# XTENT INC Form DEF 14A June 08, 2009

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# **SCHEDULE 14A**

)

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934 (Amendment No.

Filed by the Registrant ý

Filed by a Party other than the Registrant o

Check the appropriate box:

- o Preliminary Proxy Statement
- o Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
- ý Definitive Proxy Statement
- o Definitive Additional Materials
- o Soliciting Material Pursuant to §240.14a-12

XTENT, INC.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

ý No fee required.

- o Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.
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  - (2) Aggregate number of securities to which transaction applies:
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- (4) Proposed maximum aggregate value of transaction:
- (5) Total fee paid:
- o Fee paid previously with preliminary materials.
- o Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.
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#### XTENT, INC. NOTICE OF SPECIAL MEETING OF STOCKHOLDERS TO BE HELD ON JULY 9, 2009

#### To our Stockholders:

You are cordially invited to attend a special meeting of stockholders of XTENT, Inc., a Delaware corporation, or XTENT. The meeting will be held on July 9, 2009, at 9:00 a.m., local time, at our principal executive offices located at 125 Constitution Drive, Menlo Park, California 94025-1118 for the following purposes:

1.

To consider and vote upon a proposal to approve the voluntary dissolution and liquidation of XTENT pursuant to a Plan of Complete Liquidation and Dissolution in substantially the form attached to the accompanying proxy statement as *Appendix A*.

2.

To consider and vote upon a proposal to adjourn the special meeting to another date, time or place, if necessary in the judgment of the proxy holders, for the purpose of soliciting additional proxies to vote in favor of Proposal 1.

3.

To transact such other business as may properly come before the meeting and any adjournments or postponements thereof.

The foregoing matters are described in more detail in the accompanying proxy statement. A copy of the Plan of Complete Liquidation and Dissolution, or Plan of Dissolution, is included with the proxy statement as *Appendix A*. You are encouraged to read the entire proxy statement carefully. **In particular, you should consider the discussion entitled** "*Risk Factors*" beginning on page 25.

XTENT's board of directors has fixed the close of business on June 4, 2009 as the record date for the determination of stockholders entitled to notice of and to vote at the special meeting and any adjournments or postponements thereof. Each share of XTENT common stock is entitled to one vote on all matters presented at the special meeting and any adjournments or postponements thereof.

Holders of our shares of common stock are not entitled to assert dissenters' rights with respect to the Plan of Dissolution.

This notice and the accompanying proxy statement and related materials are first being mailed to holders of record of our common stock on the record date on or about June 8, 2009.

You can vote by signing, dating and mailing your proxy card in the enclosed postage prepaid envelope or following the instructions for telephone or Internet voting, whether or not you plan to attend the special meeting in person.

We hope you can attend the special meeting. However, whether or not you plan to attend, please complete, sign, date and return the accompanying proxy card as soon as possible in the enclosed postage prepaid envelope. If you attend the meeting, you may revoke your proxy and vote in person if you wish. The proposal to approve the Plan of Dissolution requires the affirmative vote of a majority of the outstanding shares of our common stock. Therefore, it is very important that your shares be represented.

XTENT's board of directors has approved the Plan of Dissolution and determined that it is advisable and in our best interests and the best interests of our stockholders. The board of directors unanimously recommends that you vote "FOR" approval of both proposals described in the accompanying proxy statement.

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A copy of XTENT's annual report on Form 10-K for the year ended December 31, 2008, a copy of Amendment No. 1 to our annual report on Form 10-K/A for the year ended December 31, 2008 and a copy of our quarterly report on Form 10-Q for the quarter ended March 31, 2009, all of which contain important business and financial information about XTENT and should be read carefully, are being delivered with this notice and proxy statement as *Appendices B, C* and *D* respectively.

# BY ORDER OF THE BOARD OF DIRECTORS

Gregory D. Casciaro President, Chief Executive Officer and Director June 8, 2009 Menlo Park, California

**IMPORTANT NOTICE REGARDING THE AVAILABILITY OF PROXY MATERIALS FOR THE SPECIAL MEETING OF STOCKHOLDERS TO BE HELD ON JULY 9, 2009**: A complete set of proxy materials relating to the special meeting is available on the Internet. These materials, consisting of the Notice of Special Meeting, Proxy Statement and form of proxy card, are available at *http://investor.xtentinc.com/*.

# YOUR VOTE IS IMPORTANT.

ALL STOCKHOLDERS ARE INVITED TO ATTEND THE SPECIAL MEETING IN PERSON. WHETHER OR NOT YOU PLAN TO ATTEND THE SPECIAL MEETING, YOU SHOULD READ THE ACCOMPANYING PROXY STATEMENT CAREFULLY, AND VOTE YOUR SHARES BY COMPLETING, SIGNING AND DATING THE ENCLOSED PROXY CARD AS PROMPTLY AS POSSIBLE AND RETURNING IT IN THE ENCLOSED POSTAGE PREPAID ENVELOPE; OR, YOU MAY VOTE VIA THE INTERNET OR BY TELEPHONE, IN EACH CASE AS INSTRUCTED ON THE ENCLOSED PROXY CARD. PLEASE NOTE, HOWEVER, THAT IF YOUR SHARES ARE HELD OF RECORD BY A BROKER, BANK OR OTHER NOMINEE AND YOU WISH TO VOTE AT THE MEETING, YOU MUST OBTAIN FROM THE RECORD HOLDER A PROXY ISSUED IN YOUR NAME AND BRING AN ACCOUNT STATEMENT OR LETTER FROM THE NOMINEE INDICATING YOUR BENEFICIAL OWNERSHIP AS OF THE RECORD DATE. A FAILURE TO VOTE YOUR SHARES WILL HAVE THE EFFECT OF A VOTE AGAINST THE PLAN OF DISSOLUTION.

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# PROXY STATEMENT FOR SPECIAL MEETING OF STOCKHOLDERS TO BE HELD ON JULY 9, 2009

#### General

The Board of Directors of XTENT, Inc., a Delaware corporation, is soliciting the enclosed proxy from you. The proxy will be used at our Special Meeting of Stockholders to be held on July 9, 2009, beginning at 9:00 a.m., local time, at our principal executive offices located at 125 Constitution Drive, Menlo Park, California 94025-1118, and at any postponements or adjournments thereof. This Proxy Statement contains important information regarding the meeting. Specifically, it identifies the matters upon which you are being asked to vote, provides information that you may find useful in determining how to vote and describes the voting procedures.

In this Proxy Statement: the terms "we," "our," "XTENT" and our "Company" each refer to XTENT, Inc.; the term "proxy materials" means this Proxy Statement, filed with the U.S. Securities and Exchange Commission, or SEC on May 15, 2009, the enclosed proxy card, our annual report on Form 10-K for the year ended December 31, 2008, filed with the U.S. Securities and Exchange Commission, or SEC, on March 24, 2009, a copy of which is being delivered with this Proxy Statement as Appendix B, amendment No. 1 to our annual report on Form 10-K/A for the year ended December 31, 2008, filed with the SEC on April 30, 2009, a copy of which is being delivered with this Proxy Statement as Appendix C, and our quarterly report on Form 10-Q for the quarter ended March 31, 2009, filed with the SEC on May 15, 2009, a copy of which is being delivered with this Proxy Statement as Appendix D, all of which you should read; and the term "Special Meeting" means our Special Meeting of Stockholders to be held on July 9, 2009, and any postponements or adjournments thereof.

We are sending these proxy materials on or about June 8, 2009 (the "*Proxy Date*"), to all stockholders of record at the close of business on June 4, 2009 (the "*Record Date*").

#### **Proposals**

At the Special Meeting, our stockholders will consider and vote upon:

1.

proposal to approve the voluntary dissolution and liquidation of XTENT pursuant to a Plan of Complete Liquidation and Dissolution in substantially the form attached to this proxy statement as *Appendix A*; and

2.

proposal to adjourn the Special Meeting to another date, time or place, if necessary in the judgment of the proxy holders, for the purpose of soliciting additional proxies to vote in favor of Proposal 1.

#### **Record Date and Voting Securities**

Only holders of record of our common stock as of the close of business on June 4, 2009, the record date for the Special Meeting, are entitled to notice of and to vote at the Special Meeting and any adjournments or postponements thereof. At the close of business on June 1, 2009, there were 23,384,718 shares of our common stock outstanding held by 105 holders of record.

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Each holder of common stock is entitled to one vote for each share of common stock held of record on the record date. Holders of common stock are entitled to vote on all proposals properly presented at the Special Meeting. Shares cannot be voted at the Special Meeting unless the holder thereof is present or represented by proxy.

#### Quorum

Under Delaware law, a quorum consisting of a majority of the shares entitled to vote must be represented in person or by proxy for the transaction of business at the Special Meeting. Once a share is represented for any purpose at the Special Meeting, other than solely to object to holding the meeting or transacting business at the meeting, the share will be deemed present for quorum purposes for the remainder of the meeting and for any adjournment of the meeting unless a new record date is or must be set for that adjourned meeting. Shares may be represented and deemed present for quorum purposes by any of the following methods:

if the holder has returned a signed and dated proxy card, even if the proxy card is marked as an abstention; or

if the holder attends the Special Meeting (other than solely to object to holding the meeting or transacting business at the meeting), even if the holder abstains from voting.

Broker non-votes, which occur when a broker, bank or other nominee has not received specific voting instructions from a beneficial owner of shares held in street name and indicates that the broker, bank or other nominee does not have discretionary authority to vote a particular matter on the proxy card, also will be deemed present for purposes of determining whether a quorum is achieved.

#### **Required Votes**

*Required Vote for Proposal 1.* The approval of the Plan of Dissolution requires the affirmative vote of a majority of the outstanding shares of our common stock. Abstentions and broker non-votes will have the same effect as votes against the proposal to approve the Plan of Dissolution.

*Required Vote for Proposal 2.* The approval of any adjournment of the Special Meeting requires that the votes cast in favor of the proposal exceed the votes cast against the proposal at the Special Meeting. Abstentions from voting and broker non-votes will have no impact on the vote on Proposal 2.

#### Our board of directors unanimously recommends voting "FOR" approval of both Proposals 1 and 2.

#### Voting by Proxy

Our board of directors has selected Gregory D. Casciaro (our President and Chief Executive Officer, as well as a Director) and Ronald C. Austin (our Secretary), the persons named as proxies in the proxy card accompanying this proxy statement, to serve as proxies at the Special Meeting. The shares of common stock represented by each executed and returned proxy card will be voted in accordance with the directions indicated on the proxy card. If you sign your proxy card without giving specific instructions, XTENT will vote your shares "FOR" the proposals being made at the Special Meeting unless your shares are held in street name in a brokerage account. The proxy cards also confer discretionary authority to vote the shares authorized to be voted thereby on any matter that properly may be presented for action at the Special Meeting and any adjournments or postponements thereof. We know of no other business to be presented at the Special Meeting, and no other matters properly may be presented for a vote at the Special Meeting.

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You can vote by signing, dating and mailing your proxy card in the postage prepaid envelope or following the instructions for telephone or Internet voting, whether or not you plan to attend the Special Meeting in person.

# YOUR VOTE IS VERY IMPORTANT, REGARDLESS OF THE NUMBER OF SHARES YOU OWN. PLEASE VOTE AS SOON AS POSSIBLE TO MAKE SURE THAT YOUR SHARES ARE REPRESENTED AT THE SPECIAL MEETING. TO VOTE YOUR SHARES, PLEASE COMPLETE, DATE, AND SIGN THE ENCLOSED PROXY AND MAIL IT PROMPTLY IN THE ENCLOSED POSTAGE PREPAID ENVELOPE; OR YOU MAY VOTE VIA THE INTERNET OR BY TELEPHONE, IN EACH CASE AS INSTRUCTED ON THE ENCLOSDED PROXY CARD, WHETHER OR NOT YOU PLAN TO ATTEND THE SPECIAL MEETING.

#### **Revocation of Proxy**

You may revoke a proxy or change your vote at any time by taking any of the following actions before your proxy is voted at the Special Meeting:

signing and delivering to the Secretary of XTENT a new proxy card relating to the same shares and bearing a later date;

delivering a written notice of revocation bearing a date later than the date of your proxy card to the Secretary of XTENT; or

attending the Special Meeting and voting in person, although attendance at the Special Meeting will not, by itself, revoke a proxy.

You should send any notice of revocation or completed new proxy card, as the case may be, to the Secretary of XTENT at the following address: XTENT, Inc., 125 Constitution Drive, Menlo Park, California 94025-1118.

#### **Expenses of Solicitation**

XTENT will bear the expense of the solicitation of proxies from our stockholders. We have not retained a proxy solicitor in connection with the Special Meeting. We will solicit proxies in person or by mail, telephone, facsimile or other electronic means. Our directors, officers and regular employees who solicit proxies will not receive additional compensation.

Following the original mailing of the proxy statement and any other soliciting materials, we will request brokers, banks and other nominees and record holders of our common stock (1) to forward copies of the proxy statement and any other soliciting materials to each beneficial owner for whom they hold shares, and (2) to request authority for the exercise of proxies. In addition, we may reimburse any of these brokers, banks and other nominees and record holders for their reasonable out-of-pocket expenses in forwarding such materials.

#### Voting in Person

If you attend the Special Meeting and wish to vote in person, you will be given a ballot at the Special Meeting. Please note, however, that if your shares are held of record by a broker, bank or other nominee and you would like to vote in person at the Special Meeting, you must bring to the Special Meeting an account statement or letter from the broker, bank or other nominee indicating that you were the beneficial owner of the shares on June 4, 2009, the record date for the Special Meeting. As a beneficial owner, you may not vote these shares in person at the meeting unless you obtain a "legal proxy" from the broker, trustee or nominee that holds your shares, giving you the right to vote the shares at the meeting.

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#### **Abstentions and Broker Non-Votes**

Only shares voted "FOR" Proposal 1 will be counted as votes "FOR" approval of the Plan of Dissolution. If you sign your proxy card without giving specific instructions, the Company will vote your shares "FOR" the proposals being made at the Special Meeting unless your shares are held in street name in a brokerage account.

Brokers, banks or other nominees who hold shares of our common stock in street name for a customer who is the beneficial owner of those shares may not exercise voting authority on the customer's shares with respect to the actions proposed in this proxy statement without specific instructions from the customer. Proxies submitted by a broker, bank or other nominee that do not exercise this voting authority are referred to as "broker non-votes." If your common stock is held in street name, your broker, bank or nominee will vote your shares only if you provide instructions on how to vote by filling out the voter instruction form sent to you by your broker, bank or nominee with this proxy statement. Accordingly, you are urged to complete, sign, date and return the enclosed proxy card to indicate your vote and fill out the voter instruction form, if applicable.

Abstentions and broker non-votes will be included in determining the presence of a quorum at the Special Meeting, but will have the same effect as voting against the approval of the Plan of Dissolution. Abstentions and broker non-votes will have no impact on the vote on Proposal 2.

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# QUESTIONS AND ANSWERS REGARDING THIS SOLICITATION AND VOTING AT THE SPECIAL MEETING

# Q.

# Why am I receiving these proxy materials?

#### A:

You are receiving these proxy materials from us because you were a stockholder of record at the close of business on the Record Date which was June 4, 2009. As a stockholder of record, you are invited to attend the meeting and are entitled to and requested to vote on the items of business described in this Proxy Statement.

#### Q.

# What is the purpose of the Special Meeting?

#### A:

At our meeting, stockholders of record will vote upon the items of business outlined in the notice of meeting (on the cover page of this Proxy Statement), each of which is described more fully in this Proxy Statement. In addition, management will respond to questions from stockholders.

#### Q.

# Who is entitled to attend the meeting?

#### A.

You are entitled to attend the meeting *only* if you were an XTENT stockholder (or joint holder) of record as of the close of business on June 4, 2009, or if you hold a valid proxy for the meeting. You should be prepared to present photo identification for admittance.

Please also note that if you are not a stockholder of record but hold shares in *street name* (that is, through a broker or nominee), you will need to provide proof of beneficial ownership as of the Record Date, such as your most recent brokerage account statement, a copy of the voting instruction card provided by your broker, trustee or nominee, or other similar evidence of ownership. You will also need to obtain a "legal proxy" from the broker, trustee or nominee that holds your shares, giving you the right to vote the shares at the meeting.

The meeting will begin promptly at 9:00 a.m., local time. Check-in will begin at 8:30 a.m., local time.

# Q.

# Who is entitled to vote at the meeting?

# A.

Only stockholders who owned our common stock at the close of business on the Record Date are entitled to notice of the Special Meeting and to vote at the meeting, and at any postponements or adjournments thereof.

#### Q.

# How many shares must be present to conduct business?

# A.

The presence at the meeting, in person or by proxy, of the holders of a majority of the shares of our common stock at the close of business on the Record Date will constitute a quorum. A quorum is required to conduct business at the meeting. Both abstentions and broker non-votes are counted for the purpose of determining the presence of a quorum.

# Q.

What will be voted on at the meeting?

# А.

The items of business scheduled to be voted on at the meeting are as follows:

a proposal to approve the voluntary dissolution and liquidation of XTENT pursuant to a Plan of Complete Liquidation and Dissolution in substantially the form attached to this proxy statement as *Appendix A*; and

2.

1.

a proposal to adjourn the Special Meeting to another date, time or place, if necessary in the judgment of the proxy holders, for the purpose of soliciting additional proxies to vote in favor of Proposal 1.

These proposals are described more fully below in this Proxy Statement. As of the date of this Proxy Statement, the only business that our board of directors intends to present or knows of that

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others will present at the meeting is set forth in this Proxy Statement. If any other matter or matters are properly brought before the meeting, it is the intention of the persons who hold proxies to vote the shares they represent in accordance with their best judgment.

#### How does the board of directors recommend that I vote?

Α.

Q.

Our board of directors recommends that you vote your shares "FOR" approval of both Proposals 1 and 2.

# Q.

А.

#### What shares can I vote at the meeting?

You may vote all shares owned by you as of the Record Date, including (1) shares held directly in your name as the stockholder of

Q.

#### What is the difference between holding shares as a stockholder of record and as a beneficial owner?

record, and (2) shares held for you as the beneficial owner through a broker, trustee or other nominee such as a bank.

#### A.

Most of our stockholders hold their shares through a broker or other nominee rather than directly in their own name. As summarized below, there are some distinctions between shares held of record and those owned beneficially.

**Stockholders of Record.** If your shares are registered directly in your name with our transfer agent, Computershare Trust Company, N.A., you are considered to be, with respect to those shares, the stockholder of record, and these proxy materials are being sent directly to you by us. As the stockholder of record, you have the right to grant your voting proxy directly to XTENT or to vote in person at the meeting. We have enclosed a proxy card for you to use.

**Beneficial Owner.** If your shares are held in a brokerage account or by another nominee, you are considered the beneficial owner of shares held in street name, and these proxy materials are being forwarded to you together with a voting instruction card. As the beneficial owner, you have the right to direct your broker, trustee or nominee how to vote and are also invited to attend the meeting. Please note that since a beneficial owner is not the stockholder of record, you may not vote these shares in person at the meeting unless you obtain a "legal proxy" from the broker, trustee or nominee that holds your shares, giving you the right to vote the shares at the meeting. Your broker, trustee or nominee has enclosed or provided voting instructions for you to use in directing the broker, trustee or nominee how to vote your shares.

#### Q.

#### How can I vote my shares without attending the meeting?

А.

Whether you hold shares directly as the stockholder of record or beneficially in street name, you may direct how your shares are voted without attending the meeting. Stockholders of record of our common stock may submit proxies by completing, signing and dating their proxy cards and mailing them in the accompanying pre-addressed envelope. XTENT stockholders who hold shares beneficially in street name may vote by mail by completing, signing and dating the voting instruction cards provided by the broker, trustee or nominee and mailing them in the accompanying pre-addressed envelope. In addition, if you are a stockholder of record, you may grant a proxy to vote your shares at the Special Meeting by telephone, by calling 1-800-652-8683 and following the simple recorded instructions, twenty-four hours a day, seven days a week, at any time prior to 11:00 p.m. Pacific Time on July 8, 2009, the day before the Special Meeting, by going to *http://www.investorvote.com/XTNT* to create an electronic ballot. If you vote by telephone or the Internet, you will be required to provide the control number contained on your proxy card. If your shares are held in street name, your proxy card may contain instructions from your broker, bank or nominee that allow you to vote your shares using the Internet or by telephone. Please consult with

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your broker, bank or nominee if you have any questions regarding the electronic voting of shares held in street name. The granting of proxies electronically is allowed by Section 212(c)(2) of the Delaware General Corporation Law, or DGCL.

#### Q.

#### How can I vote my shares in person at the meeting?

#### A.

Shares held in your name as the stockholder of record may be voted in person at the meeting. Shares held beneficially in street name may be voted in person only if you obtain a legal proxy from the broker, trustee or nominee that holds your shares giving you the right to vote the shares. *Even if you plan to attend the meeting, we recommend that you also submit your proxy card or voting instructions as described above so that your vote will be counted if you later decide not to, or are unable to, attend the meeting.* 

#### Q.

# Can I change my vote?

#### A.

You may change your vote at any time prior to the vote at the meeting. If you are the stockholder of record, you may change your vote by granting a new proxy bearing a later date (which automatically revokes the earlier proxy), by providing a written notice of revocation to our Secretary prior to your shares being voted, or by attending the meeting and voting in person. Attendance at the meeting will not cause your previously granted proxy to be revoked unless you specifically so request.

For shares you hold beneficially in street name, you may change your vote by submitting new voting instructions to your broker, trustee or nominee, or, if you have obtained a legal proxy from your broker, trustee or nominee giving you the right to vote your shares, by attending the meeting and voting in person.

# Q.

# Is my vote confidential?

#### A.

Proxy instructions, ballots and voting tabulations that identify individual stockholders are handled in a manner that protects your voting privacy. Your vote will not be disclosed either within XTENT or to third parties, except: (1) as necessary to meet applicable legal requirements, (2) to allow for the tabulation of votes and certification of the vote, and (3) to facilitate a successful proxy solicitation. Occasionally, stockholders provide written comments on their proxy card, which are then forwarded to XTENT management.

# Q.

# How are votes counted?

# A.

If you provide specific instructions with regard to an item, your shares will be voted as you instruct on such item. If you sign your proxy card without giving specific instructions, your shares will be voted in accordance with the recommendations of the board of directors ("FOR" each of Proposals 1 and 2, and in the discretion of the proxy holders on any other matters that properly come before the meeting).

# Q.

# What is a "broker non-vote"?

# A.

Under the rules that govern brokers who have record ownership of shares that are held in street name for their clients, who are the beneficial owners of the shares, brokers have the discretion to vote such shares on routine matters. Approval of the Plan of Dissolution is considered non-routine, and therefore your broker or bank does not have the discretionary authority to vote your shares on this matter. A "broker non-vote" occurs when a broker expressly instructs on a proxy card that it is not voting on a matter, whether routine or non-routine. Approval of Proposal 2 is considered a routine matter. Therefore, if you do not otherwise instruct your broker, the broker may turn in a proxy card voting your shares "FOR" adjournment of the Special Meeting for the purpose of soliciting additional proxies to vote in favor or Proposal 1.

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# How are "broker non-votes" counted?

# A.

Q.

Broker non-votes will be counted for the purpose of determining the presence or absence of a quorum for the transaction of business, but they will not be counted in tabulating the voting result for any particular proposal.

# Q.

# How are abstentions counted?

#### A.

If you return a proxy card that indicates an abstention from voting on all matters, the shares represented will be counted for the purpose of determining both the presence of a quorum and the total number of votes cast with respect to a proposal, but they will not be voted on any matter at the meeting. In the absence of controlling precedent to the contrary, we intend to treat abstentions in this manner. Accordingly, abstentions will have the same effect as a vote "AGAINST" a proposal.

# Q.

# What happens if additional matters are presented at the meeting?

# A.

If you grant a proxy, the persons named as proxy holders, Gregory D. Casciaro (our President and Chief Executive Officer, as well as a Director) and Ronald C. Austin (our Secretary), will have the discretion to vote your shares on any additional matters properly presented for a vote at the meeting. However, other than the two proposals described in this Proxy Statement, we are not aware of any other business to be acted upon at the meeting, and no other matters properly may be presented for a vote at the Special Meeting.

# Q.

# Who will serve as inspector of election?

#### Α.

We expect a representative of Computershare Trust Company, N.A., our transfer agent, to tabulate the votes and act as inspector of election at the meeting.

# Q.

# What should I do if I receive more than one proxy?

# A.

You may receive more than one set of these proxy solicitation materials, including multiple copies of this Proxy Statement and multiple proxy cards or voting instruction cards. For example, if you hold your shares in more than one brokerage account, you may receive a separate voting instruction card for each brokerage account in which you hold shares. In addition, if you are a stockholder of record and your shares are registered in more than one name, you may receive more than one proxy card. Please complete, sign, date and return each XTENT proxy card and voting instruction card that you receive to ensure that all your shares are voted.

# Q.

# Who is soliciting my vote and who is paying the costs?

# A.

Your vote is being solicited on behalf of the board of directors of our Company, and our Company will pay the costs associated with the solicitation of proxies, including preparation, assembly, printing and mailing of this Proxy Statement.

# Q.

# How can I find out the results of the voting?

#### Α.

We intend to announce preliminary voting results at the meeting and publish final results in a Current Report on Form 8-K following the meeting.

# Q.

# What is the deadline for proposing action or director candidates for future meetings?

A.

If we have a future annual meeting, you may be entitled to present proposals for action at such a meeting, including director nominations.

**Stockholder Proposals:** We do not expect to hold another annual meeting. If there is an annual meeting held in 2010, for a stockholder proposal to be considered for inclusion in the XTENT Proxy Statement, the written proposal must be received by the Secretary of the Company at our principal executive offices no later than the close of business on the 10th day following the date on

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which notice of the annual meeting is mailed to our stockholders or public disclosure of the date of the meeting is made, whichever occurs first. Stockholder proposals must comply with the requirements of Rule 14a-8 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), and any other applicable rules established by the U.S. Securities and Exchange Commission (the "**SEC**"). Proposals should be addressed to:

Secretary XTENT, Inc. 125 Constitution Drive Menlo Park, California 94025-1118

**Nomination of Director Candidates:** If you wish to propose a director candidate for consideration by our board of directors, your recommendation should include information required by the Bylaws of XTENT and should be directed to the Secretary of XTENT at the address of our principal executive offices set forth above. In addition, the stockholder must submit the recommendation within the time period set forth above for Stockholder Proposals.

**Copy of Bylaw Provisions:** You may contact the Secretary of XTENT at our principal executive offices for a copy of the relevant bylaw provisions regarding the requirements for making stockholder proposals and nominating director candidates.

#### Q:

#### What will happen if the Plan of Dissolution is approved?

#### A:

If the Plan of Dissolution is approved by the requisite vote of our stockholders, the steps set forth below will be completed at such times as our board of directors, in its discretion and in accordance with the DGCL, deems necessary, appropriate or advisable in our best interests and the best interests of our stockholders:

the filing of a certificate of dissolution with the Secretary of State of the State of Delaware, or the Secretary of State, after obtaining a revenue clearance certificate from the Department of Finance of the State of Delaware, or Department of Finance;

the cessation of all of XTENT's business activities except for those relating to winding up and liquidating XTENT's business and affairs, including, but not limited to, prosecuting and defending suits by or against XTENT, collecting XTENT's assets, converting XTENT's assets into cash or cash equivalents, discharging or making provision for discharging XTENT's liabilities, withdrawing from all jurisdictions in which XTENT is qualified to do business and distributing XTENT's remaining property among our stockholders according to their interests;

the collection, sale, exchange or other disposition of all or substantially all of XTENT's non-cash property and assets, in one transaction or in several transactions to more than one buyer;

the payment of or the making of reasonable provision for the payment of all claims and obligations known to XTENT, and the making of such provisions as will be reasonably likely to be sufficient to provide compensation for any claim against XTENT which is the subject of a pending action, suit or proceeding to which XTENT is a party, including, without limitation, the establishment and setting aside of a reasonable amount of cash and/or property to satisfy such claims against and obligations of XTENT;

the pro rata distribution to our stockholders, or the transfer to one or more liquidating trustees, for the benefit of our stockholders under a liquidating trust, of the remaining assets of XTENT after payment or provision for payment of claims against and obligations of XTENT; and

the taking of any and all other actions permitted or required by the DGCL and any other applicable laws and regulations.

See "Proposal 1: Approval of Plan of Dissolution Principal Provisions of the Plan of Dissolution."

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# Q:

#### What will happen if the Plan of Dissolution is not approved?

#### A:

If our stockholders do not approve the Plan of Dissolution, our board of directors will explore what, if any, alternatives are available for the future of XTENT, particularly in light of the fact that we have terminated substantially all of our employees, would need significant additional capital to support our U.S. pivotal clinical trial and efforts to commercialize our products in Europe, commenced the process of winding up our business and will continue to incur net losses for the foreseeable future. We took several of these steps in the interest of preserving cash available for distribution to stockholders and in recognition of the expectation that the announcement of approval of the Plan of Dissolution would adversely affect our ability to obtain approval from the U.S. Food and Drug Administration, or FDA, for our investigational device exemption, or IDE, to proceed with our U.S. pivotal clinical trial and commercialize our products in Europe. There is currently no active business left to operate and rehiring employees may not be possible, or would take several months at a cost that we are unable to estimate.

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

See "Risk Factors Risks Related to the Plan of Dissolution."

#### Q:

# What will stockholders receive in the liquidation?

#### A:

Pursuant to the Plan of Dissolution, we intend to liquidate all of our remaining non-cash assets and, after satisfying or making reasonable provision for the satisfaction of claims, obligations and liabilities as required by law, distribute any remaining cash to our stockholders. We can only estimate the amount of cash that may be available for distribution among our stockholders. We currently estimate that the amount ultimately distributed will be between approximately \$0.11 and \$0.40 per share of common stock, assuming we are unable to sell our intellectual property. Due to the uncertainty of the value of our intellectual property, we have not provided any estimate of the proceeds of a sale of our intellectual property in the amount of liquidating distributions. If we were to receive a substantial amount of proceeds from the sale of our intellectual property it could significantly affect the estimates that we have provided. We can provide no assurance, however, that the sale of our intellectual property will result in any such additional proceeds. Many of the factors influencing the amount of cash distributed to our stockholders as a liquidating distribution cannot be currently quantified with certainty and are subject to change. Accordingly, you will not know the exact amount of any liquidating distributions you may receive as a result of the Plan of Dissolution when you vote on the proposal to approve the Plan of Dissolution. You may receive substantially less than the amount we currently estimate. See "*Proposal 1: Approval of Plan of Dissolution Estimated Liquidating Distributions.*"

#### Q:

# When will stockholders receive payment of any available liquidation proceeds?

#### A:

Although we are not able to predict with certainty the precise nature, amount or timing of any distributions, we presently expect to make an initial distribution as soon as reasonably practicable

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following the initial sale of our non-cash assets, to holders of record of our common stock as of the close of business on the Effective Date. We do not intend to make any further distributions until after we sell, liquidate or otherwise dispose of our remaining non-cash assets, consisting primarily of our drug eluting stent systems and related intellectual property, and pay or otherwise make reasonable provision for the payment of claims against and obligations of XTENT. We are not able to predict with certainty the precise nature, amount or timing of any distributions, primarily due to our inability to predict the amount of our remaining liabilities or the amount that we will expend during the course of the liquidation and the net value, if any, of our remaining non-cash assets. To the extent that the amount of our liabilities or the amounts that we expend during the liquidation are greater, or the value of our non-cash assets is less, than we anticipate, our stockholders may receive substantially less than the amount we currently estimate. Our board of directors has not established a firm timetable for any final distributions to our stockholders. Subject to contingencies inherent in winding up our business, our board of directors intends to authorize any distributions as promptly as reasonably practicable in our best interests and the best interests of our stockholders. Our board of directors, in its discretion, will determine the nature, amount and timing of all distributions. See "*Proposal 1: Approval of Plan of Dissolution Estimated Liquidating Distributions*" and "*Risk Factors Risks Related to the Plan of Dissolution*" for a discussion of the estimates and assumptions made in calculating the estimated range of liquidating distributions.

# Q:

#### What happens to my shares of common stock after the dissolution of XTENT?

#### A:

The liquidating distributions to stockholders pursuant to the Plan of Dissolution shall be in complete redemption and cancellation of all of the outstanding shares of our common stock. Thereafter, each holder of our common stock will cease to have any rights with respect to his, her or its shares, except the right to receive distributions pursuant to the Plan of Dissolution.

#### Q:

#### Should I send in my stock certificates now?

#### A:

As a condition to receipt of the liquidating distributions, our board of directors or trustees may require our stockholders to surrender to us their certificates evidencing their shares of common stock or to furnish us with evidence satisfactory to our board of directors or any trustees of the loss, theft or destruction of such certificates, together with such surety bond or other security or indemnity as may be required by and satisfactory to our board of directors or any trustees. If the surrender of stock certificates will be required following the dissolution, we will send you written instructions regarding such surrender. Any distributions otherwise payable by us to stockholders who have not surrendered their stock certificates, if requested to do so, may be held in trust for such stockholders, without interest, pending the surrender of such certificates (subject to escheat pursuant to the laws relating to unclaimed property).

#### Q:

# Can I still sell my shares?

# A:

Yes, for a limited period of time. However, our board of directors may direct that our stock transfer books be closed and recording of transfers of common stock discontinued as of the earliest of:

the close of business on the record date fixed by our board of directors for the first or any subsequent installment of any liquidating distribution;

the close of business on the date on which our remaining assets are transferred to a liquidating trust; or

the date on or as soon as reasonably practicable after which we file our certificate of dissolution under the DGCL.

No. You should not forward your stock certificates before receiving instructions to do so.

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We expect that our board of directors will close our stock transfer books on or around the Effective Date. The Effective Date will be determined following the receipt of a revenue clearance certificate from the Department of Finance and will be announced as soon as reasonably practicable after that time. Thereafter, certificates representing shares of our common stock will not be assignable or transferable on our books except by will, intestate succession or operation of law, and we will not issue any new stock certificates, other than replacement certificates. In addition, we anticipate that we will request that our common stock be delisted from the NASDAQ Global Market at the close of business on the Effective Date. See "*Proposal 1: Approval of Plan of Dissolution Closing of Transfer Books.*"

#### Q:

#### Do I have dissenters' rights?

#### A:

No. Under the DGCL, holders of our shares of common stock are not entitled to assert dissenters' rights with respect to the Plan of Dissolution.

# Q:

#### What do stockholders need to do now?

A:

After carefully reading and considering the information contained in this proxy statement and the documents delivered with and incorporated by reference into this proxy statement, each stockholder should complete, sign and date his or her proxy card and mail it in the enclosed postage prepaid envelope as soon as possible so that his or her shares may be represented at the Special Meeting.

#### Q:

#### Who should I contact with questions?

A:

If you have any additional questions about the Special Meeting or the proposals presented in this proxy statement, you should contact:

Ronald C. Austin, Secretary XTENT, Inc. 125 Constitution Drive Menlo Park, California 94025-1118 Telephone: (650) 433-4834

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#### SUMMARY TERM SHEET

This summary term sheet highlights selected information contained in this proxy statement and may not contain all of the information that is important to you. To understand fully the legal requirements for the voluntary dissolution of XTENT, Inc. under Delaware law and the Special Meeting and for a more complete description of the terms of the Plan of Complete Liquidation and Dissolution, you should carefully read this entire proxy statement and the documents delivered with and incorporated by reference into this proxy statement. See "Incorporation by Reference." As used in this proxy statement, unless the context otherwise requires, the terms "we," "us," "our," "the Company," and "XTENT" refer to XTENT, Inc., a Delaware corporation.

The Company We are a development stage medical device company that has focused on developing and commercializing our proprietary Custom NX drug eluting stent, or DES, Systems to treat coronary artery disease, or CAD. Since inception we have devoted substantially all of our resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials. We have focused our development efforts on creating our Custom NX DES Systems, which allow a physician to deploy single or multiple stents of customizable length with a single device. In March 2009, we received CE Mark authorizing us to market our Custom NX DES Systems in the European Union and certain other countries that recognize CE Mark, but we have not yet received any other government regulatory approvals necessary to commercialize any of our products in any other countries.

Over the past four years, we have been conducting clinical trials to evaluate our Custom NX 36 and Custom NX 60 stent and stent delivery systems. In October 2008, the one year data from our CUSTOM III clinical trial, the two year data from our CUSTOM II clinical trial and the three year data from our CUSTOM I clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. We believe the data from these clinical trials provided preliminary evidence of safety and efficacy and support further development of our in situ customization approach. In March 2009, we received CE Mark for our Custom NX DES Systems authorizing us to market our products in the European Union and certain other countries that recognize the CE Mark. Even though we have received CE Mark, we do not have adequate resources to commercialize our products in the European Union.

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

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To date, we have not generated any revenue from the sale of our products. We have incurred net losses in each year since our inception in June 2002. Through March 31, 2009, we had an accumulated deficit of \$143.8 million. If the Plan of Dissolution is not approved, and we continue to operate, we would expect our losses to continue to increase as we expand our clinical trial activities and initiate commercialization activities. Since inception we have financed our operations primarily through the sale of our equity securities. In May and June 2006, we raised aggregate net cash proceeds of approximately \$30.0 million in a private placement of shares of our Series D convertible preferred stock. On February 1, 2007 we completed our initial public offering of our common stock which raised net proceeds of \$68.2 million.

In January 2009, we notified our employees that we were initiating a headcount reduction that would impact 115 of our 122 employees. The reduction was substantially completed by March 31, 2009. We also engaged Piper Jaffray & Co. in January 2009 to help us explore potential strategic alternatives, including, without limitation, a merger, a sale of substantially all our assets, a financing, or a sale of a portion of our assets, such as our peripheral stent product, our drug eluting balloon product or our bioabsorbable stent product.

Our principal executive office is located at 125 Constitution Drive, Menlo Park, California 94025-1118, and our telephone number at our principal executive office is (650) 475-9400. You can find more information about us in the documents that are delivered with and incorporated by reference into this proxy statement. See "*Incorporation by Reference*."

# THE SPECIAL MEETING OF STOCKHOLDERS

General (See page 1)	The Special Meeting of stockholders will take place on July 9, 2009, at 9:00 a.m., local time, at the Company's principal executive offices located at 125 Constitution Drive, Menlo Park, California 94025-1118. See " <i>The Special Meeting General</i> ."
Proposals (See page 1)	At the Special Meeting, our stockholders will consider and vote upon:
(See page 1)	<ol> <li>a proposal to approve the voluntary dissolution and liquidation of XTENT pursuant to a Plan of Complete Liquidation and Dissolution in substantially the form attached to this proxy statement as <i>Appendix A</i>; and</li> </ol>
	2. a proposal to adjourn the special meeting to another date, time or place, if necessary in the judgment of the proxy holders, for the purpose of soliciting additional proxies to vote in favor of Proposal 1.
	In this proxy statement, we refer to the Plan of Complete Liquidation and Dissolution as the Plan of Dissolution. See " <i>The Special Meeting Proposals</i> ."
Record Date and Voting Securities (See page 1)	Only holders of record of our common stock as of the close of business on June 4, 2009, the record date for the Special Meeting, are entitled to notice of and to vote at the Special Meeting and any adjournments or postponements thereof. Each holder of common stock is entitled to one vote for each share of common stock held of record on the record date. See " <i>The Special Meeting Record Date and Voting Securities</i> ."

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Quorum and Required Votes (See page 2)	Under Delaware law, a quorum consisting of a majority of the shares entitled to vote must be represented in person or by proxy for the transaction of business at the Special Meeting. The approval of the Plan of Dissolution requires the affirmative vote of a majority of the outstanding shares of our common stock. The approval of any adjournment of the Special Meeting requires that the votes cast in favor of the proposal exceed the votes cast against the proposal at the Special Meeting. See " <i>The Special Meeting Quorum</i> " and " <i>The Special Meeting Required Votes</i> ."
Voting by, and Revocation of, Proxy (See pages 2 and 3)	Our board of directors has selected Gregory D. Casciaro and Ronald C. Austin to serve as proxies at the Special Meeting. The shares of common stock represented by each executed and returned proxy will be voted in accordance with the directions indicated on the proxy. If you sign your proxy card without giving specific instructions, the Company will vote your shares "FOR" the proposals being made at the Special Meeting unless your shares are held in street name in a brokerage account. The proxy also confers discretionary authority to vote the shares authorized to be voted thereby on any matter that properly may be presented for action at the Special Meeting. We know of no other business to be presented at the Special Meeting, and no other matters properly may be presented for a vote at the Special Meeting.
	Provided on the by signing, during and maning your proxy card in the postage prepaid envelope provided or following the instructions for telephone or Internet voting, whether or not you plan to attend the Special Meeting in person. See " <i>The Special Meeting Voting by Proxy</i> ." Any proxy given may be revoked by the person giving it at any time before it is voted at the Special Meeting. Proxies may be revoked by signing and delivering a new proxy bearing a later date to the Secretary of XTENT, by delivering a written notice of revocation to the Secretary of XTENT bearing a later date than the date of your proxy card, or by attending the Special Meeting will not, by itself, revoke your proxy. See " <i>The Special Meeting Revocation of Proxy</i> ."
Risks Related to the Plan of Dissolution (See page 25)	Risks associated with the Plan of Dissolution include the following: the amount we distribute to our stockholders pursuant to the Plan of Dissolution may be substantially less than the amount we currently estimate if the amounts of our liabilities, other obligations and expenses and claims against us are higher than we currently anticipate;
	<ul> <li>we may continue to incur the expenses of complying with public company reporting requirements, which may be economically burdensome;</li> <li>if the amount of our contingency reserve is insufficient to satisfy the aggregate amount of our liabilities and other obligations, each stockholder may be liable to our creditors for the amount of liquidating distributions received by such stockholder under the Plan of Dissolution, which could also have adverse tax consequences;</li> <li>liquidating distributions to our stockholders could be delayed;</li> </ul>

stockholders will lose the opportunity to capitalize on potential growth opportunities from the continuation of our business; 15

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

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

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

our board of directors may revoke implementation of the Plan of Dissolution even if it is approved by our stockholders; and

if our stockholders do not approve the Plan of Dissolution, our resources may diminish completely.

If our stockholders do not approve the Plan of Dissolution, our board of directors will explore what, if any, alternatives are available for the future of XTENT, particularly in light of the fact that we have terminated substantially all of our employees, would need significant additional capital to support our U.S. pivotal clinical trial and efforts to commercialize our products in Europe, and commenced the process of winding up our business and will continue to incur net losses for the foreseeable future. We took several of these steps in the interest of preserving cash available for distribution to stockholders and in recognition of the expectation that the announcement of approval of the Plan of Dissolution would adversely affect our ability to obtain FDA approval for our IDE, proceed with our U.S. pivotal clinical trial and commercialize our products in Europe. There is currently no active business left to operate and rehiring employees may not be possible, or would take several months at a cost that we are unable to estimate.

Possible alternatives include selling all of our stock or assets, changing our business focus, continuing our efforts to identify a merger partner or a reverse merger partner, or seeking voluntary dissolution at a later time and with diminished assets. At this time, our board of directors has considered all of these options and has determined that it is in the best interests of our stockholders to dissolve XTENT, liquidate its assets and return the cash to our stockholders. The board of directors, however, retains the right to consider other alternatives should a more attractive offer arise before or after the Effective Date. If our stockholders do not approve the Plan of Dissolution, we expect that our cash resources will continue to diminish and we would face risks related to continuing our historical business described in this proxy statement. These risks could materially and adversely affect our business, financial condition or operating results and the value of our common stock, and you may lose all or part of your investment.

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You should carefully consider the risk factors beginning on page 25 of this proxy statement in evaluating whether to approve the Plan of Dissolution. These risk factors should be considered along with the other information included in this proxy statement and the documents delivered with and incorporated by reference into this proxy statement, including any forward-looking statements made in this proxy statement and such documents. See "*Special Note Regarding Forward-Looking Statements*."

# **PROPOSAL 1: APPROVAL OF PLAN OF DISSOLUTION**

General

(See page 1)

At the Special Meeting, the stockholders of XTENT will be asked to approve the voluntary dissolution and liquidation of XTENT pursuant to the Plan of Dissolution. Our board of directors approved the Plan of Dissolution, subject to stockholder approval, on May 11, 2009. Delaware law provides that a corporation may dissolve upon the recommendation of the board of directors of the corporation, followed by the approval of its stockholders. If the Plan of Dissolution is approved by the requisite vote of our stockholders at the Special Meeting and any adjournments or postponements of the Special Meeting, we intend to file a certificate of dissolution with the Secretary of State as soon as reasonably practicable after receipt of the required revenue clearance certificate from the Department of Finance. We will be dissolved upon the effective date of our certificate of dissolution, or the Effective Date. The Effective Date may be the date on which the certificate of dissolution is filed or a later date specified in the certificate of dissolution. We intend to make a public announcement in advance of the anticipated Effective Date. The effect of the dissolution will be that our corporate existence will continue, but we will not be permitted to carry on any business except that appropriate to wind up and liquidate our business and affairs.

The Plan of Dissolution provides for the voluntary dissolution, liquidation and winding up of XTENT. If the Plan of Dissolution is approved by our stockholders and implemented by us, we will, after the Effective Date, dispose of our remaining non-cash assets, consisting primarily of our drug eluting stent systems and related intellectual property, pay or make reasonable provision to pay all claims and obligations, make such provisions as will be reasonably likely to be sufficient to provide compensation for any claim against us which is the subject of a pending action, suit or proceeding to which we are a party, distribute on a pro rata basis to our stockholders our remaining assets, and, subject to statutory limitations, take all other actions necessary to wind up and liquidate the corporation's business and affairs. For more information regarding the proposed dissolution and liquidation of XTENT, see "*Proposal 1: Approval of Plan of Dissolution.*"

Reasons for Dissolution and Liquidation (See page 34) Our board of directors believes that the voluntary dissolution and liquidation of XTENT is advisable and in our best interests and the best interests of our stockholders. Our board of directors has considered at length, with the assistance of legal and financial advisors, potential strategic alternatives available to XTENT, including continuing to execute on our strategic plan and further developing our drug eluting stent systems. Our board of directors, in making its determination, considered, in addition to other pertinent factors:

the potential enhanced stockholder value that might be derived if we were to continue to pursue our strategic plan;

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the risks associated with our ongoing business operations, including the risks associated with our drug eluting stent technology in a relatively early stage of development;

the time and costs, including the costs of needed capital, associated with trying to bring our Custom NX DES Systems to market;

our general business prospects;

the unavailability of significant additional capital to conduct our U.S. pivotal clinical trial or commercialize our products in Europe and the continued significant distress in the financing and capital markets;

the fact that we engaged Piper Jaffray & Co. in September 2008 to solicit interest in a financing to support our ongoing operations, including obtaining FDA approval for our IDE, proceeding with our U.S. pivotal clinical trial and commercializing our products in Europe, and were unable to secure additional funding; and

the fact that our efforts with the assistance of Piper Jaffray & Co. to identify a merger, reverse merger, asset sale, strategic partnership or other business combination transaction that would have a reasonable likelihood of providing value to our stockholders in excess of the amount the stockholders would receive in a liquidation, or that would mitigate the risks of our ongoing operations, did not result in the identification of any likely transactions.

