercise prices for options outstanding was $0.02 to $0.29 and $0.24 to $2.50, respectively.

2004 Employee Stock Purchase Plan

In November 2004, the Company's Board of Directors and stockholders approved the 2004 Employee Stock Purchase Plan (the "2004 Purchase Plan"). The 2004 Purchase Plan became effective on December 14, 2004. The 2004 Purchase Plan provides eligible employees of the Company the opportunity to purchase the Company's

common stock during specified periods. The employees are able to purchase shares of the Company's common stock at a price per share equal to the lower of: (a) 85% of the fair market value of a share of the Company's common stock on the first date of an offering period; or (b) 85% of the fair market value of a share of the Company's common stock on the date of purchase. There were no purchases of the Company's common stock under the 2004 Purchase Plan during 2004.

Deferred Stock Compensation

No employee stock compensation expense was reflected in the Company's reported net loss in any period prior to 2003, as all options granted had an exercise price equal to the estimated fair value of the underlying common stock on the date of the grant. During 2003, stock options were granted with exercise prices that were equal to the estimated fair value of the common stock at the date of grant as determined by the Board of Directors. Subsequent to the commencement of the initial public offering process, the Company reassessed the fair value of its common stock and determined that certain of the stock options granted during 2003 were granted at exercise prices that were below the reassessed fair value of the common stock on the date of grant. Accordingly, deferred stock compensation of $1.9 million was recorded during 2003 in accordance with APB Opinion No. 25. The deferred stock compensation will be amortized on a straight-line basis over the vesting period of the related awards, which is generally four years. For 2003, the Company recorded employee stock-based compensation expense of $130,000. During 2004, additional deferred stock compensation of $27.8 million was recorded, and total employee stock-based compensation expense of $5.0 million was recorded.

On June 30, 2004, the Company entered into various executive officer agreements which provide for the acceleration of vesting of stock options to purchase 308,700 shares of common stock previously granted to such executives upon a change of control of the Company. This resulted in modifications to the original stock options for which the Company recorded $877,000 of deferred stock compensation related to 260,750 unvested options, representing the difference between the original exercise price and the reassessed fair value of the Company's common stock at the time of the modification. The amount is being amortized on a straight-line basis over the remaining vesting period. During 2004, total employee stock-based compensation expense of $162,000 was recorded associated with these modified stock options.

Stock Options Granted to Nonemployees

Stock compensation arrangements with non-employees are accounted for in accordance with SFAS No. 123, as amended by SFAS No. 148, and EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a fair value approach. The compensation costs of these arrangements are subject to remeasurement over the vesting terms as earned.

The following table illustrates the weighted-average assumption for the Black-Scholes model used at year end in determining the fair value of options granted to non-employees:

	Years Ended December 31,		
	2002	2003	2004
Dividend yield	0%	0%	0%
Risk-free interest rate	4.17%	4.33%	4.25%
Volatility	0.7	0.7	0.7
Expected life	10 years	10 years	10 years

During the years ended December 31, 2002, 2003 and 2004, we granted options to purchase 135,282, 82,740 and 308,490 shares, respectively, of common stock to consultants. The weighted-average exercise price of these

options was $0.26 per share for the years ended December 31, 2002 and 2003, and $0.75 per share for year ended December 31, 2004. These options generally vest over a four-year period. The related stock-based compensation expense, calculated in accordance with EITF 96-18, was $37,000, $44,000, and $1.3 million during the years ended December 31, 2002, 2003 and 2004, respectively.

Reserved Shares

The Company has reserved shares of common stock for future issuance as follows (in thousands):

	December 31,	
	2003	2004
Conversion of redeemable convertible preferred stock :		
Series A	273	—
Series B	644	—
Series C	3,802	—
Series D	10,012	—
Exercise of warrants to purchase common stock and redeemable convertible preferred stock	595	495
Employee stock purchase plan	—	473
Stock option plans	2,821	7,302
	18,147	8,270

9. Related-Party Transactions

Calmedica License Agreement

In November 2001, the Company entered into an agreement with Calmedica International, LLC (Calmedica) pursuant to which the Company was granted a non-exclusive worldwide license to develop and commercialize products covered by certain Calmedica patents. As consideration for the grant of the license, the Company issued 357,000 shares of its common stock to Calmedica valued at $212,500. The estimated fair value of the common stock issued was recorded as research and development expense in 2001. The Company also agreed to pay Calmedica certain royalties based on net sales of products, if any, which incorporate the Calmedica patents. No royalties have been paid to date. None of the Company's planned products incorporate the Calmedica patents. As a part of this agreement, Calmedica purchased 504,000 shares of the Company's common stock for cash at a purchase price of $0.60 per share and 126,000 shares of the Company's Series B preferred stock at a purchase price of $2.38 per share. The Company's Chief Executive Officer is a member of Calmedica.