Our board of directors has concluded that a statutory dissolution and liquidation under Delaware law is the preferred strategy among the alternatives available to XTENT, is in the best interests of our stockholders and has adopted the Plan of Dissolution and recommends that our stockholders approve the Plan of Dissolution. See "*Proposal 1: Approval of Plan of Dissolution Reasons for Dissolution and Liquidation*."

Dissolution and Liquidation (See page 37) If the Plan of Dissolution is approved by the requisite vote of our stockholders, the steps set forth below will be completed at such times as our board of directors, in its discretion and in accordance with the DGCL deems necessary, appropriate or advisable in the best interest of XTENT and its stockholders:

> the filing of a certificate of dissolution with the Secretary of State after obtaining a revenue clearance certificate from the Department of Finance;

the cessation of all of XTENT's business activities except for those relating to winding up and liquidating XTENT's business and affairs, including, but not limited to, prosecuting and defending suits by or against XTENT, collecting XTENT's assets, converting XTENT's assets into cash or cash equivalents, discharging or making provision for discharging XTENT's liabilities, withdrawing from all jurisdictions in which XTENT is qualified to do business and distributing XTENT's remaining property among our stockholders according to their interests;

the collection, sale, exchange or other disposition of all or substantially all of XTENT's non-cash property and assets, in one transaction or in several transactions to more than one buyer;

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the payment of or the making of reasonable provision for the payment of all claims and obligations known to XTENT, and the making of such provisions as will be reasonably likely to be sufficient to provide compensation for any claim against XTENT which is the subject of a pending action, suit or proceeding to which XTENT is a party, including, without limitation, the establishment and setting aside of a reasonable amount of cash and/or property to satisfy such claims against and obligations of XTENT;

the pro rata distribution to our stockholders, or the transfer to one or more liquidating trustees, for the benefit of our stockholders under a liquidating trust, of the remaining assets of XTENT after payment or provision for payment of claims against and obligations of XTENT; and

the taking of any and all other actions permitted or required by the DGCL and any other applicable laws and regulations.

See "Proposal 1: Approval of Plan of Dissolution Principal Provisions of the Plan of Dissolution."

Authority of Officers and Directors (See page 37) The approval of the Plan of Dissolution by our stockholders also will authorize, without further stockholder action, our board of directors to do and perform, or to cause our officers to do and perform, any and all acts and to make, execute, deliver or adopt any and all agreements, resolutions, conveyances, certificates and other documents of every kind that our board of directors deems necessary, appropriate or desirable, in the absolute discretion of the board of directors, to implement the Plan of Dissolution and the transactions contemplated thereby, including, without limitation, all filings or acts required by any state or federal law or regulation to wind up its affairs. See "*Proposal 1: Approval of Plan of Dissolution Principal Provisions of the Plan of Dissolution Authority of Officers and Directors*."

**Liquidating Trust** If deemed necessary, appropriate or desirable by our board of directors, in (See page 38) furtherance of the liquidation and distribution of our assets to stockholders in accordance with our Plan of Dissolution, we may transfer to one or more liquidating trustees, for the benefit of our stockholders under a liquidating trust, any or all of our assets, including any cash intended for distribution to creditors and stockholders not disposed of at the time of dissolution of XTENT. Any trustee so appointed shall succeed to all right, title and interest of XTENT of any kind and character with respect to such transferred assets and, to the extent of the assets so transferred and solely in its capacity as trustee, shall assume all of our claims and obligations, including any unsatisfied claims and unknown or contingent liabilities. Whether or not a trust shall have been previously established, if it should not be feasible for us to make the final liquidating distribution to our stockholders of all our assets and properties prior to the third anniversary of the filing of our certificate of dissolution, then, on or before such date, we will be required to establish a trust and transfer any remaining assets and properties to the trustees. See "Proposal 1: Approval of Plan of Dissolution Principal Provisions of the Plan of Dissolution Liquidating Trust."

Cancellation of Common Stock (See page 39) The liquidating distributions to stockholders pursuant to the Plan of Dissolution shall be in complete redemption and cancellation of all of the outstanding shares of our common stock. As a condition to receipt of the liquidating distribution, our board of directors or any trustees may require our stockholders to surrender to us their certificates evidencing their shares

of common stock or to furnish us with evidence satisfactory to our board of directors or any trustees of the loss, theft or destruction of such certificates, together with such surety bond or other security or indemnity as may be required by and satisfactory to our board of directors or any trustees. See "Proposal 1: Approval of Plan of Dissolution Principal Provisions of the Plan of Dissolution Cancellation of Common Stock."

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Amendment. If for any reason our board of directors determines that such action would **Modification or** be in the best interest of XTENT, our board of directors may, in its sole **Revocation of** discretion and without requiring further stockholder approval, revoke the Plan Plan of Dissolution and all action contemplated thereunder, to the extent of Dissolution permitted by the DGCL. Our board of directors may not amend or modify (See page 39) the Plan of Dissolution under circumstances that would require additional stockholder approval under the DGCL and federal securities laws without complying with such requirements. The Plan of Dissolution would be void upon the effective date of any such revocation. See "Proposal 1: Approval of Plan of Dissolution Principal Provisions of the Plan of Dissolution Amendment, Modification or Revocation of Plan of Dissolution." Estimated Although we are not able to predict with certainty the precise nature, Liquidating amount or timing of any distributions, we presently expect to make an initial distribution, as soon as reasonably practicable following the initial Distributions sale of our non-cash assets, to holders of record of our common stock as of (See page 40) the close of business on the Effective Date. We do not intend to make any further distributions until after we sell, liquidate or otherwise dispose of our remaining non-cash assets, consisting primarily of our drug eluting stent systems and related intellectual property, and pay or make reasonable provision to pay all claims against and obligations of XTENT. We currently estimate that the amount ultimately distributed will be between approximately \$0.11 and \$0.40 per share of common stock, assuming we are unable to sell our non-cash assets. We are not able to predict with certainty the precise nature, amount or timing of any distributions, primarily due to our inability to predict the amount of our remaining liabilities or the amount that we will expend during the course of the liquidation and the net value, if any, of our remaining non-cash assets. Our board of directors has not established a firm timetable for any final distributions to our stockholders. Subject to contingencies inherent in winding up our business, our board of directors intends to authorize any distributions as promptly as reasonably practicable in our best interests and the best interests of our stockholders. Our board of directors, in its discretion, will determine the nature, amount and timing of all distributions. See "Proposal 1: Approval of Plan of Dissolution Estimated Liquidating Distributions" and "Risk Factors Risks Related to the Plan of Dissolution" for a discussion of the estimates and assumptions made in calculating the estimated range of liquidating distributions. Due to the uncertainty of the value of our intellectual property, we have not provided any estimate of the proceeds of a sale of our intellectual property in the amount of liquidating distributions. If we were to receive a substantial amount of proceeds from the sale of our intellectual property it could significantly affect the estimates that we have provided. We can provide no assurance, however, that the sale of our intellectual property will result in any such additional proceeds. Many of the factors influencing the amount of cash distributed to our stockholders as a liquidating distribution cannot be currently quantified with certainty and are subject to change. Accordingly, you will not know the exact amount of any liquidating distributions you may receive as a result of the Plan of Dissolution when you vote on the proposal to approve the Plan of Dissolution. You may receive substantially less than the amount we currently estimate. Conduct of the After the Effective Date, our corporate existence will continue but we may Company not carry on any business except that appropriate to wind up and liquidate

Following Dissolution (See page 43) our business and affairs, including, without limitation, collecting and disposing of our assets, satisfying or making reasonable provision for the satisfaction of our liabilities and, subject to legal requirements, distributing our remaining property among our stockholders. See "*Proposal 1: Approval of Plan of Dissolution Conduct of the Company Following Dissolution.*"

Sale of Remaining Assets (See page 43)	The Plan of Dissolution gives our board of directors the authority to dispose of all of our remaining property and assets without further stockholder approval. Stockholder approval of the Plan of Dissolution will constitute approval of any and all such future asset dispositions on such terms and at such prices as our board of directors, without further stockholder approval, may determine to be in our best interests and the best interests of our stockholders. We intend to sell our remaining non-cash assets, consisting primarily of our drug eluting stent systems and related intellectual property, on such terms as are approved by our board of directors in our best interests and the best interests of our stockholders. We may conduct sales by any means, including by competitive bidding or private negotiations, to one or more purchasers in one or more transactions over a period of time. We intend to distribute the cash proceeds from any sale of our remaining non-cash assets to our stockholders within twelve months of such sale. In addition to our drug eluting stent systems and related intellectual property, our remaining non-cash assets include our pre-clinical and clinical trial data and related regulatory filings, Custom NX DES Systems designs and related documentation, tooling, manufacturing and test equipment, furniture and supplies. See " <i>Proposal 1: Approval of Plan of Dissolution Sale of Remaining Assets.</i> "
Contingency Reserve (See page 43)	Under the DGCL, we are required, in connection with our dissolution, to satisfy or make reasonable provision for the satisfaction of all claims and liabilities. Following the Effective Date, we will pay all expenses and other known liabilities and establish a contingency reserve, consisting of cash or other assets, that our board of directors believes will be adequate for the satisfaction of all current, contingent or conditional claims and liabilities. We also may seek to acquire insurance coverage and take other steps our board of directors determines are reasonably calculated to provide for the satisfaction of the reasonably estimated amount of such liabilities. We are currently unable to provide a precise estimate of the amount of the contingency reserve or the cost of insurance or other steps we may undertake to make provision for the satisfaction of liabilities and claims, but any such amount will be deducted before the determination of amounts available for distribution to stockholders. From time to time, we may distribute to our stockholders on a pro rata basis any portions of the contingency reserve that our board of directors deems no longer to be required. See " <i>Proposal 1: Approval of Plan of Dissolution Contingency Reserve.</i> "
Potential Liability of Stockholders (See page 44)	Under the DGCL, if the amount of the contingency reserve and other measures calculated to provide for the satisfaction of liabilities and claims are insufficient to satisfy the aggregate amount ultimately found payable in respect of our liabilities and claims against us, each stockholder could be held liable for amounts due to creditors up to the amounts distributed to such stockholder under the Plan of Dissolution. See " <i>Proposal 1: Approval of Plan of Dissolution Potential Liability of Stockholders</i> ."
Reporting Requirements (See page 44)	Whether or not the Plan of Dissolution is approved, we have an obligation to continue to comply with the applicable reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, even though compliance with such reporting requirements may be economically burdensome and of minimal value to our stockholders. If the Plan of Dissolution is approved by our stockholders, in order to curtail expenses, we intend, on or about the Effective Date, to seek relief from the Securities and Exchange Commission, or SEC, to suspend our reporting obligations under the Exchange Act, and ultimately to terminate the registration of our common stock. We anticipate that, if granted such relief, we would continue to file current reports on Form 8-K to disclose material events

relating to our dissolution and liquidation along with any other reports that the SEC might require. However, the SEC may not grant us the requested relief. See "*Proposal 1: Approval of Plan of Dissolution Reporting Requirements.*"

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Closing of Transfer Books (See page 45)	Our board of directors may direct that our stock transfer books be closed and recording of transfers of common stock discontinued as of the earliest of: the close of business on the record date fixed by our board of directors for the first or any subsequent installment of any liquidating distribution; the close of business on the date on which our remaining assets are transferred to a liquidating trust; or
	the date on which we file our certificate of dissolution under the DGCL.
	We expect that our board of directors will close our stock transfer books on or around the Effective Date. The Effective Date will be determined following the receipt of a revenue clearance certificate from the Department of Finance and will be announced as soon as reasonably practicable after that time. Thereafter, certificates representing shares of our common stock will not be assignable or transferable on our books except by will, intestate succession or operation of law, and we will not issue any new stock certificates, other than replacement certificates. See " <i>Proposal 1:</i> <i>Approval of Plan of Dissolution Closing of Transfer Books.</i> "
Cessation of Trading of Common Stock (See page 45)	We anticipate that we will request that our common stock be delisted from the NASDAQ Global Market at the close of business on the Effective Date and that trading will be suspended on the Effective Date or as soon thereafter as is reasonably practicable. As noted above, we also currently expect to close our stock transfer books on or around the Effective Date and to discontinue recording transfers and issuing stock certificates (other than replacement certificates) at that time. Accordingly, it is expected that trading in our shares of common stock will cease after the Effective Date. See " <i>Proposal 1: Approval of Plan of Dissolution Cessation of Trading of Common Stock</i> ."
Absence of Dissenters' Rights (See page 45)	Under the DGCL, holders of shares of our common stock are not entitled to assert dissenters' rights with respect to the Plan of Dissolution. See "Proposal 1: Approval of Plan of Dissolution Absence of Dissenters' Rights."
Regulatory Approvals (See page 45)	We are not aware of any U.S. federal or state regulatory requirements or governmental approvals or actions that may be required to consummate the Plan of Dissolution, except for compliance with applicable SEC regulations in connection with this proxy statement and compliance with the DGCL. Additionally, our dissolution requires that we obtain a revenue clearance certificate from the Department of Finance certifying that we have paid or provided for all taxes and penalties, if any, of XTENT. See " <i>Proposal 1: Approval of Plan of Dissolution Regulatory Approvals.</i> "
Interests of Management in the Dissolution of the Company (See page 46)	Our directors and current executive officers have vested and exercisable options to purchase an aggregate of 17,378,964 shares of our common stock, 134,000 of which have exercise prices below \$1.01per share, which was the closing sales price of our common stock on the NASDAQ Global Market on April 30, 2009. Pursuant to the terms of the plans under which the options were granted we are required to give notice to option holders prior to a proposed liquidation or dissolution of XTENT and any options that have not been exercised prior to the Effective Date will automatically terminate on the Effective Date. See "Security Ownership of Certain

*Beneficial Owners and Management*" for information on the number of shares and options held by our directors and executive officers.

	In connection with the Plan of Dissolution, we will continue to compensate our officers and employees at their existing compensation levels in connection with their services provided, and our employees are entitled to receive retention payments. In addition, in January 2009, upon the recommendation of our compensation committee, our board of directors established a non-equity retention program for certain employees, including our executive officers. The program was established in order to provide an incentive for these personnel to continue their employment with XTENT in order to complete the headcount reduction, pursue strategic alternatives, and in the absence thereof, wind down and dissolve XTENT. Under the retention program, we expect to make retention payments to all five of our current employees, including \$283,950 to Gregory D. Casciaro, our President and Chief Executive Officer and \$131,700 to Philippe Marco, our Vice President of Quality Assurance, Clinical and Regulatory Affairs.
	Following dissolution, we will continue to indemnify our directors, officers, employees, consultants and agents in accordance with our certificate of incorporation, bylaws and contractual arrangements for actions taken in connection with the Plan of Dissolution and the winding up of our business and affairs. As part of our dissolution process, we will purchase insurance policies and coverage for periods subsequent to the Effective Date. See " <i>Proposal 1: Approval of Plan of Dissolution Principal Provisions of the Plan of Dissolution Interests of Management in the Dissolution of the Company</i> ."
Certain Material U.S. Federal Income Tax Consequences (See page 46)	After the approval of the Plan of Dissolution and until our liquidation is completed, we will continue to be subject to U.S. federal income tax on our taxable income, if any, such as interest income, gain from the sale of any remaining assets or income from operations. Upon the sale of any of our assets in connection with our liquidation, we will recognize gain or loss in an amount equal to the difference between the fair market value of the consideration received for each asset sold and our adjusted tax basis in the asset sold. We should not recognize any gain or loss upon the distribution of cash to our stockholders in liquidation of their shares of our common stock. We currently do not anticipate making distributions of property other than cash to stockholders in our liquidation. In the event we were to make a liquidating distribution of property other than cash to our stockholders, we will recognize gain or loss upon the distribution of such property as if we sold the distributed property for its fair market value on the date of the distribution. We currently do not anticipate that our dissolution and liquidation pursuant to the Plan of Dissolution will produce a material corporate tax liability for U.S. federal income tax purposes.

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In general, for U.S. federal income tax purposes, we intend that amounts received by our stockholders pursuant to the Plan of Dissolution will be treated as full payment in exchange for their shares of our common stock. As a result of our dissolution and liquidation, stockholders generally will recognize gain or loss equal to the difference between the sum of the amount of cash and the fair market value (at the time of distribution) of property, if any, distributed to them and their tax basis for their shares of our common stock. In general, a stockholder's gain or loss will be computed on a "per share" basis. If we make more than one liquidating distribution, which is expected, each liquidating distribution will be allocated proportionately to each share of stock owned by a stockholder, and the value of each liquidating distribution will be applied against and reduce a stockholder's tax basis in his or her shares of stock. In general, a stockholder will recognize gain as a result of a liquidating distribution to the extent that the aggregate value of the distribution and prior liquidating distributions received by the stockholder with respect to a share exceeds the stockholder's tax basis for that share. Any loss generally will be recognized by a stockholder only when the stockholder receives our final liquidating distribution to stockholders, and then only if the aggregate value of all liquidating distributions with respect to a share is less than the stockholder's tax basis for that share. Gain or loss recognized by a stockholder generally will be capital gain or loss and will be long term capital gain or loss if the stock has been held for more than one year. The deductibility of capital losses is subject to limitations. Stockholders are urged to consult their own tax advisors as to the specific tax consequences to them of our dissolution and liquidation pursuant to the Plan of Dissolution. See "Proposal 1: Approval of Plan of Dissolution Certain Material U.S. Federal Income Tax Consequences." The approval of the Plan of Dissolution requires the affirmative vote of a **Required Vote** majority of the outstanding shares of our common stock. Abstentions and (See page 49) broker non-votes will have the same effect as votes against the proposal to approve the Plan of Dissolution. Members of our board of directors who beneficially owned an aggregate of approximately 51% of the outstanding shares of common stock as of April 30, 2009 have indicated that they will vote in favor of the Plan of Dissolution. See "Proposal 1: Approval of Plan of Dissolution Required Vote." Recommendation Our board of directors has determined that the voluntary dissolution and liquidation of XTENT pursuant to the Plan of Dissolution is advisable and our Board of is in our best interests and the best interests of our stockholders. Our Directors board of directors has approved the Plan of Dissolution and (See page 49) unanimously recommends that stockholders vote "FOR" Proposal 1. See "Proposal 1: Approval of Plan of Dissolution Recommendation of our

#### **PROPOSAL 2: APPROVAL OF ADJOURNMENT OF SPECIAL MEETING** TO SOLICIT ADDITIONAL PROXIES

Board of Directors.'

**Required Vote** The approval of any adjournment of the Special Meeting requires that the

(See page 52)	votes cast in favor of the proposal exceed the votes cast against the proposal at the Special Meeting. See " <i>Proposal 2: Approval of</i> <i>Adjournment of Special Meeting to Solicit Additional Proxies General.</i> "					
Recommendation of	<b>Our board of directors unanimously recommends that stockholders</b> <b>vote "FOR" Proposal 2.</b> See " <i>Proposal 2: Approval of Adjournment of</i>					
our Board of	Special Meeting to Solicit Additional Proxies Recommendation of our					
Directors	Board of Directors."					
(See page 52)						
	24					

#### **RISK FACTORS**

You should carefully consider the risks described below, together with all the other information included in this proxy statement and the documents delivered with and incorporated by reference into this proxy statement, before making a decision about voting on the proposals submitted for your consideration. This Proxy Statement contains forward-looking statements within the meaning of the federal securities laws. These statements include, but are not limited to, those concerning the following: regarding future events, our future financial performance, business strategy, product introductions and plans and objectives of management for future operations, regulatory approvals, and clinical timelines. Forward-looking statements are subject to risks and uncertainties that could cause actual results and events to differ materially. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Proxy Statement.

#### **Risks Related to the Plan of Dissolution**

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

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

If any of the estimates regarding the Plan of Dissolution, including the net proceeds from the sale of our tooling, manufacturing and test equipment, furniture and supplies, and the expense of satisfying outstanding obligations, liabilities and claims during the liquidation process are inaccurate, the amount we distribute to our stockholders may be substantially less than the amount we currently estimate. Given the current macroeconomic conditions, for purposes of our estimates in this proxy statement we have assigned no value to our drug eluting stent systems and related intellectual property. If claims are asserted against us, including any claims related to payments to suppliers or other vendors or claims from patients in our clinical trials, we will have to defend or resolve such claims before making distributions to our stockholders, which will reduce amounts otherwise available for distribution to our stockholders;

We have made estimates regarding the expense of personnel required and other operating expenses (including legal, accounting and other professional fees) necessary to dissolve and liquidate XTENT. Our actual expenses could vary significantly and depend on the timing and manner of the sale of our non-cash assets. If the timing differs from our plans, we may incur additional expenses above our current estimates, which could substantially reduce funds available for distribution to our stockholders; and

We have assumed that all material contract rights can be effectively transferred to third parties. If we are unable to obtain any required consents with the counterparties to those contracts, our ability to transfer such rights may be impaired.

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

Whether or not the Plan of Dissolution is approved, we have an obligation to continue to comply with the applicable reporting requirements of the Exchange Act, even though compliance with such reporting requirements may be economically burdensome and of minimal value to our stockholders. If

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the Plan of Dissolution is approved by our stockholders, in order to curtail expenses, we intend, on or about the Effective Date, to seek relief from the SEC to suspend our reporting obligations under the Exchange Act, and ultimately to terminate the registration of our common stock. We anticipate that, if granted such relief, we would continue to file current reports on Form 8-K to disclose material events relating to our dissolution and liquidation along with any other reports that the SEC might require. To the extent that we are unable to suspend our obligation to file periodic reports with the SEC, we will be obligated to continue complying with the applicable reporting requirements of the Exchange Act and, as a result, will be required to continue to incur the expenses associated with these reporting requirements, which will reduce the cash available for distribution to our stockholders. These expenses include, among others, those costs relating to:

the preparation, review, filing and dissemination of SEC filings;

maintenance of effective internal controls over financial reporting; and

audits and reviews conducted by our independent registered public accountants.

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

After the Effective Date, our corporate existence will continue, but we will not be able to carry on any business except for the purpose of winding up the business and affairs of XTENT. Following the Effective Date, we will pay or make reasonable provision to pay all claims and obligations, including all contingent, conditional or unmatured contractual or statutory claims, known to us. We also may obtain and maintain insurance coverage or establish and set aside a reasonable amount of cash or other assets as a contingency reserve to satisfy claims against and obligations of XTENT. In the event that the amount of the contingency reserve, insurance and other measures calculated to provide for the satisfaction of liabilities and claims are insufficient to satisfy the aggregate amount ultimately found payable in respect of our liabilities and claims against us, each stockholder could be held liable for amounts due to creditors up to the amounts distributed to such stockholder under the Plan of Dissolution. In such event, a stockholder could be required to return all amounts received as distributions pursuant to the Plan of Dissolution and ultimately could receive nothing under the Plan of Dissolution. Moreover, for U.S. federal income tax purposes, payments made by a stockholder in satisfaction of our liabilities not covered by the cash or other assets in our contingency reserve or otherwise satisfied through insurance or other reasonable means generally would produce a capital loss for such stockholder in the year the liabilities are paid. The deductibility of any such capital loss generally would be subject to limitations under the Internal Revenue Code of 1986, as amended, or the Code. See "*Proposal 1: Approval of Plan of Dissolution Certain Material U.S. Federal Income Tax Consequences.*"

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

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

if a creditor or other third party seeks an injunction against the making of distributions to our stockholders on the ground that the amounts to be distributed are needed to provide for the satisfaction of our liabilities or other obligations;

if we become a party to lawsuits or other claims asserted by or against us, including any claims or litigation arising in connection with our decision to liquidate and dissolve, payments to suppliers or other vendors or claims from patients in our clinical trials;

if we are unable to sell our remaining non-cash assets or if such sales take longer than expected;

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if we are unable to resolve claims with creditors or other third parties, or if such resolutions take longer than expected; or

if the issuance of the revenue clearance certificate required to file our certificate of dissolution with the Secretary of State is delayed.

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

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

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

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

As a result of our dissolution and liquidation, for U.S. federal income tax purposes, our stockholders generally will recognize gain or loss equal to the difference between (i) the sum of the amount of cash and the fair market value (at the time of distribution) of property, if any, distributed to them, and (ii) their tax basis for their shares of our common stock. Liquidating distributions pursuant to the Plan of Dissolution may occur at various times and in more than one tax year. Any loss generally will be recognized by a stockholder only when the stockholder receives our final liquidating distribution to stockholders, and then only if the aggregate value of all liquidating distributions with respect to a share is less than the stockholder's tax basis for that share. Stockholders are urged to consult their own tax advisors as to the specific tax consequences to them of our dissolution and liquidation pursuant to the Plan of Dissolution. See "*Proposal 1: Approval of Plan of Dissolution Certain Material U.S. Federal Income Tax Consequences*."

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

Our board of directors may direct that our stock transfer books be closed and recording of transfers of common stock discontinued as of the earliest of (x) the close of business on the record date fixed by our board of directors for the first or any subsequent installment of any liquidating distribution, (y) the close of business on the date on which our remaining assets are transferred to a liquidating trust, or (z) the date on or as reasonably practicable after the date on which we file our certificate of dissolution under the DGCL. We expect that our board of directors will close our stock transfer books on or around the Effective Date. The Effective Date will be determined following the receipt of a revenue clearance certificate from the Department of Finance and will be announced as



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soon as reasonably practicable after that time. Thereafter, certificates representing shares of our common stock will not be assignable or transferable on our books except by will, intestate succession or operation of law, and we will not issue any new stock certificates, other than replacement certificates. In addition, we anticipate that we will request that our common stock be delisted from the NASDAQ Global Market and that trading will be suspended on the Effective Date or as soon thereafter as is practicable.

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

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

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

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

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

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

If our stockholders do not approve the Plan of Dissolution, our board of directors will explore what, if any, alternatives are available for the future of XTENT, particularly in light of the fact that we have terminated substantially all of our employees, would need significant additional capital to support our U.S. pivotal clinical trial and efforts to commercialize our products in Europe, commenced the process of winding up our business and will continue to incur net losses for the foreseeable future. There is currently no active business left to operate and rehiring employees may not be possible, or would take several months at a cost that we are unable to estimate.



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

#### If our stockholders do not approve the Plan of Dissolution, our resources may diminish completely.

If our stockholders do not approve the Plan of Dissolution, our board of directors will explore what, if any, alternatives are available for the future of XTENT, particularly in light of the fact that we have terminated substantially all of our employees, would need significant additional capital to support our U.S. pivotal clinical trial and efforts to commercialize our product in Europe, and commenced the process of winding up our business and will continue to incur net losses for the foreseeable future. We took several of these steps in the interest of preserving cash available for distribution to stockholders and in recognition of the expectation that the announcement of approval of the Plan of Dissolution would adversely affect our ability to obtain approval from the FDA for our IDE, proceed with our U.S. pivotal clinical trial and commercialize our product in Europe. There is currently no active business left to operate and rehiring employees may not be possible, or would take several months at a cost we are unable to estimate.

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

#### If our stockholders do not approve the Plan of Dissolution, our stock price may be adversely affected.

On May 14, 2009, the trading day immediately prior to our announcement that our board of directors had approved the Plan of Dissolution, the closing sales price of our common stock on the NASDAQ Global Market was \$1.00. From May 15, 2009 to June 1, 2009, the sales price of our common stock on the NASDAQ Global Market has ranged from a high of \$1.04 and a low of \$0.21. If our stockholders do not approve the Plan of Dissolution, our stock price may be adversely affected due to the market's doubt as to our ability to restart and operate successfully our drug eluting stent business or to pursue successfully other strategic alternatives, and we may not be able to retain our listing on the NASDAQ Global Market.

## Continuing to pursue the commercialization of our Custom NX DES Systems would require significant changes to our current operations, which may not be possible to implement in a timely manner, if at all.

If our stockholders do not approve the Plan of Dissolution and our board of directors determines that we should pursue our historical business model of seeking to commercialize our Custom NX DES Systems for the treatment of coronary artery disease, or CAD, and peripheral artery disease, or PAD, we will need to significantly change our current operations. We would need significant additional



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capital to start our U.S. pivotal clinical trial and commercialize our product in Europe. Pursuing the commercialization of our Custom NX DES Systems would require us to:

attract and retain additional personnel, including a senior management team and other key employees;

obtain IDE approval from the FDA and start our U.S. pivotal clinical trial;

begin validation activities for commercialization of our products in Europe; and

resume our other clinical efforts and clinical support functions.

Implementing the changes necessary to pursue the commercialization of our Custom NX DES Systems will require time and resources, and the parties with whom we must do business may be reluctant to work with us given our announced intention to wind up our trials, business and affairs. We may not be able to implement these changes in a timely manner, if at all, which would have a material and adverse effect on our ability to pursue our historical business model.

In addition to the risks described above, you should carefully consider the risks described in our Annual Report on Form 10-K for the year ended December 31, 2008 which was filed with the SEC on March 24, 2009, and a copy of which is being delivered with this proxy statement as *Appendix B* and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 which was filed on May 15, 2009, and a copy of which is being delivered with this proxy statement as *Appendix B* and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 which was filed on May 15, 2009, and a copy of which is being delivered with this proxy statement as *Appendix D*.

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#### **PROPOSAL 1: APPROVAL OF PLAN OF DISSOLUTION**

#### General

At the Special Meeting, our stockholders will be asked to approve the voluntary dissolution and liquidation of XTENT pursuant to the Plan of Dissolution. Our board of directors approved the Plan of Dissolution, subject to stockholder approval, on May 11, 2009. A copy of the Plan of Dissolution is attached as *Appendix A* to this proxy statement and incorporated herein by reference. The material features of the Plan of Dissolution are summarized below, including a summary of the Principal Provisions of the Plan of Dissolution beginning on page 37. We urge stockholders to read carefully the Plan of Dissolution in its entirety.

#### Background to the Proposed Dissolution and Liquidation

In September 2008, the Company initiated a search for additional financing and engaged Piper Jaffray & Co., or Piper Jaffray, as our placement agent and financial advisor. On our behalf, Piper Jaffray contacted approximately 100 venture capitalists, hedge funds, potential corporate partners and private equity investors. In addition, senior management and members of the Board of Directors actively contacted investors, industry participants, and other strategic entities in an effort to secure funding or a strategic partnership. Many of the investors contacted by Piper Jaffray, our management, and our board of directors did not respond or declined to receive additional information. During the fourth quarter of 2008, meetings were held with over 20 potential investors some of whom conducted extensive due diligence. At the end of the process, none of the potential investors submitted a term sheet or definitive documents for a financing. Concurrently, we explored the potential for debt financing arrangements with a number of lenders without success. The difficulty of raising capital due to the credit crisis and the amount of capital needed to fund the ongoing operations of XTENT were significant factors in our inability to raise additional funds. Our board of directors similarly determined in consultation with Piper Jaffray, that a follow-on public offering would be highly dilutive, expensive and unlikely to raise the requisite capital and was therefore not feasible.

Recognizing the ongoing credit crisis and a deteriorating economy would likely continue to have a substantial effect on our fundraising efforts and due to the lack of investor interest in completing a financing, on October 28, 2008 our board of directors created a strategic alternatives committee, or the Strategic Alternatives Committee, comprised of independent directors. The members of the Strategic Alternatives Committee were directors Henry A. Plain, Jr., Arthur T. Taylor, Allan R. Will and Michael A. Carusi. Director Edward W. Unkart was added to the Strategic Alternatives Committee on December 9, 2008. The other independent board members were invited, but not required, to participate in the Strategic Alternatives Committee meetings. The Strategic Alternatives Committee was formed to assist management in evaluating strategic alternatives to the equity and debt financings previously attempted. The Strategic Alternatives Committee adopted a charter and met five times to consider strategic alternatives which included, without limitation, additional types of equity and debt financings, licensing arrangements, corporate partnerships, sale of distribution rights, forward mergers, reverse mergers, a sale of substantially all assets, a divestiture of some assets, and a going private transaction. The Strategic Alternative Committee also considered redirecting XTENT's resources to focus on the development of a peripheral stent system rather than on the Custom NX DES Systems, which were designed for coronary applications. The Strategic Alternatives Committee also reviewed various operating models. In this context, the Strategic Alternatives Committee discussed whether changes in the management structure would make a meaningful difference in XTENT's ability to continue as a stand-alone entity. The Strategic Alternatives Committee authorized management to hire a former senior investment banker as a strategic advisor and authorized management to solicit interest from investment bankers for the purpose of retaining a financial advisor that could assist our board of directors in a review and evaluation of its strategic alternatives.

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On January 6, 2009, the Strategic Alternatives Committee discussed various operating models, the engagement of financial advisors to assist XTENT in its search for strategic alternatives and a potential reduction in headcount. On January 21, 2009, the Compensation Committee of our board of directors met to discuss, among other things, a potential reduction in headcount. Later that same day, the board of directors met and authorized management to engage Piper Jaffray as its financial advisor to assist management and the board of directors in evaluating strategic alternatives. The board of directors also concluded that based on a review of the operating models and the information available to it at the time, XTENT would not be able to continue as a stand-alone entity without raising capital or engaging in a strategic partnership. The board of directors approved an initiative to reduce XTENT's headcount by eliminating 115 positions in order to preserve cash. This reduction represented approximately 94% of XTENT's total workforce, and the reduction was completed with respect to all but five impacted employees in March 2009. The timing of the completion of the headcount reduction permitted us to comments from the FDA regarding our application for CE Mark and to comments from the FDA regarding our application for IDE approval.

On January 23, 2009 we publicly announced our engagement of Piper Jaffray to help us explore potential strategic alternatives, including, without limitation, a merger, a sale of substantially all our assets, a financing, or a sale of a portion of our assets, such as our peripheral stent technology, our drug eluting balloon technology or our bioabsorbable stent technology.

On January 29, 2009, Piper Jaffray began contacting potential strategic buyers for XTENT or its assets. Piper Jaffray contacted 75 parties in connection with the review of strategic alternatives. Concurrently, our management and our board of directors directly contacted several potential strategic buyers in an effort to secure investment in, or the acquisition of, XTENT. Twenty-one parties signed nondisclosure agreements and entered into due diligence. Eleven parties passed on the opportunity to engage in a transaction with XTENT and by March 6, 2009, nine initial proposals had been received. Piper Jaffray reviewed the nine initial proposals with our board of directors on March 10, 2009. Following this meeting, our board of directors instructed Piper Jaffray to negotiate for terms and conditions that were more favorable to the XTENT stockholders. As a result, Piper Jaffray communicated with the parties, and on March 13, 2009 presented the revised proposals, which had been received from most of the parties, and one additional proposal to our board of directors. XTENT did not receive any proposals from special purpose acquisition companies, or SPACs, offering to use their cash to fund the ongoing operations of XTENT.

Five of the ten proposals involved a reverse merger of a third party into XTENT. The only publicly traded company that proposed such a transaction had a market capitalization at the time of less than \$10 million. All of these proposals involved the use of XTENT's cash to fund ongoing operations in the combined company and two of them were submitted by parties that did not have a stent or closely related business. Three of the five reverse merger candidates also explicitly stated that they had no interest in XTENT's non-cash assets or the continuation of its business operations. Our board of directors decided not to pursue two of the five reverse merger proposals further because one of the proposals did not offer any premium over the value of our cash and our board determined that the other proposal did not offer a significant enough value proposition for our stockholders. In addition, one of the proposals involved a significant increase in risk for our stockholders due to the unrelated nature of its business. Management and multiple directors attended presentations made by the other three parties to explore potential synergies and evaluate the value propositions for XTENT's stockholders. Management also obtained additional information from Piper Jaffray related to the proposals submitted by these parties. Ultimately, our board of directors concluded that the premiums being offered by these parties, coupled with their value propositions and the increased risk of combining XTENT with any of the five reverse merger candidates, did not outweigh the value our stockholders would likely realize in a liquidation of XTENT.



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Three of the ten proposals involved either the acquisition of XTENT's assets in exchange for the other party's stock or a merger of XTENT into the other party resulting in XTENT's stockholders receiving shares of the other party's stock. Two of these three parties were publicly traded companies that did not have stent businesses and that had market capitalizations at the time below \$50 million. Our board of directors decided not to pursue transactions with two of the three parties because one of the proposals required a substantial further investment and the other proposal was from a private company that was offering illiquid private company stock and was unable to provide our stockholders with cash consideration. Management and several of our directors attended a presentation made by the remaining party to explore potential synergies and evaluate the value proposition for XTENT stockholders. Our board of directors concluded that the premium offered, coupled with the value proposition and increased risk of combining XTENT with this party, did not outweigh the value our stockholders would likely realize in a liquidation of XTENT. In addition, for both of the public companies submitting proposals, our board of directors considered the fact that our stockholders could make their own decision to invest if they received their pro rata share of our cash in a liquidating distribution.

The remaining two proposals were submitted by parties that were intending to use their cash to acquire XTENT or its assets. Company A was a non-U.S. company that was intending to acquire the entire company and continue to run its business from the U.S. Following submission of its proposal, Company A conducted due diligence and we received feedback indicating that Company A decided not to pursue a transaction because: 1) the cost of manufacturing our product was greater than they expected and 2) the additional investment required to conduct our U.S. pivotal clinical trial and increase our manufacturing capacity in order to support that trial or to commercialize our Custom NX DES Systems in the European Union was too substantial. Company B was a U.S. company and we believe that it was unable to raise the necessary funds to acquire our assets and never submitted a firm proposal or asset purchase agreement following delivery of its initial proposal. After giving each of these two parties additional time to reconsider their offers, our board of directors concluded that these two parties were not moving forward with actionable transactions. Our board of directors then attempted, without success, to reconnect with certain major medical device companies to solicit interest in an asset acquisition, business combination, or strategic corporate partnership.

While our board was considering the proposals discussed above, we received CE Mark on March 16, 2009 authorizing us to market our Custom NX DES Systems in the European Union and certain other countries that recognize CE Mark. Upon learning that our CE Mark was imminent, Piper Jaffray contacted certain major medical device companies again to determine if they would reconsider the prospect of a transaction with XTENT based on the receipt of the CE Mark. None of these companies expressed interest.

Our board of directors and the Strategic Alternatives Committee met 18 times to discuss the status of efforts to explore strategic alternatives, to consider the proposals discussed above or to discuss various scenarios for operating XTENT on a stand-alone basis as an alternative to liquidation. Our board of directors considered the potential for enhancing the value to stockholders by continuing operations with a reduced cash burn or trying to increase our manufacturing capacity in order to support the commercialization of our Custom NX DES Systems. The risks of such continued operations were also considered, including the further use of existing cash, the investments required to launch our products commercially in Europe and to obtain IDE approval and commence our U.S. pivotal clinical trial, the fact that no third party acquirer was placing significant value on our technology, the manufacturing cost of producing our Custom NX DES Systems, and the risk of not being able to obtain necessary financing in the future even if certain milestones were obtained. On May 8, 2009 our board of directors reviewed financial aspects of a liquidation analysis prepared by management reflecting an analysis of assets and potential liabilities. Our board of directors weighed liquidating XTENT against the potential for an acquisition of XTENT at a valuation materially in excess of the estimated liquidation value reflected in management's liquidation analysis, or the potential for a

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strategic transaction that would provide significant value to the stockholders in excess of the liquidation amount. Based on the extensive efforts already undertaken to obtain financing or a strategic alternative, our board of directors concluded that neither of such transactions was likely in the near term. Our board of directors, in consultation with our financial advisors, also considered the macroeconomic conditions, which had not improved sufficiently to enable raising capital and the state of the medical device industry generally. Our board of directors also took note of the lack of interest in a business combination or other strategic transaction by financial and strategic acquirers, despite solicitation efforts by Piper Jaffray and in numerous cases directly by management and the board of directors.

On May 11, 2009 our board of directors reviewed the liquidation analysis again and concluded that it appeared unlikely that a business combination transaction at a valuation materially in excess of the estimated liquidation value could be achieved in the near term. This conclusion was based on the lack of success, despite extensive efforts to identify additional funding, a business combination transaction or any other strategic transactions that would provide value to our stockholders or reduce the cost of ongoing operations. In reaching this conclusion, our board of directors did not believe it was useful or cost effective to request an opinion or appraisal from our financial advisor with respect to the dissolution and liquidation of XTENT. Our board of directors concluded that an auction of XTENT's assets followed by a statutory dissolution and liquidation was the option that was in the best interests of XTENT and our stockholders and adopted the Plan of Dissolution and recommended approval of the Plan to our stockholders.

On May 15, 2009, we issued a press release announcing that our board of directors had approved the Plan of Dissolution.

#### **Reasons for Dissolution and Liquidation**

In arriving at its determination that the Plan of Dissolution is advisable and in our best interests and the best interests of our stockholders and is the preferred strategic option for XTENT, our board of directors carefully considered the terms of the Plan of Dissolution and the dissolution process under Delaware law, as well as other available strategic alternatives. As part of our evaluation process, our board of directors considered the risks and timing of each alternative available to XTENT, as well as management's financial projections, and consulted with management and our legal and financial advisors. In approving the Plan of Dissolution, our board of directors considered several of the factors set out above as well as the following factors:

the significant operational costs associated with our clinical trials and ongoing research and development efforts, which we had reduced to the extent management believed reasonable to permit continuation of our efforts, and the relatively long period of time before we could assess the success of our efforts;

the fact that we do not have sufficient cash reserves to support commercialization of our products in the European Union;

the fact that we engaged Piper Jaffray & Co. in September 2008 to solicit interest in a financing to support our ongoing operations, including obtaining FDA approval for our IDE, proceeding with our U.S. pivotal clinical trial and commercializing our products in Europe, and were unable to secure additional funding;

the continuing crisis in the financing and capital markets, which had deepened since the middle of 2008 and is continuing, and the effect we and our financial advisors believe such crisis had on the willingness of third parties to provide XTENT with the requisite capital, as well as the significant uncertainties as to our ability to obtain future financing for our research and development efforts and future clinical trials;

the fact that we had vigorously and comprehensively explored strategic alternatives, including undertaking extensive efforts, with the assistance of Piper Jaffray & Co., to identify a merger,

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reverse merger, asset sale, strategic partnership or other business combination transaction that would have a reasonable likelihood of providing value to our stockholders in excess of the amount the stockholders would receive in a liquidation, or that would mitigate the risks of our ongoing operations, which did not result in the identification of any likely transactions;

the fact that, in addition to the efforts made by Piper Jaffray, our management and members of our board repeatedly contacted other companies and potential investors in the industry directly, including several large medical device companies, to initiate conversations regarding potential investments, mergers or strategic partnerships, without success;

the low probability that we would be presented with, or otherwise identify, within a reasonable period of time under current circumstances, any viable opportunities to engage in an attractive alternative business combination or other strategic transaction that would provide value to our stockholders;

the substantial accounting, legal and other expenses associated with being a small publicly-traded company in light of our existing and expected history of losses and path to potential revenue;

the terms and conditions of the Plan of Dissolution, including the provisions that permit our board of directors to revoke the plan if our board of directors determines that, in light of new proposals presented or changes in circumstances, dissolution and liquidation are no longer advisable and in our best interests and the best interests of our stockholders;

the fact that Delaware corporate law requires that the Plan of Dissolution be approved by the affirmative vote of holders of a majority of the shares of our common stock entitled to vote, which ensures that our board of directors will not be taking actions of which a significant portion of our stockholders disapprove;

the fact that approval of the Plan of Dissolution by the requisite vote of our stockholders authorizes our board of directors and officers to implement the Plan of Dissolution without further stockholder approval; and

the fact that stockholders are not entitled to assert dissenter's rights with respect to the Plan of Dissolution under the DGCL.

Our board of directors also considered the following negative factors in arriving at its conclusion that dissolving and liquidating XTENT is in our best interests and the best interests of our stockholders:

the uncertainty of the timing, nature and amount of any liquidating distributions to stockholders;

the risks associated with the sale of our remaining non-cash assets as part of the Plan of Dissolution;

the fact that stockholders would lose the opportunity to capitalize on the potential business opportunities and possible future growth of XTENT had we decided to continue to pursue development and commercialization of our drug eluting stent technology;

the risk that, under Delaware law, our stockholders may be required to return to creditors some or all of the liquidation distributions; and

the fact that, if the Plan of Dissolution is approved by our stockholders, stockholders would generally not be permitted to transfer shares of our common stock after the Effective Date as we would seek to suspend trading as soon thereafter as is practicable.

Our board of directors also considered the other factors described in the section entitled "*Risk Factors*" in this proxy statement and in the Company's 10-K for the year ended December 31, 2008 and its 10-Q for the quarter ended March 31, 2009 in deciding to approve, and unanimously recommending that our stockholders approve, the Plan of Dissolution.

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In view of the variety of factors considered in connection with its evaluation of the Plan of Dissolution, our board of directors did not find it practical, and did not quantify or otherwise attempt, to assign relative weight to the specific factors considered in reaching its conclusions. In addition, our board of directors did not undertake to make any specific determination as to whether any particular factor, or any aspect of any particular factor, was favorable or unfavorable to its ultimate determination, but rather conducted an overall analysis of the factors described above. In considering the factors described above, individual members of our board of directors may have given different weight to different factors.

We cannot offer any assurance that the liquidation value per share of our common stock will equal or exceed the price or prices at which such shares recently have traded or could trade in the future. However, our board of directors believes that it is in our best interests and the best interests of our stockholders to distribute to the stockholders our net assets pursuant to the Plan of Dissolution. If our stockholders do not approve the Plan of Dissolution, our board of directors will explore what, if any, alternatives are available for the future of XTENT, particularly in light of the fact that we have terminated substantially all of our employees, would need significant additional capital to support our U.S. IDE pivotal clinical trial and commercialize our product in Europe, and commenced the process of winding up our business and will continue to incur net losses for the foreseeable future. We took several of these steps in the interest of preserving cash available for distribution to stockholders. There is currently no active business left to operate and rehiring employees may not be possible, or would take several months at a cost we are unable to estimate.

Possible alternatives include selling all of our stock or assets, changing our business focus, continuing our efforts to identify a merger partner or a reverse merger partner, or seeking voluntary dissolution at a later time and with diminished assets. At this time, our board of directors has considered all of these options and has determined that it is in the best interests of our stockholders to dissolve XTENT and return the cash to our stockholders. The board of directors, however, retains the right to consider other alternatives should a more attractive offer arise before or after the Effective Date. If our stockholders do not approve the Plan of Dissolution we expect that our cash resources will continue to diminish. See "*Risk Factors Risks Related to Our Continuing Business Operations if the Plan of Dissolution is Not Approved by Our Stockholders*."

#### **Dissolution Under Delaware law**

Delaware law provides that a corporation may dissolve upon the recommendation of the board of directors of the corporation, followed by the approval of its stockholders. Following such approval, the dissolution is effected by filing certificate of dissolution with the Secretary of State. The corporation is dissolved upon the effective date of its certificate of dissolution.

Section 278 of the DGCL provides that once a corporation is dissolved, it continues its corporate existence but may not carry on any business except that appropriate to wind up and liquidate its business and affairs. The process of winding up includes:

the collection of assets and the disposal of properties that will be applied toward the satisfaction or making reasonable provision for the satisfaction of liabilities and claims or will not otherwise be distributed in kind to the corporation's stockholders;

the satisfaction or making reasonable provision for satisfaction of liabilities and claims;

subject to statutory limitations, the distribution of any remaining assets to the stockholders of the corporation; and

the taking of all other actions necessary to wind up and liquidate the corporation's business and affairs.

#### Principal Provisions of the Plan of Dissolution

This section of the proxy statement describes material aspects of the proposed Plan of Dissolution. While we believe that the description covers the material terms of the Plan of Dissolution, this summary may not contain all of the information that is important to you. You should carefully read this entire proxy statement, including the Plan of Dissolution attached as *Appendix A* to this proxy statement, and the other documents delivered with and incorporated by reference into this proxy statement for a more complete understanding of the Plan of Dissolution.

#### Approval of Plan of Dissolution

The Plan of Dissolution must be approved by the affirmative vote of a majority of the outstanding shares of our common stock. The approval of the Plan of Dissolution by the requisite vote of the holders of our common stock will constitute adoption of the Plan of Dissolution and a grant of full and complete authority for our board of directors and officers, without further stockholder action, to proceed with the dissolution and liquidation of XTENT in accordance with any applicable provision of the DGCL, including the authority to dispose of our drug eluting stent systems and related intellectual property and all of our other remaining non-cash assets.

#### Dissolution and Liquidation

If the Plan of Dissolution is approved by the requisite vote of our stockholders, the steps set forth below will be completed at such times as our board of directors, in its discretion and in accordance with the DGCL, deems necessary, appropriate or advisable in our best interests and the best interests of our stockholders:

the filing of a certificate of dissolution with the Secretary of State after obtaining a revenue clearance certificate from the Department of Finance;

the cessation of all of XTENT's business activities except those relating to winding up and liquidating XTENT's business and affairs, including, but not limited to, prosecuting and defending suits by or against XTENT, collecting XTENT's assets, converting XTENT's assets into cash or cash equivalents, discharging or making provision for discharging XTENT's liabilities, withdrawing from all jurisdictions in which XTENT is qualified to do business and distributing XTENT's remaining property among our stockholders according to their interests;

the collection, sale, exchange or other disposition of all or substantially all of XTENT's non-cash property and assets, in one transaction or in several transactions to more than one buyer;

the payment of or the making of reasonable provision for the payment of all claims and obligations known to XTENT, and the making of such provisions as will be reasonably likely to be sufficient to provide compensation for any claim against XTENT which is the subject of a pending action, suit or proceeding to which XTENT is a party, including, without limitation, the establishment and setting aside of a reasonable amount of cash and/or property to satisfy such claims against and obligations of XTENT;

the pro rata distribution to our stockholders, or the transfer to one or more liquidating trustees, for the benefit of our stockholders under a liquidating trust, of the remaining assets of XTENT after payment or provision for payment of claims against and obligations of XTENT; and

the taking of any and all other actions permitted or required by the DGCL and any other applicable laws and regulations.

#### Authority of Officers and Directors

After the Effective Date, we expect that our board of directors (or some subset thereof) and our officers will continue in their positions for the purpose of winding up the business and affairs of XTENT. Our board of directors may appoint officers, hire employees and retain independent contractors and agents in connection with the winding up process, and is authorized to pay compensation to or otherwise

compensate XTENT's directors, officers, employees, independent contractors and agents above their regular compensation in recognition of the extraordinary efforts they may be required to undertake in connection with the successful implementation of the Plan of Dissolution. Adoption of the Plan of Dissolution by the requisite vote of our stockholders will constitute approval by our stockholders of any such cash or non-cash compensation.

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The approval of the Plan of Dissolution by our stockholders also will authorize, without further stockholder action, our board of directors to do and perform, or to cause our officers to do and perform, any and all acts and to make, execute, deliver or adopt any and all agreements, resolutions, conveyances, certificates and other documents of every kind that our board of directors deems necessary, appropriate or desirable, in the absolute discretion of the board of directors, to implement the Plan of Dissolution and the transactions contemplated thereby, including, without limitation, all filings or acts required by any state or federal law or regulation to wind up its affairs.

#### Liquidating Trust

If deemed necessary, appropriate or desirable by our board of directors, in furtherance of the liquidation and distribution of our assets to stockholders in accordance with our Plan of Dissolution, we may transfer to one or more liquidating trustees, for the benefit of our stockholders under a liquidating trust, any or all of our assets, including any cash intended for distribution to creditors and stockholders not disposed of at the time of dissolution of XTENT. Our board of directors is authorized to appoint one or more individuals, corporations, partnerships or other persons, or any combination thereof, including, without limitation, any one or more of our directors, officers, employees, agents or representatives, to act as the initial trustee. Any trustee so appointed shall succeed to all right, title and interest of XTENT of any kind and character with respect to such transferred assets and, to the extent of the assets so transferred and solely in its capacity as trustee, shall assume all of our claims and obligations, including any unsatisfied claims and unknown or contingent liabilities. Any conveyance of assets to a trustee shall be deemed to be a distribution of property and assets by us to our stockholders, including for U.S. federal and state income tax purposes. Approval of the Plan of Dissolution by or stockholders shall constitute the approval of any trustee so appointed, any liquidating trust agreement, and any transfer of assets by us to the trust.

Whether or not a trust shall have been previously established, if it should not be feasible for us to make the final liquidating distribution to our stockholders of all our assets and properties prior to the third anniversary of the filing of our certificate of dissolution, then, on or before such date, we will be required to establish a trust and transfer any remaining assets and properties to the trustees. Any such distribution shall be only in the form of cash.

#### **Professional Fees and Expenses**

It is specifically contemplated that we will obtain legal and accounting advice and guidance from one or more law and accounting firms in implementing the Plan of Dissolution, and we will pay all fees and expenses reasonably incurred by us in connection with or arising out of the implementation of the Plan of Dissolution, including the prosecution, defense, settlement or other resolution of any claims or suits by or against us, the discharge, filing and disclosure of outstanding obligations, liabilities and claims, filing and resolution of claims with local, county, state and federal tax authorities, and the advancement and reimbursement of any fees and expenses payable by us pursuant to the indemnification we provide in our certificate of incorporation and bylaws, the DGCL or otherwise. In addition, in connection with and for the purpose of implementing and assuring completion of the Plan of Dissolution, we may, in the absolute discretion of the board of directors, pay any brokerage, agency, professional and other fees and expenses of persons rendering services to us in connection with collection, sale, exchange or other disposition of XTENT's property and assets and the implementation of the Plan of Dissolution.

#### Indemnification

We will continue to indemnify our directors, officers, employees, consultants, and agents to the maximum extent permitted in accordance with applicable law, our certificate of incorporation and bylaws, and any contractual arrangements, for actions taken in connection with the Plan of Dissolution

and the winding up of our business and affairs, and we will indemnify any trustees and their agents on similar terms. Our board of directors and trustees are authorized to obtain and maintain insurance for the benefit of such directors, officers, employees, consultants, agents and trustees to the extent permitted by law and as may be necessary or appropriate to cover our obligations under the Plan of Dissolution, including seeking an extension in time and coverage of XTENT's insurance policies currently in effect.

#### Liquidating Distributions

We will, as determined by our board of directors, (i) pay or make reasonable provision to pay all claims and obligations, including all contingent, conditional or unmatured contractual claims known to XTENT, (ii) make such provisions as will be reasonably likely to be sufficient to provide compensation for any claim against XTENT which is the subject of a pending action, suit or proceeding to which XTENT is a party and (iii) make such provision as will be reasonably likely to be sufficient to provide compensation for claims that have not been made known to XTENT or that have not arisen but that, based on facts known to XTENT or successor entity, are likely to arise or to become known to XTENT or successor entity within 10 years after the Effective Date. Any of our assets remaining after the payment or the provision for payment of claims against and obligations of XTENT shall be distributed by us pro rata to our stockholders. Such distribution may occur all at once or in a series of distributions and shall be in cash or assets, in such amounts, and at such time or times, as our board of directors or trustees, in their absolute discretion, may determine.

If any liquidating distribution to a stockholder cannot be made, whether because the stockholder cannot be located, has not surrendered its certificates evidencing our common stock as may be required pursuant to the Plan of Dissolution, or for any other reason, then the distribution to which such stockholder is entitled will be transferred, at such time as the final liquidating distribution is made, to the official of such state or other jurisdiction authorized or permitted by applicable law to receive the proceeds of such distribution. The proceeds of such distribution will thereafter be held solely for the benefit of and for ultimate distribution to such stockholder as the sole equitable owner thereof and will be treated as abandoned property and escheat to the applicable state or other jurisdiction in accordance with applicable law. In no event will the proceeds of any such distribution revert to or become our property.

#### Amendment, Modification or Revocation of Plan of Dissolution

If for any reason our board of directors determines that such action would be in the best interest of XTENT, our board of directors may, in its sole discretion and without requiring further stockholder approval, revoke the Plan of Dissolution and all action contemplated thereunder, to the extent permitted by the DGCL. Our board of directors may not amend or modify the Plan of Dissolution under circumstances that would require additional stockholder approval under the DGCL and federal securities laws without complying with such requirements. The Plan of Dissolution would be void upon the effective date of any such revocation.

#### **Cancellation of Common Stock**

The liquidating distributions to stockholders pursuant to the Plan of Dissolution shall be in complete redemption and cancellation of all of the outstanding shares of our common stock. As a condition to receipt of the liquidating distribution, our board of directors or trustees may require our stockholders to (i) surrender to us their certificates evidencing their shares of common stock or (ii) furnish us with evidence satisfactory to our board of directors or trustees of the loss, theft or destruction of such certificates, together with such surety bond or other security or indemnity as may be required by and satisfactory to our board of directors or trustees. Thereafter, each holder of our

common stock will cease to have any rights with respect to his, her or its shares, except the right to receive distributions pursuant to the Plan of Dissolution.

#### Liquidation Under Code Sections 331 and 336

It is intended that the Plan of Dissolution constitutes a plan of complete liquidation of XTENT within the meaning of Sections 331 and 336 of the Code. The Plan of Dissolution will be deemed to authorize the taking of such action as, in the opinion of counsel for XTENT, may be necessary to conform with the provisions of Sections 331 and 336 of the Code and the Treasury Regulations promulgated thereunder.

#### Filing of Tax Returns, Forms and Other Reports and Statements

The Plan of Dissolution authorizes our officers to make such elections for tax purposes as are deemed appropriate and in the best interest of XTENT. The Plan of Dissolution directs us to file an appropriate statement of corporate dissolution with the Internal Revenue Service, to notify all jurisdictions of any withdrawals related to qualification to do business, file final tax returns and reports as required, and the proper IRS forms related to the reporting of liquidating distributions to stockholders.

#### **Estimated Liquidating Distributions**

#### MANY OF THE FACTORS INFLUENCING THE AMOUNT OF CASH DISTRIBUTED TO OUR STOCKHOLDERS AS A LIQUIDATING DISTRIBUTION CANNOT CURRENTLY BE QUANTIFIED WITH CERTAINTY AND ARE SUBJECT TO CHANGE. ACCORDINGLY, YOU WILL NOT KNOW THE EXACT AMOUNT OF ANY LIQUIDATING DISTRIBUTIONS YOU MAY RECEIVE AS A RESULT OF THE PLAN OF DISSOLUTION WHEN YOU VOTE ON THE PROPOSAL TO APPROVE THE PLAN OF DISSOLUTION. YOU MAY RECEIVE SUBSTANTIALLY LESS THAN THE AMOUNT WE CURRENTLY ESTIMATE.

As of March 31, 2009, we had approximately \$12.7 million in current assets and investments, including approximately \$12.0 million in cash and cash equivalents, and approximately \$0.7 in other current assets. In addition to satisfying the liabilities reflected on our balance sheet, we anticipate using cash, and current assets converted to cash, between March 31, 2009 and the end of the liquidation process for a number of items, including the following:

ongoing operating, overhead and administrative expenses;

severance and termination benefits afforded to terminated employees;

operating lease obligations related to our corporate headquarters;

purchasing insurance policies and coverage for periods subsequent to the Effective Date;

expenses and reserves incurred or made in connection with the termination of our clinical trials;

expenses incurred in connection with the dissolution and our liquidation; and

professional, legal, tax, accounting, and consulting fees.

This projected liquidating distribution analysis assumes that the Plan of Dissolution will be approved by our stockholders. If the Plan of Dissolution is not approved by our stockholders, no liquidating distributions will be made. Pursuant to the Plan of Dissolution, we intend to sell our remaining non-cash assets for the best price available as soon as reasonably practicable after the Effective Date and have included estimated

proceeds of between \$750,000 and \$1,500,000 for these assets. We do not know what, if any, proceeds will be received in connection with such a sale or the sale of the intellectual property related to our drug eluting stent technology. **Due to the uncertainty of** 

the value of our intellectual property, we have not provided any estimate of the proceeds of a sale of our intellectual property in the amount of liquidating distributions. If we were to receive a substantial amount of proceeds from the sale of our intellectual property it could significantly affect the estimates that we have provided. We can provide no assurance, however, that the sale of our intellectual property will result in any such additional proceeds. The amount of any contingency reserve established by our board of directors will be deducted before the determination of amounts available for distribution to stockholders. Based on the foregoing, we currently estimate that the amount ultimately distributed to our stockholders will be between approximately \$0.11 and \$0.40 per share of common stock. The following estimates are not guarantees, do not reflect the total range of possible outcomes and have not been audited or reviewed by our independent registered public accounting firm. You may receive substantially less than the amount we currently estimate, or you may not receive any liquidating distributions if the Plan of Dissolution is not approved by our stockholders.

#### **Estimated Liquidating Distributions to Stockholders**

	w Range of Net Proceeds	High Range of Net Proceeds		
Current Assets and Investments as of April 30, 2009 (a)	\$ 11,604,000	\$	11,604,000	
Non-Cash Assets Other Than Intellectual Property (b)	750,000		1,500,000	
Total Estimated Assets	12,354,000		13,104,000	
Employee Compensation (c)	(1,110,000)		(909,000)	
Professional Fees (legal, tax, accounting, other)	(900,000)		(405,000)	
Insurance (d)	(700,000)		(638,000)	
Other Operating Expenses (e)	(750,000)		(522,000)	
Total Operating Expenses	(3,460,000)		(2,474,000)	
Total Estimated Liabilities and Reserves (f)	(6,192,000)		(1,195,000)	
Estimated Cash to Distribute to Stockholders (b)	2,702,000		9,435,000	
Shares Outstanding (g)	23,539,260		23,539,260	
Estimated Per Share Distribution	\$ 0.11	\$	0.40	

#### Notes:

(a)

Consists of approximately \$10.9 million in cash and cash equivalents and approximately \$0.7 million in other current assets.

(b)

Consists of property, equipment, furniture and supplies. Due to the uncertainty of the value of our intellectual property, we have not included the value of our intellectual property in Non-Cash Assets.

(c)

Includes (i) approximately \$0.3 million and \$0.4 million in high and low estimates, respectively, in compensation to be paid to employees through July 31, 2009, assuming that we maintain current compensation levels, (ii) approximately \$0.6 million and \$0.7 million in the high and low estimates, respectively, in retention and termination benefits afforded to employees upon termination

(d)

Includes director and officer liability, product liability and other insurance premiums.

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(e)

Consists of ongoing operating, overhead and administrative expenses through July 31, 2009, including independent contractor fees, dissolution and liquidation expenses, compliance and travel costs, as well as other customary operating expenses.

#### (f)

Includes (i) approximately \$0.7 million and \$0.9 million in the high and low estimates, respectively, in accounts payable and accrued liabilities, (ii) approximately \$0.5 million and \$5.3 million in the high and low estimates, respectively, reserved in connection with resolution of pending and potential litigation, claims, assessments and related obligations and liabilities.

(g)

Consists of 23,352,904 shares of common stock outstanding as of April 30, 2009 and 313,230 shares of common stock issuable upon exercise of in-the-money stock options, assuming cashless exercise of vested stock options to purchase an aggregate of 186,356 shares of common stock having a weighted-average exercise price of \$0.40 and based upon a closing sales price of our common stock on the NASDAQ Global Market of \$1.01 on April 30, 2009.

Pursuant to the Plan of Dissolution, we intend to liquidate all of our remaining non-cash assets and, after paying or making reasonable provision for the payment of claims against and obligations of XTENT as required by law, distribute any remaining cash to our stockholders. We may defend suits and incur claims, liabilities and expenses (such as salaries and benefits, directors' and officers' insurance, payroll and local taxes, facilities expenses, legal, accounting and consulting fees, rent, clinical trial termination and related expenses and miscellaneous office expenses) following approval of the Plan of Dissolution and during the three years following the Effective Date. Satisfaction of these claims, liabilities and expenses and expenses available for ultimate distribution to stockholders. While we cannot predict the actual amount of our liabilities, other obligations and expenses and claims against us, we believe that available cash and any amounts received from the sale of our remaining non-cash assets will be adequate to provide for the satisfaction of our liabilities, other obligations and expenses to stockholders. The estimated range of approximately \$0.11 and \$0.40 per share is our best current estimate of the aggregate amount of cash that will ultimately be available for distribution to stockholders.

Assuming that the Plan of Dissolution is approved by the requisite vote of our stockholders, we intend to sell, liquidate or otherwise dispose of our remaining non-cash assets, consisting of our drug eluting stent systems and related intellectual property, pre-clinical and clinical trial data and related regulatory filings, Custom NX DES Systems designs and related documentation, tooling, manufacturing and test equipment, furniture and supplies, and pay or make reasonable provision for the payment of claims against and obligations of XTENT. Although we are not able to predict with certainty the precise nature, amount or timing of any distributions, we presently expect to make an initial distribution, as soon as reasonably practicable following the initial sale of our non-cash assets, to holders of record of our common stock as of the close of business on the Effective Date. We currently estimate that the amount ultimately distributed will be between approximately \$0.11 and \$0.40 per share of common stock, assuming we are unable to sell our non-cash assets. We are not able to predict with certainty the precise nature, amount or timing of any distributions, primarily due to our inability to predict the amount of our remaining liabilities or the amount that we will expend during the course of the liquidation, the timing of any sales of our remaining non-cash assets and the net value, if any, of our remaining non-cash assets. To the extent that the amount of our liabilities or the amounts that we expend during the liquidation are greater than we anticipate, our stockholders may receive substantially less than the amount we currently estimate. Our board of directors has not established a firm timetable for any final distributions to our stockholders. Subject to contingencies inherent in winding up our business, our board of directors intends to authorize any distributions as promptly as reasonably practicable in our best interests and the best interests of our stockholders. Our board of directors, in its discretion, will determine the nature, amount and timing of all distributions. See "Risk Factors Risks Related to the Plan of Dissolution."



#### **Conduct of the Company Following Dissolution**

Assuming that the Plan of Dissolution is approved by the requisite vote of our stockholders, we intend to file a certificate of dissolution with the Secretary of State as soon as reasonably practicable after receipt of the required revenue clearance certificate from the Department of Finance. We intend to make a public announcement in advance of the anticipated Effective Date. After the Effective Date, our corporate existence will continue but we may not carry on any business except that appropriate to wind up and liquidate our business and affairs, including, without limitation, collecting and disposing of our assets, satisfying or making reasonable provision for the satisfaction of our liabilities and, subject to legal requirements, distributing our remaining property among our stockholders.

#### Sale of Remaining Assets

The Plan of Dissolution gives our board of directors the authority to dispose of all of our remaining property and assets without further stockholder approval. Stockholder approval of the Plan of Dissolution will constitute approval of any and all such future asset dispositions on such terms and at such prices as our board of directors, without further stockholder approval, may determine to be in our best interests and the best interests of our stockholders. We intend to contract with one or more third parties to assist us in selling our remaining non-cash assets, consisting primarily of our drug eluting stent systems and related intellectual property, on such terms as are approved by our board of directors in our best interests and the best interests of our stockholders. We may conduct sales by any means, including by competitive bidding or private negotiations, to one or more purchasers in one or more transactions over a period of time. We intend to distribute the cash proceeds from any sale of our remaining non-cash assets include our pre-clinical and clinical trial data and related regulatory filings, Custom NX DES Systems designs and related documentation, tooling, manufacturing and test equipment, furniture and supplies.

The prices at which we will be able to sell our remaining non-cash assets will depend largely on factors beyond our control, including, without limitation, the supply and demand for such assets, changes in interest rates, the condition of financial markets, the availability of financing to prospective purchasers of the assets and regulatory approvals. The net price that we receive for our remaining non-cash assets will be reduced to the extent that we contract with brokers or agents to assist in the sale of such assets. We currently intend to contract with one or more third parties to assist us in selling our non-cash assets. In addition, we may not obtain as high a price for a particular asset as we might secure if we were not in liquidation. Upon the sale of any of our assets in connection with our liquidation, we will generally recognize gain or loss in an amount equal to the difference between (i) the fair market value of the consideration received for each asset sold and (ii) our adjusted tax basis in the asset sold. See "*Certain Material U.S. Federal Income Tax Consequences*" below.

#### **Contingency Reserve**

Under the DGCL, we are required, in connection with our dissolution, to satisfy or make reasonable provision for the satisfaction of all claims and liabilities. Following the Effective Date, we will pay all expenses and other known liabilities and establish a contingency reserve, consisting of cash or other assets, that our board of directors believes will be adequate for the satisfaction of all current, contingent or conditional claims and liabilities. We also may seek to acquire insurance coverage and take other steps our board of directors determines are reasonably calculated to provide for the satisfaction of the reasonably estimated amount of such liabilities. We are currently unable to provide a precise estimate of the amount of the contingency reserve or the cost of insurance or other steps we may undertake to make provision for the satisfaction of liabilities and claims, but any such amount will be deducted before the determination of amounts available for distribution to stockholders.

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The actual amount of the contingency reserve may vary from time to time and will be based upon estimates and opinions of our board of directors, derived from consultations with management and outside experts, if our board of directors determines that it is advisable to retain such experts, and a review of our estimated contingent liabilities and our estimated ongoing expenses, including, without limitation: anticipated salary, retention, compensation and benefits payments; estimated investment banking, auction broker, legal and accounting fees; clinical trial termination and related regulatory expenses; rent; payroll and other taxes; miscellaneous office expenses; facilities costs; expenses accrued in our financial statements; and costs related to public company reporting matters. We anticipate that expenses for professional fees and other expenses of liquidation may be significant. Our established contingency reserve may not be sufficient to satisfy all of our obligations, expenses and liabilities, in which case a creditor could bring a claim against one or more of our stockholders for the total amount distributed by us to that stockholder or stockholders pursuant to the Plan of Dissolution. From time to time, we may distribute to our stockholders on a pro rata basis any portions of the contingency reserve that our board of directors deems no longer to be required.

#### Potential Liability of Stockholders

Under the DGCL, if the amount of the contingency reserve and other measures calculated to provide for the satisfaction of liabilities and claims are insufficient to satisfy the aggregate amount ultimately found payable in respect of our liabilities and claims against us, each stockholder could be held liable for amounts due to creditors up to the amounts distributed to such stockholder under the Plan of Dissolution.

The potential for stockholder liability regarding a distribution continues for three years after the Effective Date. Under the DGCL, our dissolution does not remove or impair any remedy available against XTENT, our directors, officers or stockholders for any right or claim existing, or any liability incurred, prior to such dissolution or arising thereafter, unless the action or other proceeding thereon is not commenced within three years after the Effective Date.

If we were held by a court to have failed to make adequate provision for our expenses and liabilities or if the amount ultimately required to be paid in respect of such liabilities exceeded the amount available from the contingency reserve, a creditor could seek an injunction against us to prevent us from making distributions to stockholders under the Plan of Dissolution. Any such action could delay and substantially diminish liquidating distributions to our stockholders.

#### **Reporting Requirements**

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

#### **Closing of Transfer Books**

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

The liquidating distributions to stockholders pursuant to the Plan of Dissolution shall be in complete redemption and cancellation of all of the outstanding shares of our common stock. As a condition to receipt of the liquidating distribution, our board of directors or trustees may require our stockholders to (i) surrender to us their certificates evidencing their shares of common stock or (ii) furnish us with evidence satisfactory to our board of directors or any trustees of the loss, theft or destruction of such certificates, together with such surety bond or other security or indemnity as may be required by and satisfactory to our board of directors or any trustees. Thereafter, each holder of our common stock will cease to have any rights with respect to his, her or its shares, except the right to receive distributions pursuant to the Plan of Dissolution.

If the surrender of stock certificates will be required following the dissolution, we will send you written instructions regarding such surrender. Any distributions otherwise payable by us to stockholders who have not surrendered their stock certificates, if requested to do so, may be held in trust for such stockholders, without interest, pending the surrender of such certificates (subject to escheat pursuant to the laws relating to unclaimed property).

#### **Cessation of Trading of Common Stock**

We anticipate that we will request that our common stock be delisted from the NASDAQ Global Market at the close of business on the Effective Date and that trading will be suspended on the Effective Date or as soon thereafter as is practicable. As noted above, we also currently expect to close our stock transfer books on or around the Effective Date and to discontinue recording transfers and issuing stock certificates (other than replacement certificates) at that time. Accordingly, it is expected that trading in our shares of common stock will cease after the Effective Date.

#### Absence of Dissenters' Rights

Under the DGCL, holders of our shares of common stock are not entitled to assert dissenters' rights with respect to the Plan of Dissolution.

#### **Regulatory Approvals**

We are not aware of any U.S. federal or state regulatory requirements or governmental approvals or actions that may be required to consummate the Plan of Dissolution, except for compliance with applicable SEC regulations in connection with this proxy statement and compliance with the DGCL. Additionally, our dissolution requires that we obtain a revenue clearance certificate from the Department of Finance certifying that we have paid or provided for every license fee, tax increase or penalty of XTENT. In order to obtain the revenue clearance certificate, we must file an application with the Department of Finance. If our stockholders approve the Plan of Dissolution, we intend to file

such application as soon as reasonably practicable after the Special Meeting. We intend to file our certificate of dissolution with the Secretary of State as soon as reasonably practicable after our receipt of the revenue clearance certificate.

#### Interests of Management in the Dissolution of the Company

Our directors, including Gregory D. Casciaro, our President and Chief Executive Officer, Timothy D. Kahlenberg, our Chief Financial Officer and Philippe Marco, our Vice President of Quality, Clinical and Regulatory Affairs have vested and exercisable options to purchase an aggregate of 1,040,332 shares of our common stock, 134,000 of which have exercise prices below \$1.01 per share, which was the closing sales price of our common stock on the NASDAQ Global Market on April 30, 2009. Pursuant to the terms of the plans under which the options were granted, we are required to give notice to option holders prior to a proposed liquidation or dissolution of the company and any options that have not been exercised prior to the Effective Date will automatically terminate on the Effective Date. Because the exercise prices of none of the options held by our directors and executive officers are less than the estimated per share liquidating distribution to be made to stockholders under the Plan of Dissolution, we do not expect that any options held by our directors and exercised prior to their termination. See "Security Ownership of Certain Beneficial Owners and Management" for information on the number of shares and options held by our directors and executive officers.

We do not expect to pay any additional fees to our non-employee directors or committee members after May 11, 2009, the date our board of directors approved the Plan of Dissolution.

We also expect to continue compensating our officers and employees at their existing compensation levels in connection with their services provided during the implementation of the Plan of Dissolution. In addition, in January 2009, upon the recommendation of our compensation committee, our board of directors established a non-equity retention program for certain employees, including our executive officers. The program was established in order to provide an incentive for these personnel to continue their employment with the Company in order to complete the headcount reduction, pursue strategic alternatives, and in the absence thereof, wind down and dissolve XTENT. Under the retention program, we expect to make retention payments to all five of our current employees, including \$283,950 to Gregory D. Casciaro, our President and Chief Executive Officer and \$131,700 to Philippe Marco, our Vice President of Quality Assurance, Clinical and Regulatory Affairs.

Following dissolution, we will continue to indemnify our directors, officers, employees, consultants, and agents to the maximum extent permitted in accordance with applicable law, our certificate of incorporation and bylaws, and any contractual arrangements, for actions taken in connection with the Plan of Dissolution and the winding up of our business and affairs, and we will indemnify any trustees and their agents on similar terms. Our board of directors and any trustees are authorized to obtain and maintain insurance for the benefit of such directors, officers, employees, consultants, agents and any trustees to the extent permitted by law and as may be necessary or appropriate to cover our obligations under the Plan of Dissolution, including seeking an extension in time and coverage of XTENT's insurance policies currently in effect.

#### Certain Material U.S. Federal Income Tax Consequences

The following discussion is a general summary of the material U.S. federal income tax consequences of the dissolution and liquidation of XTENT pursuant to the Plan of Dissolution to XTENT and its stockholders. The discussion does not address all of the U.S. federal income tax considerations that may be relevant to particular stockholders in light of their particular circumstances, or to stockholders that are subject to special treatment under U.S. federal income tax laws, including, without limitation, financial institutions, persons that are partnerships or other pass-through entities,

non-U.S. individuals and entities, or persons who acquired their shares of our common stock through stock options or other compensatory arrangements. This discussion does not address the U.S. federal income tax considerations applicable to holders of options to purchase our common stock. Furthermore, this discussion does not address any U.S. federal estate and gift or alternative minimum tax consequences or any state, local or foreign tax consequences of our dissolution and liquidation pursuant to the Plan of Dissolution.

The following discussion is based on the Code, applicable Treasury Regulations, and administrative and judicial interpretations thereof, each as in effect as of the date hereof, all of which may change, possibly with retroactive effect. The discussion assumes that shares of our common stock are held as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment).

The following discussion has no binding effect on the IRS or the courts. Liquidating distributions pursuant to the Plan of Dissolution may occur at various times and in more than one tax year. We can give no assurance that the U.S. federal income tax treatment described herein will remain unchanged at the time of our liquidating distributions. No ruling has been requested from the IRS with respect to any tax consequences of the Plan of Dissolution, and we will not seek any such ruling or an opinion of counsel with respect to any such tax consequences.

#### THE FOLLOWING DISCUSSION DOES NOT PURPORT TO BE A COMPLETE ANALYSIS OF THE POTENTIAL TAX CONSEQUENCES RELATING TO THE PLAN OF DISSOLUTION AND IS NOT TAX ADVICE. STOCKHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE SPECIFIC TAX CONSEQUENCES TO THEM IN CONNECTION WITH OUR DISSOLUTION AND LIQUIDATION PURSUANT TO THE PLAN OF DISSOLUTION, INCLUDING TAX RETURN REPORTING REQUIREMENTS AND THE EFFECT OF FEDERAL, STATE, LOCAL, FOREIGN AND OTHER TAX LAWS.

#### Material U.S. Federal Income Tax Consequences to the Company

After the approval of the Plan of Dissolution and until our liquidation is completed, we will continue to be subject to U.S. federal income tax on our taxable income, if any, such as interest income, gain from the sale of any remaining assets or income from operations. Upon the sale of any of our assets in connection with our liquidation, we will recognize gain or loss in an amount equal to the difference between (i) the fair market value of the consideration received for each asset sold and (ii) our adjusted tax basis in the asset sold. We should not recognize any gain or loss upon the distribution of cash to our stockholders in liquidation of their shares of our common stock. We currently do not anticipate making distributions of property other than cash to stockholders in our liquidation. In the event we were to make a liquidating distribution of property other than cash to our stockholders, we will recognize gain or loss upon the distribution of such property as if we sold the distributed property for its fair market value on the date of the distribution. We currently do not anticipate that our dissolution and liquidation pursuant to the Plan of Dissolution will produce a material corporate tax liability for U.S. federal income tax purposes.

#### Material U.S. Federal Income Tax Consequences to Stockholders

In general, for U.S. federal income tax purposes, we intend that amounts received by our stockholders pursuant to the Plan of Dissolution will be treated as full payment in exchange for their shares of our common stock. As a result of our dissolution and liquidation, stockholders generally will recognize gain or loss equal to the difference between (i) the sum of the amount of cash and the fair market value (at the time of distribution) of property, if any, distributed to them and (ii) their tax basis for their shares of our common stock. In general, a stockholder's gain or loss will be computed on a "per share" basis. If we make more than one liquidating distribution, which is expected, each liquidating distribution will be allocated proportionately to each share of stock owned by a stockholder,

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and the value of each liquidating distribution will be applied against and reduce a stockholder's tax basis in his or her shares of stock. In general, a stockholder will recognize gain as a result of a liquidating distribution to the extent that the aggregate value of the distribution and prior liquidating distributions received by the stockholder with respect to a share exceeds the stockholder's tax basis for that share. Any loss generally will be recognized by a stockholder only when the stockholder receives our final liquidating distribution to stockholders, and then only if the aggregate value of all liquidating distributions with respect to a share is less than the stockholder's tax basis for that share. Gain or loss recognized by a stockholder generally will be capital gain or loss and will be long term capital gain or loss if the stock has been held for more than one year. The deductibility of capital losses is subject to limitations.

In the unlikely event we make a liquidating distribution of property other than cash to our stockholders, a stockholder's tax basis in such property immediately after the distribution generally will be the fair market value of the property received by the stockholder at the time of distribution. Gain or loss realized upon the stockholder's future sale of that property generally would be measured by the difference between the proceeds received by the stockholder in the sale and the tax basis of the property sold.

In the event that our liabilities are not fully covered by the cash or other assets in our contingency reserve or otherwise satisfied through insurance or other reasonable means (See "*Contingency Reserve*" above), payments made by a stockholder in satisfaction of those liabilities generally would produce a capital loss for such stockholder in the year the liabilities are paid. The deductibility of any such capital loss would generally be subject to limitations under the Code.

#### Reporting of Liquidating Distributions and Back-Up Withholding

After the close of each taxable year, we will provide stockholders and the IRS with a statement of the amount of cash distributed to our stockholders in our liquidation and our best estimate as to the value of any property distributed to them during the relevant taxable year. In the unlikely event we make a liquidating distribution of property other than cash to our stockholders, no assurance can be given that the IRS will not challenge our valuation of the distributed property. Any stockholder owning at least 5% (by vote or value) of our total outstanding stock may be subject to special rules regarding information to be provided with the stockholder's U.S. federal income tax returns. Stockholders should consult their own tax advisors as to the specific tax consequences to them in connection with our dissolution and liquidation pursuant to the Plan of Dissolution, including tax return reporting requirements. Liquidating distributions made to our stockholders pursuant to the Plan of Dissolution may be subject to back-up withholding (currently at a rate of 28%) requirements. Back-up withholding generally will not apply to payments made to exempt recipients, including corporations or financial institutions, or individuals who furnish their correct taxpayer identification number or a certificate of foreign status and other required information. Back-up withholding is not an additional tax. Rather, amounts withheld generally may be used as a credit against a stockholder's U.S. federal income tax liability or the stockholder may claim a refund of any excess amounts withheld by timely and duly filing a claim for refund with the IRS.

#### **Accounting Treatment**

If our stockholders approve the Plan of Dissolution, we will change our basis of accounting from that of an operating developmental stage enterprise, which contemplates realization of assets and satisfaction of liabilities in the normal course of business, to the liquidation basis of accounting. Under the liquidation basis of accounting, assets are stated at their estimated net realizable values and liabilities are stated at their estimated settlement amounts. Recorded liabilities will include the estimated expenses associated with carrying out the Plan of Dissolution. For periodic reporting, a statement of net assets in liquidation will summarize the liquidation value per outstanding share of

common stock. Valuations presented in the statement will represent management's estimates, based on present facts and circumstances, of the net realizable values of assets, estimated satisfaction amounts of liabilities, and expenses associated with carrying out the Plan of Dissolution based upon management assumptions.

The valuation of assets and liabilities will necessarily require many estimates and assumptions, and there will be substantial uncertainties in carrying out the provisions of the Plan of Dissolution. Ultimate values realized for our assets and ultimate amounts paid to satisfy our liabilities are expected to differ from estimates recorded in annual or interim financial statements.

#### **Required Vote**

All holders of our common stock as of the record date are entitled to vote on Proposal 1. The approval of the Plan of Dissolution requires the affirmative vote of a majority of the outstanding shares of our common stock. Abstentions and broker non-votes will have the same effect as votes against Proposal 1. It is intended that shares represented by the enclosed form of proxy will be voted in favor of Proposal 1 unless otherwise specified in such proxy.

Members of our board of directors who beneficially owned an aggregate of approximately 51% of the outstanding shares of common stock as of April 30, 2009 have indicated that they will vote in favor of Proposal 1.

#### **Recommendation of our Board of Directors**

Our board of directors has determined that the voluntary dissolution and liquidation of XTENT pursuant to the Plan of Dissolution is advisable and in our best interests and the best interests of our stockholders. Our board of directors has approved the Plan of Dissolution and unanimously recommends that stockholders vote "FOR" approval of the Plan of Dissolution.

#### SELECTED FINANCIAL DATA

Set forth below is selected financial data for XTENT for the periods indicated. We derived the selected statement of operations data for the years ended December 31, 2008, 2007 and 2006 and balance sheet data as of December 31, 2008 and 2007 from our audited financial statements that are included in our Annual Report on Form 10-K for the year ended December 31, 2008, a copy of which is being delivered with this proxy statement as *Appendix B*. We derived the selected statement of operations data for the years ended December 31, 2005 and 2004 and the balance sheet data as of December 31, 2006, 2005, and 2004 from our audited financial statements which are not being delivered with or incorporated by reference into this proxy statement. We derived the statements of operations data for the cumulative period from June 13, 2002 (Inception) to March 31, 2009 and the three months ended March 31, 2009 and the balance sheet data as of March 31, 2009, a copy of which is being delivered with this proxy statements that are included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009, a copy of which is being delivered with this proxy statement as *Appendix D*. Our historic results are not necessarily indicative of the results that may be expected in the future. You should read this data together with our financial statements and related notes included in our Annual Report on Form 10-Q for the quarter ended March 31, 2009, as well as the sections of each of those reports entitled "*Management's Discussion and Analysis of Financial Condition and Results of Operations.*"

Our board of directors approved the Plan of Dissolution, subject to stockholder approval, on May 11, 2009. The information presented below and delivered with and incorporated by reference into this proxy statement does not include any adjustments necessary to reflect the possible future effects on recoverability of the assets or satisfaction of liabilities that may result from adoption of the Plan of Dissolution or our potential to complete such a plan in an orderly manner.

	,	Three months Ended March 31,	Year Ended December 31,							
	2009	2009	2008	2007	2006(1)	2005	2004			
	(in thousands, except per share data)									
Operating expenses: Research and development	\$ 110,238	\$ 1.651	\$ 31,170	\$ 30.888	\$ 18.023	\$ 12 130	\$ 7118			
General and administrative	37,223	2,763	10,917	11,269	7,258	2,214	1,883			
Impairment of long-lived assets	2,494	2,494	10,717	11,20)	7,230	2,217	1,005			
1 0	,									
Total operating expenses	149,955	9,911	42,087	42,157	26,181	14,353	9,001			
	(140.055)	(0.011)	(42,087)	(40,157)	(2( 191)	(14.252)	(0.001)			
Loss from operations	(149,955)	(9,911)	(42,087)	(42,157)	(26,181)	(14,353)	(9,001)			
Interest and other income, net	6,118	55	966	3,363	1,137	323	110			
	, ,			,	,					
Net loss	(143,837)	(9,856)	(41,121)	(38,794)	(25,044)	(14,030)	(8,891)			
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock	(13,095)				(13,095)					
I I I I I I I I I I I I I I I I I I I					( - ) /					
Net loss attributable to common stockholders	\$ (156,932)	\$ (9,856)	\$ (41,121)	\$ (38,794)	\$ (38,139)	\$ (14,030)	\$ (8,891)			
Net loss per share attributable to common										
stockholders basic and diluted	:	\$ (.42)	\$ (1.78)	\$ (1.87)	\$ (13.96)	\$ (6.84)	\$ (5.00)			
Weighted-average common shares outstanding basic and diluted		23,324	23,116	20,703	2,732	2,052	1,779			

(1)

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

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		As of arch 31,	December 31,					
	101	2009	2008	2007	2006	2005	2004	
				(in thous				
Balance Sheet Data								
Cash and cash equivalents	\$	11,960	\$13,373	\$13,366	\$ 23,105	\$ 6,564	\$ 4,761	
Short-term investments			5,752	44,394				
Working capital		10,867	17,070	54,581	21,066	5,588	4,143	
Total assets		14,178	23,995	62,415	27,121	8,675	6,136	
Reedeemable convertible preferred stock					75,593	35,900	20,406	
Total stockholders' equity (deficit)		12,412	21,508	58,331	(50,780)	(28,372)	(14,925)	
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### PROPOSAL 2: APPROVAL OF ADJOURNMENT OF SPECIAL MEETING TO SOLICIT ADDITIONAL PROXIES

### General

At the Special Meeting, we may ask our stockholders to vote on a proposal to adjourn the Special Meeting to another date, time or place, if deemed necessary in the judgment of the proxy holders, for the purpose of soliciting additional proxies to vote in favor of Proposal 1. Any adjournment of the Special Meeting may be made without notice, other than by the announcement made at the Special Meeting, if the votes cast in favor of the adjournment proposal by the holders of shares of our common stock entitled to vote on the proposal exceed the votes cast against the proposal at the Special Meeting. However, if the adjournment is for more than 120 days from the date set for the original meeting, a new record date for the adjourned meeting shall be fixed and a new notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the adjourned meeting. If we adjourn the Special Meeting to a later date, we will transact the same business and, unless we must fix a new record date, only the stockholders who were eligible to vote at the original meeting will be permitted to vote at the adjourned meeting.

### **Required Vote**

The approval of any adjournment of the Special Meeting requires that the votes cast in favor of the proposal exceed the votes cast against the proposal at the Special Meeting. Abstentions from voting and broker non-votes will have no impact on the vote on Proposal 2.

### **Recommendation of our Board of Directors**

Our board of directors unanimously recommends that stockholders vote "FOR" approval of Proposal 2.

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### SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Except as otherwise noted, the following table sets forth, as of April 30, 2009, information with respect to the beneficial ownership of our common stock by (i) each person, or group of affiliated persons, known by us to be the beneficial owner of more than 5% of our common stock, (ii) each of our current directors, (iii) each of our named executive officers and (iv) all directors and executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC. Beneficial ownership means that a person has or shares voting or investment power of a security, and includes shares underlying options and warrants that are currently exercisable or exercisable within 60 days after the measurement date. This table is based on information supplied by officers, directors and principal stockholders. Except as otherwise indicated, we believe that the beneficial owners of our common stock listed below, based on the information each of them has given to us, have sole investment and voting power with respect to their shares, except where community property laws may apply.

Unless otherwise indicated, we deem shares of common stock subject to options and warrants that are exercisable within 60 days of April 30, 2009 to be outstanding and beneficially owned by the person holding the options and warrants for the purpose of computing percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the ownership percentage of any other person.

Beneficial Owner	Beneficial ( Number of Shares	Ownership Options and Warrants Exercisable Within 60 Days	Percentage of Shares Outstanding Approximate Percent Owned
5% Stockholders	Shares	00 Days	Owned
Morgenthaler Partners VI, L.P(1)	5,085,243		21.0%
Funds affiliated with Advanced Technology Ventures (2)	2,999,393		12.4%
Funds affiliated with Latterell Venture Partners (3)	2,828,190		11.7%
St. Paul Venture Capital VI, L.L.C. (4)	2,615,135		10.8%
Davidson Kempner Partners (5)	1,290,913		5.3%
State of Wisconsin (6)	1,290,432		5.3%
Named Executive Officers and Directors			
Gregory D. Casciaro (7)	566,778	423,790	4.0%
Timothy D. Kahlenberg		194,376	0.8%
Phillipe Marco (8)	71,050	72,661	0.6%
Henry A. Plain, Jr. (9)	459,656	26,667	2.0%
Michael A. Carusi	2,999,393	10,000	12.4%
Michael L. Eagle		10,000	*
Robert E. Flaherty	3,685	30,000	0.1%
Edward W. Unkart	8,333	30,000	0.2%
Allan R. Will	2,775,291	10,000	11.5%
Christopher M. Smith		10,000	*
Arthur T. Taylor		10,000	*
All executive officers and directors as a group			
(11 persons)	17,378,964	827,494	75.3%

(1)

Includes 5,085,243 shares held by Morgenthaler Partners VI, L.P. Voting and investment power are shared by Robert C. Bellas, Jr., Gary J. Morgenthaler, Robert D. Pavey, John D. Lutsi, G. Gary

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Shaffer, Gary R. Little, Peter G. Taft, Theodore A. Laufik and Paul R. Levine, the managing members of Morgenthaler Management Partners VI, L.L.C., the general partner of Morgenthaler Partners VI, L.P., with respect to shares held by Morgenthaler Partners VI, L.P. Each managing member disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein. The address for Morgenthaler Partners VI, L.P. is 2710 Sand Hill Road, Suite 100, Menlo Park, CA 94025.

### (2)

Includes 2,409,589 shares held by Advanced Technology Ventures VII, L.P., 402,776 shares held by Advanced Technology Ventures VII, L.P., 96,694 shares held by Advanced Technology Ventures VII (B), L.P., 46,477 shares held by Advanced Technology Ventures VII (C), L.P., 25,708 shares held by ATV Entrepreneurs VI, L.P., 14,359 shares held by ATV Entrepreneurs VII, L.P., and 3,790 shares held by ATV Alliance 2002, L.P. ATV Associates VII, L.L.C. is the general partner of Advanced Technology Ventures VII, L.P., Advanced Technology Ventures VII (B), L.P., Advanced Technology Ventures VII (C), L.P. and ATV Entrepreneurs VII, L.P., ATV Associates VI, L.P., Advanced Technology Ventures VII (C), L.P. and ATV Entrepreneurs VII, L.P. ATV Capital Management, Inc. is the sole member of ATV Alliance Associates, L.L.C., the general partner of ATV Alliance 2002, L.P. Michael A. Carusi, Steve Baloff, Bob Hower, Jean George and Bill Wiberg, as managing directors of ATV Associates VII, L.P., Advanced Technology Ventures VII (C), L.P., Advanced Technology Ventures VII, L.P., Advanced Technology Ventures VII (C), L.P., and ATV Entrepreneurs VII, L.P., Michael A. Carusi, Steve Baloff and Pieter Schiller, as managing directors of ATV Associates VI, L.L.C., share voting and investment power with respect to shares held by Advanced Technology and investment power with respect to shares held by Advanced Technology Ventures VI, L.P. and ATV Entrepreneurs VI, L.P. Jean George, as the sole manager of ATV Alliance Associates, L.L.C., has voting and investment power with respect to shares held by ATV Alliance 2002, L.P. Each managing director and manager disclaims beneficial ownership of these shares, except to the extent of his

### (3)

Includes 2,020,425 shares held by Latterell Venture Partners II, L.P., 586,574 shares held by Latterell Venture Partners, L.P., 196,458 shares held by Latterell Venture Partners III, L.P., 9,822 shares held by LVP III Associates, L.P., 4,911 shares held by LVP III Partners, L.P., and 10,000 shares held by Latterell Management Company, L.L.C. Latterell Capital Management, L.L.C. is the general partner of Latterell Venture Partners, L.P., Latterell Capital Management II, L.L.C. is the general partner of Latterell Venture Partners, L.P., Latterell Capital Management II, L.L.C. is the general partner of Latterell Venture Partners III, L.P., LVP III Associates, L.P. and LVP III Partners, L.P. Patrick F. Latterell, Stephen M. Salmon and James N. Woody are the members of Latterell Capital Management, L.L.C., Latterell Capital Management III, L.L.C. and Latterell Capital Management III, L.L.C., Latterell Capital Management III, L.L.C. and Latterell Capital Management III, L.L.C., Latterell Capital Management III, L.L.C. and Latterell Capital Management III, L.L.C., Latterell Capital Management III, L.L.C. and Latterell Capital Management III, L.L.C., Latterell Capital Management III, L.L.C. and Latterell Management III, L.L.C. and Latterell Capital Management Company, L.L.C. and Share voting and investment power. Each member disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein. Mr. Latterell's address is c/o Latterell Venture Partners, 1 Embarcadero Center, Suite 4050, San Francisco, CA 94111.