Financial Advisor Agreements

In December 2001, the Company entered into a financial advisor agreement with Musket Research Associates, Inc. in connection with its Series C preferred stock financing. David Musket is a member of the Company's Board of Directors and is the sole stockholder and President of Musket Research Associates, Inc. Pursuant to the agreement, Musket Research Associates, Inc. acted as a nonexclusive advisor and finder in connection with the Company's Series C convertible preferred stock financing. The Company paid Musket Research Associates, Inc. a fee of $278,224 in 2002 in connection with this financing. Musket Research Associates, Inc. also purchased 131,582 shares of Series C convertible preferred stock at $2.74 per share concurrent with the closing of the financing.

In January 2003, the Company entered into a financial advisor agreement with Musket Research Associates, Inc. in connection with its Series D convertible preferred stock financing. Pursuant to the agreement, Musket

Research Associates, Inc. acted as a nonexclusive advisor and finder in connection with the Company's Series D convertible preferred stock financing, and the Company paid Musket Research Associates, Inc. a fee of $1,042,146 in 2003 in connection with this financing. Musket Research Associates, Inc. also purchased 174,999 shares of Series D convertible preferred stock at $2.86 per share concurrent with the closing of the financing.

In June 2004, the Company entered into a financial advisor agreement with Musket Research Associates, Inc. in connection with its Series E convertible preferred stock financing. Pursuant to the agreement, Musket Research Associates, Inc. acted as a nonexclusive advisor and finder in connection with the Series E convertible preferred stock financing, and the Company paid Musket Research Associates, Inc. a fee of $972,890 in August 2004 in connection with the financing. Musket Research Associates, Inc. also purchased 84,000 shares of Series E convertible preferred stock at $5.95 per share concurrent with the closing of the financing.

Officer Loan

In August 2002, the Company loaned $100,000 to one of its officers under a non-recourse promissory note that bore 4.74% interest. The note was secured by a pledge of certain shares of the Company's common stock owned by the officer. In September 2004, the Company forgave all outstanding principal and interest on the loan and recorded an associated charge of $111,000 in research and development expense.

10. Subsequent Events

Legal Proceedings

On February 1, 2005, Angiotech Pharmaceuticals, Inc. and Boston Scientific Corporation (as Angiotech's licensee) initiated legal proceedings against the Company in the District Court in the Hague, Netherlands, seeking: a declaration that the Company's CoStar stent infringes European Patent No. (EP) 0 706 376 B1 in the Netherlands and other countries designated in EP 0 706 376 B1; an order that the Company and its affiliates cease any infringement of EP 0 706 376 B1 in the Netherlands and other designated European countries; an order that the Company not use its CE marketing approval, if obtained by the Company, for three years or for a period of time which the District Court deems appropriate and/or at the choice of Boston Scientific and Angiotech; an order requiring the Company to withdraw all information and documentation concerning the clinical trials the Company has conducted in the Netherlands from all relevant regulatory authorities worldwide; an order requiring the Company to pay 2,460 euros per sale of its CoStar stent in Europe or, at the choice of Boston Scientific and Angiotech, 2,460 euros per day that the Company does not comply; an order that the Company indemnify Boston Scientific and Angiotech or surrender its profit on sales of its CoStar stent in countries covered by EP 0 706 376 B1; and an order that the Company pay the costs of the proceedings.

On February 18, 2005, the Company initiated proceedings against Angiotech and the University of British Columbia in the High Court of Justice in the United Kingdom requesting that the court invalidate EP 0 706 376 B1 based on the grounds that all claims of the patent either lack novelty or are obvious in light of the state of scientific knowledge at the priority date of the patent. A trial date for this proceeding has been set for October 4, 2005.

On March 31, 2005, the Company filed an Application to Revoke Australian Patent Nos. 728873, 771815 and 693797 owned by Angiotech and University of British Columbia in the Federal Court of Australia (Victoria District Registry), on the bases, among others, that the patents are invalid in light of the state of scientific knowledge as of the priority date of the patents and that they are not enabled for the claimed subject matter.

11. Selected Quarterly Data Financial (Unaudited)

The following table contains selected unaudited consolidated statement of operations data (in thousands, except per share amounts).

	Fiscal 2004 Quarter Ended			
	March 31	June 30	September 30	December 31
Net loss	$(3,966)	$(4,916)	$ (6,881)	$(10,106)
Net loss attributable to common stockholders	$(4,759)	$(5,724)	$(31,152)	$(10,794)
Basic and diluted net loss per share attributable to common stockholders	$ (1.32)	$ (1.56)	$ (8.21)	$ (1.32)

	Fiscal 2003 Quarter Ended			
	March 31	June 30	September 30	December 31
Net loss	$(1,717)	$(2,749)	$ (2,410)	$ (4,093)
Net loss attributable to common stockholders	$(1,924)	$(2,963)	$ (2,766)	$ (4,796)
Basic and diluted net loss per share attributable to common stockholders	$ (0.59)	$ (0.89)	$ (0.82)	$ (1.39)

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures. Based on their evaluation as of December 31, 2004, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) were effective to ensure, at the reasonable assurance level, that the information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and instructions for such reports.

Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting during the quarter ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive Proxy Statement for our 2005 Annual Meeting of Stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended (the "Proxy Statement"), not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the Proxy Statement is incorporated herein by reference.

Item 10. Directors and Executive Officers of the Registrant.

The information required by this Item with respect to Executive Officers may be found under the caption, "Executive Officers of the Registrant" in Item 1 of this Annual Report on Form 10-K. The information required by this Item with respect to Directors, including information with respect to audit committee financial experts, may be found under the section entitled "Proposal 1—Election of Directors" appearing in the Proxy Statement. Such information is incorporated herein by reference. Information with respect to compliance with Section 16(a) of the Securities Exchange Act of 1934 and our code of ethics may be found in the sections entitled "Section 16(a) Beneficial Ownership Reporting Compliance" and "Proposal 1—Election of Directors—Code of Conduct," respectively, appearing in the Proxy Statement. Such information is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item is incorporated herein by reference to the information from the Proxy Statement under the section entitled "Executive Compensation."

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item with respect to security ownership of certain beneficial owners and management is incorporated herein by reference to the information from the Proxy Statement under the section entitled "SecurityOwnership of Certain Beneficial Owners and Management." The information required by this Item with respect to securities authorized for issuance under our equity compensation plans is incorporated herein by reference to the information from the Proxy Statement under the section entitled "Equity Compensation Plan Information."

Item 13. Certain Relationships and Related Transactions.

The information required by this Item is incorporated herein by reference to the information from the Proxy Statement. under the section entitled "Certain Relationships and Related Transactions."

Item 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated herein by reference to the information from the Proxy Statement under the section entitled "Proposal 2—Ratification of Selection of Independent Registered Public Accounting Firm."

PART IV

Item 15. Exhibits and Financial Statement Schedules.

The following documents are filed as part of this Annual Report on Form 10-K:

1. *Financial Statements*

See Index to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K, which is incorporated herein by reference.

2. *Financial Statement Schedules*

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

3. *The following exhibits are included herein or incorporated herein by reference:*

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Amended and Restated Bylaws.
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2(3)	Form of Common Stock Certificate.
10.1(3)	Investor Rights Agreement, dated July 30, 2004, between the Registrant and certain of its stockholders.
10.2(3)*	Form of Indemnity Agreement by and between the Registrant and its directors and executive officers.
10.3(3)*	Form of Employment, Confidential Information, Invention Assignment, and Arbitration Agreement by and between the Registrant and its executive officers.
10.4(3)*	Form of Executive Officer Agreement by and between the Registrant and its executive officers.
10.5(3)*	1999 Stock Plan.
10.6(3)*	Forms of Stock Option Agreements under the 1999 Stock Plan.
10.7(3)*	2004 Equity Incentive Plan.
10.8(3)*	Form of Stock Option Agreement under the 2004 Equity Incentive Plan.
10.9(3)*	2004 Non-Employee Directors' Stock Option Plan.
10.10(3)*	Form of Stock Option Agreement under the 2004 Non-Employee Directors' Stock Option Plan.
10.11(3)*	2004 Employee Stock Purchase Plan.
10.12(3)*	Form of Indemnification Letter Agreement between the Registrant and John F. Shanley.
10.13(3)*	Employment Letter Agreement, dated March 4, 2004, between the Registrant and Frank Litvack, M.D.
10.14(3)*	Employment Letter Agreement, dated April 15, 2002, between the Registrant and John F. Shanley.
10.15(3)*	Employment Letter Agreement, dated July 16, 2002, between the Registrant and Michael Boennighausen.
10.16(3)*	Employment Letter Agreement, dated December 8, 2003, between the Registrant and Earle L. Canty.