### (4)

SPVC VI, LLC (formerly St. Paul Venture Capital VI, LLC) is jointly managed by Split Rock Partners, LLC. and Vesbridge Partners, L.L.C.; however, voting and investment power has been delegated solely to Split Rock Partners, LLC. Allan R. Will, David Stassen, Michael Gorman and James Simons, as managing directors of Split Rock Partners, LLC, share voting and investment power with respect to the shares held by SPVC VI, LLC. Split Rock Partners, LLC and each of its managing directors disclaim beneficial ownership of these shares, except to the extent of his or their pecuniary interest therein. Mr. Will's address is c/o Split Rock Partners, L.L.C., 1600 El Camino Real, Suite 290, Menlo Park, CA 94025. The address for SPVC VI, LLC is 10400 Viking Drive, Suite 550, Eden Prairie, MN 55344.

(5)

Based on a Form 13G/A filed with the SEC on February 17, 2009.

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Based on a Form 13G filed with the SEC on February 3, 2009.

### (7)

(6)

Includes 3,400 shares held by Mr. Casciaro as custodian for his minor son and minor daughter under the California Uniform Transfer to Minors Act. Also includes 1,700 shares held by Mr. Casciaro's adult daughter as to which Mr. Casciaro disclaims beneficial ownership

### (8)

167 of these shares are subject to our right of repurchase as of April 30, 2009.

### (9)

Henry A. Plain, Jr.'s address is c/o Morgenthaler Ventures, 2710 Sand Hill Road, Suite 100, Menlo Park, CA 94025.

### Market for Our Common Stock

Our common stock trades on the NASDAQ Global Market under the symbol "XTNT." The following table sets forth, for the periods indicated, the high and low closing sales prices for our common stock as quoted on the NASDAQ Global Market for each full quarterly period. The closing sales price of our common stock on the NASDAQ Global Market was \$1.00 on May 14, 2009, the trading day prior to the announcement that our board of directors approved the Plan of Dissolution. The closing sales price of our common stock on the NASDAQ Global Market was \$1.01 on April 30, 2009.

	2009		200	8	2007	
Fiscal Year Ended December 31,	High	Low	High	Low	High	Low
First Quarter	\$1.26	\$0.90	\$10.00	\$4.60	\$16.48	\$11.23
Second Quarter (1)	1.26	0.18	6.52	2.50	13.97	8.74
Third Quarter			3.14	1.05	10.54	7.74
Fourth Quarter			1.31	0.25	10.84	8.50

(1)

For the second quarter of 2009, reflects high and low sales prices through April 30, 2009.

As of April 30, 2009, there were approximately 107 holders of record of our common stock. No cash dividends have ever been paid on our common stock.

### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements, and other information with the SEC. You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street NE, Washington, DC 20549-2521. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website at *http://www.sec.gov* that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. You may also find the materials we file with the SEC on the "Investor Relations" section of our website at *http://www.XTENTinc.com*. Information on our website is not incorporated by reference into, or made a part of, this proxy statement.

### HOUSEHOLDING

Beneficial owners, but not record holders, of our common stock who share a single address may receive only one copy of this proxy statement, unless their broker, bank or other nominee has received contrary instructions from any beneficial owner at that address. This practice, known as "householding," is designed to reduce printing and mailing expenses. If any beneficial owner at such an address wishes to discontinue householding and receive a separate copy of the proxy statement, they should notify their broker, bank or other nominee. Beneficial owners sharing an address to which a single copy of the proxy statement was delivered can also request prompt delivery of a separate copy of

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the proxy statement by contacting us at XTENT, Inc., 125 Constitution Drive, Menlo Park, California 94025-1118, Attention: Secretary, or at (650) 433-4834.

### WHO CAN HELP ANSWER YOUR QUESTIONS

If you have additional questions about the Special Meeting, you should contact:

Ronald C. Austin, Secretary XTENT, Inc. 125 Constitution Drive Menlo Park, California 94025-1118 Telephone: (650) 433-4834

### **OTHER BUSINESS**

We know of no other business to be presented at the Special Meeting, and no other matters properly may be presented for a vote at the Special Meeting. If any other business properly were to come before the Special Meeting, it is intended that the shares represented by proxies would be voted with respect thereto in accordance with the best judgment of the persons named in the accompanying form of proxy.

### **INCORPORATION BY REFERENCE**

The SEC allows us to "incorporate by reference" information into this proxy statement, which means that we can disclose important information to you by referring you to other documents that we have filed separately with the SEC and delivered to you with this proxy statement. This proxy statement incorporates by reference the following documents:

our annual report on Form 10-K for the year ended December 31, 2008, as filed with the SEC on March 24, 2009, a copy of which is attached hereto as *Appendix B*;

our current reports on Form 8-K, as filed on with the SEC on January 27, 2009, February 11, 2009, February 20, 2009, April 6, 2009 and May 15, 2009; and

amendment No. 1 on Form 10-K/A to our annual report on Form 10-K for the year ended December 31, 2008, as filed with the SEC on April 30, 2009, a copy of which is attached hereto as *Appendix C*.

our quarterly report on Form 10-Q for the quarter ended March 31, 2009, as filed with the SEC on May 15, 2009, a copy of which is attached hereto as *Appendix D*.

In addition, all documents we file pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date hereof and prior to the date of the Special Meeting or any adjournment or postponement thereof will be deemed to be incorporated by reference herein and made a part hereof from the date of the filing of such documents.

A copy of our annual report on Form 10-K for the year ended December 31, 2008 is being delivered with this proxy statement as *Appendix B*, a copy of amendment No. 1 on Form 10-K/A to our annual report on Form 10-K for the year ended December 31, 2008 is being delivered with this proxy statement as *Appendix C*, and a copy of our quarterly report on Form 10-K for the quarter ended March 31, 2009 is being delivered with this proxy statement as *Appendix D*. We will provide without charge to each person to whom a copy of this proxy statement is delivered, upon the written or oral request of such person and by first class mail or other equally prompt means within one business day of

receipt of such request, a copy of any and all of the documents incorporated by reference herein and not otherwise delivered to such person (not including the exhibits to such documents, unless such exhibits are specifically incorporated by reference in such documents). Requests for such copies should

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be directed in writing to XTENT, Inc., 125 Constitution Drive, Menlo Park, California 94025-1118, Attention: Secretary, or by calling (650) 433-4834. See "*Where You Can Find More Information*."

Any statement contained in a document incorporated by reference into this proxy statement will be deemed to be modified or superseded for purposes of this proxy statement to the extent that a statement contained in this proxy statement modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this proxy statement.

### BY ORDER OF THE BOARD OF DIRECTORS

Gregory D. Casciaro President, Chief Executive Officer and Director June 8, 2009 Menlo Park, California

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### Appendix A

### PLAN OF COMPLETE LIQUIDATION AND DISSOLUTION OF XTENT, INC.

The following Plan of Complete Liquidation and Dissolution (the "*Plan of Dissolution*"), dated as of May 11, 2009, shall effect the dissolution and complete liquidation of XTENT, Inc., a Delaware corporation (the "*Company*"), in accordance with Section 275 and other applicable provisions of the Delaware General Corporation Law (the "*DGCL*") and Sections 331 and 336 of the Internal Revenue Code of 1986, as amended (the "*Code*").

1. Adoption of Plan. The board of directors of the Company (the "Board of Directors") has adopted resolutions deeming it advisable and in the best interest of the stockholders of the Company to dissolve and liquidate the Company, adopt the Plan of Dissolution, and call a special meeting (the "Meeting") of the holders of the Company's common stock (the "Common Stock") to approve the dissolution and liquidation of the Company (including the sale of all or substantially all of the Company's assets), adopt the Plan of Dissolution and ratify the Company's actions taken to date on the Plan of Dissolution. If stockholders holding a majority of the outstanding shares of Common Stock vote in favor of the proposed dissolution and liquidation of the Company (including sale of all or substantially all of the Company's assets) and the adoption of the Plan of Dissolution at the Meeting, the Plan of Dissolution shall constitute the adopted Plan of Dissolution of the Company as of the date of the Meeting, or such later date on which the stockholders may approve the Plan of Dissolution if the Meeting is adjourned to a later date (the "Meeting Date").

2. Cessation of Business Activities. After the Effective Date (as defined below) and in accordance with Section 278 of the DGCL, the Company shall not engage in any business activities except for the purpose of winding up and liquidating its business and affairs, including, but not limited to, prosecuting and defending suits, whether civil, criminal or administrative, by or against the Company, collecting its assets, converting its assets into cash or cash equivalents, discharging or making provision for discharging its liabilities, withdrawing from all jurisdictions in which it is qualified to do business, distributing its remaining property among its stockholders according to their interests, and doing every other act necessary to wind up and liquidate its business and affairs, but not for the purpose of continuing the business for which the Company was organized.

3. *Certificate of Dissolution.* After the Meeting Date, the officers of the Company shall, at such time as the Board of Directors, in its absolute discretion, deems necessary, appropriate or desirable, obtain any certificates required from the Delaware tax authorities and, upon obtaining such certificates and paying such taxes as may be owing, and securing the necessary stockholder approvals, the Company shall file with the Secretary of State of the State of Delaware a certificate of dissolution (the "*Certificate of Dissolution*") in accordance with the DGCL specifying the date upon which the Certificate of Dissolution will become effective (the "*Effective Date*").

4. *Liquidation Process*. From and after the Effective Date and subject to the provisions hereof, the Company shall complete the following corporate actions:

a. Sale of All or Substantially All of the Non-Cash Assets. The Company shall determine whether and when to collect, sell, exchange or otherwise dispose of all or substantially all of its non-cash property and assets, including but not limited to all tangible assets, intellectual property and other intangible assets, in one or more transactions upon such terms and conditions as the Board of Directors, in its absolute discretion, deems expedient and in our best interests and the best interests of our stockholders, without any further vote or action by the Company's stockholders. The Company's non-cash assets and properties may be sold in one transaction or in

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several transactions to one or more buyers. The Company shall not be required to obtain appraisals, fairness opinions or other third-party opinions as to the value of its properties and assets in connection with the liquidation. In connection with such collection, sale, exchange and other disposition, the Company shall collect or make provision for the collection of all accounts receivable, debts and claims owing to the Company.

b. *Liquidation of Assets*. The Company shall determine whether and when to transfer the Company's property and assets to a liquidating trust (established pursuant to Section 6 hereof).

c. *Payment Obligations.* The Company shall, as determined by the Board of Directors, (i) pay or make reasonable provision to pay all claims and obligations, including all contingent, conditional or unmatured contractual claims known to the Company, (ii) make such provisions as will be reasonably likely to be sufficient to provide compensation for any claim against the Company which is the subject of a pending action, suit or proceeding to which the Company is a party and (iii) make such provision as will be reasonably likely to be sufficient to provide company is a party and (iii) make such provision as will be reasonably likely to be sufficient to provide company is a party and (iii) make such provision as will be reasonably likely to be sufficient to provide compensation for claims that have not been made known to the Company or that have not arisen but that, based on facts known to the Company or successor entity, are likely to arise or to become known to the Company or successor entity within 10 years after the Effective Date. Such claims shall be paid as required by applicable law. If there are insufficient assets of the Company, such claims and obligations of the Company shall be paid or provided for in accordance with their priority and, among claims of equal priority, ratably to the extent of assets of the Company legally available therefor. If and to the extent deemed necessary, appropriate or desirable by the Board of Directors or the Trustees (as defined in Section 6 below), in their absolute discretion, the Company may establish and set aside a reasonable amount of cash and/or property (the "*Contingency Reserve*") to satisfy such claims and obligations against the Company, including, without limitation, tax obligations, and all expenses related to the sale of the Company's property and assets, all expenses related to the collection and defense of the Company's property and assets, and the liquidation and dissolution provided for in this Plan.

d. *Distributions to Stockholders*. Any assets of the Company remaining after the payment of claims or the provision for payment of claims and obligations of the Company as provided in subsection (c) above shall be distributed by the Company pro rata to its stockholders. Such distribution may occur all at once or in a series of distributions and shall be in cash or assets, in such amounts, and at such time or times, as the Board of Directors or the Trustees, in their absolute discretion, may determine.

5. *Cancellation of Common Stock.* The distributions to stockholders pursuant to Sections 4 and 8 (the "*Liquidating Distribution*") shall be in complete redemption and cancellation of all of the outstanding shares of Common Stock. As a condition to receipt of the Liquidating Distribution, the Board of Directors or the Trustees, in their absolute discretion, may require the stockholders to (i) surrender their certificates evidencing the Common Stock to the Company or its agents for recording of such distributions thereon, or (ii) furnish the Company with evidence satisfactory to the Board of Directors or the Trustees of the loss, theft or destruction of their certificates evidencing the Common Stock, together with such surety bond or other security or indemnity as may be required by and satisfactory to the Board of Directors or the Trustees. The Board of Directors, in its absolute discretion, may direct that the Company's stock transfer books be closed and recording of transfers of Common Stock discontinued as of the earliest of (x) the close of business on the record date fixed by the Board of Directors for the first or any subsequent installment of any Liquidating Distribution, (y) the close of business on the date on which the remaining assets of the Company are transferred to the Trust, or (z) the date on which the Company files its Certificate of Dissolution under the DGCL (such date, the "*Record Date*"), and thereafter certificates representing shares of Common Stock will not be assignable or transferable on the books of the Company except by will, intestate succession or operation of law.

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6. Liquidating Trust. If deemed necessary, appropriate or desirable by the Board of Directors, in its absolute discretion, in furtherance of the liquidation and distribution of the Company's assets to the stockholders in accordance with the provisions hereof, as a final Liquidating Distribution or from time to time, the Company may transfer to one or more liquidating trustees, for the benefit of its stockholders (the "Trustees") under a liquidating trust (the "Trust"), any assets of the Company, including cash, intended for distribution to creditors and stockholders not disposed of at the time of dissolution of the Company, including the Contingency Reserve. The Board of Directors is hereby authorized to appoint one or more individuals, corporations, partnerships or other persons, or any combination thereof, including, without limitation, any one or more officers, directors, employees, agents or representatives of the Company, to act as the initial Trustee or Trustees for the benefit of the stockholders and to receive any assets of the Company. Any Trustees appointed as provided in the preceding sentence shall succeed to all right, title and interest of the Company of any kind and character with respect to such transferred assets and, to the extent of the assets so transferred and solely in their capacity as Trustees, shall assume all of the claims and obligations of the Company as provided in Section 4(b) hereof, including, without limitation, any unsatisfied claims and unknown or contingent liabilities. Further, any conveyance of assets to the Trustees shall be deemed to be a distribution of property and assets by the Company to the stockholders for the purposes of Section 4(d) of this Plan. Any such conveyance to the Trustees shall be treated for U.S federal and state income tax purposes as if the Company made such distribution to the stockholders and the assets conveyed shall be held in trust for the stockholders of the Company. The Company, subject to this Section 6 and as authorized by the Board of Directors, in its absolute discretion, may enter into a liquidating trust agreement with the Trustees, on such terms and conditions as the Board of Directors, in its absolute discretion, may deem necessary, appropriate or desirable. Adoption of the Plan of Dissolution by holders of a majority of the outstanding shares of Common Stock shall constitute the approval of the stockholders of any such appointment, any such liquidating trust agreement and any transfer of assets by the Company to the Trust as their act and as a part hereof as if herein written.

7. Abandoned Property. If any Liquidating Distribution to a stockholder cannot be made, whether because the stockholder cannot be located, has not surrendered its certificates evidencing the Common Stock as required hereunder or for any other reason, then the distribution to which such stockholder is entitled (unless transferred to the Trust established pursuant to Section 6) shall be transferred, at such time as the final Liquidating Distribution is made by the Company, to the extent permitted by law, to the official of such state or other jurisdiction authorized by applicable law to receive the proceeds of such distribution. The proceeds of such distribution shall thereafter be held solely for the benefit of and for ultimate distribution to such stockholder as the sole equitable owner thereof and shall be treated as abandoned property and escheat to the applicable state or other jurisdiction in accordance with applicable law. In no event shall the proceeds of any such distribution revert to or become the property of the Company.

8. *Final Liquidating Distribution.* Whether or not a Trust shall have been previously established pursuant to Section 6, if it should not be feasible for the Company to make the final Liquidating Distribution to its stockholders of all assets and all properties of the Company prior to the third anniversary of the filing of its Certificate of Dissolution, then, on or before such date, the Company shall be required to establish a Trust and transfer any remaining assets and properties (including, without limitation, any uncollected claims, contingent assets and the Contingency Reserve) to the Trustees as set forth in Section 6. Not more than three years from the date of its creation, the liquidating trust shall make a final distribution of any remaining assets to the holders of the beneficial interests of the Trust. Any such distribution shall be only in the form of cash.

9. *Stockholder Consent to Sale of Assets.* Approval of the proposed dissolution and adoption of the Plan of Dissolution by holders of a majority of the outstanding shares of Common Stock shall constitute the approval of the stockholders of the Company of the dissolution of the Company and the

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sale, exchange or other disposition in liquidation of all or substantially all of the property and assets of the Company pursuant to the terms hereof, whether such sale, exchange or other disposition occurs in one transaction or a series of transactions, and shall constitute ratification of all contracts for sale, exchange or other disposition which are conditioned on adoption of the Plan of Dissolution.

10. *Expenses of Dissolution.* In connection with and for the purposes of implementing and assuring completion of the Plan of Dissolution, the Company may, in the absolute discretion of the Board of Directors, pay any brokerage, agency, professional, legal and other fees and expenses of persons rendering services to the Company in connection with the collection, sale, exchange or other disposition of the Company's property and assets and the implementation of the Plan of Dissolution. Adoption of the Plan of Dissolution shall constitute approval of such payments by the stockholders of the Company.

11. *Employees and Independent Contractors*. In connection with effecting the dissolution of the Company and for the purpose of implementing and assuring completion of the Plan of Dissolution, the Company may, in the absolute discretion of the Board of Directors, hire employees and retain independent contractors and agents as the Board of Directors deems necessary or desirable to supervise the dissolution and liquidation. The Company may, in the absolute discretion of the Board of Directors, but subject to applicable legal and regulatory requirements, pay the Company's officers, directors, employees, independent contractors, agents and representatives, or any of them, compensation or additional compensation above their regular compensation, in money or other property, as severance, bonus, or in any other form, in recognition of the extraordinary efforts they, or any of them, will be required to undertake, or actually undertake, or otherwise necessary retain the services of any of them, in connection with the implementation of the Plan of Dissolution. Adoption of the Plan of Dissolution shall constitute approval of any such compensation by the stockholders of the Company.

12. Indemnification. The Company shall continue to indemnify its officers, directors, employees, independent contractors and agents to the maximum extent permitted in accordance with applicable law, its certificate of incorporation and bylaws and any contractual arrangements, for actions taken in connection with the Plan of Dissolution and the winding up of the affairs of the Company and shall indemnify the Trustees and its agents on similar terms. The Company's obligation to indemnify such persons may also be satisfied out of the assets of the Trust. The Board of Directors and the Trustees, in their absolute discretion, are authorized to obtain and maintain insurance for the benefit of such officers, directors, employees, independent contractors, agents and Trustees to the extent permitted by law and as may be necessary or appropriate to cover the Company's obligations hereunder, including seeking an extension in time and coverage of the Company's insurance policies currently in effect.

13. Amendment, Modification or Abandonment of Plan. If for any reason the Board of Directors determines that such action would be in the best interest of the Company, the Board of Directors may, in its sole discretion and without requiring further stockholder approval, revoke the Plan of Dissolution and all action contemplated thereunder, to the extent permitted by the DGCL. The Board of Directors may not amend or modify the Plan of Dissolution under circumstances that would require additional stockholder approval under the DGCL and the federal securities laws without complying with the DGCL and the federal securities laws. Upon the revocation or abandonment of the Plan of Dissolution, the Plan of Dissolution shall be void.

14. *Tax Matters.* It is intended that this Plan of Dissolution shall be a plan of complete liquidation of the Company in accordance with the terms of Sections 331 and 336 of the Code. The Plan of Dissolution shall be deemed to authorize the taking of such action as, in the opinion of counsel for the Company, may be necessary to conform with the provisions of said Sections 331 and 336 and the regulations promulgated thereunder. The Company's officers shall be authorized to cause the Company to make such elections for tax purposes as are deemed appropriate and in the best interest of

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the Company including, without limitation, the making of an election under Code Section 336(e), if applicable. Within thirty (30) days after the Effective Date, the Company shall file with the Internal Revenue Service an appropriate statement of corporate dissolution on IRS Form 966, as required by Section 6043 of the Code, and such additional forms and reports with the Internal Revenue Service as may be necessary or appropriate in connection with the Plan of Dissolution and the carrying out thereof. The Company shall notify all jurisdictions of any withdrawals related to qualification to do business. The Company shall make arrangements authorizing one or more representatives or agents to maintain such Company records as may be appropriate for purposes of any tax audit of the Company occurring during the process of dissolution or after liquidation.

15. *Power of Board of Directors and Officers.* The Board of Directors is hereby authorized, without further action by the Company's stockholders, to do and perform, or cause the officers of the Company, subject to approval of the Board of Directors, to do and perform, any and all acts, and to make, execute, deliver or adopt any and all agreements, resolutions, conveyances, certificates and other documents of every kind that are deemed necessary, appropriate or desirable, in the absolute discretion of the Board of Directors, to implement the Plan of Dissolution and the transactions contemplated hereby, including, without limitation, all filings or acts required by any state or Federal law or regulation to wind up its affairs.

Appendix B

# **UNITED STATES**

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# **FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2008

or

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

Commission File Number 001-33282

# XTENT, INC.

(Exact name of Registrant as specified in its charter)

**Delaware** (State of incorporation)

41-2047573 (I.R.S. Employer Identification No.)

125 Constitution Drive Menlo Park, California 94025-1118 (Address of principal executive offices, including Zip Code)

(650) 475-9400 (Registrant s telephone number, including area code)

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

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

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

None

(Title of Class)

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

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

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

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

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

Large accelerated filer O

Accelerated filer 0

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

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant, based upon the closing sale price of the common stock on the last day of its second fiscal quarter of 2008 was \$12,804,108. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

At March 5, 2009, the Registrant had 23,324,756 shares of Common Stock outstanding.

### XTENT, INC.

### FISCAL YEAR 2008 FORM 10-K ANNUAL REPORT

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### PART 1

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. These statements include, but are not limited to, those concerning the following: regarding future events, our future financial performance, business strategy, product introductions and plans and objectives of management for future operations, regulatory approvals, and clinical timelines. Forward-looking statements are subject to risks and uncertainties that could cause actual results and events to differ materially. For a detailed discussion of these risks and uncertainties, see PART I, ITEM 1A, Risk Factors below in this Form 10-K. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-K.

### **ITEM 1. BUSINESS**

### Overview

We are a development stage medical device company focused on developing and commercializing our innovative customizable drug eluting stent, or DES, systems for the treatment of coronary artery disease, or CAD. Our drug eluting stent systems are designed to enable physicians to customize both length and diameter of the stent at the site of the diseased section of the artery, or lesion, which we refer to as in situ customization. Our stent systems are designed to treat longer lesions than currently available drug eluting stents and to treat multiple lesions with the use of a single device. Our stent systems, the Custom NX 36 and the Custom NX 60, include a modular cobalt chromium stent design as well as a proprietary delivery system. In addition, our stents have a drug coating that is made of Biolimus A9, an anti-inflammatory drug, and PolyLactic Acid, a biodegradable polymer, which in combination are intended to reduce the incidence of restenosis, or renarrowing of the previously treated artery over time. We believe our technology, if approved by regulatory authorities, will enable us to compete in the approximately \$4 billion worldwide drug eluting stent market.

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

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

### **Recent Developments**

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

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

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

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

### **Status of Regulatory Approval**

Our Custom NX DES Systems are combination devices that include a stent and drug coating, for which we must receive regulatory approval as a medical device before we can market the systems. We are conducting clinical trials to evaluate our Custom NX 36 and Custom NX 60 stent and stent delivery systems. In October 2008, the one year data from our CUSTOM III clinical trial, the two year data from our CUSTOM II clinical trial and the three year data from our CUSTOM I clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. We believe the data from these clinical trials provided preliminary evidence of safety and efficacy and support further development of our in situ customization approach.

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

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

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

### **Market Opportunity**

Coronary artery disease, or CAD, is the most common form of cardiovascular disease and the number one cause of death in the United States and Europe. CAD is primarily caused by the accumulation of fat-laden cells, also known as plaque, in the arteries leading to the heart. Over time, the accumulation of plaque in an artery, known as a lesion, narrows the diameter of its lumen, or inner channel, and may significantly

reduce or stop blood flow. A reduction in blood flow to the heart can cause chest pain, a heart attack or potentially death. CAD accounts for over 650,000 deaths annually in the United States and, according to the American Heart Association, affects over 13 million Americans. Risk factors for CAD include old age, smoking, diabetes, obesity, sedentary lifestyle and an individual s genetic history.

### **Evolution of Treatments for Coronary Artery Disease**

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

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

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

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

*Drug Eluting Stents.* The most recent innovation in PCI was the development of drug eluting stents, or DES. Drug eluting stents were designed to address both causes of restenosis. Currently marketed drug eluting stents are conventional bare metal stents that are coated with a drug that is designed to reduce the formation of scar tissue in the

artery. This advance has resulted in a significant reduction in restenosis. As a result, following their introduction in Europe in 2002 and in the United States in 2003, drug eluting stents brought about a rapid shift in physician treatment of CAD and were used in 89% of the stent procedures in the United States in 2005. Drug eluting stents were used in approximately 1.5 million of the 2.2 million coronary stent procedures performed worldwide in 2005, and represented a \$4 billion market according to Millennium Research Group. However, in 2006 some clinical data emerged that indicated drug eluting stents were associated with higher rates of late stent thrombosis, which could lead to heart attacks or death, when compared to patients who received bare metal stents. In response, the FDA evaluated this clinical data during a public meeting of its Circulatory System Devices Advisory Panel on December 7 and 8, 2006. As a result of this clinical data, the use of bare metal stents has reportedly increased, and the use of drug eluting stents has correspondingly decreased, at certain hospitals in the United States and elsewhere. More recent data from 2007 indicate that in spite of a higher incidence of late stent thrombosis, overall rates of death and myocardial infarction for DES are not significantly different than overall rates of death and myocardial infarction for bare metal stents. According to Millennium Research Group, in 2007 drug eluting stents were used exclusively in 65% of all stent procedures in the United States and 53% of stent procedures worldwide (including the US). The total worldwide market for DES in 2007 was \$4.56 billion. Drug eluting stents are significantly more expensive than bare metal stents, with average costs in the United States that are approximately 2 to 2.5 times the cost of a bare metal stent.

### Evolution of Delivery Methods for Percutaneous Coronary Interventions

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

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

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

### Limitations of Current Percutaneous Coronary Intervention Therapies

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

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

• *Multiple Catheter Exchanges.* Currently available delivery systems require a catheter exchange for every additional balloon or stent used. In addition to the catheter exchanges required by the use of multiple stents, a

procedure may require insertion and inflation of a balloon both before and after placement of each stent. Each catheter exchange increases procedure time, cost and exposure to radiation from additional x-ray imaging.

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

• Inaccurate Placement of Stents. Inaccurate placement of stents, or longitudinal geographic miss, results in portions of a lesion remaining exposed, increasing the likelihood of thrombosis and the need for reintervention. Longitudinal geographic miss occurs when a stent fails to adequately cover a target lesion because the stent is either shorter than the lesion or it is placed in the wrong position, leaving the proximal or distal edge of the lesion untreated. We believe that longitudinal geographic miss occurs due in part to the difficulty of accurately pre-selecting the necessary stent length and diameter. We believe this is caused by the limitations of two dimensional x-ray images, as well as changes in the shape of the artery that can occur due to device delivery. In addition, we believe that physicians may select shorter stents to ensure deliverability and avoid covering healthy artery side-branches. In Johnson & Johnson s STLLR clinical trial, longitudinal geographic miss was observed in 47.6% of procedures, resulting in higher rates of thrombosis and reinterventions.

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

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

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

### The XTENT Solution

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

• In Situ Customization. Our Custom NX DES Systems are designed to allow physicians to determine and deploy the appropriate length of stent for the patient while inside the artery at the site of the lesion, or in situ. This ability to customize stent length in situ may help ensure coverage of the lesion and reduce the planning required prior to catheter insertion. Additionally, because our stents can be customized, we believe our six Custom NX stent configurations, comprised of three different diameters for each of our two lengths, may address the same lesions that could be treated with approximately 40 of the fixed-length stent configurations offered by our competitors.

• **Treatment of Multiple Lesions With a Single Device.** Our stents are comprised of multiple segments that are interdigitated. With the insertion of a single device, the physician can choose to distribute the 6mm segments across multiple lesions in a customized manner.

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

• **Treatment of Long Lesions Without Multiple Overlapping Stents.** Our Custom NX 60 is designed to effectively treat longer sections of diseased artery as compared with current fixed-length alternatives. Our Custom NX 60 can deliver up to 60mm of stent, while currently available drug eluting stents are typically 33mm or shorter. We believe our ability to cover a long lesion with a single stent may reduce the need to use one or more overlapping stents to treat long lesions. Overlapping stents have been associated with complications such as in-hospital non-Q wave myocardial infarction, subacute thrombosis, non-focal, delayed endothelialization and greater potential for stent fracture.

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

• *Improved Stent Placement Accuracy.* Our Custom NX DES Systems are designed to allow the physician to incrementally increase the length and diameter of the stent deployed while the delivery catheter is positioned in the patient s diseased artery. Prior to stent deployment, the physician can view the x-ray image to confirm complete coverage of the disease and deploy additional stent segments if desired. During deployment, stent diameter can be adjusted by controlling the pressure of the balloon inflation. We believe our products may also eliminate the need to use a separate post-deployment balloon because the balloon in our catheter can be shortened and reused during the procedure. Post-dilatation can be used to optimize stent expansion and improve stent apposition to the vessel wall. Stent under expansion and incomplete stent apposition have been demonstrated to contribute to stent thrombosis. We believe that this post-dilatation capability will enable a single stent deployed by our Custom NX DES Systems to treat a long lesion in an artery of varying diameters with one device. Current stent technologies are fixed-length and cannot be adjusted to address varying diameters with a single device. We believe the ability to use a single device to customize the length and diameter of the stent while in the patient s artery may reduce the incidence of geographic miss and the resulting problems of thrombosis and reinterventions.

• **Increased Stent Flexibility and Deliverability.** Our stents incorporate a modular design consisting of multiple small individual segments that are interdigitated, which we believe provides increased stent flexibility. We believe this flexibility may allow an artery to better maintain its natural shape, as well as move and flex with contractions of the heart, which may improve long-term patient outcomes. Changes in artery shape following stent procedures have been associated with major adverse cardiac events, or MACE. Our stent s increased flexibility may be particularly well suited for long lesions where the issues of deliverability and anatomical conformity are more important. In addition, our stent is delivered to the lesion covered by a lubriciously coated sheath, which helps the device slide along the vessel walls as it is pushed through a patient s vascular system. Current delivery systems leave stents exposed, which can hinder delivery if stents catch on diseased tissue or on the artery wall.

• **Biodegradable Polymer as Our Drug Carrier.** Late stent thrombosis with DES has multiple causes but may be in part due to physiologic reactions to durable polymers. Our drug coating is biodegradable, leaving behind a thin permanent primer. Our primer has been commonly used for approximately 30 years on cardiac defibrillators, pacemakers and neurostimulators, all of which have been implanted in patients for periods of time at least as long as our stents are intended to be implanted, as well as catheters, needles and other medical device components. As a result, we believe our primer has insignificant physiological response when used in the body. We believe the biodegradability of the polymer used in our drug coating may reduce the potential for late-stent thrombosis, or the occurrence of thrombosis 30 or more days after the procedure, that may be associated with durable polymers.

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

### **Our Strategy**

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

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

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

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

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

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

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

• **Provide the Highest Quality Products for Our Customers.** We have focused on patient safety and product quality. We incorporate these principles in every aspect of our organization including product development, manufacturing, quality assurance and clinical research. We would intend to build on this foundation by offering only the highest quality products to patients and physician customers.

### **Our Technology Platform**

We have developed a proprietary percutaneous coronary interventional therapy, consisting of drug eluting stents up to 36mm or 60mm in length and a stent delivery system. The integration of these components as a complete system is designed to provide a physician the ability to use one device to treat single long lesions or to customize therapy by deploying multiple custom-length stents to more than one lesion without removing or exchanging catheters.

### Our Stent and Drug Coating

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

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

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

### **Our Delivery System**

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

The distal end of the catheter contains a marker for visualization and our proprietary mechanism for separating the interdigitated segments. The method of action for separation is mechanical in nature and can be quickly repeated multiple times. Our delivery system also has a handle attached to the catheter that is used by the physician to control the deployment and separation of our stents. A dial on the handle allows the precise deployment of the necessary length of stent by pulling back the outer sheath. After deployment, if needed, the physician can shorten and reposition the balloon within the stented segment to further expand a portion of the stent against the artery wall. This feature is not currently offered in any commercially available stent delivery system and is intended to simplify the procedure by avoiding the need for an additional balloon for post-deployment stent diameter adjustments. After treatment of a specific lesion, our Custom NX DES Systems are designed to be reset and used to treat additional lesions, provided that all stent segments have not been deployed.

### **Our Procedure**

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

### **Products Under Development**

Our goal is to provide physicians with new and proprietary stent platforms that allow customization of treatment options for patients with CAD. Pursuant to this goal we have initiated several products and projects intended to expand the application of our technology and leverage the advantages of custom stenting in new applications. As a result of our recent reduction in headcount, we have suspended all development work with respect to these projects.

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

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

*Bioabsorbable Stent Technology.* Bioabsorbable stents are designed to remain in the treated artery as long as therapeutically needed, then become fully absorbed by the arterial tissue. Although bioabsorbable stents offer potential promise, further research is required in order to demonstrate that bioabsorbable stents can provide non-inferior safety and efficacy results to current alternatives. Our customizable bioabsorbable stent technology may offer significant potential benefits versus fixed length bioabsorbable stents. It consists of a series of bioabsorbable stent segments. These segments allow the user to customize the length of stent for the lesion treated by controlling the number of discrete segments to be deployed *in situ*. After the first customizable stent deployment, with the remaining stent available inside the catheter, the system can be reset and used to treat additional lesions. To date, we have demonstrated the ability to expand small polymer tube stent proxies infused with gold nanoparticles using low pressure balloons,

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

**Clinical Development Program** 

**Description of Common Clinical Measures** 

The safety, efficacy and performance of drug eluting stents are assessed using common metrics. Data collected at the time of stent implantation is compared with data collected when a patient is reassessed at follow-up. The time periods for follow-up are usually 30 days and six to nine months in pivotal clinical trials for CE Mark in the European Union, and 30 days and nine months for clinical trials under an IDE application in the United States conducted to support FDA approval of a PMA application. Competitors with drug eluting stents currently being sold in the United States have completed large, prospective, randomized clinical trials that enrolled approximately 1,000 and 1,300 patients each. We anticipate that a total of up to approximately 2,100 patients will be necessary to support our FDA approval.

**Our Clinical Trials** 

We have completed enrollment in four clinical trials. We are pursuing a clinical development strategy to demonstrate that our proprietary technology platform permits the customization of certain parameters of the therapy in situ including length of the stent, diameter of the stent and

number of lesions treated. Additionally, we plan to evaluate additional capabilities of our Custom NX DES Systems traditionally not performed by drug eluting stent systems including balloon shortening for partial expansion and post-deployment reinflation.

The following table summarizes our completed and ongoing clinical trials. The data from the CUSTOM I, II and III clinical trials were included in the application we submitted to our designated Notified Body to obtain the CE Mark that we received in March 2009 authorizing us to market our Custom NX DES Systems in the European Union. Additionally, we have used this information to support our IDE application to the FDA for the design of our planned U.S. pivotal clinical trial.

Clinical Trial	Number of Patients	Device Characteristics	Description	Status
CUSTOM I	30	<ul> <li>Maximum length: 36mm</li> <li>Diameter: 3.0mm</li> <li>Guide catheter: 7 french</li> <li>Single deployment</li> </ul>	First-in-man feasibility study to evaluate safety and efficacy in patients with a coronary lesion treatable with 36mm of stent	Completed
CUSTOM II	100	<ul> <li>Maximum length: 60mm</li> <li>Diameter: 3.0mm</li> <li>Guide catheter: 6-7 french</li> <li>Multiple deployments</li> </ul>	Feasibility study to evaluate safety and efficacy in patients with long or multiple coronary lesions	Completed
CUSTOM III	90	<ul> <li>Maximum length: 60mm</li> <li>Diameters: 2.5mm, 3.0mm</li> <li>Guide catheter: 6 french</li> <li>Multiple deployments</li> </ul>	Feasibility study to evaluate safety and efficacy in patients with long or multiple coronary lesions using a range of stent diameters	Completed
CUSTOM PK	28	<ul> <li>Maximum length: 60mm</li> <li>Diameters: 2.5mm, 3.0mm</li> <li>Guide catheter: 6 french</li> <li>Single deployment</li> </ul>	Pharmacokinetics study assessing blood concentration of Biolimus A9 drug at various time-points post stent implantation	Completed
CUSTOM CARE	200	<ul> <li>Maximum length: 60mm</li> <li>Diameters: 2.5, 3.0, 3.5mm</li> <li>Guide catheter: 6 french</li> <li>Multiple deployments</li> </ul>	Pre-market registry to confirm device performance, refine user training and prepare product launch	Initiated

*CUSTOM I.* Our CUSTOM I clinical trial was designed to evaluate the preliminary safety and efficacy of in situ customization using our proprietary stent technology and drug coating, consisting of a 36mm stent to treat diseased coronary artery lesions in 2.6 to 3.1mm diameter arteries. Enrollment of 30 patients was completed in July 2005 at three cardiology centers in Europe. Patients were reassessed at 30 days, four months, eight months and 12 months and annually for another 4 years.

The clinical trial included a patient population considered high risk for CAD, including those with long lesions and lesions in small arteries. The mean reference diameter and lesion length were 2.6mm and 17.7mm, respectively. In October 2008, the three year data from our CUSTOM I clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. There were a total of four MACE events reported 36 months after the treatment procedure. The results from our CUSTOM I clinical trial do not necessarily predict the outcome of a large-scale clinical trial, which will be required for obtaining FDA approval for our products in the United States.

*CUSTOM II.* Our CUSTOM II clinical trial was designed to evaluate the safety of in situ customization for long lesions and multiple lesions using our Custom NX 60 DES catheter system. The Custom NX60 was used to treat patients with long lesions or lesions in multiple diseased coronary arteries ranging from 2.5 to 3.0mm in diameter and up to two lesions. Enrollment of 100 patients was completed in October 2006 at ten cardiology centers in Europe. Of the 100 patients enrolled in CUSTOM II, 69 patients were enrolled in the long lesion cohort that consisted of patients with lesions greater than 20mm in length. The remaining 31 patients were enrolled in the two-lesion cohort. Patients were reassessed at 30 days, six months and 12 months. Follow up is scheduled to occur annually for five years. In October 2008, the two year data from our CUSTOM II clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. There were a total of 15 MACE events reported at two years post treatment procedure. The results from our CUSTOM II clinical trial do not necessarily predict the outcome of a large-scale clinical trial, which will be required for obtaining FDA approval for our products in the United States.

*CUSTOM III.* Our CUSTOM III clinical trial was designed to evaluate in situ customization for long lesions and multiple lesions using an enhanced version of our Custom NX DES Systems. The enhanced version included a number of changes to the handle improving ease-of-use for physicians. The primary endpoint of the study was safety with secondary endpoints. Enrollment in the CUSTOM III trial began in September 2006 and was completed in August 2007. In October 2008, the one year data from our CUSTOM III clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. There were a total of 11 MACE events reported at one year post treatment procedure. The results from our CUSTOM II clinical trial do not necessarily predict the outcome of a large-scale clinical trial, which will be required for obtaining FDA approval for our products in the United States.

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

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

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

#### CUSTOM I, II and III Summary of Clinical Trial Results

Clinical Outcomes	CI + CII + CIII N = 220 6M	CI + CII + CIII N = 220 12M	CI + CII N = 130 24M	C-I N=30 36M
Cardiac Death [n]	1	1	1	1
MI [n]	8	8	10	2
Q-Wave	2	2	3	
Non Q-Wave	6	6	6	2
TLR [n]	10	13	7	1
Total MACE [%]	8.6%	5 10%	14.6%	13.3%
Early Stent Thrombosis (30 days or less)	2	2	2	0
Late Stent Thrombosis (more than 30 days)	0	0	1	0

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

#### **Required Clinical Trials**

In order to obtain reimbursement in selected European countries and FDA approval in the United States, we will need to undertake large-scale pivotal studies similar to those conducted by competitors who have marketed drug eluting stents. We anticipate that a total of up to approximately 2,100 patients will be necessary to support FDA approval. The clinical trial design and sample size will be determined based on the safety and efficacy data from our CUSTOM I, II and III clinical trials. We currently anticipate these clinical trials will require evaluation of our stent in a randomized, controlled manner against one of the marketed drug eluting stents in patients with CAD. We believe the clinical measures will be the endpoints commonly used in drug eluting stent clinical trials. We expect that safety will be measured through MACE rates or target lesion revascularization while efficacy endpoints will include late loss of lumen diameter, binary restenosis rate or percent volume obstruction.

Two of the currently marketed drug eluting stents, Johnson & Johnson s Cypher and Boston Scientific s Taxus Express2, have undergone similar evaluations in order to obtain market approvals. However, the Cypher and Taxus Express2 stents were evaluated in comparison to their respective bare metal versions. The SIRIUS and TAXUS IV clinical trials enrolled 1,058 and 1,314 patients, respectively. Medtronic s Endeavor, has undergone evaluation where it was compared to the Cypher or Taxus drug eluting stents. The ENDEAVOR III and IV Trials enrolled 436 and 1,548 patients respectively. Abbott Laboratories Xience V stent obtained market approval on the basis of the SPIRIT First, SPIRIT II and SPIRIT III trials enrolling an aggregate of 1,362 patients. The SPIRIT III trial enrolled 1,002 patients and compared Xience V to the Taxus stent.

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

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

#### **Regulatory Filing Process**

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

#### **Post-Approval Registries**

At the time of our product launches in Europe and in the United States we expect to undertake post-approval surveillance registries to document the performance of our Custom NX DES Systems on an ongoing basis. We expect that these studies will have large patient population sample sizes, and will focus on identifying and monitoring occurrences of adverse events. The estimated size of the post market registry to be undertaken upon European launch is approximately 1,000 patients.

#### **Our Relationship with Biosensors**

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

Pursuant to the agreement, we received a worldwide, non-exclusive, license to use Biosensors drug coating, with royalties payable to Biosensors based on net sales of our products. The field of use for this license is limited to coronary and peripheral delivery of a series of short stent segments on a catheter where the physician has the ability to select the number of segments to be deployed. In Japan, our field of use is further limited to treating long lesions, multiple vessels or small vessels in coronary and peripheral applications.

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

The drug coating consists of Biolimus A9, an anti-inflammatory drug that is a derivative of rapamycin, and PolyLactic Acid, or PLA, a biodegradable polymer. Biolimus A9 has a chemical structure designed specifically for localized drug delivery from the surface of a stent and to inhibit restenosis. We are contractually restricted from obtaining Biolimus A9 from any other source or commercializing any products that incorporate rapamycin or its derivatives other than Biolimus A9. The license expires or is terminable upon, among other things:

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

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

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

In addition to paying royalties to Biosensors for the license, we also purchase the drug and polymer components exclusively from Biosensors. Our agreement with Biosensors prohibits us from making, using or selling a stent coated with rapamycin or a derivative of rapamycin other than Biolimus A9. We are obligated to assign to Biosensors any inventions for which our employees are inventors or co-inventors and which are either (i) derived from Biosensors confidential information or, (ii) related to the process for applying their drug coating to stents if developed prior to the effective date of the restated agreement or if co-invented with Biosensors. Biosensors must assign to us any inventions that are determined to be improvements to our stent or stent systems which are derived from our confidential information.

Biolimus A9 is manufactured by a Japanese pharmaceutical company and then shipped to Biosensors to be mixed with the PLA to make their proprietary drug coating. Biosensors ships the drug coating or the components of the coating to us and we apply it to our stents prior to final assembly and sterilization. Biosensors will perform stability testing of the drug and polymer and any other testing required to respond to agency questions about the MAF as required for approval of our DES systems in the United States, Japan, and Europe. Our agreement with Biosensors allows us to perform all other testing of the drug coating required for regulatory approvals and for lot release during commercialization.

#### Manufacturing

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

Final assembly, drug coating, and packaging of all of our products take place inside a controlled environment room of approximately 8,000 square feet that satisfies the requirements of a Class 10,000 level clean room. We have no experience manufacturing commercial quantities of our products. We believe our manufacturing facilities, processes and quality systems currently meet all regulatory requirements for the manufacture of devices for use in clinical trials and that with further refinements will meet all requirements for products for commercial distribution.

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

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

Our Menlo Park facility was inspected by the California Food and Drug Branch in May 2005 and was issued a device manufacturing license. In June 2008, our manufacturing facility was audited for the purpose of assessing the quality system to ISO 13485:2003 and the Medical Device Directive, or MDD 93/42/EC, requirements, and our registration was recertified. We expect to be audited again in the second or third quarter of 2009, but we do not believe that we have adequate personnel to pass the audit. We will not be able to commercialize our product until we successfully pass the audit. The facility has been registered with the FDA since September 2004. A separate FDA inspection of the manufacturing facility and quality system will occur as part of the premarket approval, or PMA, process for our products. When we obtain additional manufacturing space, we will need to be inspected by the FDA and if we move to another location, the facility may also need to be ISO recertified and recertified by the California Food and Drug Branch.

#### Competition

The coronary stent industry is highly competitive. Many of our competitors have significantly greater financial resources, human resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Many of these competitors also have more established reputations with our target customers and developed worldwide distribution channels. These competitors include Abbott Laboratories, Boston Scientific, Cook, Johnson & Johnson and Medtronic. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business. As a result, we cannot assure you that we will be able to compete effectively against these competitors or their products.

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

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

There are a number of companies developing or marketing treatments for coronary restenosis that are directly competitive with our technology. In particular, Boston Scientific has developed a paclitaxel eluting stent, the Taxus Express2 stent, which is marketed in the United States, Europe and other international markets. The Taxus Liberte, its next generation Taxus stent, is marketed in the United States, Europe and other international markets. Medtronic received FDA approval for its zotarolimus eluting stent, Endeavor, in February 2008 and immediately began marketing the product. Johnson & Johnson has developed a stent coated with rapamycin, the Cypher stent, which is marketed in the United States, Europe and other international markets. Abbott Laboratories Everolimus eluting stent, Xience V, received FDA approval in July 2008 and is marketed in the United States, Europe and other international markets. The Taxus Express2 stent, the Taxus Liberte stent, the Cypher stent, the Abbott Xience V stent and the Endeavor stent are currently the only FDA approved drug eluting stents in the United States. Conor Medsystems, which was acquired by Johnson & Johnson in January 2007, also developed a paclitaxel eluting stent, CoStar. In 2006, Conor received CE Mark for the CoStar stent in Europe and other international markets and began marketing through distribution partners. Conor also

completed the COSTAR II randomized controlled trial in the United States comparing Costar stent versus Taxus Express-2. Costar failed to meet its primary endpoint in COSTAR II and Johnson & Johnson has since decided to stop marketing Costar outside the United States and redesigned the product with a drug coating based on sirolimus rather than paclitaxel.

Outside the United States, there are a number of additional stents that have marketing approval. In January 2008, Biosensors and Terumo both received CE Mark for their Biolimus A9-eluting stents. Biosensors markets its BioMatrix stent through a direct sales force and distributors. Terumo primarily uses distributors to market its NOBORI stent internationally. Biosensors also markets a paclitaxel eluting stent, Axxion, in Europe and other international markets. Sorin Group has developed a tacrolimus eluting stent, Janus, which is marketed in Europe. In addition to its Endeavor stent, Medtronic has another zotarolimus eluting stent named Endeavor CR (Resolute) which has received CE Mark and which has a different polymer than the one used on the Endeavor stent. Additionally, many of the companies referenced above, and other potential competitors are in the process of developing new drug eluting stents. Competitors with stents used in PAD applications include Abbott Laboratories, C.R. Bard, Boston Scientific, Cook Group, Edwards Lifesciences, ev3, Johnson & Johnson, Medtronic and W.L. Gore & Associates.

#### **Research and Development**

Since inception, we have devoted a significant amount of resources to develop our Custom NX DES Systems. Our research and development expenses were \$31.2 million in 2008, \$30.9 million in 2007 and \$18.9 million in 2006. If we are able to obtain additional funding or complete a strategic transaction that provides adequate resources, we expect our research and development expenditures to increase as we continue to devote significant resources to developing our products, in particular, completing the clinical trials necessary to support regulatory approval.

#### Sales and Marketing

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

If we are able to obtain additional funding or complete a strategic transaction that provides adequate resources, we intend to commercialize our Custom NX DES Systems in certain key markets in both Europe and Asia Pacific. We expect to rely on third-party distributors, with our sales and clinical support, in select markets in Europe, all of Asia Pacific and the rest of the world. Following FDA approval, we expect to market our products in the United States through a direct sales force. We plan to market our products to physicians who perform interventional procedures in hospitals and to other personnel who make purchasing decisions on behalf of hospitals. In order for physicians to adopt our Custom NX DES Systems, we must show strong clinical evidence that our products are safe and effective. In addition, we must show that the product is easy to use and cost-effective. Because our products are based on a new technology, we will provide focused high level training and support. We would need to include within the sales organization clinical specialists who are skilled in training cardiologists in the use of our products.

#### **Intellectual Property**

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

As of December 31, 2008, we had 19 issued U.S. patents, 62 pending U.S. patent applications, one pending Israeli patent application, and 40 pending international patent applications filed pursuant to the Patent Cooperation Treaty, or PCT, 27 of which have entered the national phase in Europe, Japan, Canada, and Australia. All of our issued U.S. patents except two will expire between 2021 and 2023. Our other two issued U.S. patents, which cover technologies that we at present are not pursuing commercially, expire in 2014 and 2016, respectively. In addition, we have one U.S. patent under exclusive license covering methods of performing angioplasty on multiple lesions of varying lengths, which expires in 2012. As of December 31, 2008, one of our pending U.S. patent applications had been allowed by the U.S. Patent and Trademark Office, or USPTO. We are prosecuting or intend to prosecute our PCT patent applications in the national phase in Europe, Japan, Canada and Australia. Our pending U.S. and international patent applications, if issued, will expire between 2021 and 2027.

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

customization of stent length through selected deployment of stent segments, manipulation of stent segments within the catheter, separation of deployed stents from the undeployed stents and the interdigitation of the stent segments. Other pending patent applications in our portfolio, if issued with their present claims, will cover various other drug eluting stent technologies including detachable linked stent segments, self-expanding stents and delivery systems for PAD treatment applications, durable and bioabsorbable polymer stents molded at the site of treatment, stent coating technologies for creating topographical features such as drug reservoirs on the stent surface and for elution of multiple drugs, and bifurcation stents and delivery systems.

We have entered into a license agreement with Biosensors for non-exclusive rights to use its drug coating on our stents. See Our Relationship with Biosensors. Under this agreement we have a non-exclusive license to certain issued patents owned by Biosensors covering Biolimus A9 and stent coatings containing Biolimus A9 and certain polymers.

We have also entered into a license agreement with SurModics giving us non-exclusive rights in certain of its patents and patent applications to allow us to coat our catheter's sheath with SurModics lubricious coating. This agreement terminates upon the expiration of the last-to-expire patent licensed to us under the agreement, or earlier if we fail to begin bona-fide commercial sales by July 1, 2009 or thereafter if we have four consecutive quarters during which we fail to pay a royalty to SurModics.

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

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

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

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

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

#### **Third-Party Patent Rights**

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

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

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

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

Various patents owned by third parties are directed to stent structures and materials. These patents include a group of Lau patents that were owned by Guidant Corporation, a subsidiary of Boston Scientific whose stent technology has been acquired by Abbott Vascular subject to certain rights retained by Boston Scientific, which are directed to flexible stent structures. The Boneau family of patents, owned by Medtronic, are directed to stents comprising multiple closed-loop elements.

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

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

Certain patents owned by third parties relate to methods for coating stents. The Hossainy family of patents that were held by Guidant Corporation are directed to methods of coating stents with a primer layer and a reservoir layer.

#### **Third Party Reimbursement**

In most countries throughout the world, a significant portion of a patient s medical expenses is covered by third-party payors. In many countries including the United States, third-party payors consist of both government funded insurance programs and private insurance programs. While each payor develops and maintains its own coverage and reimbursement policies, the vast majority of payors have established policies for drug

eluting stents. We believe that our products generally will fall within the existing reimbursement guidelines, although some refinement in policies may be indicated for our products. Before reimbursement may be obtained for our Custom NX DES Systems in the United States, FDA approval will be required.

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

under regulatory changes to the methodology for calculating payments for current inpatient procedures for certain hospitals, Medicare payment rates for surgical and cardiac procedures have been decreased, including approximately 10% to 14% reductions for those procedures using drug eluting stents. The reductions are being transitioned over a three year period that began in fiscal year 2007. In 2007, CMS also implemented revised reimbursement codes that better reflect the severity of the patient s condition in the hospital inpatient prospective payment system.

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

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

#### **Government Regulation**

#### United States

Our products are combination products because they are comprised of two or more regulated components, a drug and a device, that are physically combined and produced as a single product. In the United States, a combination product is assigned by the FDA to one of the Agency s Centers, such as the Center for Drug Evaluation and Research, or CDER, or the Center for Devices and Radiological Health, or CDRH. The Center to which the product is assigned will have primary jurisdiction over the premarketing review and approval of the combination product. The FDA identifies the Center with primary authority over a combination product based on an assessment of the combination product s primary mode of action. Because the primary mode of action for our products is that of a medical device, they will be regulated as devices by the FDA under the Federal Food, Drug, and Cosmetic Act, and CDRH will have primary jurisdiction over our PMA application. We believe that the drug component of our products will be reviewed by CDER, which will consult with and assist CDRH in its review of our PMA applications. The drug will not require separate FDA approval.

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

- product design and development;
- product testing;

- product manufacturing;
- product safety;
- product labeling;
- product storage;
- recordkeeping;
- premarket approval;

- advertising and promotion; and
- product sales and distribution.

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

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

Clinical Trials. A clinical trial is almost always required to support a PMA application. Clinical trials for our product candidates require the submission of an application for an investigational device exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Our IDE application includes the MAF for the drug coating aspects of our products that Biosensors submits to the FDA on our behalf. We filed our IDE application in September 2007, and in October 2007, we received questions back from the FDA. In February 2009, we resubmitted our IDE application, and expect to receive a response from the FDA by the end of the first quarter of 2009. We will not be able to initiate our CUSTOM IV trial until we receive IDE approval, and even if we receive IDE approval, we will not be able to initiate our IDE trial unless we obtain additional financing, or we consummate a strategic transaction that permits us to initiate our IDE trial. The IDE must be approved in advance by the FDA for a specified number of patients. Clinical trials may begin once the application is reviewed and cleared by the FDA and the appropriate institutional review boards at the clinical trial sites. Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an institutional review board at the relevant clinical trial site and in accordance with applicable regulations and policies including, but not limited to, the FDA s good clinical practice, or GCP, regulations. We, the FDA or the institutional review board at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to clinical trial subjects outweigh the anticipated benefits.

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

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

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

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

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

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

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

- fines, injunctions, consent decrees and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;

• refusing our requests for premarket approval or new intended uses;

- withdrawing premarket approvals that are already granted; and
- criminal prosecution.

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

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

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

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

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

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

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

#### International

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

The primary regulatory environment in Europe is that of the European Union, which consists of twenty five countries encompassing most of the major countries in Europe. Three member states of the European Free Trade Association, Norway and Lichtenstein, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Other countries, such as Switzerland, have entered into Mutual Recognition Agreements and allow the marketing of medical devices that meet E.U. requirements. The European Union has adopted numerous directives and the European Committees for Standardization, or CEN, have promulgated voluntary standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directive and, accordingly, can be commercially distributed throughout the member states of the European Union, the member states of the European Free Trade Association and countries which have entered into a Mutual Recognition Agreement. The method of assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a designated Notified Body, an independent and neutral institution appointed in one of the countries in the European Union to conduct the conformity assessment. This assessment is conducted by the designated Notified Body in one member state of the European Union, the European Free Trade Association or one country which has entered into a Mutual Recognition Agreement and is required for most of the medical devices in order for a manufacturer to obtain CE Marking and to commercially distribute the product throughout these countries. This assessment may also consist of an audit of the manufacturer s quality system and specific testing of the manufacturer s device so as to ensure compliance with ISO 13485 certification, which are voluntary harmonized standards. Compliance with these ISO certifications establishes that some of the general requirements of the directives are presumed to be fulfilled. See Manufacturing.

#### Employees

As of December 31, 2008, we had 127 employees, with three employees in sales and marketing, 66 employees in manufacturing, 24 employees in research and development, 13 employees in general and administrative and 21 employees in clinical, regulatory and quality assurance. In January 2009, we announced an initiative to reduce our headcount by 115 positions to be completed during March 2009.

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

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

#### ITEM 1A. RISK FACTORS

#### **Risks Related to Our Business**

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

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

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

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

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

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

We have significantly reduced our headcount and limited our business activities. Before we could resume the operations required in order to commercialize our product, we would need to rehire a significant number of employees or hire and train new employees that can perform their jobs according to our specifications. There can be no assurance that we will be able to rehire our former employees or hire and train qualified new employees in a timely manner, or at all. In addition, before we can commercialize our product in Europe, we need to increase our manufacturing capacity and validate our manufacturing process to demonstrate compliance with applicable quality standards. This validation

would likely take six to nine months to complete. Further, under the terms of the agreements we have with several of our suppliers, we are required to provide regular forecasts of the components we plan to purchase from them during a particular period. These suppliers are obligated to supply us only with the number of components that we previously forecasted. Therefore, once manufacturing operations commence, it may take several months before we have adequate supplies of critical components required to make our products.

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

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

- fund our operations and clinical trials;
- continue our research and development;
- scale-up our manufacturing operations;
- defend, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- commercialize our products, if any such products receive regulatory approval for commercial sale; and
- acquire or in-license companies, products or intellectual property.

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

- the nature and timing of any strategic transaction we may complete, if any;
- the scope, rate of progress and cost of our clinical trials and other research and development activities;

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

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

- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our products and any products that we may develop;
- the effect of competing technological and market developments;
- licensing technologies for future development; and

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

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

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

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

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

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

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

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

In order to obtain IDE approval from the FDA allowing us to initiate our CUSTOM IV clinical trial in the United States and in order to obtain the premarket approval, or PMA, allowing us to commercialize our Custom NX DES Systems in the United States, we need Biosensors to submit acceptable MAFs related to our drug coating to the FDA on our behalf. We believe the MAF which Biosensors has submitted to the

FDA for purposes of our IDE application is sufficient to support an IDE approval, but we expect the FDA to conduct additional assessments of the MAF as part of our PMA review, and they may have additional questions at that time. Any delays Biosensors experiences or problems it has in responding to questions the FDA may have concerning the MAF may substantially delay the commercial launch of our product in the United States.

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

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

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

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

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

- we may experience delays in our development program, including initiation and completion of our clinical trials;
- any products that are approved may not be accepted in the marketplace by physicians and patients;
- physicians may not receive adequate coverage and reimbursement for procedures using our products;
- any rapid technological change may make our technology and products obsolete;
- we may not be able to manufacture our Custom NX DES Systems in commercial quantities or at an acceptable cost;

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

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

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

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

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

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

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

- our stent systems may not be safe or effective or may not otherwise meet the FDA s requirements;
- the data from our pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities we or our suppliers use may not meet stringent regulatory requirements;

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

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

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

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

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

the FDA and the European regulatory agencies have issued new guidelines for the approval of drug eluting stents which require additional clinical data and may prolong the process for obtaining regulatory approval.

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

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

- Engineering testing,
- Biocompatibility testing,
- Animal studies,
- Chemistry and manufacturing controls,

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- Clinical pharmacology and drug release,
- Drug pharmacology, toxicology and safety data,
- Clinical studies, and
- Post approval studies.

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

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

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

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

- the supplier of our drug coating is unable or refuses to meet our demand;
- our license agreement with Biosensors terminates for any reason, including insolvency; or
- the supplier of our drug coating does not meet regulatory quality requirements and other specifications, certain regulatory approvals need to be obtained.

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

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

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

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

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

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

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

#### that suggested in the recent studies regarding late-stent thrombosis.

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

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

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

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

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

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

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

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

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

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

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

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

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

• changes in governmental regulations or administrative actions;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

regulations administered by the FDA and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following enforcement actions:

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

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

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

Moreover, any modification to a device that has received FDA approval that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new approval from the FDA. If the FDA disagrees with any determination by us that new approval is not required, we may be required to cease marketing or to recall the modified product until we obtain approval. In addition, we could also be subject to significant regulatory fines or penalties.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or efficacy of our products, and we will be required to report adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR or GMP, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties. For example, Boston Scientific has initiated significant recalls of its stent products due to manufacturing and other quality issues associated with the products.

Further, healthcare laws and regulations may change significantly in the future. Any new healthcare laws or regulations may adversely affect our business. A review of our business by courts or regulatory authorities may result in a determination that could adversely affect our operations. Also, the healthcare regulatory environment may change in a way that restricts our operations.

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

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

**Risks Related to Our Intellectual Property** 

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

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

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

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

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

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

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

Other third-party patents are directed to stent delivery catheter technology. There are also a number of patents that were held by Guidant Corporation directed to rapid exchange catheters for angioplasty and stent delivery. These include, without limitation, the Yock and Horzewski

families of patents, directed to rapid exchange angioplasty catheters, and the Lau family of patents directed to rapid exchange stent catheters. Boston Scientific owns other patents directed to rapid exchange angioplasty catheters, including, the Bonzel family of patents. Medtronic owns certain patents directed to guidewire handling technology in stent delivery catheters, including certain patents issued to Crittenden and Kramer. A patent issued to

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

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

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

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

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

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

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

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

• pay damages, including up to treble damages and the other party s attorneys fees, which may be substantial;

• cease the development, manufacture, use and sale of products that infringe the patent rights of others, including our Custom NX DES Systems, through a court-imposed sanction called an injunction;

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

• discontinue manufacturing or other processes incorporating infringing technology; or

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

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

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

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

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

Our ability to protect our products from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. As of December 31, 2008 we had seven issued U.S. patents, one of which is under exclusive license, covering certain aspects of the technology that we intend to commercialize and a number of other issued patents and pending patent applications in the United States and abroad. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering medical devices and pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any of our issued patents may not provide us with commercially meaningful protection for our products or afford us a commercial advantage against our competitors or their competitive products

or processes. In addition, patents may not issue from any pending or future patent applications owned by or licensed to us, and moreover, patents that have issued to us or may issue in the future may not be valid or enforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing products like ours, despite our patent rights.

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

patent. Patent applications filed in countries outside the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO to determine priority of invention in the United States. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the United States. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States, and many companies have encountered significant difficulties in protecting our intellectual property rights in foreign jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

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

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

We are aware that another medical business that holds patents to certain stent designs has used the name XTENT for limited purposes in the past. If it turns out that the other business has superior trademark rights in the name, and if the other business were to challenge our use of the XTENT name, we would then need to convince a court that there is no likelihood of consumer confusion. If we were unsuccessful in court, then we could be held liable for trademark infringement and we might then have to change our name as well as pay monetary damages. If we were forced to change our name, we may suffer from a loss of brand recognition, we may be required to retrieve product and interrupt supply, and may have to devote substantial resources advertising and marketing our products under a new brand name.

#### **Risks Related to Commercialization**

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

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

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions in the United States and abroad. Most of the companies developing or marketing competing products are publicly traded or divisions of publicly-traded companies, and these companies enjoy several competitive advantages, including: • greater financial and human resources for product development, sales and marketing, and patent litigation;

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;

• additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;

• established distribution networks; and

• greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products and marketing approved products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the research methodology used may not be successful in identifying potential products;
- competitors may develop alternatives that render our products obsolete;
- our products may not be deployed safely or effectively;

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

• our clinical trials may not be successful; and

• we may not receive regulatory approval.

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

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

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

#### **Risks Related to Our Industry**

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

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

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

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

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

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

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

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

#### **Risks Related to Our Operations**

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

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

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

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

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring us to include a report of management on our internal control over financial reporting in our annual report on Form 10-K for the year ended December 31, 2008. In addition, in our annual report on Form 10-K for the year ending December 31, 2009, the independent registered public accounting firm auditing our financial statements

must attest to the effectiveness of our internal control over financial reporting. We may be unable to comply with these requirements by the applicable deadlines. We will be testing our internal control over financial reporting in connection with Section 404 requirements and could, as part of that documentation and testing, identify material weaknesses, significant deficiencies or other areas requiring further attention or improvement.

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

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

- the results of our clinical trials;
- the timing of our regulatory approvals;
- announcements related to litigation;
- statements made by Biosensors relating to regulation or supply of the drug coating;
- the announcement of new products or service enhancements by us or our competitors;
- quarterly variations in our or our competitors results of operations;

• changes in earnings estimates, investors perceptions, recommendations by securities analysts or our failure to achieve analysts earning estimates;

• the low trading volume of our common stock;

· developments in our industry, including changes in third-party reimbursement; and

• general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

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

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

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

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

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

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

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

• a classified board so that only one of the three classes of directors on our board of directors is elected each year;

- elimination of cumulative voting in the election of directors;
- procedures for advance notification of stockholder nominations and proposals;
- the ability of our board of directors to amend our bylaws without stockholder approval;

• a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and our amended and restated bylaws; and

• the ability of our board of directors to issue up to 10,000,000 shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our board of directors may determine.

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

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

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic

factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

#### **ITEM 2. PROPERTIES**

We currently occupy a facility of approximately 50,000 square feet in Menlo Park, California, under a lease which expires on May 31, 2012. Under the terms of our lease agreement for these facilities, our landlord may terminate our lease at any time on or after May 1, 2010 if it has obtained certain redevelopment rights with respect to the leased premises, and we may terminate the lease at anytime on or after May 1, 2010 for any reason. We believe that our existing facility is adequate to meet our needs for at least the next 12 months and we expect that it will be available to us through such period. As we begin commercialization of our products, we expect that we will need additional space. We cannot assure you that suitable additional space will be available in the future on commercially reasonable terms as needed.

#### **ITEM 3. LEGAL PROCEEDINGS**

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

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

None.

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#### PART II

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

#### **Stock Information**

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

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

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

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

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

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

#### Securities Authorized for Issuance Under Equity Compensation Plans

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

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights(1) (a)	Weighted-aver exercise price outstanding options, warra and rights (b)	e of g unts	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)(2) (c)
Equity compensation plans approved by security holders	2.510.678	\$	5.48	2,442,643
Equity compensation plan not approved	,,		NT/ A	, ,
by security holders Total	2,510,678		N/A	2,442,643

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

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

#### **Stock Performance Graph**

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

#### XTENT, Inc.

#### Nasdaq Medical Devices, Instruments and Supplies, Manufacturers

and Distributers Stocks Index

Nasdaq Stock Market - U.S. Index

#### ITEM 6. SELECTED FINANCIAL DATA

We derived the selected statements of operations data for the years ended December 31, 2008, 2007 and 2006 and the period from June 13, 2002 (Inception) to December 31, 2008 and balance sheet data as of December 31, 2008 and 2007 from our audited financial statements that are included elsewhere in this Form 10-K. We derived the selected statements of operations data for the years ended December 31, 2005 and 2004 and the balance sheet data as of December 31, 2006, 2005, and 2004 from our audited financial statements not included in this Form 10-K.Our historic results are not necessarily indicative of the results that may be expected in the future. You should read this data together with our

financial statements and related notes included elsewhere in this report and the information under Management s Discussion and Analysis of Financial Condition and Results of Operations.

	Peri June (I Ince Dece	mulative od from 13, 2002 Date of ption) to mber 31, 2008 sands, except J	per sl	2008 nare data)		Year 2007		ed December 2006 (2)	· 31,	2005		2004
Operating expenses:	<i>•</i>	105 504	<b>^</b>	01.150	<b>•</b>	20.000	<b>•</b>	10.022	<i>•</i>	10 100	<b>^</b>	<b>5</b> 110
Research and development	\$	105,584	\$	31,170	\$	30,888	\$	18,923	\$	12,139	\$	7,118
General and administrative		34,460		10,917		11,269		7,258		2,214		1,883
Total operating expenses		140,044		42,087		42,157		26,181		14,353		9,001
Loss from operations		(140,044)		(42,087)		(42,157)		(26,181)		(14,353)		(9,001)
		(110,011)		(12,007)		(12,157)		(20,101)		(11,555)		(),001)
Interest and other income, net		6,063		966		3,363		1,137		323		110
Net loss		(133,981)		(41,121)		(38,794)		(25,044)		(14,030)		(8,891)
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock		(13,095)						(13,095)				
Net loss attributable to common												
stockholders	\$	(147,076)	\$	(41,121)	\$	(38,794)	\$	(38,139)	\$	(14,030)	\$	(8,891)
Net loss per share attributable to common stockholders - basic and diluted (1)			\$	(1.78)	\$	(1.87)	\$	(13.96)	\$	(6.84)	\$	(5.00)
Weighted-average common shares outstanding - basic and diluted				23,116		20,703		2,732		2,052		1,779

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

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

	2008	2007	ember 31, 2006 housands)	2005	2004
Balance Sheet Data					
Cash and cash equivalents	\$ 13,373	\$ 13,366	\$ 23,105	\$ 6,564	\$ 4,761
Short-term investments	5,752	44,394			
Working capital	17,070	54,581	21,066	5,588	4,143
Total assets	23,995	62,415	27,121	8,675	6,136
Reedeemable convertible preferred stock			75,593	35,900	20,406
Total stockholders equity (deficit)	21,508	58,331	(50,780)	(28,372)	(14,925)

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

## **Business Overview**

We are a development stage medical device company focused on developing and commercializing our proprietary Custom NX DES Systems to treat coronary artery disease, or CAD. Since inception we have devoted substantially all of our resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials. We have focused our development efforts on creating our Custom NX DES Systems, which allow a physician to deploy single or multiple stents of customizable length with a single device. We have not yet received any government regulatory approvals necessary to commercialize any of our products.

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

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

To date, we have not generated any revenue from our development activities and will not be able to generate revenue until one of our products is approved, if ever. We have incurred net losses in each year since our inception in June 2002. Through December 31, 2008, we had an accumulated deficit of \$134.0 million. Provided we are able to obtain adequate financing, we expect our losses to continue to increase as we expand our clinical trial activities and initiate commercialization activities. Since inception we have financed our operations primarily through the sale of our equity securities. In May and June 2006, we raised aggregate net cash proceeds of approximately \$30.0 million in a private placement of shares of our Series D convertible preferred stock. On February 1, 2007 we completed our initial public offering of our common stock which raised net proceeds of \$68.2 million.

#### **Recent Developments**

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

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

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

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

#### **Financial Operations**

#### Revenue

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

#### **Research and Development**

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

## General and Administrative

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

**Results of Operations** 

Comparison of Years Ended December 31, 2008 And 2007

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

**Research and Development** 

	20		ber 31,	2007	Dollar Change
		(in thou	isands)		
Research and development expenses	\$	31,170	\$	30,888	\$ 282

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

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

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

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

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

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

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

## General and Administrative

	Years Decem 2008		2007	Dollar Change
	(in thou	isands)		
General and administrative expenses	\$ 10,917	\$	11,269	\$ (352)

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

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

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

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

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

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

Interest and Other Income, Net

Years Ended December 31,

Dollar

	2008			2007	Change
		(in tho	usands)		
Interest and other income, net	\$	966	\$	3,363	\$ (2,397)

The \$2.4 million decrease in interest and other income for the year ended December 31, 2008, compared to the year ended December 31, 2007, was primarily attributable to a decrease in the average levels of cash, cash equivalents and short-term investments as well as lower average interest rates.

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

As of December 31, 2008, we had net operating loss carry-forwards of approximately \$94.8 million available to reduce future taxable income, if any, for Federal and California state income tax purposes. The Federal income tax net operating loss carry-forward begins expiring in 2022, and the California state income tax net operating loss carry-forward begins expiring in 2015. As of December 31, 2008, we had research and development credit carry-forwards of approximately \$4.2 million and \$4.4 million available to reduce future taxable income, if any, for Federal and California state income tax purposes, respectively. The Federal income tax research and development credits carry-forwards begin expiring in 2022, and the California state income tax research and development credits carry-forwards begin expiring in 2022, and the California state income tax research and development credits carry-forwards begin expiring in 2022, and the California state income tax research and development credits carry-forwards begin expiring in 2022, and the California state income tax research and development credits carry-forwards begin expiring in 2022, and the California state income tax research and development credits carry-forward indefinitely.

Section 382 of the Internal Revenue Code generally imposes an annual limitation on the amount of net operating loss carry-forwards that may be used to offset taxable income when a corporation has undergone significant changes in its stock ownership. We have internally reviewed the applicability of the annual limitations imposed by Section 382 caused by previous changes in our stock ownership and believe such limitations should not be significant. Future ownership changes, including changes resulting from any future sales of our equity securities, may adversely affect our ability to use our

remaining net operating loss carry-forwards. If our ability to use net operating loss carry-forwards is limited, we may be subject to tax on our income earlier than we would otherwise be had we been able to fully utilize our net operating loss carry-forwards.

## Comparison of Years Ended December 31, 2007 And 2006

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

## **Research and Development**

	Years Decem	Ended ber 31,		Dollar
	2007 (in tho	iconde)	2006	Change
Research and development expenses	\$ 30,888	\$	18,923	\$ 11,965

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

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

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

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

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

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

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

## General and Administrative

	Years Decemb 2007	ber 31,	2006	Dollar Change
	(in thou	isands)		
General and administrative expenses	\$ 11,269	\$	7,258	\$ 4,011

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

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

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

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

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

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

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

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

## Interest and Other Income, Net

		Years Decem	Ended ber 31,		Dollar
	,	2007		2006	Change
		(in thou	isands)		
Interest and other income, net	\$	3,363	\$	1,137	\$ 2,226

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

## Liquidity And Capital Resources

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

	D	As of ecember 31, 2008		As of December 31, 2007
	+	,	usands)	
Cash and cash equivalents	\$	13,373	\$	13,366
Short-term investments		5,752		44,394
Total cash and cash equivalents and short-term investments	\$	19,125	\$	57,760

#### Sources of Liquidity

We are in the development stage and have incurred losses since our Inception in June 2002. As of December 31, 2008, we had an accumulated deficit of \$134.0 million. Prior to our Initial Public Offering, we funded our operations from the private placements of our convertible preferred stock resulting in aggregate net proceeds of \$75.6 million through December 31, 2006. On February 1, 2007, we completed our Initial Public Offering, raising \$68.2 million in net proceeds. Upon completion of the reduction in force in March 2009, our cash requirements will be greatly

reduced and we are working with Piper Jaffray & Co. to explore potential strategic alternatives, which may include, without limitation, a merger, a sale of substantially all our assets, a financing, or a sale of a portion of our assets, such as our peripheral stent product, our drug eluting balloon product or our bioabsorbable stent product. If we are not successful in identifying and completing a strategic transaction or securing adequate funding, we may not be able to continue our operations and may need to wind up our business and liquidate our assets.

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

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

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#### Summary of Cash Flows

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

	Year I Decemi		
	2008		2007
	(in thou	isands)	
Net cash used in operating activities	\$ (37,401)	\$	(34,353)
Net cash provided by (used in) investing activities	37,151		(44,858)
Net cash provided by financing activities	257		69,472
Net increase (decrease) in cash and cash equivalents	7	\$	(9,739)

#### **Operating Activities**

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

#### **Investing** Activities

Net cash provided by investing activities was \$37.2 million for the year ended December 31, 2008, compared to net cash used in investing activities of \$44.9 million for the year ended December 31, 2007. Net cash provided by investing activities for the year ended December 31,

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

## **Financing** Activities

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

#### **Operating Capital and Capital Expenditure Requirements**

To date, we have not commercialized any products. Even though we received CE Mark in March 2009 authorizing us to market our products in the European Union, we will not be able to commercialize our product unless we obtain additional financing, or we consummate a strategic transaction that permits us to commercialize in Europe. We can provide no assurance that such a financing or strategic transaction will be available on terms agreeable to us, or at all. We anticipate that we will continue to incur substantial net losses for the next several years as we develop our products, conduct and complete clinical trials, pursue additional applications for our technology platform, expand our clinical development team and corporate infrastructure, and prepare for the potential commercial launch of our products. Our current cash and cash equivalents and short-term investments are not sufficient to meet the cash requirements of these activities.

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

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

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

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

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

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

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

- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;

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

## the effect of competing technological and market developments; and

licensing technologies for future development.

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

## **Contractual Obligations**

•

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

	Payments Due by Period									
Contractual Obligations		Total		2009		2010 to 2012 housands)	t	2013 o 2015		2016 l Later
Operating lease	\$	1,694	\$	479	\$	1,215	\$		\$	
Minimum royalty obligations		1,680		155		540		540		445
Total	\$	3,374	\$	634	\$	1,755	\$	540	\$	445

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

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

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

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

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

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

#### **Off-Balance Sheet Arrangements**

Since inception, we have not engaged in any off-balance sheet activities as defined in Regulation S-K Item 303(a)(4).

#### **Critical Accounting Policies and Estimates**

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

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

## **Clinical Trial Accruals**

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

## Stock-Based Compensation

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

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

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

• the grants involved illiquid securities in a private company;

• the options to acquire shares of our common stock were subject to vesting, generally vesting over a four-year period;

• our performance and the status of our research and development efforts;

• our stage of development and business strategy, including the status and timing of expected CE Mark clearance and our PMA submission with the FDA and the likelihood and timing of product launch;

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

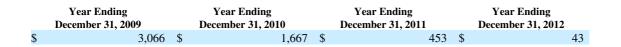
• the likelihood of achieving a liquidity event for the shares of our common stock, such as an initial public offering or sale of our company, given market conditions; and

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

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

Effective January 1, 2006, we adopted SFAS 123(R) using the prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards granted, modified and settled to our employees and directors after January 1, 2006. During 2008, we granted stock options to employees to purchase approximately 1,079,000 shares of common stock with a weighted-average exercise price of \$6.04 per share under the Black-Scholes valuation model.

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



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

#### **Recent Accounting Pronouncements**

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

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

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

No. 159 is effective for fiscal years beginning after November 15, 2007. Currently, we have not expanded our eligible items subject to the fair value option under SFAS No. 159. The adoption of SFAS 159 has not impacted our results of operations and financial condition.

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

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

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

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

## Interest rate risk

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

#### Exchange rate risk

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

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

## **ITEM 8. FINANCIAL STATEMENTS**

# XTENT, INC.

## INDEX TO FINANCIAL STATEMENTS

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of XTENT, Inc.

(a development stage company)

In our opinion, the accompanying balance sheets and the related statements of operations, of stockholders equity (deficit) and of cash flows present fairly, in all material respects, the financial position of XTENT, Inc. (a development stage company) at December 31, 2008 and 2007, and the results of its operations and its cash flows, for each of the three years in the period ended December 31, 2008 and, cumulatively for the period from June 13, 2002 (Inception) to December 31, 2008, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

#### /s/ PRICEWATERHOUSECOOPERS LLP

San Jose, California March 24, 2009

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## XTENT, INC.

## (a development stage company)

## **BALANCE SHEETS**

#### (in thousands, except per share amounts)

		Decem		
	20	008		2007
ASSETS				
Current assets:				
Cash and cash equivalents	\$	13,373	\$	13,366
Short-term investments		5,752		44,394
Prepaid expenses and other current assets		432		905
Total current assets		19,557		58,665
Property and equipment, net		4,100		3,601
Other non-current assets		338		149

Total assets	\$ 23,995	\$ 62,415
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 943	\$ 1,960
Accrued liabilities	1,544	2,124
Total current liabilities	2,487	4,084
Commitments and Contingencies (note 6)		
Stockholders equity		
Common stock: \$0.001 par value 100,000 shares authorized at December 31, 2008 and		
December 31, 2007 23,325 and 23,015 shares issued and outstanding at December 31,		
2008 and December 31, 2007, respectively	23	23
Additional paid-in capital	155,511	151,496
Deferred stock-based compensation	(56)	(364)
Accumulated other comprehensive income	11	36
Deficit accumulated during the development stage	(133,981)	(92,860)
Total stockholders equity	21,508	58,331
Total liabilities and stockholders equity	\$ 23,995	\$ 62,415

The accompanying notes are an integral part of these financial statements

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## XTENT, INC.

## (a development stage company)

## STATEMENTS OF OPERATIONS

## (in thousands, except per share amounts)

	Y 2008	ear Ei	nded December 31 2007	,	2006	Pe Jur (In	mmulative riod from ne 13, 2002 ception) to cember 31, 2008
Operating expenses:							
Research and development (1)	\$ 31,170	\$	30,888	\$	18,923	\$	105,584
General and administrative (1)	10,917		11,269		7,258		34,460
Total operating expenses	42,087		42,157		26,181		140,044
Loss from operations	(42,087)		(42,157)		(26,181)		(140,044)
Interest and other income, net	966		3,363		1,137		6,063
Net loss	(41,121)		(38,794)		(25,044)		(133,981)
Deemed dividend related to beneficial conversion feature of							
redeemable convertible preferred stock					(13,095)		(13,095)

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Net loss attributable to common stockholders	\$	(41,121)	\$	(38,794)	\$ (38,139) \$	(147,076)
Net loss per share attributable to common stockholders -						
basic and diluted	\$	(1.78)	\$	(1.87)	\$ (13.96)	
Weighted-average common shares outstanding - basic and						
diluted		23,116		20,703	2,732	
(1) Includes the following stock-based compensation charge	s:					
Research and development	\$	1,41	8 \$	1,490	\$ 1,258 \$	4,479
General and administrative	\$	2,43	5 \$	2,088	\$ 986 \$	5,589

The accompanying notes are an integral part of these financial statements

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## XTENT, INC.

## (a development stage company)

# STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

## (in thousands, except per share amounts)

	Comm Shares	on Stock Amount	Additional Paid-in Capital	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders Equity (Deficit)
Inception:							
Issuance of common stock to founders at							
\$0.001 per share in exchange for cash	1,625	\$ 2	\$ 2	\$	\$	\$	\$ 4
Exercise of stock options for cash at \$0.001							
per share	62						
Stock-based compensation for non employees		2					2
Net loss						(2,124)	(2,124)
Balance at December 31, 2002	1,687	2	4			(2,124)	(2,118)
Issuance of common stock for services							
received in July 2003	15		6				6
Stock-based compensation for non-employees			6				6
Exercise of stock options for cash at \$0.20 per							
share	10		2				2
Net loss						(3,977)	(3,977)
Balance at December 31, 2003	1,712	2	18			(6,101)	(6,081)
Issuance of common stock for services							
received in May 2004	100		40				40
Exercise of stock options for cash at \$0.20							
and \$0.40 per share	10		2				2
Stock-based compensation for non-employees			5				5
Net loss						(8,891)	(8,891)
Balance at December 31, 2004	1,822	2	65			(14,992)	(14,925)

Exercise of stock options for cash at \$0.20	1 1 ( 1	1	12				
and \$0.40 per share Vesting of restricted common stock from	1,161	1	43				44
early exercises			159				159
Deferred stock-based compensation			1,272	(1,272)			107
Amortization of deferred stock-based							
compensation				226			226
Stock-based compensation for non-employees			154			(11000)	154
Net loss Balance et December 31, 2005	2,983	3	1,693	(1,046)		(14,030) (29,022)	(14,030)
Balance at December 31, 2005	2,985	5	1,095	(1,040)		(29,022)	(28,372)
Issuance of common stock for services	15		185				185
Exercise of stock options for cash at \$0.20 to							
\$3.50 per share	354		92				92
Vesting of restricted common stock from							
early exercises			115				115
Amortization of deferred stock-based compensation				302			302
Reversal of deferred stock-based				302			302
compensation			(71)	71			
Stock-based compensation for non-employees			539				539
Employee stock-based compensation under							
SFAS No. 123R			1,403				1,403
Beneficial conversion feature on issuance of							
Series C & D redeemable convertible preferred stock			13,095				13,095
Deemed dividend related to Beneficial			15,075				15,075
conversion feature on the issuance of							
Series C & D redeemable convertible							
preferred stock			(13,095)				(13,095)
Net loss	2.252	2	2.056	((72)		(25,044)	(25,044)
Balance at December 31, 2006	3,352	3	3,956	(673)		(54,066)	(50,780)
Common stock issued in connection with our							
Initial Public Offering	4,700	5	68,232				68,237
Conversion of redeemable convertible							
preferred stock to common stock upon Initial							
Public Offering	14,744	15	75,578				75,593
Exercise of stock options for cash at \$0.20 to \$3.50 per share	192		111				111
Issuance of common stock under employee	172		111				111
stock purchase plan	27		249				249
Vesting of restricted common stock from							
early exercises			101				101
Amortization of deferred stock-based				285			285
compensation Reversal of deferred stock-based				283			283
compensation			(24)	24			
Stock-based compensation for non-employees			155				155
Employee stock-based compensation under							
SFAS No. 123R			3,138			(20.50.0)	3,138
Net loss						(38,794)	(38,794)
Net unrealized gains on available-for-sale securities					36		36
Total comprehensive loss					50		(38,758)
Balance at December 31, 2007	23,015	23	151,496	(364)	36	(92,860)	58,331
Exercise of stock options for cash at \$0.20 to	175		106				106
\$9.20 per share Issuance of common stock under employee	175		100				106
stock purchase plan	85		151				151
Issuance of common stock for patent rights	50		150				150
Vesting of restricted common stock from							
early exercises			63				63
Amortization of deferred stock-based				242			242
compensation Reversal of deferred stock-based				242			242
compensation			(66)	66			
Stock-based compensation for non-employees			21				21
-							

Employee stock-based compensation under											
SFAS No. 123R					3,590						3,590
Net loss										(41,121)	(41,121)
Net unrealized loss on available-for-sale											
securties								(25)			(25)
Total comprehensive loss											(41,146)
Balance at December 31, 2008	23,325	\$	23	\$	155,511	\$	(56) \$	11	\$	(133,981) \$	21,508
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The accompanying notes are an integral part of these financial statements

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## XTENT, INC.

## (a development stage company)

## STATEMENTS OF CASH FLOWS

## (in thousands)

	Y 2008	ear En	ided December 31, 2007	2006	Cummulative Period from June 13, 2002 (Date of Inception) to December 31, 2008
Cash flows from operating activities:					
Net loss	\$ (41,121)	\$	(38,794)	\$ (25,044)	\$ (133,981)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization	1,304		1,137	789	4,021
Accretion of securities discount	(366)		(1,705)		(2,071)
Loss (gain) on sale of investments	(26)		20		(6)
Loss on disposal of property and equipment	25		81	10	188
Stock-based compensation expense	3,853		3,578	2,244	10,068
Stock issued in exchange for services and patents	150			185	381
Changes in operating assets and liabilities:					
Prepaid expenses and other current assets	(30)		(290)	(206)	(712)
Accrued interest receivable on securities	344		(372)		(28)
Accounts payable	(1,017)		1,100	332	828
Accrued liabilities	(517)		892	783	1,656
Net cash used in operating activities	(37,401)		(34,353)	(20,907)	(119,656)
Cash flows from investing activities:					
Purchase of investments	(24,084)		(118,238)		(142,322)
Proceeds from maturities of investments	53,130		71,579		124,709
Proceeds from sale of investments	9,963		3,986		13,949
Purchase of property and equipment	(1,830)		(2,185)	(1,661)	(8,306)
Restricted cash	(30)			150	(30)
Proceeds from sale of property and equipment	2			3	20
Net cash provided by (used in) investing activities	37,151		(44,858)	(1,508)	(11,980)

Cash flows from financing activities:				
Proceeds from issuance of redeemable convertible				
preferred stock, net of issuance costs			39,692	75,592
Proceeds from initial public offering, net of offering costs		69,112	(875)	68,237
Principal payments on capital lease obligations				(23)
Proceeds from issuance of common stock and exercise of				
stock options	257	360	139	1,203
Net cash provided by financing activities	257	69,472	38,956	145,009
Net increase (decrease) in cash and cash equivalents	7	(9,739)	16,541	13,373
Cash and cash equivalents at beginning of period	13,366	23,105	6,564	
Cash and cash equivalents at end of period	\$ 13,373	\$ 13,366	\$ 23,105 \$	13,373
Supplemental disclosure of noncash investing and				
financing activities:				
Deferred stock-based compensation	\$	\$	\$ \$	1,272
Reversal of deferred stock-based compensation	\$ (66)	\$ (24)	\$ (71) \$	(161)
Dividend related to beneficial conversion feature of				
redeemable convertible preferred stock	\$	\$	\$ (13,095) \$	(13,095)
Equipment acquired under capital leases	\$	\$	\$ \$	(23)
Vesting of restricted common stock from early exercises	\$ 63	\$ 101	\$ 115 \$	438
Deferred initial public offering costs	\$	\$ 875	\$ \$	875
Changes in net unrealized gains on investments	\$ (25)	\$ 36	\$ \$	11

The accompanying notes are an integral part of these financial statements

#### B-63

## XTENT, INC.

#### (a development stage company)

## NOTES TO FINANCIAL STATEMENTS

## NOTE 1. DESCRIPTION OF BUSINESS

The Company

XTENT, Inc. (the Company ) was incorporated in the state of Delaware on June 13, 2002 (Inception), and is focused on developing and commercializing innovative drug eluting stent systems for the treatment of coronary artery disease. The Company is in the development stage and since inception has devoted substantially all of its time and efforts to developing products, raising capital and recruiting personnel.

The Company has incurred net operating losses each year since inception. At December 31, 2008, the Company had an accumulated deficit of \$134.0 million and cash and cash equivalents and short term investments of \$19.1 million. The Company has not achieved positive cash flows from operations. In May and June 2006, the Company completed a Series D redeemable convertible preferred stock financing and raised

approximately \$30.0 million in cash and on February 1, 2007 completed its initial public offering raising net proceeds of \$68.2 million (the Initial Public Offering ). In January 2009, the Company announced an initiative to reduce its workforce by 115, or 94%. See Note 13. The Company plans to explore strategic financing alternatives in the first half of 2009, which may include, without limitation, a merger, a sale of substantially all Company assets, a financing, or a sale of a portion of Company assets, such as the peripheral stent product, the drug eluting balloon product, or the bioabsorbable stent product. If the Company is successful in identifying and completing a suitable strategic transaction, substantial changes may be made in its operations. Upon completion of the headcount reduction in the first quarter of 2009, the Company expects that it will have enough cash and cash equivalents to fund limited operations through at least December 31, 2009. If a strategic transaction is not completed or adequate funding is not obtained, the Company will be unable to continue operations and may need to wind up its business and liquidate its assets.

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

## NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements or the original issuance date, if later, and reported amounts of expenses during the reporting period. The primary estimates underlying our financial statements include the fair value of our investment portfolio, income tax valuation, and assumptions regarding variables used in calculating the fair value of our equity awards. Actual results could differ from those estimates.

### Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company deposits cash and cash equivalents with high credit quality financial institutions. Cash equivalents consist primarily of money market funds and U.S. Treasury notes.

#### Investments

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

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

investment. Realized gains and losses on investments sold are included in interest and other income, net in the Company s statement of operations.

## **XTENT, INC.**

#### (a development stage company)

## NOTES TO FINANCIAL STATEMENTS

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

#### **Restricted Cash**

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

**Concentration of Credit Risk** 

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

## **Risks and Uncertainties**

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

The Company has a limited operating history and has yet to generate any revenues from customers. To date, the Company has been funded by private equity financings and its Initial Public Offering in February 2007. The Company plans to explore strategic financing alternatives in the first half of 2009, which may include, without limitation, a merger, a sale of substantially all Company assets, a financing, or a sale of a portion of Company assets, such as the peripheral stent product, the drug eluting balloon product, or the bioabsorbable stent product.

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

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

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

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

Based on the prolific litigation that has occurred in the stent industry and the fact that the Company may pose a competitive threat to some large and well-capitalized companies who own or control patents relating to stents and their use, manufacture and delivery, one or more third parties may assert a patent infringement claim against the Company based on

## XTENT, INC.

#### (a development stage company)

## NOTES TO FINANCIAL STATEMENTS

one or more of these patents. A number of these patents are owned by very large and well-capitalized companies that are active participants in the stent market. Because patent applications can take many years to issue, there may be currently pending applications, unknown to the Company, which may later result in issued patents that pose a material risk to the Company.