Exhibit Number	Description of Document
10.17(3)*	Employment Letter Agreement, dated January 5, 2000, between the Registrant and Stephen H. Diaz.
10.18(3)*	Employment Letter Agreement, dated September 10, 2003, between the Registrant and Cindy A. Lynch.
10.19(3)*	Employment Letter Agreement, dated October 20, 2003, between the Registrant and Jeff Tillack.
10.20(3)*	Employment Letter Agreement, dated August 31, 2004, between the Registrant and Azin Parhizgar.
10.21(3)*	Employment Letter Agreement, dated March 25, 2002, between the Registrant and Brett Trauthen.
10.22(3)	Lease Agreement, dated November 21, 2003, between the Registrant and Willow Park Holding Company II, LLC.
10.23(3)*	Secured Promissory Note, dated August 2, 2002, by John F. Shanley in favor of the Registrant.
10.24(3)*	Security Agreement, dated August 2, 2002, between the Registrant and John F. Shanley.
10.25(3)*	Loan Forgiveness Letter, dated September 14, 2004, from the Registrant to John F. Shanley.
10.26(3)†	International Distribution Agreement, dated July 1, 2004, between Conor Medsystems Ireland, Ltd. and Interventional Technologies Pvt., Ltd.
10.27(3)†	Distribution Agreement, dated May 25, 2004, between Conor Medsystems Ireland, Ltd. and Biotronik AG.
10.28(3)†	Collaborative License and Supply Agreement, dated April 4, 2003, between the Registrant and Phytogen International LLC.
10.29(3)	Amendment to Distribution Agreement, dated August 18, 2004, between Conor Medsystems Ireland, Ltd. and Biotronik AG.
10.30(3)†	Distributor Agreement, dated November 19, 2004, between Conor Medsystems Ireland, Ltd. and Getz Bros. Co., Ltd.
10.31(3)†	Distributor Agreement, dated November 19, 2004, between Conor Medsystems Ireland, Ltd. and St. Jude Medical Australia Pty Ltd.
10.32(3)†	Distributor Agreement, dated November 19, 2004, between Conor Medsystems Ireland, Ltd. and St. Jude Medical (Hong Kong) Limited.
10.33(3)	Convertible Loan Agreement, dated November 19, 2004, between the Registrant and St. Jude Medical, Inc.
10.34(4)*	Non-Employee Director Cash Compensation Arrangements, effective as of January 19, 2005.
10.35(4)*	Amendment to Employment Letter Agreement, dated January 19, 2005, between the Registrant and Azin Parhizgar, Ph.D.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature pages hereto).
31.1	CEO Certification required by Rule 13a-14(a) or Rule 15d-14(a).
31.2	CFO Certification required by Rule 13a-14(a) or Rule 15d-14(a).
32.1(5)	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).

* Management contract or compensation plan or arrangement.

† Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(1) Filed as Exhibit 3.2 to the Registrant's registration statement on Form S-1 (No. 333-119174), filed with the SEC on September 22, 2004, as amended, and incorporated herein by reference.

(2) Filed as Exhibit 3.6 to the Registrant's registration statement on Form S-1 (No. 333-119174), filed with the SEC on September 22, 2004, as amended, and incorporated herein by reference.

(3) Filed as the like numbered Exhibit to the Registrant's registration statement on Form S-1 (No. 333-119174), filed with the SEC on September 22, 2004, as amended, and incorporated herein by reference.

(4) Filed as the like numbered Exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on January 25, 2005, and incorporated herein by reference.

(5) This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Conor Medsystems under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

CONOR MEDSYSTEMS, INC.
(Registrant)

By: /s/ FRANK LITVACK, M.D.
Frank Litvack, M.D.
Chairman and Chief Executive Officer

Dated: March 31, 2005

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Frank Litvack, M.D. and Michael Boennighausen, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his name in any and all capacities, to sign any and all 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 Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ FRANK LITVACK, M.D. **Frank Litvack, M.D.**	Chairman and Chief Executive Officer (Principal Executive Officer)	March 31, 2005
/s/ MICHAEL BOENNIGHAUSEN **Michael Boennighausen**	Vice President, Finance and Administration and Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2005
/s/ DAVID M. CLAPPER **David M. Clapper**	Director	March 31, 2005
_____ **John H. Friedman**	Director	
/s/ JOHN F. SHANLEY **John F. Shanley**	Director	March 31, 2005
/s/ GEORGE M. MILNE, JR., PH.D. **George M. Milne, Jr., Ph.D.**	Director	March 31, 2005
/s/ DAVID B. MUSKET **David B. Musket**	Director	March 31, 2005
_____ **Carl Simpson**	Director	