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

#### Segment Information

The Company currently operates as one business segment focusing on the development and commercialization of innovative drug eluting stent systems for the treatment of coronary artery disease. The Company is not organized by market and is managed and operated as one business. A single management team reports to the chief operating decision maker who comprehensively manages the entire business.

#### Fair Value of Financial Instruments

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

#### **Property and Equipment**

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

## Impairment of Long-Lived Assets

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

## **Research and Development**

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

## Income Taxes

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

## XTENT, INC.

## (a development stage company)

## NOTES TO FINANCIAL STATEMENTS

#### Comprehensive Income (Loss)

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

#### Net Loss per Common Share

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

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

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

#### (a development stage company)

## NOTES TO FINANCIAL STATEMENTS

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

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

#### Stock-Based Compensation

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

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

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

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

#### **Beneficial Conversion Feature**

When the Company issues equity securities which are convertible into common stock at a discount from the common fair value at the commitment date, the difference between the fair value of the common stock and the conversion price multiplied by the number of shares issuable upon conversion is recognized as a beneficial conversion feature. The beneficial conversion feature is presented as a deemed dividend to the related security holders with an offsetting amount to additional paid in capital and will be amortized over the period from the issue date to the first conversion date. Since the equity securities were immediately convertible into common stock by the holder at any time, the Company recorded and immediately amortized a beneficial conversion charge (deemed dividend) of approximately \$13.1 million in connection with its Series C and D redeemable convertible preferred stock financings in January, May and June 2006.

## (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

#### **Recent Accounting Pronouncements**

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

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

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

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

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

## (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

## NOTE 3. INVESTMENTS

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

As of December 31, 2008	А	mortized Cost	U	nrealized Gains (in tho	Unrealize Losses usands)	d	Fair Value
U.S. government and agency securities	\$	5,741	\$	11	\$		\$ 5,752
As of December 31, 2007		ortized Cost	-	realized Gains (in thou	Unrealized Losses sands)		Fair Value
Commercial paper	\$	4,685	\$	21	\$		\$ 4,706
U.S. government and agency securities		33,694		21		(9)	33,706
Corporate bonds		5,979		3		(-)	5,982

## Fair Value Measurements

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

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

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

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

## (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

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

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

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

## NOTE 4. PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

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

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

## (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

## NOTE 5. ACCRUED LIABILITIES

Accrued liabilities consist of the following:

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

# NOTE 6. COMMITMENTS AND CONTINGENCIES

### **Operating Lease Commitments**

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

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

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

Rent expense for the years ended December 31, 2008, 2007, and 2006, and cumulatively for the period from June 13, 2002 (Inception) to December 31, 2008 was approximately \$407,000, \$333,000, \$224,000 and \$1.3 million, respectively. The terms of the facility lease provide for rental payments on a monthly basis and on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid.

### License Agreements

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

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

#### (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

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

#### **Purchase Commitments**

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

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

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

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

On April 7, 2008, the Company entered into an agreement with Vascotube GMBH under which the Company has committed to purchase minimum quantities of material over the next twelve month period. As of December 31, 2008, the Company has a remaining commitment in the amount of approximately \$389,000 remaining under this agreement. See Note 13, Subsequent Events.

### Contingencies

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

#### Indemnification

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

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

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# **XTENT, INC.**

#### (a development stage company)

## NOTES TO FINANCIAL STATEMENTS

# NOTE 7. PREFERRED STOCK

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

#### NOTE 8. COMMON STOCK

On January 22, 2007, the Company effected a 1-for-2 reverse stock split of its common stock and redeemable convertible preferred stock pursuant to the filing of an Amended and Restated Certificate of Incorporation. Such Amended and Restated Certificate of Incorporation also

provided for the automatic conversion of the then outstanding shares of redeemable convertible preferred stock into shares of common stock. All share and per share amounts included in the Company s financial statements have been adjusted to reflect this reverse stock split for all periods presented.

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

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

#### Restricted common stock

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

# NOTE 9. STOCK PLANS

#### **Employee Stock Purchase Plan**

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

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

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

#### (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

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

#### Stock Option Plans

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

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

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

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

# (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

Stock option activity is as follows:

				Ontions O	utstanding	
			V	Veighted	Weighted	
	Shares	Number		Average	Average	Aggregate
	Available for Grant	of Shares	1	Exercise Price	Contractual Term (years)	Intrinsic Value
	ior Grant		s, except		ge exercise price)	value
			<i>·</i>	5		
Shares reserved at plan inception	625					
Options granted	(178)	178	\$	0.20		
Options exercised		(62)		0.20		
Balances, December 31, 2002	447	116		0.20		
Additional shares reserved	435					
Options granted	(493)	493		0.34		
Options exercised	(1)3)	(10)		0.20		
Balances, December 31, 2003	389	599		0.32		
,		•••				
Additional shares reserved	1,050					
Options granted	(1,162)	1,162		0.40		
Options exercised		(10)		0.20		
Options forfeited/expired	20	(20)		0.24		
Balances, December 31, 2004	297	1,731		0.38		
Additional shares reserved	1,013					
Options granted	(686)	686		0.42		
Options exercised	(000)	(1,161)		0.38		
Options forfeited/expired	131	(1,101)		0.40		
Balances, December 31, 2005	755	1,125		0.40		
	,00	1,120		0.10		
Additional shares reserved	500					
Options granted	(1,166)	1,166		4.80		
Options exercised		(354)		0.39		
Options cancelled	43	(43)		1.50		
Balances, December 31, 2006	132	1,894	\$	3.09		
Additional shares recorded	400					
Additional shares reserved Options granted	(561)	561		10.32		
Options exercised	(501)	(192)		0.58		
Options cancelled	96	(192)		4.57		
Balances, December 31, 2007	67	2,167	\$	5.12		
		2,107	Ψ	5.12		
Additional shares reserved	1,821					
Options granted	(1,079)	1,079		6.04		
Options exercised		(175)		0.61		
- F						
Options cancelled	555	(555) 2,516		6.75		

Options vested and expected to vest				
at December 31, 2008	2,429	\$ 5.45	7.87	\$ 1
Options vested and exercisable at				
December 31, 2008	1,209	\$ 4.75	7.03	\$ 1

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

# (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

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

Ontions ()	Outstanding at December 31	Options Vested and Exercisable at December 31, 2008					
Exercise Price	JULI 31, 24	Weighted - Average Exercise Price					
\$0.20 - \$0.20	304	5.42	292	\$	0.39		
\$0.54 - \$1.5	190	6.98	137		1.19		
\$2.10 - \$2.99	339	9.45	22		2.50		
\$3.50 - \$4.56	408	7.61	227		3.52		
\$5.00 - \$5.20	339	8.50	125		5.15		
\$6.52 - \$7.82	62	7.99	43		7.72		
\$8.00 - \$8.94	114	7.72	78		8.77		
\$9.06 - \$9.99	548	8.66	191		9.67		
\$10.08 - \$11.20	134	8.15	58		10.78		
\$12.32 - \$16.00	78	7.99	36		13.39		
	2,516	7.91	1,209	\$	4.75		

Options Ou	tstanding at December 31	, 2007 Weighted - Average	Options Exerc Decemb	isable	at					
Exercise Price	Number	Remaining Contractual Life (Years)	Number		Average Exercise Price					
Price Number Life (Years) Number Price (in thousands, except weighted average remaining contractual life and weighted average exercise price)										
\$0.20 - \$0.20	35	5.08	35	\$	0.20					
\$0.40 - \$0.40	426	6.61	312		0.40					
\$0.54 - \$1.50	217	7.90	103		1.13					
\$3.50 - \$3.50	522	8.32	209		3.50					
\$5.20 - \$7.82	239	8.47	111		6.05					
\$8.00 - \$9.20	300	9.30	36		9.20					
\$9.58 - \$10.52	244	9.77	5		9.99					
\$11.00 - \$13.00	143	9.03	25		11.86					
\$15.44 - \$15.44	11	9.11			0					
\$16.00 - \$16.00	30	9.08			0					

2,167	8.27	836	\$ 2.79

#### (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

The weighted-average per share fair value of options granted to employees during the years ending December 31, 2008, 2007 and 2006 was \$3.04, \$5.11, and \$9.07 per share, respectively.

#### **Deferred Stock-Based Compensation**

In May 2003, the Company determined the fair value of common stock to be \$0.40 per share, upon issuance of its Series B redeemable convertible preferred stock. At December 31, 2005, the fair value of the common stock was determined to be \$7.94 per share. All options granted were intended to be exercisable at a price per share not less than fair market value of the shares of the Company s stock underlying those options on their respective dates of grant. The Board of Directors determined these fair market values in good faith based on the best information available to the Board of Directors and Company s management at the time of the grant. Although the Company believes these determinations accurately reflect the historical value of the Company s common stock, management has retroactively revised the valuation of its common stock for the purpose of calculating stock-based compensation expense for all grants after December 31, 2004 through our Initial Public Offering on February 1, 2007. The Company s progress against milestones in these areas was used to estimate the fair value of its common stock. In accordance with the requirements of APB 25, the Company has recorded deferred stock-based compensation for the difference between the exercise price of the stock options and the fair value of the Company s common stock at the date of grant for options granted during 2004 and 2005. This deferred stock-based compensation is amortized to expense on a straight-line basis over the period during which the options vest, generally over four years.

During the year ended December 31, 2005, the Company recorded deferred stock-based compensation related to these stock options of approximately \$1,272,000, net of cancellations. During the years ended December 31, 2008 and 2007, the Company recorded cancellations of deferred stock-based compensation of approximately \$66,000 and \$24,000, respectively.

Amortization of deferred stock-based compensation was approximately \$242,000, \$285,000 and \$302,000 for the years ended December 31, 2008, 2007 and 2006, respectively. For options granted during 2007 and 2006, the fair value of the stock on the date of grant is considered when determining the fair value of the stock option under the provisions of SFAS 123(R).

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

Grants Made During the Quarter Ended:	Number of Options Granted	Av Ex P Per	ighted- /erage /ercise Price · Share nds, except v	Av I V Per	ighted- /erage Fair /alue · Share average pric	Weighted- Average Intrinsic Value Per Share
March 31, 2005	515	\$	0.40	\$	1.66	\$ 1.26

June 30, 2005	23	0.54	4.16	3.62
September 30, 2005	79	0.54	5.42	4.88
December 31, 2005	30	0.54	7.48	6.94
March 31, 2006	174	1.50	9.20	7.70
June 30, 2006	735	3.92	11.19	7.27
September 30, 2006	190	8.74	12.32	3.58
December 31, 2006	67	11.94	13.85	1.91
March 31, 2007	66	15.01	15.82	0.81

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

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## XTENT, INC.

#### (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

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

	Year Ended December 31,							
		2008	(in	2007 thousands)		2006		
Research and development	\$	1,418	\$	1,490	\$	1,258		
General and administrative		2,435		2,088		986		
Total stock-based compensation expense	\$	3,853	\$	3,578	\$	2,244		

No income tax benefit has been recognized relating to stock-based compensation expense and no tax benefits have been realized from exercised stock options.

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

The Company estimates the fair value of stock options using the Black-Scholes option valuation model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards.

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

Year Ended December 31, 2008	Year Ended December 31, 2007	Year Ended December 31, 2006
60% to 76%	51% to 54%	58% to 70%
2.45% to 3.57%	3.51% 5.10%	4.38% 4.95%
0%	0%	0%
4.5 to 4.65	4.65	5.75 to 6.25
42% to 120%	42% to 50%	N/A
.81% to 3.56%	3.56% 5.13%	N/A
0%	0%	N/A
0.5	.49 to .79	N/A
	December 31, 2008 60% to 76% 2.45% to 3.57% 0% 4.5 to 4.65 42% to 120% .81% to 3.56% 0%	December 31, 2008         December 31, 2007 $60\%$ to 76% $51\%$ to $54\%$ $2.45\%$ to $3.57\%$ $3.51\%$ $0\%$ $0\%$ $4.5$ to $4.65$ $42\%$ to $120\%$ $42\%$ to $50\%$ $8.1\%$ to $3.56\%$ $0\%$ $0\%$ $0\%$

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

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

#### (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

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

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

#### Non-Employee Stock-based Compensation

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

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

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

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

#### NOTE 10. INCOME TAXES

Due to the Company s operating loss, there was no provision for federal or state income taxes for the years ended December 31, 2008, 2007 and 2006. The Company recorded a tax benefit of \$39,000 for the year ended December 31, 2008 primarily due to recognition of a benefit of \$39,000 for a U.S. federal refundable credit as provided by the Housing and Economic Recovery Act of 2008 ( The Recovery Act ). The Recovery Act, signed into law in July 2008, allows taxpayers to claim refundable alternative minimum tax or research and development credit carryovers if they forego bonus depreciation on certain qualified fixed assets placed in service from the period between April and December 2008.

## (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

The tax effects of temporary differences and carry-forwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	December 31,				
		2008		2007	
Deferred tax assets:					
Net operating loss carryforwards	\$	37,754	\$	25,321	
Research & development credit carryforwards and other		7,111		5,257	
Capitalized start-up costs		10,917		8,515	
Other		2,384		1,749	
		58,166		40,842	
Valuation allowance		(58,166)		(40,842)	
Net deferred tax assets	\$		\$		

The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of such assets. The valuation allowance increased \$17,324,000, \$16,768,000 and \$11,024,000 during the years ended December 31, 2008, 2007 and 2006, respectively.

As of December 31, 2008, the Company had net operating loss carry-forwards of approximately \$94.8 million each available to reduce future taxable income, if any, for federal and California state income tax purposes. The federal net operating loss carry-forward begins expiring in 2022, and state net operating loss carry-forward begins expiring in 2015.

As of December 31, 2008, the Company had research and development credit carry-forwards of approximately \$4.2 million and \$4.4 million available to reduce future taxable income, if any, for federal and California state tax purposes, respectively. The federal credit carry-forwards begin expiring in 2022, and the state credits carry-forward indefinitely.

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

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

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

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

# NOTE 11. REDUCTION IN FORCE

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

# NOTE 12. EMPLOYEE BENEFIT PLANS

The Company adopted a 401(k) Profit Sharing Plan and Trust covering substantially all of its employees. Company contributions to the plan are discretionary and as of December 31, 2008, no contributions have been made.



## (a development stage company)

# NOTES TO FINANCIAL STATEMENTS

## NOTE 13. SUBSEQUENT EVENTS

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

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

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

#### NOTE 14. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

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

	N	Aarch 31,	(in t	Fiscal 2008 Qu June 30, housands, except	Sej	otember 30,	Dec	cember 31,
Net loss	\$	(12,457)	\$	(12,886)	\$	(8,665)	\$	(7,113)
Net loss attibutable to common stockholders	\$	(12,457)	\$	(12,886)	\$	(8,665)	\$	(7,113)
Net loss per share attributable to common stockholders -								
basic and diluted	\$	(0.54)	\$	(0.56)	\$	(0.37)	\$	(0.31)
Weighted-average common shares outstanding used in computing basic and diluted net loss per common share		22,923		23,033		23,211		23,294

	Fiscal 2007 Quarters Ended										
	)			, _ ,						· · · · · ·	
			(in thousands, except per share amounts)								
Net loss	\$	(7,935)	\$	(9,456)	\$	(9,539)	\$	(11,864)			
Net loss attibutable to common stockholders	\$	(7,935)	\$	(9,456)	\$	(9,539)	\$	(11,864)			
	\$	(0.55)	\$	(0.42)	\$	(0.42)	\$	(0.52)			

Net loss per share attributable to common stockholders -				
basic and diluted				
Weighted-average common shares outstanding used in				
computing basic and diluted net loss per common share	14,482	22,551	22,656	22,790
	B-82			
	D 02			

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

None.

ITEM 9A.

# CONTROLS AND PROCEDURES

# **Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of our most recent fiscal year. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2008.

#### **Changes in Internal Control Over Financial Reporting**

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

#### Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based

on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2008. This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management s report in this Annual Report on Form 10-K.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2009 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our 2008 fiscal year (the 2009 Proxy Statement ).

# ITEM 11. EXECUTIVE COMPENSATION

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

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

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

# ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

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

# ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

# PART IV

# ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

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

(3) Exhibits.

#### Exhibit Number

ımber		Description
3.2	(1)	Amended and Restated Certificate of Incorporation.
3.4	(1)	Amended and Restated Bylaws.
4.1	(1)	Specimen Common Stock certificate of the Registrant.
10.1	(1)	Form of Indemnification Agreement for directors and executive officers.
10.2	(1)	2002 Stock Plan and form of stock option agreements used thereunder.
10.3	(1)	2006 Equity Incentive Plan and form of stock option agreement used thereunder.
10.4	(1)	2006 Employee Stock Purchase Plan.
10.5	(1)	Amended and Restated Investor Rights Agreement dated May 5, 2006 by and among the Registrant and certain stockholders.
10.6	(1)	Business Park Lease dated September 15, 2003, as amended November 22, 2005, by and between the Registrant and 125 Constitution Associates, L.P. for office space located at 125 Constitution Drive, Menlo Park, California, 94025-1118.
10.7	(1)	License Agreement dated May 4, 2004 as amended February 9, 2005, by and between the Registrant, Biosensors International Group, Ltd. (formerly Sun Biomedical, Ltd.), and Biosensors Europe SA (an affiliate of Occam International, B.V.)
10.8	(1)	Master License Agreement dated December 30, 2002, as amended June 30, 2006, by and between the Registrant and SurModics, Inc.
10.9	(1)	License Agreement dated July 10, 2006 by and between the Registrant and Millimed A/S.
10.10	(2)	Supply Agreement dated April 2, 2007 by and between Registrant and Fortimedix B.V.
10.11	(3)	Second Amendment to Lease dated May 17, 2007 by and between the Registrant and 125 Constitution Associates, L.P.
10.12	(4)	Amended and Restated License Agreement dated December 3, 2007 by and between Registrant, Biosensors International Group, Ltd. and Biosensors Europe S.A.
10.13	(5)	Amended 2006 Equity Incentive Plan and form of stock option agreement used thereunder.
23.1		Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1		Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2		Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1		Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the
		Sarbanes-Oxley Act of 2002.
32.2		Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the
		Sarbanes-Oxley Act of 2002.

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

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

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

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

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

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

# SIGNATURES

Pursuant to the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on our behalf by the undersigned, thereunto duly authorized.

Date: March 24, 2009

# **XTENT**, Inc.

By:

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

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

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

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

/s/ ALLAN R. WILL Allan R. Will Director

March 24, 2009

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Appendix C

# **UNITED STATES**

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# **FORM 10-K/A**

Amendment No. 1

(Mark One)

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

For the fiscal year ended December 31, 2008

or

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

Commission File Number 001-33282

# XTENT, INC.

(Exact name of Registrant as specified in its charter)

**Delaware** (State of incorporation)

41-2047573 (I.R.S. Employer Identification No.)

125 Constitution Drive Menlo Park, California 94025-1118

(Address of principal executive offices, including Zip Code)

### (650) 475-9400

(Registrant s telephone number, including area code)

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

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

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

None

(Title of Class)

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

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

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

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

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

Large accelerated filer o

Accelerated filer o

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

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

The aggregate market value of the voting stock held by non-affiliates of the Registrant, based upon the closing sale price of the common stock on the last day of its second fiscal quarter of 2008 was \$12,804,108. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

At March 5, 2009, the Registrant had 23,324,756 shares of Common Stock outstanding.

### EXPLANATORY NOTE

XTENT, Inc. is filing this Amendment No. 1 on Form 10-K/A to its Annual Report on Form 10-K for the fiscal year ended December 31, 2008, originally filed on March 24, 2009, for the purpose of including the information required by Part III of Form 10-K. Except as set forth herein, no other changes are made to our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

### PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

#### **Executive Officers and Directors**

The following table sets forth certain information concerning our executive officers and directors, as of April 1, 2009:

Name	Age	Position
Gregory D. Casciaro	52	President, Chief Executive Officer and Director
Timothy D. Kahlenberg	49	Chief Financial Officer
Randolph E. Campbell	51	Chief Technical Officer
Philippe H. Marco, M.D.	45	Vice President of Quality Assurance, Clinical and Regulatory Affairs
Henry A. Plain, Jr.(2)	51	Chairman of the Board of Directors
Michael A. Carusi	43	Director
Michael L. Eagle(2)(3)	61	Director
Robert E. Flaherty(1)(2)	63	Director
Edward W. Unkart(1)	59	Director
Christopher M. Smith(3)	46	Director
Arthur T. Taylor(1)	52	Director
Allan R. Will(3)	55	Director

(1)

Member of the audit committee.

(2)

Member of the compensation committee.

(3)

Member of the nominating and corporate governance committee.

*Gregory D. Casciaro* has served as our President and Chief Executive Officer and is a member of our board since September 2004. From February 2000 to August 2003, Mr. Casciaro was the President and Chief Executive Officer and a director of Orquest, a medical technology company. Mr. Casciaro holds a B.A. in Business Administration from Marquette University.

*Timothy D. Kahlenberg* has served as our Chief Financial Officer since April 2006. From May 2005 to April 2006, Mr. Kahlenberg was the director of finance at Medtronic, a medical technology company. From August 1999 to February 2004, Mr. Kahlenberg was the President and Chief Financial Officer of LuMend, a developer of medical devices to treat chronic total occlusions, which was acquired by Cordis Corporation, a Johnson & Johnson company, in September 2005. Mr. Kahlenberg holds a B.S. in Quantitative Business Analysis and an M.B.A. from Indiana University.

*Randolph E. Campbell* has served as our Chief Technical Officer since April 2004. From October 2001 to April 2004, Mr. Campbell served as the Vice President of Manufacturing at Emphasys Medical, a developer of medical devices for the treatment of chronic obstructive pulmonary disease. From January 1994 to September 2001, Mr. Campbell was the Vice President of Operations at Perclose, a developer of vascular access closure devices, which was acquired by Abbott Laboratories in November 1999. Mr. Campbell holds a B.S. in Chemical Engineering from the University of California, Berkeley.

*Philippe H. Marco, M.D.* has served as our Vice President of Quality Assurance, Clinical and Regulatory Affairs since January 2003. From July 1996 to December 2002, Dr. Marco served as the Director of Medical Affairs at Perclose. Following the acquisition of Perclose by Abbott Laboratories, Dr. Marco was responsible for worldwide clinical and regulatory affairs for Abbott Laboratories cardiovascular device division. Dr. Marco holds a M.D. from the University of Limoges and the University of Toulouse and completed a fellowship at the Pacific Foundation for Cardiovascular Research at Sequoia Hospital.

*Henry A. Plain, Jr.* has served on our board since June 2002 and as Chairman of our board since October 2004. Mr. Plain also served as our President and Chief Executive Officer from June 2002 to October 2004. Mr. Plain has been a General Partner at Morgenthaler Ventures, a venture capital firm, since September 2007 and he has been the Vice Chairman of the board of directors of The Foundry since July 2000. From February 1993 to November 1999, Mr. Plain was the President and Chief Executive Officer and a member of the board of directors of Perclose and directed Perclose through an initial public offering, a secondary offering and an acquisition by Abbott Laboratories in November 1999. Following the acquisition of Perclose by Abbott Laboratories, Mr. Plain served as the President of Perclose and Vice President of Hospital Products Division at Abbott Laboratories until May 2000. Mr. Plain also serves on the boards of several privately-held medical device companies. Mr. Plain holds a B.S. in Business Administration from the University of Missouri, Columbia.

*Michael A. Carusi* has served on our board since May 2003. He has been a General Partner at Advanced Technology Ventures, a venture capital firm, since October 1998. Mr. Carusi also serves on the board of TranS1, Inc., a public medical device company and on the boards of several privately-held life sciences and medical device companies. Mr. Carusi holds a B.S. in Mechanical Engineering from Lehigh University and an M.B.A. from Dartmouth College.

*Michael L. Eagle* has served on our board since August 2007. Mr. Eagle was Vice President-Manufacturing for Eli Lilly and Company from 1993-2001. He is a former CEO of IVAC Corporation, and Sr. VP of the Medical Devices and Diagnostics Division of Eli Lilly (later Guidant Corporation). He retired from Eli Lilly and Company in 2001. He serves on the board of directors of Somaxon Pharmaceutical, Micrus Endovascular and Symphony Medical. Mr. Eagle received his B.S. in Mechanical Engineering from Kettering University and his M.B.A. from the Krannert School of Management at Purdue University.

*Robert E. Flaherty* has served on our board since January 2007. Mr. Flaherty has served as Chairman, President and Chief Executive Officer of Athena Diagnostics, a commercial laboratory company, since 1992. Athena Diagnostics was acquired by Thermo Fisher Scientific in November 2006. Prior to Athena Diagnostics, Mr. Flaherty was employed by Becton, Dickinson and Company, a medical technology company, and held various positions including President of the Becton Dickinson Division. Mr. Flaherty holds a B.S. in Industrial Engineering from Lehigh University and an M.B.A. from Harvard University.

*Christopher M. Smith* has served on our board of directors since June 2008. He is the President of Cochlear Americas, a manufacturer of implantable hearing devices. Prior to Cochlear, he was a Consultant for Warburg Pincus, a direct equity healthcare investor, where he assisted Warburg in identifying market opportunities for investment. From August 2000 to October 2003, Mr. Smith served as Group President for Gyrus Group Plc, (a UK listed company), and as President and CEO-Director of Gyrus Medical. Mr. Smith also serves on the board of a private company. Mr. Smith received his B.S. in Journalism and Marketing from Texas A&M University.

*Arthur T. Taylor* has served on our board since June 2008. From November 2007 to May 2008, he was Vice-President, General Manager, Kyphon Products, Spinal & Biologics Business, Medtronic Inc. Prior to that, he was Chief Operating Officer of Kyphon, a medical device company, from 2006 until the company s acquisition by Medtronic in November 2007, having served as Chief Financial Officer of

Kyphon from 2004 to 2006. Prior to joining Kyphon, he was Senior Vice President, Chief Financial Officer of Terayon Communication Systems (subsequently acquired by Motorola) a broadband access and video processing technology company, from February 2003 to July 2004. Mr. Taylor holds a B.S. in Business Administration from San Diego State University and an M.B.A. from the University of Southern California.

*Edward W. Unkart* has served on our board since August 2006. Since January 2009, Mr. Unkart has been an independent consultant. From January 2005 to December 2008, Mr. Unkart served as Vice President of Finance and Administration and Chief Financial Officer of SurgRx, a manufacturer of medical devices used in surgery, which was acquired by Johnson & Johnson in October 2008. From June 2004 to December 2004, Mr. Unkart was an independent consultant. From May 2001 to May 2004, Mr. Unkart served as Vice President of Finance and Administration and Chief Financial Officer of Novacept, a manufacturer of medical devices for women shealthcare, which was acquired by Cytyc Corporation in March 2004. Mr. Unkart currently serves on the board of directors of VNUS Medical Technologies, a publicly-traded medical device company, and is the chairperson of its audit committee. Mr. Unkart also serves on the board of directors of a privately-held medical device company. Mr. Unkart is a Certified Public Accountant and holds a B.S. in Statistics and an M.B.A. from Stanford University.

*Allan R. Will* has served on our board since July 2002 and as Chairman of our board from July 2002 to October 2004. Mr. Will has been a Managing Director of Split Rock Partners, a venture capital firm, since July 2004. From November 2002 to June 2004, Mr. Will was a General Partner at St. Paul Venture Capital, a venture capital firm. Mr. Will is the founder and Chairman of the board of directors of The Foundry and served as its Chief Executive Officer from 1998 until 2002. Mr. Will also served as the interim Chief Executive Officer of Concentric Medical from 2001 to 2002, as Chief Executive Officer of Evalve from 1999 to 2000, as the President and Chief Executive Officer of AneuRx from 1994 to 1997. Mr. Will also serves on the boards of several privately-held medical device companies. Mr. Will holds a B.S. in Zoology from the University of Maryland and an M.S. in Management from the Massachusetts Institute of Technology.

### **Executive Officers**

Our executive officers are elected by, and serve at the discretion of, our board of directors. There are no family relationships among our directors and officers.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors, officers and beneficial owners of more than 10% of our Common Stock to file with the SEC and the National Association of Securities Dealers reports of ownership on Form 3 and reports of changes in ownership on Form 4 or Form 5. Such persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Based solely on our review of the copies of such forms received by us, or written representations from certain reporting persons that no forms were required for those persons, we believe that during the 2008 fiscal year, all filing requirements applicable to our officers, directors and greater than 10% beneficial owners were complied with except as set forth in this paragraph. On February 12, 2008, Brian J. Walsh, Jeffrey J. Grainger, Gregory D. Casciaro, Timothy D. Kahlenberg, Randolph E. Campbell, Philippe Marco and Anne-Marie Hodkinson each filed a Form 4 reporting one transaction that occurred on January 29, 2008.

### **Corporate Governance**

*Code of Business Conduct and Ethics.* We are committed to maintaining the highest standards of business conduct and ethics. We have adopted a Code of Business Conduct and Ethics (the Code ) for our directors, officers (including our principal executive officer and principal financial officer) and employees.

The Code reflects our values and the business practices and principles of behavior that support this commitment. We expect all of our directors, officers and employees to act ethically at all times. The Code satisfies SEC rules for a code of ethics required by Section 406 of the Sarbanes-Oxley Act of 2002, as well as the Nasdaq listing standards requirement for a code of conduct. The Code is available on our website at www.xtentinc.com under Company Investor Relations Corporate Governance. We will post any amendment to the Code, as well as any waivers that are required to be disclosed by the rules of the SEC or the Nasdaq, on our website. Any person may obtain a copy of our Code, free of charge, by making a request in writing to: XTENT, Inc. 125 Constitution Drive, Menlo Park, CA 94025, Attention: Investor Relations.

*Audit Committee.* Our board has a separate audit committee established in accordance with section 3(a)(58)(a) of the Securities Exchange Act of 1934, as amended (the Exchange Act ). The audit committee is responsible for the appointment, compensation and oversight of our external auditors. It reviews and provides direction with regard to our internal accounting procedures and reviews our financial statements and filings. The audit committee currently consists of Messrs. Taylor, Flaherty and Unkart. Mr. Unkart is the chairperson of our audit committee and our board has determined that both he and Mr. Taylor are our audit committee financial experts, as currently defined under the SEC rules. Our board has determined that all the members of our audit committee are considered to be independent within the meaning of applicable SEC and Nasdaq rules regarding audit committee members.

### ITEM 11. EXECUTIVE COMPENSATION

#### **Compensation Discussion and Analysis**

#### Overview

This compensation discussion and analysis section describes all material elements of our compensation programs for our chief executive officer, chief financial officer and each of our other three most highly compensated executive officers as of the end of the last fiscal year. We refer to these persons as our named executive officers.

The compensation committee of our board of directors has the primary authority for and is the decision-making body on all matters related to the compensation of our named executive officers. The compensation committee establishes compensation philosophy and approves all aspects of our executive compensation including plan design and administration.

#### **Compensation Program Objectives and Philosophy**

The goal of our compensation program is to provide competitive compensation to attract and retain executives with a proven track record of success in the medical device and biotech industries. The variable components of total compensation are designed to allow for above market median pay when executives achieve all of their pre-specified goals.

Our compensation program is designed to:

emphasize competitive market-based compensation packages, focusing on aligning individual performance and results with pay; and

• encourage strong organizational performance by establishing challenging goals and utilizing incentive programs tied to key business objectives to reward tangible business results.

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Our philosophy is to position total compensation at a level that is commensurate with our public company, pre-revenue status, relative to other comparable medical device and biotech companies. To this end, the compensation committee carefully reviewed the total compensation levels and the mix of

compensation components that contribute to total compensation using public information from 23 peer group companies.

#### **Peer Companies**

The compensation committee considers relevant market practices when setting executive compensation to ensure our ability to attract and retain high-caliber talent. In assessing market competitiveness, the compensation of our executive officers is reviewed against executive compensation at a designated set of companies (the executive peer group ). The executive peer group consists of 23 public medical device and biotech companies that:

- are similar to us in key parameters (i.e., revenue, net income, market capitalization, number of employees); and
- have executive officer positions that are comparable to ours in terms of breadth, complexity and scope of responsibilities.

The executive peer group is intended to reflect the nature of the business activities we are undertaking in order to develop our products. Our Custom NX DES System is a combination device which includes a novel interdigitated modular stent design and a Biolimus A9®/PolyLactic acid drug coating. Our compensation committee believes that because of the complexities associated with the development of this combination device, a peer group consisting entirely of medical device companies is not appropriate. As such, the executive peer group is comprised of two independent peer groups, medical device companies and biotech companies. To estimate competitive market values, medical device company comparator benchmarks are weighted at 67%, and biotech company comparator benchmarks are weighted at 33%. The companies comprising our executive peer group are set forth below:

*Medical Device Peers.* Bovie Medical, DexCom, Endocare, Endologix, Hansen Medical, Insulet Corporation, NMT Medical, Northstar Neuroscience, Oculus Innovative Sciences, Power Medical Interventions, SenoRx, TranS1, and Vyteris Holdings.

*Biotechnology Peers.* ACADIA Pharmaceuticals, Anika Therapeutics, Cytori Therapeutics, Dynavax Technologies, MDRNA, Osiris Therapeutics, Renovis, Rigel Pharmaceuticals, Unigene Laboratories and Vical.

#### **Independent Compensation Consultant**

The compensation committee has historically engaged Compensia, Inc., an independent outside consulting firm, to advise the compensation committee on matters related to executive officer compensation. Specifically, Compensia conducts a biennial review of proxies submitted by our Executive Peer Group to provide information on total compensation for named executive officers. Compensia also provides the compensation committee with relevant market data, updates on market trends, advice and guidance on compensation design and program administration.

### **Targeted** Compensation

Our compensation committee strives to set compensation targets that are competitive with the compensation practices of the executive peer group. It relies on proxy statements and its compensation consultant, Compensia for data on market pay practices and trends. To ensure the ability to attract and retain key executive officers the compensation committee formalized an executive pay philosophy in 2007, which positions the compensation of our executive officers between the 50th and 75th percentiles of the Executive Peer Group.

#### **Target Pay Position**

Base Salary	Annual Performance Bonus	Long-Term Incentives
62.5th Percentile of the	50th Percentile of the Executive Peer	50th Percentile of the Executive Peer
Executive Peer Group	Group	Group

#### 2009 Compensation

In January 2009, we announced that we had engaged Piper Jaffray & Co. to assist us in pursuing strategic alternatives which may include the sale of some or all of our assets or other types of merger or acquisition transactions intended to maximize shareholder value. In light of our ongoing efforts to explore such strategic alternatives and the uncertainty as to the structure of any strategic transaction we may consummate, or whether we will consummate a transaction at all, the compensation committee elected not to make any adjustments to executive salaries for 2009. In addition, the compensation committee has not established any equity incentive program for 2009, and except for the retention program described below, has not established any non-equity incentive program.

In January 2009, upon the recommendation of our compensation committee, our board of directors established a non-equity retention program for certain employees, including our executive officers. The program was established in order to provide an incentive for these personnel to continue their employment with the Company in order to complete the headcount reduction and facilitate a strategic transaction. The retention amounts for the officers are set forth below:

Name	Title	F	on-Equity Retention Amounts
Gregory D. Casciaro	President and Chief Executive Officer	\$	283,950
Timothy D. Kahlenberg	Chief Financial Officer	\$	96,180
Randolph E. Campbell	Chief Technical Officer	\$	114,150
Philippe Marco	Vice President, Quality Assurance, Clinical and Regulatory Affairs	\$	131,700
Anne-Marie Hodkinson	Vice President, Human Resources	\$	69,000

March 31, 2009 was the last day of employment for our Vice President of Human Resources, Anne-Marie Hodkinson and our Chief Financial Officer, Timothy D. Kahlenberg. Mr. Kahlenberg continues to provide services to us as a consultant. Ms. Hodkinson and Mr. Kahlenberg were paid the applicable retention amounts set forth above. On March 31, 2009, \$98,980 of Randolph E. Campbell s retention amount became payable. The remainder will be paid to Mr. Campbell provided he remains employed through an additional retention period.

#### **Components of Executive Compensation**

Our executive compensation programs consist of three major components to reward and motivate our executive officers: base salary, annual non-equity incentives and long-term equity incentives.

Individual performance has a significant impact on determining each compensation component. Each executive officer s annual performance is measured based on a thorough review of his or her contributions toward achievement of corporate goals and objectives. For executive officers other than Gregory D. Casciaro, our President and Chief Executive Officer, this annual review is conducted by Mr. Casciaro, with the feedback of peers and board members and then presented to our compensation committee for review and comment. The compensation committee conducts Mr. Casciaro s review with the chairman of the board soliciting input from board members.

*Base Salary.* Our base salary program focuses on remaining competitive, paying for performance, and properly compensating those executives with a broad scope of responsibilities. Salary levels are also adjusted based on the knowledge, skills and ability each executive brings to his or her role.

Generally, in the fourth quarter of each year, the executive officers annual base salaries for the following year are reviewed and approved by the compensation committee based on performance during the calendar year. Salary increases are based on a number of factors including:

- individual performance during the calendar year;
- salary relative to the Executive Peer Group;
- past performance and salary increases; and
- scope, complexity and level of responsibility.

The compensation committee reviews and approves base salaries for our named executive officers annually following a review of the above criteria.

#### Non-Equity Incentive Programs

*2008 Non-Equity Actual Payments.* During 2008, our Chief Executive Officer, Gregory D. Casciaro, was eligible to receive non-equity incentive program payments based upon the achievement of certain milestones and corporate objectives. Our compensation committee generally determines these milestones by the end of the first quarter of each year and assesses Mr. Casciaro s individual performance against the milestones throughout the year. Non-equity incentive amounts at threshold, target and maximum levels were based on the achievement of seven regulatory, operational and financial milestones. The threshold, target and maximum amounts represent the amount to be paid if all milestones are achieved at the threshold, target and maximum performance levels, respectively. Because non-equity incentive payments are based on the achievement of separate milestones, actual amounts paid could be less than the threshold, target and maximum amounts if some, but not all, milestones were achieved at their respective performance levels. Each respective milestone was determined by the compensation committee at the beginning of the calendar year. If all 2008 milestones were achieved at the target level, Mr. Casciaro would have received a non-equity incentive payment equal to 50% of his 2008 annual salary. If all milestones were achieved at the threshold level, he would have received a payment equal to 75% of the target amount. If all milestones were achieved at the maximum level, he would have received a payment equal to 125% of the target amount. Based on this structure, Mr. Casciaro would not have earned any non-equity incentive payments if no milestones were and would have earned up to, but not more than, a maximum non-equity incentive of \$221,625 if all milestones were achieved at the maximum performance level, as follows:

Threshold			Target	Maximum			
\$	106,380		\$ 177,300		\$	221,625	

Mr. Casciaro s actual earnings under the 2008 Non-Equity Incentive Program, based on the achievement of one objective at the threshold level were \$26,595 which amount was paid after verification and approval by our compensation committee.

The structure of the non-equity incentive program for the named executive officers was similar to that for Mr. Casciaro, except that each officer s target level non-equity incentive was equal to 30% of his or her base salary, and payments were tied to achievement of four regulatory, financial and operational corporate milestones. As with Mr. Casciaro s program, the threshold level payments were 75% of the target level payments and the maximum payments were 125% of the target level payments, as follows:

Named Executive Officer	Title	Threshold	Target	Maximum
Timothy D. Kahlenberg	Chief Financial Officer	\$ 59,513	\$ 79,350	\$ 99,188
Randolph E. Campbell	Chief Technical Officer	\$ 59,153	\$ 78,870	\$ 98,588
Philippe Marco	Vice President of Quality Assurance, Clinical			
	and Regulatory Affairs	\$ 53,865	\$ 71,820	\$ 89,775

Actual earnings under the 2008 Non-Equity Incentive Program were based on the achievement of one objective at the threshold level as verified and approved by the compensation committee and were as follows:

Named Executive				
Officer	Payment			
Timothy D. Kahlenberg	\$	14,880		
Randolph E. Campbell	\$	15,353		
Philippe Marco	\$	13,466		

At the time the 2008 Non-Equity Incentive Program was established in the fourth quarter of 2007, Anne-Marie Hodkinson was not an officer of the corporation however, she subsequently became an officer in the first quarter of 2008. For 2008, the compensation committee approved the payment of a bonus to Ms. Hodkinson in the amount of \$10,294.

Finally, in addition to the amounts set forth above, the Company s Board of Directors approved the payment of \$62,256 to each of Gregory D. Casciaro and Timothy D. Kahlenberg. These payments were made in the first quarter of 2009 to fulfill commitments made to these officers resulting from a reduction in 2008 equity incentive grants made to Mr. Casciaro and Mr. Kahlenberg and their acceptance of the remainder of their equity incentive grants at above market exercise prices.

**2008** *Stock Option Grants.* We believe equity ownership is important to provide our executive officers with long-term incentives to build value for our stockholders. In 2007, our board of directors implemented an equity incentive program for which all employees who joined the Company prior to July 1, 2007 were eligible, including executive officers. The program was intended to motivate employees to achieve certain corporate goals, to encourage retention, and to recognize performance. The program considered each officer s performance rating measured on a scale of 1 to 4. In determining eligibility for a stock option award and the number of stock options to be awarded, individual performance was given a 50% weighting. The achievement of certain predetermined corporate objectives was also given a 50% weighting. Targeted awards were benchmarked at the market median of our Executive Peer Group. Following completion of each executive s performance review and analysis of the achievement of identified corporate objectives for 2007 (one of three corporate objectives was achieved); individual awards were made to our executives utilizing the aforementioned calculation. Mr. Casciaro received a stock option grant of 81,225 shares. Stock option grants for the other officers ranged from 14,575 shares to 33,345 shares. The options for 2007 were granted to employees on January 29, 2008 following an automatic increase in our stock option pool, at an exercise price of \$9.96 per share with monthly vesting over a three year period commencing on the date of grant.

On March 31, 2008, options for 2008 were granted to employees at an exercise price of \$5.00 per share with monthly vesting over a three year period commencing on the date of grant. These grants were made to approximately 120 individuals, including our executive officers.

In August 2008, under an annual stock option refresh program, each of our officers also received a refresh stock option grant consistent with industry and market practices. Target ranges for the number of options granted to officers were established by our compensation committee, utilizing market data from

Compensia. For each officer, the August 2008 grant, when added to the options previously granted to that officer in March 2008 fell within the applicable target range. Within the target ranges, the number of options granted was based on performance evaluations. The grants were made at an exercise price of \$2.10 per share with monthly vesting over four years, except for the options granted to Mr. Casciaro and Mr. Kahlenberg which were made at an exercise price of \$4.50 per share.

Consistent with our practice in 2008, in the event recruiting resumes at the Company, our compensation committee will grant market-based options to all newly hired employees, other than executive officers, within stock option guidelines approved by our board. In the event any of the grants reviewed by the compensation committee are outside the range contained within the new hire stock option guidelines, we expect to obtain approval from our board in addition to the compensation committee. Each executive officer is initially provided with an option grant when he or she is hired or promoted based upon his or her position and relevant prior experience. These initial grants generally vest over a four year period commencing on the date employment starts or the promotion occurs, with 25% of the options granted vesting on the one year anniversary of that date and the remaining options vesting monthly thereafter. We spread the vesting of our options over four years to compensate executives for their contribution over a period of time. In addition to the initial option grants, our compensation committee recommends, and our board grants, additional options to retain our executives and combine the achievement of corporate goals and strong individual performance. Options are granted based on a combination of individual contributions and general corporate achievements, including clinical trial enrollment, product development and financial management. For example, if we were to hire a new vice president of business development, we would provide such executive with an initial option grant for a number of shares that is consistent with the market data that we receive from Compensia for comparable companies in the Executive Peer Group and information we receive from third-party compensation surveys. We would target a range between the 50th and 75th percentile of the levels at such comparable companies. On an annual basis, our compensation committee would assess the appropriate individual and corporate goals for this executive and provide additional option grants based upon the achievement by the executive of both individual and corporate goals. If recruiting resumes, we would expect to continue to provide new employees with initial option grants in 2009 to provide long-term compensation incentives and will continue to rely on performance-based and retention grants in 2009 to provide additional incentives for current employees. In the future our compensation committee and board may consider awarding additional or alternative forms of equity incentives, such as grants of restricted stock, restricted stock units and other performance based awards.

The specific provisions of our equity incentive plans are as set forth below:

*2002 Stock Plan.* Our sole director at the time adopted our 2002 Stock Plan in July 2002, and our stockholders approved our 2002 Stock Plan in July 2002. Our board has determined not to grant any additional awards under the 2002 Stock Plan, however, the 2002 Stock Plan will continue to govern the terms and conditions of the outstanding awards granted thereunder.

A total of 3,146,711 shares of our common stock are authorized for issuance under the 2002 Stock Plan. As of December 31, 2008, options to purchase a total of 1,205,361 shares of our common stock were issued and outstanding, and a total of 1,941,350 shares of our common stock had been issued upon the exercise of options and stock purchase rights granted under the 2002 Stock Plan.

Our 2002 Stock Plan provides for the grant of options and stock purchase rights to our service providers. Stock purchase rights and nonstatutory stock options may be granted to our employees, directors and consultants, and incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, may be granted only to our employees. Our compensation committee administers the 2002 Stock Plan. The administrator has the authority to determine the terms and conditions of the options and stock purchase rights granted under the 2002 Stock Plan.

Our 2002 Stock Plan does not allow for the transfer of awards other than by will or the laws of descent and distribution and only the recipient of an award may exercise such award during his or her lifetime.

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Our 2002 Stock Plan provides that in the event of our merger with or into another corporation, or a sale of substantially all of our assets, the successor corporation or its parent or subsidiary will assume or substitute for each outstanding stock purchase right and option. If the outstanding stock purchase rights or options are not assumed or substituted, they will become fully vested and exercisable for a 15-day period from the date the administrator provides notice of the vesting of outstanding options and stock purchase rights and will terminate at the end of such 15-day period.

### 2006 Equity Incentive Plan

Our board adopted, and our stockholders approved, our 2006 Equity Incentive Plan in August 2006. The 2006 Equity Incentive Plan became effective upon completion of our initial public offering in February 2007. In April 2008, our board adopted the Amended 2006 Equity Incentive Plan, or the Amended Plan, and in June 2008, our stockholders approved the Amended Plan. The reasons for amending the plan were to satisfy certain provisions of Section 162(m) of the Internal Revenue Code and to increase the number of shares available for issuance under the plan by 900,000 shares.

Our Amended Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors and consultants.

As of December 31, 2008, 2,669,413 shares of our common stock were reserved for issuance pursuant to the Amended Plan and 1,305,317 of those shares were issued and outstanding. In addition, the shares reserved for issuance under our Amended Plan include (a) those shares reserved but unissued under the 2002 Stock Plan as of January 31, 2007 (b) shares returned to the 2002 Stock Plan as the result of termination of options or the repurchase of shares (provided that the maximum number of shares that may be added to the 2006 Equity Incentive Plan pursuant to (a) and (b) is 600,000 shares). The number of shares available for issuance under the Amended Plan increases annually on the first day of each fiscal year by an amount equal to the lesser of (i) 4% of the outstanding shares of common stock as of the last day of our immediately preceding fiscal year; (ii) 1,500,000 shares; or (iii) an amount of shares determined by our board.