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EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-121230) pertaining to the 2004 Equity Incentive Plan, the 2004 Employee Stock Purchase Plan, and the 2004 Non-Employee Directors' Stock Option Plan of Conor Medsystems, Inc. of our report dated March 23, 2005, with respect to the consolidated financial statements of Conor Medsystems, Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 29, 2005

EXHIBIT 31.1

CERTIFICATION

I, Frank Litvack M.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Conor Medsystems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2005

/s/ FRANK LITVACK, M.D.

Frank Litvack, M.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Michael Boennighausen certify that:

1. I have reviewed this Annual Report on Form 10-K of Conor Medsystems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2005

/s/ MICHAEL BOENNIGHAUSEN

Michael Boennighausen
Vice President, Finance and Administration and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Frank Litvack, M.D., Chief Executive Officer of Conor Medsystems, Inc. (the "Company"), and Michael Boennighausen, Chief Financial Officer of the Company, each hereby certify that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2004, and to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 31st day of March, 2005.

/s/ FRANK LITVACK, M.D.

Frank Litvack, M.D.
Chief Executive Officer

/s/ MICHAEL BOENNIGHAUSEN

Michael Boennighausen
Chief Financial Officer

Corporate Information

Board of Directors
Frank Litvack, MD, Chairman and Chief Executive Officer, Conor Medsystems
John F. (Jeff) Shanley, Founder and Chief Technology Officer, Conor Medsystems
David Clapper, President and Chief Executive Officer, SurgRx Inc.
John H. Friedman, Managing Partner, Easton Hunt Capital Partners, LP
George M. Milne, Jr., Ph.D., Venture Partner, Radius Ventures
David B. Musket, President, Musket Research Associates, Inc.; Managing Director, ProMed Partners, LP
Carl Simpson, Partner, Versant Ventures

Executive Officers
Frank Litvack, MD, Chairman and Chief Executive Officer
John F. (Jeff) Shanley, Founder and Chief Technology Officer
Azin Parhizgar, Ph.D., Vice President and Chief Operating Officer
Michael Boennighausen, Vice President, Finance and Administration and Chief Financial Officer
Earle L. Canty, Vice President, Regulatory Affairs and Quality Assurance
Stephen H. Diaz, Vice President, Engineering and Pilot Production
Cindy A. Lynch, Vice President, Intellectual Property
Jeff Tillack, Vice President, Operations

Outside General Counsel
Cooley Godward LLP
Palo Alto, CA

Independent Registered Public Accounting Firm
Ernst & Young LLP
Palo Alto, CA

Transfer Agent
Mellon Investor Services LLC
P.O. Box 3338
South Hackensack, NJ 07606-1938
(800) 304-3098
www.melloninvestor.com

Corporate Headquarters
Conor Medsystems, Inc.
1003 Hamilton Court
Menlo Park, CA 94025
Phone: (650) 614-4100
Fax: (650) 614-4125

Investor Relations
Conor Medsystems common stock is traded on NASDAQ National Market, under the symbol CONR. Conor welcomes inquiries from its stockholders and other interested investors. Questions regarding stock certificates should be addressed to the Transfer Agent, Mellon Investor Services LLC.

For more information on Conor's activities, additional copies of this annual report or other financial materials, please contact:

Conor Medsystems, Inc.
Investor Relations
1003 Hamilton Court
Menlo Park, CA 94025
Phone: (650) 614-4100
Fax: (650) 614-4125

Further information may be obtained on the Company's website, www.conormed.com.

Annual Meeting of Stockholders
The Annual Meeting of Stockholders will be held on Wednesday June 22, 2005 at 10:00 a.m. at Conor Medsystems corporate headquarters.

Forward-looking Statements
This Annual Report contains "forward-looking" statements that involve risks and uncertainties. Such statements include, but are not limited to, our expectations with respect to regulatory submissions and approvals and our clinical trials, our expectations with respect to our intellectual property position and our estimates regarding our capital requirements. Words such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions are intended to identify forward-looking statements. Actual results may differ materially as a result of a number of factors, including those set forth under "Risk Factors" at the end of Item 1, Part I of our Annual Report on Form 10-K for the year ended December 31, 2004. We assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

CONOR
MEDSYSTEMS

Conor Medsystems, Inc 1003 Hamilton Court Menlo Park CA 94025 (650) 614-4100

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