The board of directors, or our compensation committee, or a committee of directors or of other individuals satisfying applicable laws and appointed by the board of directors, referred to below as the Administrator will administer the Amended Plan. To make grants to certain of our officers and key employees, the members of the committee must qualify as non-employee directors under Rule 16b-3 of the Securities Exchange Act of 1934, or the Exchange Act, and as outside directors under Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, so that we can receive a federal tax deduction for certain compensation paid under the Amended Plan.

Subject to the terms of the Amended Plan, the Administrator has the sole discretion to select the employees, consultants, and directors who will receive Awards, to determine the terms and conditions of Awards, to modify or amend each Award, subject to the restrictions of the Amended Plan, and to interpret the provisions of the Amended Plan and outstanding Awards. The Administrator may implement an exchange program under which (i) outstanding Awards may be surrendered or cancelled in exchange for Awards of the same type, Awards of a different type, or cash, (ii) participants would have the opportunity to transfer any outstanding Awards to a financial institution or other person or entity selected by the Administrator, and/or (iii) the exercise price of an outstanding Award could be reduced.

The Amended Plan provides for an automatic grant to outside directors of an option to purchase 30,000 shares, referred to below as the Initial Award, on the date the person first becomes an outside director plus an additional option to purchase 10,000 shares, referred to below as the Annual Award, on the date of each annual stockholder s meeting, provided he or she will have served on the Board for at least the preceding six (6) months. Each Initial Award will vest and become exercisable as to one-third (1/3) of the shares subject to the option on each annual anniversary of its date of grant and each Annual Award will

vest and become exercisable as to 100% of the shares on the day prior to the following year s annual stockholder meeting, but in no event later than December 31 of the calendar year following the calendar year during which the Annual Award is granted, provided the participant continues to serve as a director through such dates.

The Administrator is able to grant nonstatutory stock options and incentive stock options under the Amended Plan. The Administrator determines the number of shares subject to each option, although the Amended Plan provides that a participant may not receive options for more than 600,000 shares in any fiscal year, except in connection with his or her initial employment with the Company, in which case he or she may be granted an option covering up to an additional 1,200,000 shares.

The Administrator determines the exercise price of options granted under the Amended Plan, provided the exercise price must be at least equal to the fair market value of our common stock on the date of grant. In addition, the exercise price of an incentive stock option granted to any participant who owns more than 10% of the total voting power of all classes of our outstanding stock must be at least 110% of the fair market value of the common stock on the grant date.

The term of each option will be stated in the Award agreement. The term of an option may not exceed ten years, except that, with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding capital stock, the term of an incentive stock option may not exceed five years.

After a termination of service with the Company, a participant will be able to exercise the vested portion of his or her option for the period of time stated in the Award agreement. If no such period of time is stated in the participant s Award agreement, the participant will generally be able to exercise his or her option for (i) three months following his or her termination for reasons other than death or disability, and (ii) twelve months following his or her termination due to death or disability.

Awards of restricted stock are rights to acquire or purchase shares of our common stock, which vest in accordance with the terms and conditions established by the Administrator in its sole discretion. For example, the Administrator may set restrictions based on the achievement of specific performance goals. The Administrator, in its discretion, may accelerate the time at which any restrictions will lapse or be removed. The Award agreement generally will grant us a right to repurchase or reacquire the shares upon the termination of the participant service with the Company for any reason, including death or disability. The Administrator will determine the number of shares granted pursuant to an Award of restricted stock, but no participant will be granted a right to purchase or acquire more than 300,000 shares of restricted stock during any fiscal year, except that a participant may be granted up to an additional 600,000 shares of restricted stock in connection with his or her initial employment with us.

Awards of restricted stock units result in a payment to a participant only if the vesting criteria the Administrator establishes is satisfied. For example, the Administrator may set vesting criteria based on the achievement of specific performance goals. The restricted stock units will vest at a rate determined by the Administrator; provided, however, that after the grant of restricted stock units, the Administrator, in its sole discretion, may reduce or waive any vesting criteria for such restricted stock units. Upon satisfying the applicable vesting criteria, the participant will be entitled to the payout as determined by the Administrator. The Administrator, in its sole discretion, may pay earned restricted stock units that are fully paid in cash will not reduce the number of shares available for grant under the Amended Plan. On the date set forth in the Award agreement, all unearned restricted stock units will be forfeited to the Company. The Administrator determines the number of restricted stock units granted to any participant, but during any year, no participant may be granted more than 300,000 restricted stock units during any year, except that the participant may be granted up to an additional 600,000 restricted stock units in connection with his or her initial employment with us.

The Administrator is able to grant stock appreciation rights, or SARs, which are the rights to receive the appreciation in fair market value of common stock between the exercise date and the date of grant. We can pay the appreciation in cash, shares of common stock, or a combination thereof. The Administrator, subject to the terms of the Amended Plan, has complete discretion to determine the terms and conditions of SARs granted under the Amended Plan, provided, however, that the exercise price may not be less than 100% of the fair market value of a share on the date of grant and the term of a SAR may not exceed ten years. No participant will be granted SARs covering more than 600,000 shares during any fiscal year, except that a participant may be granted SARs covering up to an additional 1,200,000 shares in connection with his or her initial employment with us.

After termination of service with the Company, a participant is able to exercise the vested portion of his or her SAR for the period of time stated in the Award agreement. If no such period of time is stated in a participant s Award agreement, a participant may generally be able to exercise his or her vested SARs for the same period of time as applies to stock options.

The Administrator is able to grant performance units and performance shares, which are Awards that result in a payment to a participant only if the performance goals or other vesting criteria the Administrator may establish are achieved or the Awards otherwise vest. Earned performance units and performance shares are paid, in the sole discretion of the Administrator, in the form of cash, shares, or in a combination thereof. The Administrator establishes performance or other vesting criteria in its discretion, which, depending on the extent to which they are met, will determine the number and/or the value of performance units and performance shares to be paid out to participants. The performance units and performance shares vest at a rate determined by the Administrator; provided, however, that after the grant of a performance unit or performance share. During any fiscal year, no participant receives more than 300,000 performance shares and no participant will receive performance units having an initial value greater than \$5,000,000, except that a participant may be granted performance shares covering up to an additional 600,000 shares in connection with his or her initial employment with us. Performance units have an initial value established by the Administrator on or before the date of grant. Performance shares will have an initial value equal to the fair market value of a share of our common stock on the grant date.

Awards of restricted stock, restricted stock units, performance shares, performance units and other incentives under the Amended Plan may be made subject to the attainment of performance goals relating to one or more business criteria within the meaning of Section 162(m) of the Code and may provide for a targeted level or levels of achievement including: earnings per share, enrollment rates in clinical and similar trials, financings and capital raising events, operating cash flow, operating income, product development, product approval, profit after-tax, profit before-tax, regulatory approval, regulatory filings, return on assets, return on equity, return on sales, revenue, and total shareholder return. The performance goals may differ from participant to participant and from Award to Award, may be used alone or in combination, may be used to measure our performance as a whole or one of our business units, and may be measured relative to a peer group or index.

To the extent necessary to comply with the performance-based compensation provisions of Section 162(m) of the Code, with respect to any Award granted subject to performance goals, within the first twenty-five percent (25%) of the performance period, but in no event more than ninety (90) days following the commencement of any performance period (or such other time as may be required or permitted by Section 162(m) of the Code), the Administrator will, in writing: (i) designate one or more participants to whom an Award will be made, (ii) select the performance goals applicable to the performance period, (iii) establish the performance goals, and amounts of such Awards, as applicable, which may be earned for such performance goals, and (iv) specify the relationship between performance goals and the amounts of such Awards, as applicable, to be earned by each participant for such performance period. Following the completion of each performance period, the Administrator will certify in writing whether the applicable performance goals have been achieved for such performance period. In determining the amounts earned by a participant, the Administrator will have the right to reduce or eliminate, but not to

increase, the amount payable at a given level of performance to take into account additional factors that the Administrator may deem relevant to the assessment of individual or corporate performance for the performance period. A Participant will be eligible to receive payment pursuant to an Award for a performance period only if the performance goals for such period are achieved.

Awards granted under the Amended Plan are generally not transferable, and all rights with respect to an Award granted to a participant generally will be available during a participant s lifetime only to the participant.

In the event of a merger or Change in Control, each outstanding Award will be treated as the Administrator determines, including, without limitation, that each Award be assumed or an equivalent option or right substituted by the successor corporation or a parent or subsidiary of the successor corporation. The Administrator shall not be required to treat all Awards similarly in the transaction. In the event that the successor corporation does not assume or substitute for the Award, unless the Administrator provides otherwise, the participant will fully vest in and have the right to exercise all of his or her outstanding Options and Stock Appreciation Rights, including shares as to which such Awards would not otherwise be vested or exercisable, all restrictions on Restricted Stock and Restricted Stock Units will lapse, and, with respect to Awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at one hundred percent (100%) of target levels and all other terms and conditions met. In addition, if an Option or Stock Appreciation Right is not assumed or substituted in the event of a Change in Control, the Administrator will notify the participant in writing or electronically that the Option or Stock Appreciation Right will be fully vested and exercisable for a period of time determined by the Administrator in its sole discretion, and the Option or Stock Appreciation Right will terminate upon the expiration of such period.

With respect to Awards granted to an outside director that are assumed or substituted for, if on the date of or following such assumption or substitution the participant s status as a director or a director of the successor corporation, as applicable, is terminated other than upon a voluntary resignation by the participant, unless such resignation is at the request of the acquiror, then the participant will fully vest in and have the right to exercise options and/or stock appreciation rights as to all of the shares underlying such Award, including those shares which would not otherwise be vested or exercisable, all restrictions on restricted stock and restricted stock units will lapse, and, with respect to performance units and performance shares, all performance goals or other vesting criteria will be deemed achieved at one hundred percent (100%) of target levels and all other terms and conditions met.

The Administrator will have the authority to amend, alter, suspend or terminate the Amended Plan, except that stockholder approval will be required for any amendment to the Amended Plan to the extent required by any applicable laws. No amendment, alteration, suspension or termination of the Amended Plan will impair the rights of any participant, unless mutually agreed otherwise between the participant and the Administrator and which agreement must be in writing and signed by the participant and us. The Amended Plan will terminate on August 2, 2016, unless the Board of Directors terminates it earlier.

#### Federal Tax Aspects

The following paragraphs are a summary of the general federal income tax consequences to U.S. taxpayers and the Company of Awards granted under the Amended Plan. Tax consequences for any particular individual may be different.

No taxable income is reportable when a nonstatutory stock option with an exercise price equal to the fair market value of the underlying stock on the date of grant is granted to a participant. Upon exercise, the participant will recognize ordinary income in an amount equal to the excess of the fair market value, on the exercise date, of the shares purchased over the exercise price of the option. Any taxable income recognized in connection with an option exercise by an employee of ours is subject to tax withholding by

us. Any additional gain or loss recognized upon any later disposition of the shares would be capital gain or loss.

As a result of Code Section 409A and the Treasury regulations promulgated thereunder, or Section 409A, however, nonstatutory stock options and stock appreciation rights granted with an exercise price below the fair market value of the underlying stock or with a deferral feature may be taxable to the recipient in the year of vesting in an amount equal to the difference between the then fair market value of the underlying stock and the exercise price of such awards and may be subject to an additional 20% federal income tax plus penalties and interest. In addition, during each subsequent tax year, until the option is exercised or terminates, the option may be subject to additional annual income and penalty taxes, plus interest charges, on any increase in value of the underlying stock. Finally, certain states, such as California, have adopted similar tax provisions.

No taxable income is reportable when an incentive stock option is granted or exercised, except for purposes of the alternative minimum tax, in which case taxation is the same as for nonstatutory stock options. If the participant exercises the option and then later sells or otherwise disposes of the shares more than two years after the grant date and more than one year after the exercise date, the difference between the sale price and the exercise price will be taxed as capital gain or loss. If the participant exercises the option and then later sells or otherwise disposes of the shares before the end of the two- or one-year holding periods described above, he or she generally will have ordinary income at the time of the sale equal to the fair market value of the shares on the exercise date, or the sale price if less, minus the exercise price of the option.

No taxable income is reportable when a stock appreciation right with an exercise price equal to the fair market value of the underlying stock on the date of grant is granted to a participant. Upon exercise, the participant will recognize ordinary income in an amount equal to the amount of cash received and the fair market value of any shares received. Any additional gain or loss recognized upon any later disposition of the shares would be capital gain or loss.

A participant generally will not have taxable income at the time an Award of restricted stock, restricted stock units, performance shares or performance units are granted. Instead, he or she will recognize ordinary income in the first taxable year in which his or her interest in the shares underlying the Award becomes either (i) freely transferable, or (ii) no longer subject to substantial risk of forfeiture. However, the recipient of a restricted stock Award may elect to recognize income at the time he or she receives the Award in an amount equal to the fair market value of the shares underlying the Award, less any cash paid for the shares, on the date the Award is granted.

Code Section 409A, which was added by the American Jobs Creation Act of 2006, provides certain new requirements on non-qualified deferred compensation arrangements. Awards granted with a deferral feature will be subject to the requirements of Section 409A, including discount stock options and stock appreciation rights discussed above. If an Award is subject to and fails to satisfy the requirements of Section 409A, the recipient of that Award may recognize ordinary income on the amounts deferred under the Award, to the extent vested, which may be prior to when the compensation is actually or constructively received. Also, if an Award that is subject to Section 409A fails to comply with Section 409A s provisions, Section 409A imposes an additional 20% federal income tax on compensation recognized as ordinary income, as well as interest on such deferred compensation. Some states may also apply a penalty tax. For example, California imposes a 20% penalty tax in addition to the 20% federal penalty tax.

The Company generally will be entitled to a tax deduction in connection with an Award under the Amended Plan in an amount equal to the ordinary income realized by a participant and at the time the participant recognizes such income (for example, the exercise of a nonstatutory stock option). Special rules limit the deductibility of compensation paid to the Company s Chief Executive Officer (i.e., its principal executive officer) and to each of its three most highly compensated executive officers for the taxable year, other than the principal executive officer or principal financial officer. Under Code Section 162(m), the annual compensation paid to any of these specified executives will be deductible only to the extent that it

does not exceed \$1,000,000. However, the Company can preserve the deductibility of certain compensation in excess of \$1,000,000 if the conditions of Section 162(m) are met. These conditions include stockholder approval of the Amended Plan, setting limits on the number of Awards that any individual may receive and for Awards other than certain stock options, establishing performance criteria that must be met before the Award actually will vest or be paid. The Amended Plan has been designed to permit the Administrator to grant Awards that qualify as performance-based for purposes of satisfying the conditions of Section 162(m), thereby permitting the Company to continue to receive a federal income tax deduction in connection with such Awards.

#### 401(k) Plan

We maintain a retirement savings plan, or a 401(k) Plan, for the benefit of our eligible employees. Employees eligible to participate in our 401(k) Plan are those employees who have attained the age of 21. Currently, employees may elect to defer their compensation up to the statutorily prescribed limit. We may, but have not, matched employee contributions or made discretionary contributions to the 401(k) Plan. An employee s interests in his or her deferrals are 100% vested when contributed. The 401(k) Plan is intended to qualify under Sections 401(a) and 501(a) of the Internal Revenue Code. As such, contributions to the 401(k) Plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) Plan, and all contributions are deductible by us when made.

#### **Executive Time Off**

Our executive officers do not receive a guaranteed amount of Paid Time Off (PTO), but participate instead in an Executive Time Off plan. Our executive officers are expected to manage personal time off in a manner that does not impact performance or achievement of goals. Until December 31, 2005, executives participated in the PTO benefit program which was offered to all of our employees at that time. Upon termination, executives who participated will be entitled to payment of their accrued benefits that existed at December 31, 2005. Officers hired or promoted since the implementation of the Executive Time Off policy will be transitioned to the officer plan at the time of hire or promotion. Consistent with the balance of executive officers, any accrued but unused PTO will be paid at termination. We have accrued \$50,754 in earned, but unpaid PTO for its named executive officers.

#### 2006 Employee Stock Purchase Plan

Our executive officers and all of our other employees may participate in our 2006 Employee Stock Purchase Plan. We believe that allowing them the opportunity to participate in the 2006 Employee Stock Purchase Plan provides them further incentive towards ensuring our success and accomplishing our corporate goals.

The specific provisions of our 2006 Employee Stock Purchase Plan are set forth below.

Our Board adopted, and our stockholders approved, our 2006 Employee Stock Purchase Plan in August 2006 and it became effective upon completion of our initial public offering in February 2007. A total of 1,190,468 shares of our common stock are available for sale. As of December 31, 2008, a total of 111,921 shares of our common stock had been issued through the 2006 Employee Stock Purchase Plan. In addition, our 2006 Employee Stock Purchase Plan provides for annual increases in the number of shares available for issuance under the 2006 Employee Stock Purchase Plan on the first day of each fiscal year equal to the lesser of:

- 3% of the outstanding shares of our common stock on the first day of such fiscal year;
- 1,000,000 shares; or
- such other amount as may be determined by our Board.

Our compensation committee administers the 2006 Employee Stock Purchase Plan. Our compensation committee has full and exclusive authority to interpret the terms of the 2006 Employee Stock Purchase Plan and determine eligibility to participate subject to the conditions of our 2006 Employee Stock Purchase Plan as described below.

All of our employees are eligible to participate if they are employed by us (or any participating subsidiary) for at least 20 hours per week and more than five months in any calendar year. However, an employee may not be granted an option to purchase stock under the 2006 Employee Stock Purchase Plan if such employee:

• immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock; or

• holds rights to purchase stock under all of our employee stock purchase plans that accrue at a rate that exceeds \$25,000 worth of stock for each calendar year.

Our 2006 Employee Stock Purchase Plan is intended to qualify under Section 423 of the Code. Each offering period includes purchase periods, which will be the approximately six-month period commencing with one exercise date and ending with the next exercise date. The offering periods are scheduled to start on the first trading day on or after May 15 and November 15 of each year, except for the first such offering period, which commenced on February 1, 2007 (the date of our IPO) and ended on November 15, 2007.

Our 2006 Employee Stock Purchase Plan permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation, which includes a participant s base straight time gross earnings, certain commissions, overtime and shift premium, but exclusive of payments for incentive compensation, bonuses and other compensation. A participant may purchase a maximum of 1,250 shares during a six-month purchase period.

Amounts deducted and accumulated by the participant are used to purchase shares of our common stock at the end of each six-month purchase period. The purchase price of the shares will be 85% of the lower of the fair market value of our common stock on the first trading day of each offering period or on the exercise date. If the fair market value of our common stock on the exercise date is less than the fair market value on the first trading day of the offering period, participants will be withdrawn from the current offering period following their purchase of shares on the purchase date and will be automatically re-enrolled in a new offering period. Participants may end their participation at any time during an offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon termination of employment with us.

A participant may not transfer rights granted under the 2006 Employee Stock Purchase Plan other than by will, the laws of descent and distribution, or as otherwise provided under the 2006 Employee Stock Purchase Plan.

In the event of our merger or change in control, as defined under the 2006 Employee Stock Purchase Plan, a successor corporation may assume or substitute for each outstanding option. If the successor corporation refuses to assume or substitute for the option, the offering period then in progress will be shortened, and a new exercise date will be set. The administrator will notify each participant that the exercise date has been changed and that the participant s option will be exercised automatically on the new exercise date unless prior to such date the participant has

withdrawn from the offering period.

Our 2006 Employee Stock Purchase Plan will automatically terminate in 2016, unless we terminate it sooner. In January 2009, the plan was suspended when we announced the initiative to reduce our headcount by 94%. Our board has the authority to amend, suspend or terminate our 2006 Employee Stock Purchase Plan, except that, subject to certain exceptions described in the 2006 Employee Stock

Purchase Plan, no such action may adversely affect any outstanding rights to purchase stock under our 2006 Employee Stock Purchase Plan.

#### Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information regarding common stock that may be issued upon the exercise of options, warrants and rights under our 2002 Stock Plan, 2006 Equity Incentive Plan and 2006 Employee Stock Purchase Plan as of December 31, 2008. All our equity compensation plans have been approved by our stockholders.

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

(1)

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

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

#### 2008 Summary Compensation Table

The following table sets forth summary compensation information for the years ended December 31, 2008 and December 31, 2007 for our chief executive officer, chief financial officer and each of our other three most highly compensated executive officers as of the end of the last fiscal year. We refer to these persons as our named executive officers. Except as provided below, none of our named executive officers received any other compensation required to be disclosed by law or in excess of \$10,000 annually.

Name and Principal Position	Year	Salary	]	Bonus	Option A	wards	n Equity Incentive an Compensation	All Other Compensation	Total
Gregory D. Casciaro	2008	\$ 354,598	\$	62,256(5)	\$ 6	89,361	\$ 26,595(1)	\$	1,132,810
President, Chief Executive Officer and	2007	340,960			5	16,184	115,000(1)		972,144
Director									

Timothy D. Kahlenberg Chief Financial Officer Randolph E. Campbell Chief Technical Officer	2008 2007 2008 2007	264,531 236,508 269,604 257,688	62,256(5)	470,407 398,975 203,813 143,879	14,880(2) 19,320(2) 15,353(2) 21,050(2)	812,074 654,803 488,770 422,617
Philippe H. Marco Vice President of Quality Assurance,	2008 2007	239,388 232,374		175,368 115,553	13,466(2) 18,981(2)	428,222 366,908
Clinical and Regulatory Affairs	2007	232,374		115,555	10,901(2)	300,908
Ann-Marie Hodkinson	2008	182,999		138,213	10,294(2)	331,506
Vice President of Human Resources	2007	87,913(3)	5,000(4)	20,020		112,933

(1) Represents amounts earned by Mr. Casciaro under our non-equity incentive program for the achievement of specific clinical, financing and other corporate objectives.

(2) Represents amounts earned by executives under our non-equity incentive program for achievement of specific corporate objectives.

(3) Ms. Hodkinson commenced employment in June 2007 at an annual salary of \$173,000, and became an officer of the Company in January 2008.

(4)

Represents a hiring bonus made to Ms. Hodkinson on her offer of employment.

(5) Represents payments made to Mr. Casciaro and Mr. Kahlenberg based on a commitment resulting from a reduction in their 2008 equity incentive grants and the acceptance of the remainder of the related grants at above market prices.

### Grants of Plan-Based Awards in 2008

The following table lists grants of plan-based awards made to our named executive officers in 2008 and the related total fair value of compensation for 2008.

Name	Grant Date		ed Future Payou y Incentive Plan Target		All Other Option Awards: Number of Securities Underlying Options	Exercise or Base Price of Option Awards	Grant Date Fair Value of Option Awards
Gregory D. Casciaro	12/27/2007 1/29/2008 3/31/2008 8/13/2008	\$ 106,380	\$ 177,300	\$ 221,625	81,225 60,918 33,247	5.00	\$ 415,547 154,994 ) 24,466
Timothy D. Kahlenberg	12/27/2007 1/29/2008 3/31/2008 8/13/2008	59,513	79,350	99,188	33,325 24,993 16,165	5.00	170,491 63,590 ) 11,896
Randolph E. Campbell	12/27/2007 1/29/2008 3/31/2008 8/13/2008	59,153	78,870	98,588	27,075 20,306 25,000	5.00	138,516 51,665 28,283
Philippe H. Marco	12/27/2007 1/29/2008 3/31/2008 8/13/2008	53,865	71,820	89,775	27,075 20,306 25,000	5.00	138,516 51,665 28,283
Anne-Marie Hodkinson (2)	12/27/2007	41,175	54,900	68,625			

1/29/2008	60,000	9.96	306,960
1/29/2008	1,269	9.96	6,492
3/31/2008	951	5.00	2,420
8/13/2008	42,000	2.10	47,516

(1) The amounts represent the threshold, target and maximum awards established for the 2008 non-equity compensation program as discussed in the section entitled Compensation *Discussion and Analysis*. The actual amounts earned by our Named Executive officers pursuant to these awards are set forth in the Non-Equity Incentive Plan Compensation column of the table entitled *Summary Compensation Table*.

(2) Ms. Hodkinson became an officer of the Company in January 2008.

(3) Mr. Casciaro and Mr. Kahlenberg each received a payment of \$62,256 in the first quarter of 2009 based on their acceptance of a reduction in this equity incentive award granted at above market prices.

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### Equity Incentive Awards Outstanding as of December 31, 2008

The following table lists the outstanding equity incentive awards held by our named executive officers as of December 31, 2008.

	Option Awards					Stock Awards		
Name	Number of Securities Underlying Unexercised Options Exerciable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date	Vesting Commencement Date	Number of Shares or Units of Stock that Have Not Vested (5)	Market Value of Shares or Units of Stock that Have Not Vested	
Gregory D.								
Casciaro	134,000(1)		\$0.40	2/1/2015	2/1/2005(2)			
	104,000(1)		1.50	2/1/2016	2/1/2006(2)			
	125,000(1)		5.20	6/5/2016	4/27/2006(2)			
	24,818	56,407	9.96	1/29/2018	2/1/2008(4)			
	10,153	50,765	5.00	3/31/2018	3/31/2008(2)			
	2,770	30,477	4.50(6)	8/13/2018	8/13/2008(2)			
Timothy D.								
Kahlenberg	168,911(1)		3.50	5/1/2016	5/1/2006(3)			
	10,182	23,143	9.96	1/29/2018	2/1/2008(4)			
	4,165	20,828	5.00	3/31/2018	3/31/2008(2)			
	1,347	14,818	4.50(6)	8/13/2018	8/13/2008(2)			
Randolph E.								
Campbell	61,634(1)		3.50	5/1/2016	5/1/2006(2)			
					2/1/2005(2)	2,710	\$732	
					8/3/2005(2)	959	259	
	8,272	18,803	9.96	1/29/2018	2/1/2008(4)			
	3,384	16,922	5.00	3/31/2018	3/31/2008(2)			
	2,083	22,917	2.10	8/13/2018	8/13/2008(2)			
Philippe H.								
Marco					2/1/2005(2)	1,125	304	

					8/3/2005(2)	334	9
	49,500(1)		3.50	5/1/2016	5/1/2006(2)	554	,
	8,272	18,803	9.96	1/29/2018	2/1/2008(4)		
	3,384	16,922	5.00	3/31/2018	3/31/2008(2)		
	2,083	22,917	2.10	8/13/2018	8/13/2008(2)		
nne-Marie	2,005	22,917	2.10	0/15/2010	0/15/2000(2)		
lodkinson	9,375	15,625	10.52	7/6/2017	6/28/2007(3)		
outinson	5,833	14,167	9.99	10/30/2017	10/30/2007(2)		
	13,750	46,250	9.96	1/29/2018	2/1/2008(2)		
	387	882	9.96	1/29/2018	2/1/2008(4)		
	158	793	5.00	3/31/2018	3/31/2008(2)		
	3,500	38,500	2.10	8/13/2018	8/13/2008(2)		
1)	Option may be	e early exercised.					
2)	The shares und	derlying this option	vest 1/48 per n	onth following the	e vesting commenceme	nt date.	
3) nonth thereafter.	25% of the sha	ares underlying this	option vest on	the one year anniv	rersary of the vesting co	ommencement date a	nd 1/48 pe
4)	The shares und	derlying this option	vest 1/36 per n	onth following the	a vesting commanceme	nt date	
		, <u>,</u> , , , , , , , , , , , , , , , , ,	ſ	ionui ionowing uk	e vesting commenceme	in dute.	
(5) These shares are si			to the exercise of	of early-exercise st	ock options to purchas		non stock.

### **Aggregated Option Exercises in 2008**

	Option Awards			
Name	Number of Shares Acquired on Exercise	Value Realized on Exercise (1)		
Ivaille	Acquireu on Exercise	Exercise (1)		
Gregory D. Casciaro		\$		
Timothy D. Kahlenberg	2,000	4,650		
Randolph E. Campbell				
Philippe H. Marco				
Anne-Marie Hodkinson				

<sup>(1)</sup> Value realized is based on the fair market value of our common stock on the date of exercise minus the exercise price and does not necessarily reflect proceeds actually received by the individual.

### **Employment Agreements**

Employment with us is at will. We do not have employment agreements with any of our executive officers.

### **Nonqualified Deferred Compensation**

None of our named executive officers participate in non-qualified defined contribution plans or other deferred compensation plans maintained by us. Our compensation committee, which is comprised solely of outside directors as defined for purposes of Section 162(m) of the Code, may elect to provide our officers and other employees with non-qualified defined contribution or deferred compensation benefits if the compensation committee determines that doing so is in our best interests.

### 2008 Director Compensation

The following table sets forth a summary of the compensation we paid to our non-employee directors in 2008.

Name	Fees Earned or Paid in Cash	<b>Option Awards (1)</b>	Total
Henry A. Plain, Jr. \$	60,000	\$ 103,491(2)	\$ 163,491
Michael A. Carusi	35,000	29,264(3)	64,264
Robert E. Flaherty	45,000	109,551(4)	154,551
Michael L. Eagle	45,000	51,578(5)	96,578
Christopher M. Smith	18,651	8,227(6)	26,878
Arthur T. Taylor	18,651	8,227(6)	26,878
Edward W. Unkart	50,000	121,928(7)	171,928
Allan R. Will	35,000	29,264(8)	64,264

(1) Amounts represent the expensed fair value of stock options granted in 2008, 2007 and 2006 under SFAS 123(R) excluding the impact of estimated forfeitures.

(2)	Options to purchase 45,000 shares were outstanding, of which 26,667 shares were exercisable as of December 31, 2008.
(3)	Options to purchase 20,000 shares were outstanding, of which 10,000 shares were exercisable as of December 31, 2008.
(4)	Options to purchase 50,000 shares were outstanding, of which 20,000 shares were exercisable as of December 31, 2008.
(5)	Options to purchase 40,000 were outstanding, of which 10,000 shares were exercisable as of December 31, 2008.
(6)	Options to purchase 30,000 shares were outstanding, of which no shares were exercisable at December 31, 2008.
(7)	Options to purchase 50,000 shares were outstanding, of which 30,000 shares were exercisable as of December 31, 2008.
(8)	Options to purchase 20,000 shares were outstanding, of which 10,000 shares were exercisable as of December 31, 2008.

The chairman of our board receives an annual retainer of \$60,000 for his service to our Company and each of our non-employee directors receives an annual retainer of \$35,000 for his service on our board. The chairman of the audit committee receives an additional annual retainer of \$15,000 and the chairmen of our other two standing committees, the compensation committee and the nominating and corporate governance committee, each receive an additional annual retainer in the amount of \$10,000.

Our 2006 equity incentive plan provides that all non-employee directors will be eligible to receive all types of awards (except for incentive stock options) under the 2006 equity incentive plan, including discretionary awards. Each non-employee director appointed to our board, except for those directors who become non-employee directors by ceasing to be employee directors, receives an automatic initial nonstatutory stock option to purchase 30,000 shares of common stock upon such appointment. In addition, non-employee directors who have been directors for at least the preceding six months receive a subsequent nonstatutory stock option to purchase 10,000 shares of common stock immediately following each annual meeting of our stockholders. All options granted under the automatic grant provisions will have a term of

ten years and an exercise price equal to fair market value on the date of grant. Each initial option to purchase 30,000 shares becomes exercisable as to one-third of the shares subject to the option on each anniversary of its date of grant, provided the non-employee director remains a director on such dates. Each annual option to purchase 10,000 shares becomes exercisable as to 100% of the shares subject to the option on the day prior to the one-year anniversary of the date of such grant, provided the non-employee director remains a director on such date.

We also reimburse each non-employee member of our board for out-of-pocket expenses incurred in connection with attending our board and committee meetings. In addition, we have in the past granted directors options to purchase our common stock pursuant to the terms of our 2002 Stock Plan. As explained above, our 2006 equity incentive plan provides for the automatic grant of options to our non-employee directors. See Stock Options 2006 equity incentive plan.

### **Potential Payments Following a Change in Control**

The following summaries set forth potential payments payable to our executive officers upon termination of employment following a change in control of us under their current change of control agreements with us. The compensation committee of our board may, at their discretion, amend or add benefits to these arrangements as they deem advisable.

### **Executive** Officers

We have entered into change of control agreements with Gregory D. Casciaro, Timothy D. Kahlenberg, Randolph E. Campbell and Philippe Marco that provide for severance benefits in the event that a covered employee s employment with us terminates as a result of an involuntary termination at any time within 12 months after a change of control as follows:

• all options held by the employee will become fully vested and any right we may have to repurchase any shares held by the employee will lapse; and

• certain health coverage and benefits for that employee will be paid by us until the earlier of six months from the date of such employee s termination or until the employee begins working at another company that offers comparable benefits.

For the purpose of our change of control agreements, change of control means:

• any merger or consolidation of us with any other corporation that would result in our voting securities outstanding immediately prior to such transaction no longer continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 50% of the total voting power of the surviving entity outstanding immediately after such merger or consolidation; or

• any person becoming the beneficial owner, directly or indirectly, of our securities representing 50% or more of the total voting power represented by our then outstanding voting securities.

Under Mr. Marco s change of control agreement, change of control also includes a liquidation of the Company or a sale of all or substantially all of the Company s assets.

For the purpose of our change of control agreements, involuntary termination means:

• a significant reduction of the employee s duties, position or responsibilities relative to the employee s duties, position or responsibilities in effect immediately prior to such reduction, or the removal of the employee from such position, duties and responsibilities, unless the employee is provided with comparable duties, position and responsibilities; provided,

however, that a reduction in duties, position or responsibilities solely by virtue of our being acquired and made part of a larger entity (as, for example, when our Chief Financial Officer remains as such following a Change of Control but is not made the Chief Financial Officer of the acquiring corporation) shall not constitute an involuntary termination;

• a substantial reduction, without good business reasons, of the facilities and perquisites (including office space and location) available to the employee immediately prior to such reduction;

• a reduction of the employee s base salary as in effect immediately prior to such reduction;

• a material reduction in the kind or level of employee benefits to which the employee is entitled immediately prior to such reduction with the result that the employee s overall benefits package is significantly reduced;

• the relocation of the employee to a facility or a location more than fifty (50) miles from his current location;

• any purported termination of the employee which is not effected as a result of (i) any act of personal dishonesty taken by the employee in connection with his responsibilities as an employee which is intended to result in substantial personal enrichment of the employee, (ii) employee s conviction of a felony which our board reasonably believes has had or will have a material detrimental effect on our reputation or business, (iii) a willful act by the employee which constitutes misconduct and is injurious to us, (iv) continued willful violations by the employee of the employee s obligations to us after there has been delivered to the employee a written demand for performance from us which describes the basis for our belief that the employee has not substantially performed his duties, or (v) for which the grounds relied upon by us are not valid; or

• our failure to obtain the assumption of the change of control agreement by any successor entity.

Based on a market value of \$0.27 per share as of December 31, 2008, and the number of options and shares held by each of our executive officers that were unvested as of December 31, 2008, the estimated value of acceleration of these options and shares held by each executive officer is shown in the following table, as well as the maximum value of benefits which would be paid on behalf of each officer upon a change of control.

	Value of Acce	elerated	Value of Benefits in
Name	Options and S	hares (1)	Change of Control
Timothy D. Kahlenberg	\$	\$	10,773
Randolph E. Campbell			10,823
Philippe H. Marco			10,765
Anne-Marie Hodkinson			10,673

(1) All option exercises prices are above the market value of the Company s stock at December 31, 2008.

### Gregory D. Casciaro

We have entered into a slightly different change of control agreement with Gregory D. Casciaro that provides for additional severance benefits in the event that Mr. Casciaro s employment with us terminates as a result of his involuntary termination at any time after a change of control as follows:

all options held by him will become fully vested and any right we may have to repurchase any shares held by him will lapse;

• monthly severance payments equal to his last monthly base salary prior to his termination for a period of 12 months following the date of his termination; and

• certain health coverage and benefits for Mr. Casciaro will be paid until the earlier of 12 months from the date of his termination or until he begins employment with another company that offers comparable benefits.

In addition to the severance benefits described above, our change of control agreement with Mr. Casciaro also provides for a change of control benefit. Upon a change of control without termination, Mr. Casciaro will immediately vest in 50% of the unvested shares underlying options then held by him and our right to repurchase 50% of shares previously purchased by him that are subject to vesting, will lapse.

The definitions for involuntarily termination and change of control discussed above for the change of control agreements with each of our other employees at the level of vice president or above are identical to those included in our change of control agreement with Mr. Casciaro.

Based on Mr. Casciaro s current base salary, we estimate that the value of his severance payments to be \$354,958. Based on a market value of \$0.27 per share as of December 31, 2008, and the number of options held by Mr. Casciaro that were unvested as of December 31, 2008, we estimate the value of acceleration of these options would have no value. The maximum value of his benefits that would be paid upon a change of control would be \$20,457.

### Members of our Board of Directors

We have also entered into agreements with each non-employee member of our board under which all unvested shares underlying options then held by such director will become fully vested and immediately exercisable if such director is terminated without cause within 12 months of a change of control.

### Additional Change of Control Provisions

Each of our 2002 Stock Plan, 2006 equity incentive plan and 2006 Employee Stock Purchase Plan also contains change of control provisions as described above. See Stock Options 2002 Stock Plan, 2006 Equity Incentive Plan and 2006 Employee Stock Purchase Plan.

### Limitations on Liability and Indemnification

Our amended and restated certificate of incorporation and bylaws provide that we will indemnify our directors and executive officers, and may indemnify our other officers, employees and other agents, to the fullest extent permitted by the General Corporation Law of the State of Delaware.

We have entered into indemnification agreements with our directors, executive officers and others. Under these agreements, we are required to indemnify them against all expenses, judgments, fines, settlements and other amounts actually and reasonably incurred in connection with any actual or threatened proceeding, if any of them may be made a party to such proceeding because he or she is or was one of our directors or officers. We are obligated to pay these amounts only if the officer or director acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, our best interests. With respect to any criminal proceeding, we are obligated to pay these amounts only if the officer or director was unlawful. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification there under.

In addition, our amended and restated certificate of incorporation provides that the liability of our directors for monetary damages shall be eliminated to the fullest extent permissible under the General Corporation Law of the State of Delaware. This provision in our amended and restated certificate of incorporation does not eliminate a director s duty of care and, in appropriate circumstances; equitable remedies such as an injunction or other forms of non-monetary relief would remain available. Each director continues to be subject to liability for any breach of the director s duty of loyalty to us and for acts or omissions not in good faith or involving intentional misconduct or knowing violations of law. This provision also does not affect a director s responsibilities under any other laws, such as the federal securities laws or other state or federal laws.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

We have a directors and officers liability insurance that insures such persons against the costs of defense, settlement or payment of a judgment under certain circumstances. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

#### **Compensation Committee Interlocks and Insider Participation**

The members of our compensation committee are Robert E. Flaherty (chairperson), Henry A. Plain, Jr. and Michael L. Eagle. No member of the compensation committee is an executive officer of our company. Henry A. Plain, Jr. served as our President, Chief Executive Officer and Chief Financial Officer from June 2002 to October 2004. No executive officer of our company currently serves on the board of directors of any entity whose executive officers included a director of our company.

### **REPORT OF THE COMPENSATION COMMITTEE**

The compensation committee has reviewed and discussed the Compensation Discussion and Analysis included in this Annual Report with management of the Company, and based upon those discussions, the committee has recommended to the Company s board of directors that the Compensation Discussion and Analysis be included in this Annual Report.

The foregoing report is provided by the undersigned members of the compensation committee.

Robert E. Flaherty, Chair

Henry A. Plain, Jr.

Mike L. Eagle

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

### Security Ownership of Certain Beneficial Owners and Management

The following table provides information relating to the beneficial ownership of XTENT common stock as of January 24, 2009, except where otherwise noted, by:

• each stockholder known by us to own beneficially more than 5% of our common stock;

• each of our executive officers named in the summary compensation table below (our Chief Executive Officer, Chief Financial Officer and our three other most highly compensated executive officers);

• each of our directors; and

• all of our directors and executive officers as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has the sole voting power, shared voting power, or investment power and includes any shares that the individual has the right to acquire within 60 days of January 24, 2009 through the exercise of any stock option or other right. The number and percentage of shares beneficially owned is computed on the basis of 23,324,756 shares of XTENT common stock outstanding as of January 24, 2009. Shares of our common stock that a person has the right to acquire within 60 days of January 24, 2009 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person or entity named in the table has sole voting and dispositive power with respect to the shares set forth opposite such person s or entity s name. The address for those persons for whom an address is not otherwise provided is c/o XTENT, Inc., 125 Constitution Drive, Menlo Park, California 94025-1118.

	Beneficial Ow Number of Shares	nership Options and Warrants Exercisable Within 60 Days	Percentage of Shares Outstanding Approximate Percent Owned
Beneficial Owner			
5% Stockholders			
Morgenthaler Partners VI, L.P.(1)	5,085,243		21.0%
Funds affiliated with Advanced Technology Ventures (2)	2,999,393		12.4%
Funds affiliated with Latterell Venture Partners (3)	2,828,190		11.7%
SPVC VI, LLC (4)	2,615,135		10.8%
Davidson Kempner Partners	1,290,913		5.3%
State of Wisconsin	1,290,432		5.3%
Named Executive Officers and Directors			
Gregory D. Casciaro (5)	566,778	411,138	4.0%
Timothy D. Kahlenberg		189,027	0.8%
Randolph E. Campbell (6)	261,770	90,643	1.5%
Anne-Marie Hodkinson		40,130	0.2%
Phillipe Marco (7)	71,050	67,573	0.6%
Henry A. Plain, Jr. (8)	459,656	26,667	2.0%
Michael A. Carusi (2)	2,999,393	10,000	12.4%
Michael L. Eagle		10,000	0.0%
Robert E. Flaherty	3,685	30,000	0.1%
Edward W. Unkart	8,333	30,000	0.2%
Christopher M. Smith			0.0%
Arthur T. Taylor			0.0%
Allan R. Will (4)	2,775,291	10,000	11.5%
All executive officers and directors as a group (13 persons)	17,640,734	915,178	65.9%

(1) Includes 5,085,243 shares held by Morgenthaler Partners VI, L.P. Voting and investment power are shared by Robert C. Bellas, Jr., Gary J. Morgenthaler, Robert D. Pavey, John D. Lutsi, G. Gary Shaffer, Gary R. Little, Peter G. Taft, Theodore A. Laufik and Paul R. Levine, the managing members of Morgenthaler Management Partners VI, L.L.C., the general partner of Morgenthaler Partners VI, L.P., with respect to shares held by Morgenthaler Partners VI, L.P. Each managing member disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein. The address for Morgenthaler Partners VI, L.P. is 2710 Sand Hill Road, Suite 100, Menlo Park, CA 94025.

(2) Includes 2,409,589 shares held by Advanced Technology Ventures VII, L.P., 402,776 shares held by Advanced Technology Ventures VI, L.P., 96,694 shares held by Advanced Technology Ventures VII (B), L.P., 46,477 shares held by Advanced Technology Ventures VII (C), L.P., 25,708 shares held by ATV Entrepreneurs VI, L.P., 14,359 shares held by ATV Entrepreneurs VII, L.P., and 3,790 shares held by ATV Alliance 2002, L.P. ATV Associates VII, L.L.C. is the general partner of Advanced Technology Ventures VII (B), L.P., Advanced Technology Ventures VII (C), L.P. ATV Associates VI, L.P. and ATV Entrepreneurs VII, L.P. ATV Associates VI, L.L.C. is the general partner of Advanced Technology Ventures VII (C), L.P. ATV Associates VI, L.P. and ATV Entrepreneurs VI, L.P. ATV Associates VI, L.L.C. is the general partner of Advanced Technology Ventures VI, L.P. and ATV Entrepreneurs VI, L.P. ATV Capital Management, Inc. is the sole member of ATV Alliance

Associates, L.L.C., the general partner of ATV Alliance 2002, L.P. Michael A. Carusi, Steve Baloff, Bob Hower, Jean George and Bill Wiberg, as managing directors of ATV Associates VII, L.L.C., share voting and investment power with respect to shares held by Advanced Technology Ventures VII, L.P., Advanced Technology Ventures VII (B), L.P., Advanced Technology Ventures VII (C), L.P., and ATV Entrepreneurs VII, L.P. Michael A. Carusi, Steve Baloff and Pieter Schiller, as managing directors of ATV Associates VI, L.L.C., share voting and investment power with respect to shares held by Advanced Technology Ventures VI, L.P. and ATV Entrepreneurs VI, L.P. Jean George, as the sole manager of ATV Alliance Associates, L.L.C., has voting and investment power with respect to shares held by ATV Alliance 2002, L.P. Each managing director and manager disclaims beneficial ownership of these shares, except to the extent of his or her pecuniary interest therein. Mr. Carusi s address is c/o Advanced Technology Ventures, 1000 Winter Street, Suite 3700, Waltham, MA 02451.

(3) Includes 2,020,425 shares held by Latterell Venture Partners II, L.P., 586,574 shares held by Latterell Venture Partners, L.P., 196,458 shares held by Latterell Venture Partners III, L.P., 9,822 shares held by LVP III Associates, L.P., 4,911 shares held by LVP III Partners, L.P., and 10,000 shares held by Latterell Management Company, L.L.C. Latterell Capital Management, L.L.C. is the general partner of Latterell Venture Partners, I.P., Latterell Capital Management II, L.L.C. is the general partner of Latterell Venture Partners, I.P., and LVP III Partners, L.P., Latterell, Stephen M. Salmon and James N. Woody are the members of Latterell Capital Management, L.L.C., Latterell Capital Management III, L.L.C. and Latterell Capital Management, L.L.C., Latterell Capital Management III, L.L.C. and Latterell Management Company, L.L.C. and share voting and investment power. Each member disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein. Mr. Latterell venture Partners, 1 Embarcadero Center, Suite 4050, San Francisco, CA 94111.

(4) SPVC VI, LLC (formerly St. Paul Venture Capital VI, LLC) is jointly managed by Split Rock Partners, LLC. and Vesbridge Partners, L.L.C.; however, voting and investment power has been delegated solely to Split Rock Partners, LLC. Allan R. Will, David Stassen, Michael Gorman and James Simons, as managing directors of Split Rock Partners, LLC, share voting and investment power with respect to the shares held by SPVC VI, LLC. Split Rock Partners, LLC and each of its managing directors disclaim beneficial ownership of these shares, except to the extent of his or their pecuniary interest therein. Mr. Will s address is c/o Split Rock Partners, L.L.C., 1600 El Camino Real, Suite 290, Menlo Park, CA 94025. The address for SPVC VI, LLC is 10400 Viking Drive, Suite 550, Eden Prairie, MN 55344.

(5) Includes 3,400 shares held by Mr. Casciaro as custodian for his minor son and minor daughter under the California Uniform Transfer to Minors Act. Also includes 1,700 shares held by Mr. Casciaro s adult daughter as to which Mr. Casciaro disclaims beneficial ownership

(6)	2,195 of these shares are subject to our right of repurchase as of January 24, 2009.
(7)	855 of these shares are subject to our right of repurchase as of January 24, 2009.
(8)	Henry A. Plain, Jr. s address is c/o Morgenthaler Ventures, 2710 Sand Hill Road, Suite 100, Menlo Park, CA 94025.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

### **Policies and Procedures for Related Party Transactions**

As provided by our audit committee charter, our audit committee must review and approve in advance any transactions with related persons. All of our directors, officers and employees are required to report to our audit committee any such related party transaction prior to its completion.

### **Transactions with Related Persons**

None.

### **Director Independence**

Our board of directors consists of nine directors. The board has the authority to increase the size of the board from time to time. The current directors are Michael A. Carusi, Gregory D. Casciaro, Michael L. Eagle, Robert E. Flaherty, Henry A. Plain, Jr., Christopher M. Smith, Arthur T. Taylor, Edward W. Unkart and Allan R. Will. Our board has determined that Messrs. Carusi, Eagle, Flaherty, Plain, Smith, Taylor, Unkart and Will are independent directors under the listing standards established by the rules of the NASDAQ Stock Market, Inc. (Nasdaq).

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the fees paid to PricewaterhouseCoopers, LLP ( PwC ):

2008		2007 (1)
\$ 350,925	\$	380,022
		40,710
		12,375
		3,900
\$ 350.925	\$	437,007
\$	\$ 350,925	2008 \$ 350,925 \$ \$ 350,925 \$

<sup>(1)</sup> The presentation of 2007 fees has been changed to conform with 2008 presentation

In the above table, in accordance with the SEC s definitions and rules, audit fees are fees for professional services for the audit of a company s financial statements and for services that are normally provided by the accountant in connection with other statutory and regulatory filings or engagements; audit-related fees are fees for assurance and related services that are reasonably related to the performance of the audit or review of a company s financial statements; tax services fees are fees for tax compliance, tax advice and tax planning; and all other fees are fees for any services not included in the first three categories.

### **Audit Fees**

The aggregate Audit Fees to PwC in the year ended December 31, 2008 were \$350,925. This included fees for services rendered for the audit of our annual financial statements for the year ended December 31, 2008 and the review of our interim financial statements during the year ended December 31, 2008. The aggregate Audit Fees to PwC in the year ended December 31, 2007 were \$437,007, which also included the review of the financial statements included in our Registration Statement filed in connection with our initial public offering on February 1, 2007.

### **Tax Service Fees**

There were no aggregate Tax Service Fees paid to PwC in the year ended December 31, 2008. In the year ended December 31, 2007, Tax Service Fees paid were \$12,375. Tax Service Fees in 2007 represented fees for consulting services related to tax compliance.

### All Other Fees

All other fees in 2007 represent fees for Comperio, which is an online research tool.

To help ensure the independence of the independent registered public accounting firm, our audit committee has adopted a policy for the pre-approval of all audit and non-audit services to be performed for us by the independent registered public accounting firm, with the exception of up to \$20,000 in fees, which may be approved by the audit committee chair alone. Pursuant to this policy and subject to this exception, all audit and non-audit services to be performed by the independent auditor during 2009 must be approved in advance by the audit committee. The audit committee may delegate to one or more of its members the authority to grant the required approvals, provided that any exercise of such authority is presented to the full audit committee at its next regularly scheduled meeting.

All of the services provided by PricewaterhouseCoopers described in the table above were approved by our audit committee.

### PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibit Number

### Description

31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1

Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No. 1 to its Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: April 30, 2009

### **XTENT**, Inc.

By:

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this Amendment No. 1 to the registrant s Annual Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated:

Signature /s/ GREGORY D. CASCIARO Gregory D. Casciaro	<b>Title</b> President, Chief Executive Officer and Director (Principal Executive Officer)	<b>Date</b> April 30, 2009
/s/ TIMOTHY D. KAHLENBERG Timothy D. Kahlenberg	Chief Financial Officer (Principal Accounting Officer)	April 30, 2009
* Henry A. Plain, Jr.	Director	April 30, 2009
* Michael A. Carusi	Director	April 30, 2009
* Michael L. Eagle	Director	April 30, 2009
* Robert E. Flaherty	Director	April 30, 2009
* Christopher M. Smith	Director	April 30, 2009
* Arthur T. Taylor	Director	April 30, 2009
* Edward W. Unkart	Director	April 30, 2009
* Allan R. Will	Director	April 30, 2009

\* By: /s/ GREGORY D. CASCIARO Gregory D. Casciaro, Attorney-in-Fact C-32

Appendix D

# **UNITED STATES**

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

# **FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2009

or

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

For the transition period from to

Commission File Number 001-33282

# **XTENT, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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

### **125** Constitution Drive

Menlo Park, California 94025-1118

(Address of principal executive offices, including Zip Code)

### (650) 475-9400

(Registrant s telephone number, including area code)

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

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

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

Large accelerated filer O

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

Accelerated filer 0

Smaller reporting company X

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

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

## XTENT, INC.

# FORM 10-Q

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### PART I: FINANCIAL INFORMATION

### ITEM 1. CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

### XTENT, INC.

### (a development stage company)

### CONDENSED BALANCE SHEETS

### (unaudited; in thousands, except per share amounts)

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

<sup>(1)</sup> The condensed balance sheet at December 31, 2008 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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

### XTENT, INC.

### (a development stage company)

## CONDENSED STATEMENTS OF OPERATIONS

### (unaudited; in thousands, except per share amounts)

		Three Mon Marcl 2009	 d 2008	Cumulative Period from June 13, 2002 (Date of Inception) to March 31, 2009
Operating expenses:				
Research and development (1)	\$	4,654	\$ 9,421 \$	5 110,238
General and administrative (1)	·	2,763	3,442	37,223
Loss on impairment of long-lived assets		2,494	- ,	2,494
Total operating expenses		9,911	12,863	149,955
Loss from operations		(9,911)	(12,863)	(149,955)
		(9,911)	(12,003)	(149,933)
Interest and other income, net		55	406	6,118
Net loss		(9,856)	(12,457)	(143,837)
Deemed dividend related to beneficial conversion feature of redeemable convertible preferred stock				(13,095)
Net loss attributable to common stockholders	\$	(9,856)	\$ (12,457) \$	(156,932)
Net loss per share attributable to common stockholders - basic and diluted	\$	(0.42)	\$ (0.54)	
Weighted-average common shares outstanding - basic and diluted		23,324	22,923	
The state and a state common shares outstanding - basic and unuted		23,324	22,723	
(1) Includes the following stock-based compensation charges:				
Research and development	\$	256	\$ 388 \$	4,735
General and administrative	\$	508	\$ 650 \$	,

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

## XTENT, INC.

## (a development stage company)

## CONDENSED STATEMENTS OF CASH FLOWS

(unaudited; in thousands)

				Cummulative Period from June 13, 2002 (Date of Inception) to
	Three Months E 2009	nded Ma	rch 31, 2008	March 31, 2009
Cash flows from operating activities:				
Net loss	\$ (9,856)	\$	(12,457) \$	(143,837)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	347		321	4,368
Amortization of securities discount	(9)		(192)	(2,080
Gain on sale of investments			(26)	(6
Loss on disposal of property and equipment				188
Impairment of long-lived assets	2,494			2,494
Stock-based compensation expense	764		1,038	10,832
Stock issued in exchange for services				381
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	10		(732)	(702
Accrued interest receivable on securities	12		213	(16
Accounts payable	(727)		80	101
Accrued liabilities	8		446	1,664
Net cash used in operating activities	(6,957)		(11,309)	(126,613)
Cash flows from investing activities:				
Purchase of investments			(5,459)	(142,322
Proceeds from maturities of investments	5,750		9,925	130,459
Proceeds from sale of investments			9,963	13,949
Purchase of property and equipment	(241)		(304)	(8,547
Restricted cash	30			
Proceeds from sale of property and equipment			2	20
Net cash provided by (used in) investing activities	5,539		14,127	(6,441
<b>Cash flows from financing activities:</b> Proceeds from issuance of redeemable convertible preferred stock,				
net of issuance costs				75.592
Proceeds from initial public offering, net of offering costs				68,237
Principal payments on capital lease obligations				(23
Proceeds from issuance of common stock and exercise of stock				(23
options	5		32	1,208
Net cash provided by financing activities	5		32	145,014
The cash provided by manening activities	5		52	145,014
Net (decrease) increase in cash and cash equivalents	(1,413)		2.850	11,960
Cash and cash equivalents at beginning of period	13,373		13,366	11,900
cash and cash equivalents at beginning of period	10,010		10,000	
Cash and cash equivalents at end of period	\$ 11,960	\$	16,216 \$	11,960

Supplemental disclosure of noncash investing and financing activities:			
Deferred stock-based compensation	\$	\$	\$ 1,272
Reversal of deferred stock-based compensation	\$ (22)	\$ (30)	\$ (183)
Dividend related to beneficial conversion feature of redeemable			
convertible preferred stock	\$	\$	\$ (13,095)
Equipment acquired under capital leases	\$	\$	\$ (23)
Vesting of restricted common stock from early exercises	\$ 2	\$ 23	\$ 440
Deferred initial public offering costs	\$	\$	\$ 875
Changes in net unrealized gains on investments	\$ (11)	\$ 95	\$

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

### XTENT, INC.

### NOTES TO CONDENSED FINANCIAL STATEMENTS

(unaudited)

**NOTE 1 - Organization and Basis of Presentation** 

### Organization

XTENT, Inc. (the Company ) was incorporated in the state of Delaware on June 13, 2002 (inception), and is focused on developing and commercializing innovative drug eluting stent systems for the treatment of coronary artery disease. The Company is in the development stage and since inception has devoted substantially all of its time and efforts to developing products, raising capital and recruiting personnel.

The Company has incurred net operating losses each year since inception. At March 31, 2009, the Company had an accumulated deficit of \$143.8 million. The Company has not achieved positive cash flows from operations in any year since inception. In February 2007, the Company completed its initial public offering raising net proceeds of \$68.2 million. In January 2009, the Company announced a reduction in its headcount of approximately 115 employees, or 94% of its total workforce. As of March 31, 2009, the reduction was substantially complete, with six full-time employees remaining at April 30, 2009. During the first quarter of 2009, the Company was exploring strategic alternatives with the assistance of Piper Jaffray & Co., including, without limitation, a merger, a sale of substantially all Company assets, a financing, or a sale of a portion of the Company s assets, such as its peripheral stent technology, its drug eluting balloon technology, or its bioabsorbable stent technology. On May 11, 2009, the Company s board of directors concluded that it appeared unlikely that a strategic transaction at a valuation materially in excess of the estimated liquidation value would be achieved in the near term. Based on these and other factors, the board of directors concluded that a statutory dissolution and liquidation was in the best interests of the Company and its stockholders and therefore adopted a Plan of Complete Liquidation and Dissolution, or Plan of Dissolution, and recommended approval of the Plan of Dissolution by the Company s tockholders. The Plan of Dissolution is subject to approval at a special meeting of the stockholders, which is expected to be held during the second or third quarter of 2009.

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

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

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

### **Basis of Presentation**

The accompanying unaudited condensed financial statements have been prepared by the Company in accordance with the accounting principles generally accepted in the United States of America for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair statement have been included. The results for the three months ended March 31, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009, or for any future period. These unaudited condensed financial statements and notes should be read in conjunction with the audited financial statements and the notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2008, filed with the Securities and Exchange Commission on March 24, 2009.



### **NOTE 2 - Summary of Significant Accounting Policies**

#### Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company deposits cash with high credit quality financial institutions. Cash equivalents consist primarily of liquid money market funds and fixed income securities with original maturity dates of less than three months.

### Short-term Investments

Short-term investments with an original maturity of more than three months and less than one year at the date of purchase are considered to be short-term. Short-term investments consist primarily of fixed income securities. The Company classifies its investments as available-for-sale in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* and they are recorded at fair value. The fair value of short-term investments is based on quoted market prices. As of March 31, 2009, the Company did not have any short-term investments.

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

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

### **Concentration of Credit Risk**

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

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

Total comprehensive loss during the three months ended March 31, 2009 and 2008 consisted of:

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

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### Net Loss per Common Share

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

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

,457)
,049
(126)
923
0.54)
,

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

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

### **Recent and Adopted Accounting Pronouncements**

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS No. 159). SFAS No. 159 expands the use of fair value accounting but does not affect existing standards which require assets or liabilities to be carried at fair value. The objective of SFAS No. 159 is to improve financial reporting by providing companies with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently

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

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

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

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

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

### **NOTE 3 - Investments**

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

As of March 31, 2009	nortized Cost	 realized Sains (in thou	Unrealized Losses usands)	Fair Value
U.S. government and agency securities	\$ 5,741	\$ 11	\$	\$ 5,752

## NOTE 4 Fair Value Measurements

### Fair Value Measurements

SFAS No. 157, *Fair Value Measurements*, defines fair value as the price that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). SFAS No. 157 classifies the inputs used to measure fair value into the following hierarchy:

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

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

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

## Cash and Cash Equivalents

The Company s cash equivalents are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The fair value hierarchy of the Company s marketable securities at fair value in connection with the adoption of SFAS No. 157 consisted of the following as of March 31, 2009 and December 31, 2008:

	 nce as of Observable Inputs a 31, 2009 (Level 1) (in thousands)		Obser	ficant Other vable Inputs Level 2)	
Money market funds (1)	\$ 8,383	\$	8,383	\$	
U.S. government securities (1)	2,001				2,001
Commercial paper (1)	1,000				1,000
Total	\$ 11,384	\$	8,383	\$	3,001
	 Significant Other lance as of Observable Inputs nber 31, 2008 (Level 1)		vable Inputs	Obser	ficant Other vable Inputs Level 2)

(in thousands)

Money market funds (1)	\$ 11,613	\$ 11,613 \$	
U.S. Treasury Notes (1)	1,003	1	,003
U.S. government and agency securities	5,752	5	,752
Total	\$ 18,368	\$ 11,613 \$ 6	,755

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

## Assets Measured at Fair Value on a Nonrecurring Basis

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

## **NOTE 5 - Restricted Common Stock**

Certain common stock option holders have the right to exercise unvested options, subject to a repurchase right held by the Company to repurchase the stock, at the original exercise price, in the event of voluntary or involuntary termination of employment of the stockholder. In accordance with Emerging Issues Task Force Issue No. 00-23, *Issues Related to the Accounting for Stock Compensation* under APB 25 and FASB Interpretation No. 44, *Accounting for Certain Transactions* 

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

## **NOTE 6 - Stock Option Plans**

### Stock-based compensation and valuation assumptions

The Company calculates the fair value of each option award on the date of grant using the Black-Scholes option pricing model. The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding and is based on the option vesting term, contractual terms and industry peers as the Company does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. Beginning in 2008, the expected term assumption was based on the Company s historical settlement experience. ESPP terms are for the purchase period that began on November 15, 2007 and ended on May 15, 2008, and the purchase period that began on May 15, 2008 and ended on November 17, 2008. The ESPP was suspended in January 2009, and all funds for the purchase period that began on November 17, 2008 were refunded to employees.

The expected stock price volatility assumptions for the Company s stock options and ESPP for the three months ended March 31, 2008 were determined by examining the historical volatilities for industry peers in combination with the historical volatility of the Company since its Initial Public Offering on February 1, 2007. Volatility for three months ended March 31, 2009 was not assessed, as there were no stock options granted or ESPP requiring measurement during the period.

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

The expected dividend assumption is based on the Company s history and expectation of dividend payouts. In addition, forfeitures are estimated at the time of grant based on historical experience and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock option activity for the three months ended March 31, 2009 was as follows:

		Options	Outstandir	ng
	Shares Available for Grant (in thousands	Number of Shares s, except weighted averag	]	Weighted Average Exercise Price price)
Balance as of December 31, 2008	1,364	2,516	\$	5.47
Additional shares reserved Options granted	933			
Options exercised		(12)		0.43

Options forfeited/expired	444	(444)	6.61
Balance as of March 31, 2009	2,741	2,060	\$ 5.25

Non-Employee Stock-based Compensation

The Company accounts for equity instruments to or held by non-employees at their fair value on the measurement date in accordance with EITF 96-18. Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services rendered.

Stock-based compensation expense will fluctuate as the fair value of the common stock fluctuates. In connection with the grant of stock and stock options to non-employees, the Company recorded stock-based compensation charges of approximately \$0.8 million for the period from June 13, 2002 (inception) to March 31, 2009. For the three months ended March 31, 2009 and 2008, the Company recorded stock-based compensation charges for non-employees of approximately \$1,000 and \$5,000, respectively.

#### **NOTE 7 - Commitments and Contingencies**

#### **Operating Lease**

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

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

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

#### License Agreements

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

In July 2006, the Company entered into a license agreement with Millimed, Inc. for certain intellectual property related to the Company s business. In consideration for this license, the Company made an initial payment of \$350,000 in cash and issued 15,000 shares of common stock during the year ended December 31, 2006. In addition, the license agreement provided for an additional payment of \$200,000 upon achievement of certain milestones. On July 24, 2008, the Company entered into an assignment agreement with Millimed, assigning to the Company the entire and exclusive right, title and interest in previously licensed intellectual property. In consideration of this assignment the Company issued 50,000 shares of unregistered common stock to a third party at \$3.00 per share. Pursuant to the terms of the assignment agreement, the third party paid \$150,000 directly to Millimed. The \$200,000 milestone payment that was required under the original license agreement is no longer required.

#### **Purchase Commitments**

In April 2007, the Company entered into a supply agreement with Fortimedix B.V., under which Fortimedix B.V. agreed to manufacture and deliver stents for use in the Company s products. The terms of the agreement require minimum purchases over two years at contractual prices set in Euros. As of March 31, 2009, there were no outstanding purchase order commitments for stents. Under the terms of the supply agreement, any further annual purchase commitments have been delayed until the Company receives approval from the FDA to begin clinical trials in the United States.

In December 2007, the Company entered into the Amended and Restated License Agreement with Biosensors International Group, Ltd., under which the Company purchases the drug and polymer components used on its stents. As of March 31, 2009, there were no outstanding purchase commitments with Biosensors. The Company will pay royalties to Biosensors under the license agreement when revenues are generated from product sales.

### **Contingencies**

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

## Indemnifications

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

In accordance with the Company s amended and restated certificate of incorporation and bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company s request in such capacity. The Company also has entered into indemnification agreements with its directors and officers, pursuant to which it has indemnification obligations to them. There have been no claims to date and the Company has a director and officer insurance policy that may enable it to recover a portion of any amounts paid for future claims.

## **NOTE 8 - Income Taxes**

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes: An Interpretation of FASB Statement No. 109* (FIN No. 48). As of March 31, 2009, the Company has no unrecognized tax benefit.

The Company s practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties at March 31, 2009 or December 31, 2008.

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

## **NOTE 9 - Reduction in Force**

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

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

administrative in the Statement of Operations. A portion of these costs in the amount of \$0.2 million was still payable at March 31, 2009.

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

## **NOTE 10 - Subsequent Event**

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

## ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

## INTRODUCTION

The following discussion should be read in conjunction with the financial statements and the related notes included in this Form 10-Q, in our Form 10-K for the year ended December 31, 2008 and in our other filings with the Securities and Exchange Commission, or SEC. This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws. These statements include, but are not limited to, those concerning the following: future events, our future financial performance, business strategy, product introductions and plans and objectives of management for future operations, regulatory approvals and clinical timelines. Forward-looking statements are subject to risks and uncertainties that could cause actual results and events to differ materially. For a detailed discussion of these risks and uncertainties, see Part II, Item 1A Risk Factors below. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-Q.

## **BUSINESS OVERVIEW**

We are a development stage medical device company that has focused on developing and commercializing our proprietary Custom NX drug eluting stent, or DES, systems to treat coronary artery disease, or CAD. Since inception we have devoted substantially all of our resources to start-up activities, raising capital and performing research and development, including product design, testing, manufacturing and clinical trials. We have focused our development efforts on creating our Custom NX DES Systems, which allow a physician to deploy single or multiple stents of customizable length with a single device. We have not yet received any government regulatory approvals necessary to commercialize any of our products in the United States.

Over the past four years, we have been conducting clinical trials to evaluate our Custom NX 36 and Custom NX 60 stent and stent delivery systems. In October 2008, the one year data from our CUSTOM III clinical trial, the two year data from our CUSTOM II clinical trial and the three year data from our CUSTOM I clinical trial were presented at the 2008 Transcatheter Cardiovascular Therapeutics conference in Washington D.C. We believe the data from these clinical trials provides preliminary evidence of safety and efficacy and support further development of our in-situ customization approach. In March 2009, we received CE Mark approval for our Custom NX DES Systems authorizing us to market our products in the European Union and certain other countries that recognize CE Mark. Even though we have received CE Mark, we do not have adequate resources to commercialize our products in Europe.

We will need premarket approval, or PMA, from the U.S. Food and Drug Administration, or FDA, before we can market our products in the United States, which we expect would require data from a large clinical trial of up to 2,100 patients. We expected to obtain this data through our planned CUSTOM IV clinical trial, but to initiate the CUSTOM IV trial, we would first need to obtain clearance of an investigational device exemption, or IDE, from the FDA. We filed our IDE application in September 2007, and in October 2007, we received questions back from the FDA. In February 2009, we resubmitted our IDE application, and received questions back from the FDA in April 2009. Even if we receive IDE approval from the FDA, we do not have adequate resources to initiate our IDE trial.

To date, we have not generated any revenue from our development activities and will not be able to generate revenue unless we obtain additional financing to support commercialization of our products in the European Union. We have incurred net losses in each year since our inception in June 2002. Through March 31, 2009, we had an accumulated deficit of \$143.8 million.

## **RECENT DEVELOPMENTS**

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

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

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

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

We base the discussion and analysis of our financial condition, results of operations and liquidity and capital resources upon our unaudited condensed financial statements, which we prepare in accordance with U.S. generally accepted accounting principles. In preparing these financial statements, we must make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses. We evaluate our estimates based on historical experience and various other assumptions we believe are reasonable under the circumstances. Our actual results could differ materially from these estimates under different assumptions or conditions.

## FINANCIAL OPERATIONS

### Revenue

To date, we have not generated any revenue from the sale of our stent systems. Revenue generation is subject to commercial launch of our product in Europe. Even though we received CE Mark in March 2009, we do not have adequate resources to commercialize our product in the European Union.

### **Research and Development**

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

substantially completed in March 2009.

## General and Administrative

General and administrative expenses consist primarily of compensation for executive, finance, marketing and administrative personnel including stock-based compensation. Other significant expenses include professional fees for accounting and legal services associated with our efforts to obtain and maintain protection for intellectual property related to our Custom NX DES Systems. From our inception through March 31, 2009, we incurred \$37.2 million in general and administrative expenses. We expect our general and administrative expenses to decrease due to the reduction in force we substantially completed in March 2009.

### Loss on Impairment of Long-Lived Assets

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

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

## **RESULTS OF OPERATIONS**

## COMPARISON OF THREE MONTHS ENDED MARCH 31, 2009 AND 2008

Revenue

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

**Research and Development** 

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

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

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

• A decrease of \$1.5 million in personnel costs offset by a \$0.6 million increase in costs related to the reduction in force completed in March 2009;

• A decrease of \$0.4 million in expenses related to the support of our clinical research studies in 2009 as compared to the first quarter of 2008 due to activity in the first quarter of 2008 related to studies conducted to support our IDE application;

- A decrease of \$0.1 million in employee stock-based compensation; and
- A decrease of \$0.3 million in facilities and other miscellaneous expenses.

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

## General and Administrative

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

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

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

• A decrease of \$0.2 million in legal and accounting expenses;

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

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

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

	Three Mont March	I	Dollar		
	2009 (in thous	С	Change		
Loss on impairment of long-lived assets	\$ 2,494	\$	\$	2,494	

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

## Interest and Other Income, Net

		Three Mon Marc		nded	Dollar
	2	009 (in thou	isands	2008	Change
Interest and other income, net	\$	55	\$	406	\$ (351)

The \$0.4 million decrease in interest and other income, net, for the three months ended March 31, 2009, compared to the three months ended March 31, 2008, was primarily attributable to a decrease in the levels of cash, cash equivalents and short-term investments, as well as lower average interest rates.

## LIQUIDITY AND CAPITAL RESOURCES

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

	As of March 31, 2009		De	As of cember 31, 2008
Cash and cash equivalents Short-term investments	\$	11,960	\$	13,373 5,752
Total cash and cash equivalents and short-term investments	\$	11,960	\$	19,125

## Sources of Liquidity

We are in the development stage and have incurred losses since our inception in June 2002. As of March 31, 2009, we had an accumulated deficit of \$143.8 million. Prior to our Initial Public Offering in February 2007, we funded our operations from the private placements of our convertible preferred stock resulting in aggregate net proceeds of \$75.6 million through December 31, 2006. Upon completion of the reduction in force in April 2009, our cash requirements were greatly reduced. On May 11, 2009, our board of directors concluded that a statutory dissolution and liquidation was the preferred strategy and therefore adopted a Plan of Complete Liquidation and Dissolution, or Plan of Dissolution, and recommended approval of the Plan of Dissolution by our stockholders. The Plan of Dissolution is subject to approval at a special meeting of our stockholders, which is expected to be held during the second quarter of 2009.

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

### Cash Flows

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

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

### **Operating Activities**

Net cash used in operating activities was \$7.0 million for the three months ended March 31, 2009, compared to \$11.3 million for the three months ended March 31, 2008. The net cash used in operating activities for the three months ended March 31, 2009 and 2008 primarily reflects expenses related to product development and clinical trials. These expenses were partially offset by depreciation and amortization, amortization of securities discounts, gain on sale of investments, non-cash stock-based compensation and non-cash charges in operating assets and liabilities, including an asset impairment charge of \$2.5 million, based on the estimated liquidation value of long-lived assets.

### **Investing** Activities

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

### **Financing** Activities

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

## **Operating Capital and Capital Expenditure Requirements**

To date, we have not commercialized any products. We do not anticipate generating any revenue unless and until we secure additional funding to commercialize our products in the European Union and obtain FDA marketing approval for, and begin selling, our Custom NX DES Systems. If we were to continue our operations, we anticipate that we would continue to incur substantial net losses for the next several years as we develop our products, conduct and complete clinical trials, pursue additional applications for our technology platform, expand our clinical development team and corporate infrastructure, and prepare for the potential commercial launch of our products. Our current cash and cash equivalents are not sufficient to meet the cash requirements of these activities.

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

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

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

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

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

## • licensing technologies for future development.

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

## **Contractual Obligations**

Our principal commitments as of March 31, 2009 consist of obligations under operating leases and purchase obligations that we enter into through the normal course of business. See Note 7 of our Notes to Condensed Financial Statements for more detailed information.

## **Off-Balance Sheet Arrangements**

Since inception, we have not engaged in any off-balance sheet activities as defined in Regulation S-K Item 303(a)(4).

#### **Recent and Adopted Accounting Pronouncements**

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

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

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

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

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

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

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

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and investments in a variety of marketable securities, including commercial paper, money market funds and U.S. government and agency securities. Our cash and cash equivalents as of March 31, 2009 consist of liquid money market funds, U.S. government securities and commercial paper. We did not have short-term investments as of March 31, 2009. Due to the short-term nature of our investments, we believe that there is no material exposure to interest rate risk.

## Exchange rate risk

Under our Supply Agreement with Fortimedix B.V., we have market risk exposure to adverse changes in foreign exchange rates. The cost of the stents we purchase from Fortimedix requires payment in euros. Fluctuations in the euro to U.S. dollar exchange rate therefore impacts the cost of our product. To date, we have not experienced any significant negative foreign exchange transaction losses. We expect higher product costs if there is a decline in the exchange rate between the U.S. dollar and the euro. Based upon the supply agreement, any further annual purchase commitments have been delayed until we receive approval from the FDA to begin clinical trials in the United States. As a policy, we do not engage in speculative or leveraged transactions, nor do we hold financial instruments for trading purposes.

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

## **ITEM 4. CONTROLS AND PROCEDURES**

### **Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2009.

### **Changes in Internal Control Over Financial Reporting**

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended March 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II: OTHER INFORMATION

## **ITEM 1. LEGAL PROCEEDINGS**

None.

## ITEM 1A. RISK FACTORS

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

## **Risks Related to Our Plan of Dissolution**

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

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

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

• If any of the estimates regarding the Plan of Dissolution, including the net proceeds from the sale of our tooling and manufacturing and test equipment, furniture and supplies, and the expense of satisfying outstanding obligations, liabilities and claims during the liquidation process are inaccurate, the amount we distribute to our stockholders may be substantially less than the amount we currently estimate. Given the current macroeconomic conditions, for purposes of our estimates we have assigned no value to our drug eluting stent systems and related intellectual property. If claims are asserted against us, including any claims related to payments to suppliers or other vendors or claims from patients in our clinical trials, we will have to defend or resolve such claims before making distributions to our stockholders, which will reduce amounts otherwise available for distribution to our stockholders;

• We have made estimates regarding the expense of personnel required and other operating expenses (including legal, accounting and other professional fees) necessary for us to dissolve and liquidate. Our actual expenses could vary significantly and depend on the timing and manner of the sale of our non-cash assets. If the timing differs from our plans, we may incur additional expenses above our current estimates, which could substantially reduce funds available for distribution to our stockholders; and

• We have assumed that all material contract rights can be effectively transferred to third parties. If we are unable to obtain any required consents with the counterparties to those contracts, our ability to transfer such rights may be impaired.

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

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

the preparation, review, filing and dissemination of SEC filings;

- maintenance of effective internal controls over financial reporting; and
- audits and reviews conducted by our independent registered public accountants.

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

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

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

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

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

• if a creditor or other third party seeks an injunction against the making of distributions to our stockholders on the ground that the amounts to be distributed are needed to provide for the satisfaction of our liabilities or other obligations;

• if we become a party to lawsuits or other claims asserted by or against us, including any claims or litigation arising in connection with our decision to liquidate and dissolve, payments to suppliers or other vendors or claims from patients in our clinical trials;

- if we are unable to sell our remaining non-cash assets or if such sales take longer than expected;
- if we are unable to resolve claims with creditors or other third parties, or if such resolutions take longer than expected; or
- if the issuance of the revenue clearance certificate required to file our certificate of dissolution with the Secretary of State is delayed.

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

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

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

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

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

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

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

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

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

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

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

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

If our stockholders do not approve the Plan of Dissolution, our board of directors will explore what, if any, alternatives are available for our future, particularly in light of the fact that we have terminated substantially all of our employees, would need significant additional capital to support our U.S. pivotal clinical trial and efforts to commercialize our products in Europe, commenced the process of winding up our business and will continue to incur net losses for the foreseeable future. There is currently no active business left to operate and rehiring employees may

not be possible, or would take several months at a cost we are unable to estimate.

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

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

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

### **Risks Related to Our Business**

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

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

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

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

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

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

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

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

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

- fund our operations and clinical trials;
- continue our research and development;
- scale-up our manufacturing operations;
- defend, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- commercialize our products, if any such products receive regulatory approval for commercial sale; and
- acquire or in-license companies, products or intellectual property.

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

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

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

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

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

products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs.

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

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

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

We have incurred net losses since our inception in June 2002. For the years ended December 31, 2008, 2007, and 2006, we had net losses of \$41.1 million, \$38.8 million and \$25.0 million, respectively. As of March 31, 2009, we had an accumulated deficit of \$143.8 million. To date, we have financed our operations primarily through private placements of our equity securities and our Initial Public Offering, completed on February 1, 2007, and have devoted substantially all of our resources to research and development and clinical studies related to our Custom NX DES Systems, which consist of the Custom NX 36 and the Custom NX 60. Since we have only recently received CE Mark and we do not have approval from the Food and Drug Administration, or FDA, or any other regulatory authority for our products, we are only authorized to market our current products in the European Union and certain other countries that recognize CE Mark, and we have not generated any revenues since our inception. If we continue as an operating business, we expect our research and development expenses to increase significantly in connection with our clinical trials and other product development activities. If we obtain additional funding or complete a strategic transaction that provides adequate resources, we expect to incur significant sales and marketing expenses and manufacturing expenses as we commercialize our products. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses will continue to have an adverse effect on our stockholders equity.

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

In May 2004, we entered into a license agreement with Biosensors. In December 2007, we entered into an amended and restated license agreement with Biosensors which superseded the prior agreement. Pursuant to the agreement, we obtained non-exclusive rights to use Biosensors drug coating on our stent platform. The drug coating consists of Biolimus A90, an anti-inflammatory drug that is a derivative of rapamycin, and PolyLactic Acid, or PLA, a biodegradable polymer used to release the drug over time. In January 2008, Biosensors announced that it had received CE Mark approval for its BioMatrix drug eluting stent which uses the Biolimus A9 and PLA drug coating. The drug coating has not been approved for any use in the United States or any jurisdiction other than the European Union. In March 2009, we received CE Mark approval for our Custom NX DES Systems authorizing us to market our Custom NX DES Systems in the European Union and certain other countries that recognize CE Mark.

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

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

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

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

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

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

- we may experience delays in our development program, including initiation and completion of our clinical trials;
- any products that are approved may not be accepted in the marketplace by physicians and patients;
- physicians may not receive adequate coverage and reimbursement for procedures using our products;
- any rapid technological change may make our technology and products obsolete;

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

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

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

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

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

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

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

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

- our stent systems may not be safe or effective or may not otherwise meet the FDA s requirements;
- the data from our pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities we or our suppliers use may not meet stringent regulatory requirements;

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

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

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

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

On September 14, 2006, the FDA issued a *Statement on Coronary Drug-Eluting Stents*, which discusses clinical data presented at the March 2006 American College of Cardiology Scientific Sessions in Atlanta, Georgia and at the September 2006 European Society of Cardiology Annual Meeting/World Congress of Cardiology Meeting in Barcelona, Spain. This data suggested a small but significant increase in the rate of death and myocardial infarction, or heart attack, potentially due to late-stent thrombosis, in patients treated with drug eluting stents at 18 months to three years after stent implantation. The FDA stated that, while these studies have raised important questions regarding the safety and efficacy of drug eluting stents, it is not possible to fully characterize the mechanisms, risks and incidence rates of late-stent thrombosis following implantation of drug eluting stents based on currently available data. The FDA has not issued any new position to date regarding the safety of drug eluting stents. Although more recent studies have suggested that the safety of drug eluting stents is comparable to that of bare metal stents, the FDA and the European regulatory agencies have issued new guidelines for the approval of drug eluting stents which require additional clinical data and may prolong the process for obtaining regulatory approval.

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

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

• Engineering testing,

• Biocompatibility testing,

• Animal studies,

• Chemistry and manufacturing controls,

- Clinical pharmacology and drug release,
- Drug pharmacology, toxicology and safety data,
- Clinical studies, and
- Post approval studies.

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

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

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

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

- the supplier of our drug coating is unable or refuses to meet our demand;
- our license agreement with Biosensors terminates for any reason, including insolvency; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

• changes in governmental regulations or administrative actions;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

regulations administered by the FDA and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following enforcement actions:

• warning letters or untitled letters;

• fines and civil penalties;

• unanticipated expenditures;

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

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

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

Moreover, any modification to a device that has received FDA approval that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new approval from the FDA. If the FDA disagrees with any determination by us that new approval is not required, we may be required to cease marketing or to recall the modified product until we obtain approval. In addition, we could also be subject to significant regulatory fines or penalties.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or efficacy of our products, and we will be required to report adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR or GMP, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties. For example, Boston Scientific has initiated significant recalls of its stent products due to manufacturing and other quality issues associated with the products.

Further, healthcare laws and regulations may change significantly in the future. Any new healthcare laws or regulations may adversely affect our business. A review of our business by courts or regulatory authorities may result in a determination that could adversely affect our operations. Also, the healthcare regulatory environment may change in a way that restricts our operations.

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

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

#### **Risks Related to Our Intellectual Property**

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

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

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

• use of rapamycin or its analogs to treat restenosis;

- stent structures and materials;
- catheters used to deliver stents; and
- stent manufacturing and coating processes.

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

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

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

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

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

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

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

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

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

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

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

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

• pay damages, including up to treble damages and the other party s attorneys fees, which may be substantial;

• cease the development, manufacture, use and sale of products that infringe the patent rights of others, including our Custom NX DES Systems, through a court-imposed sanction called an injunction;

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

• discontinue manufacturing or other processes incorporating infringing technology; or

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

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

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

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

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

Our ability to protect our products from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. As of December 31, 2008 we had seven issued U.S. patents, one of which is under exclusive license, covering certain aspects of the technology that we intend to commercialize and a number of other issued patents and pending patent applications in the United States and abroad. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering medical devices and pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any of our issued patents may not provide us with commercially meaningful protection for our products or afford us a commercial advantage against our competitors or their competitive products or processes. In addition, patents may not issue from any pending or future patent applications owned by or licensed to us, and moreover, patents that have issued to us or may issue in the future may not be valid or enforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing products like ours, despite our patent rights.

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

our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO to determine priority of invention in the United States. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the United States. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

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

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

We are aware that another medical business that holds patents to certain stent designs has used the name XTENT for limited purposes in the past. If it turns out that the other business has superior trademark rights in the name, and if the other business were to challenge our use of the XTENT name, we would then need to convince a court that there is no likelihood of consumer confusion. If we were unsuccessful in court, then we could be held liable for trademark infringement and we might then have to change our name as well as pay monetary damages. If we were forced to change our name, we may suffer from a loss of brand recognition, we may be required to retrieve product and interrupt supply, and may have to devote substantial resources advertising and marketing our products under a new brand name.

#### **Risks Related to Commercialization**

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

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

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

• greater financial and human resources for product development, sales and marketing, and patent litigation;

• significantly greater name recognition;

• established relations with healthcare professionals, customers and third-party payors;

• additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;

• established distribution networks; and

• greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products and marketing approved products.

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

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

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

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

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

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

We currently have limited resources, facilities and experience to commercially manufacture the device component of our products and apply the drug coating to the stents. In addition, pursuant to the terms of the restated license agreement with Biosensors, we plan to perform our own drug coating formulation. Furthermore, effective March 23, 2009, we substantially completed a reduction in our headcount from 122 to 5 employees, and we fully completed that reduction by April 30, 2009. None of the remaining employees will be manufacturing personnel. In order to produce our Custom NX DES Systems in the quantities that we anticipate will be required to meet anticipated market demand, we will need to increase, or scale-up, the production process by a significant factor over our current level of production. There are technical challenges to scaling-up manufacturing capacity and developing commercial-scale manufacturing facilities that will require the investment of substantial additional funds and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required scale-up in a timely manner or at all. If we are unable to do so, we may not be able to produce products in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, if at all. If we develop and obtain regulatory approval for our products and are unable to

manufacture a sufficient supply of our products, our revenue, business and financial prospects would be adversely affected. In addition, if the scaled-up production process is not efficient or produces stents that do not meet quality and other standards, our future gross margins may decline.

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

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

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

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

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

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

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

additional or replacement suppliers for these components, and obtaining any additional regulatory approvals that may result from adding or replacing suppliers, will take a substantial amount of time. We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or foreign regulatory authorities. Furthermore, since some of these suppliers are located outside of the United States, we are subject to foreign export laws and U.S. import and customs regulations, which complicate and could delay shipments to us. Some of our suppliers are also our competitors and may be reluctant to supply components to us on favorable terms, if at all.

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

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

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

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

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

- the research methodology used may not be successful in identifying potential products;
- competitors may develop alternatives that render our products obsolete;
- our products may not be deployed safely or effectively;

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

- our clinical trials may not be successful; and
- we may not receive regulatory approval.

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

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

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

#### **Risks Related to Our Industry**

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

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

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

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

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

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

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

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

#### **Risks Related to Our Operations**

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

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

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

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

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring us to include a report of management on our internal control over financial reporting in our annual report on Form 10-K for the year ended December 31, 2008. In addition, in our annual report on Form 10-K for the year ending December 31, 2009, the independent registered public accounting firm auditing our financial statements

must attest to the effectiveness of our internal control over financial reporting. We may be unable to comply with these requirements by the applicable deadlines. We will be testing our internal control over financial reporting in connection with Section 404 requirements and could, as part of that documentation and testing, identify material weaknesses, significant deficiencies or other areas requiring further attention or improvement.

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

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

• the results of our clinical trials;

• the timing of our regulatory approvals;

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• announcements related to litigation;

• statements made by Biosensors relating to regulation or supply of the drug coating;

- the announcement of new products or service enhancements by us or our competitors;
- quarterly variations in our or our competitors results of operations;

• changes in earnings estimates, investors perceptions, recommendations by securities analysts or our failure to achieve analysts earning estimates;

• the low trading volume of our common stock;

• developments in our industry, including changes in third-party reimbursement; and

• general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

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

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

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

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

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

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

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

• a classified board so that only one of the three classes of directors on our board of directors is elected each year;

- elimination of cumulative voting in the election of directors;
- procedures for advance notification of stockholder nominations and proposals;

• the ability of our board of directors to amend our bylaws without stockholder approval;

• a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and our amended and restated bylaws; and

• the ability of our board of directors to issue up to 10,000,000 shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our board of directors may determine.

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

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

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

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None

### **ITEM 5. OTHER INFORMATION**

None.

### **ITEM 6. EXHIBITS**

Exhibit	
Number	Description
3.2(1)	Amended and Restated Certificate of Incorporation.
3.4(1)	Amended and Restated Bylaws.
4.1(1)	Specimen Common Stock certificate of the Registrant.
10.1(1)	Form of Indemnification Agreement for directors and executive officers.
10.2(1)	2002 Stock Plan and form of stock option agreements used thereunder.
10.3(1)	2006 Equity Incentive Plan and form of stock option agreement used thereunder.
10.4(1)	2006 Employee Stock Purchase Plan.
10.5(1)	Amended and Restated Investor Rights Agreement dated May 5, 2006 by and among the Registrant and certain stockholders.
10.6(1)	Business Park Lease dated September 15, 2003, as amended November 22, 2005, by and between the Registrant
	and 125 Constitution Associates, L.P. for office space located at 125 Constitution Drive, Menlo Park, California, 94025-1118.
10.8(1)	Master License Agreement dated December 30, 2002, as amended June 30, 2006, by and between the Registrant and
	SurModics, Inc.
10.9(1)	License Agreement dated July 10, 2006 by and between the Registrant and Millimed A/S.
10.10(2)	Supply Agreement dated April 2, 2007 by and between Registrant and Fortimedix B.V.
10.11(3)	Second Amendment to Lease dated May 17, 2007 by and between the Registrant and 125 Constitution Associates, L.P.
10.12(4)	Amended and Restated License Agreement dated December 3, 2007 by and between Registrant, Biosensors International
	Group, Ltd. and Biosensors Europe S.A.
10.13(5)	Amended 2006 Equity Incentive Plan and form of stock option agreement used thereunder.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the
	Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the
	Sarbanes-Oxley Act of 2002.

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

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

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

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

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

Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The confidential portions have been filed with the SEC.

### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

	XTENT, Inc.	
Date: May 15, 2009	By:	/s/ GREGORY D. CASCIARO GREGORY D. CASCIARO President and Chief Executive Officer (Principal Executive Officer)
Date: May 15, 2009	By:	/s/ TIMOTHY D. KAHLENBERG TIMOTHY D. KAHLENBERG Chief Financial Officer (Principal Accounting and Financial Officer)
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IF YOU HAVE NOT VOTED VIA THE INTERNET <u>OR</u> TELEPHONE, FOLD ALONG THE PERFORATION, DETACH AND RETURN THE BOTTOM PORTION IN THE ENCLOSED ENVELOPE.

### THIS PROXY IS SOLICITED ON BEHALF OF THE BOARD OF DIRECTORS OF

### XTENT, INC.

### SPECIAL MEETING OF STOCKHOLDERS TO BE HELD ON JULY 9, 2009

The undersigned stockholder of XTENT, Inc., a Delaware corporation, hereby acknowledges receipt of the Notice of Special Meeting of Stockholders and Proxy Statement each dated June 8, 2009 and hereby appoints Gregory D. Casciaro and Ronald C. Austin, each as proxy and attorney-in-fact, with full power of substitution, on behalf and in the name of the undersigned to represent the undersigned at the Special Meeting of Stockholders of XTENT, Inc. to be held on July 9, 2009, at 9:00 a.m., local time, at XTENT s offices located at 125 Constitution Drive, Menlo Park, California 94025-1118, and at any postponement or adjournment thereof, and to vote all shares of common stock which the undersigned would be entitled to vote if then and there personally present, on the matters set forth on the reverse side.

# THIS PROXY WILL BE VOTED AS DIRECTED OR, IF NO INDICATION IS MADE, THIS PROXY WILL BE VOTED *FOR* ALL PROPOSALS AND IN THE DISCRETION OF THE PROXY HOLDERS ON SUCH OTHER BUSINESS AS MAY COME BEFORE THE SPECIAL MEETING AND ANY ADJOURNMENT OR POSTPONEMENT THEREOF.

PLEASE SIGN, DATE AND PROMPTLY RETURN THIS PROXY IN THE ENCLOSED RETURN ENVELOPE, WHICH IS POSTAGE PREPAID IF MAILED IN THE UNITED STATES

If you vote your proxy by Internet or by telephone, you do NOT need to mail back your proxy card.

SEE REVERSE SIDE

### XTENT

Using a <u>black ink</u> pen, mark your votes with an  $\mathbf{X}$  as shown in this example. Please do not write outside the designated areas.  $\mathbf{x}$ 

### ELECTRONIC VOTING INSTRUCTIONS

You can vote by Internet or telephone!

Available 24 Hours a Day, 7 Days a Week!

Instead of mailing your proxy, you may choose one of the two voting methods outlined below to vote your proxy.

### VALIDATION DETAILS ARE LOCATED BELOW IN THE TITLE BAR.

Proxies submitted by the Internet or telephone must be received by 11:00 PM Pacific Time on July 8, 2009.

### Vote by Internet

Log on to the Internet and go to http://www.investorvote.com/XTNT

Follow the steps outlined on the secured website.

### Vote by telephone

Call toll free 1-800-652-VOTE(8683) within the United States, Canada and Puerto Rico any time on a touch tone telephone. There is NO CHARGE to you for the call.

Follow the instructions provided by the recorded message.

### A. Proposals The Board of Directors recommends a vote FOR Proposals 1 and 2.

1.	To approve the voluntary dissolution and liquidation of XTENT pursuant to the Plan of Dissolution.	For 0	Against 0	Abstain 0
2.	To adjourn the Special Meeting to another date, time or place, if necessary in the judgment of the proxy holders, for the purpose of soliciting additional proxies to vote in favor of Proposal 1.	For 0	Against 0	Abstain 0

### **B. Non-Voting Items**

### Change of Address Please print new address below

### C. Authorized Signature This section must be completed for your vote to be counted. Date and Sign Below

**NOTE**: This Proxy should be marked, signed by the stockholder(s) <u>exactly as his or her name appears hereon</u>, and returned promptly in the enclosed envelope. If the stock you are voting is registered in the name of two or more persons, each should sign. Persons signing in a fiduciary capacity should use their respective titles. If shares are held by joint tenants or as community property, both parties should sign. If shares are held by a corporation, please give the full corporate name and have a duly authorized officer sign, stating title, and if the shares are held by a partnership, please have an authorized person sign in the name of the partnership.

Date (mm/dd/yyyy)

Signature 1 Please keep signature within box.

Signature 2 - Please keep signature within box.

/ /