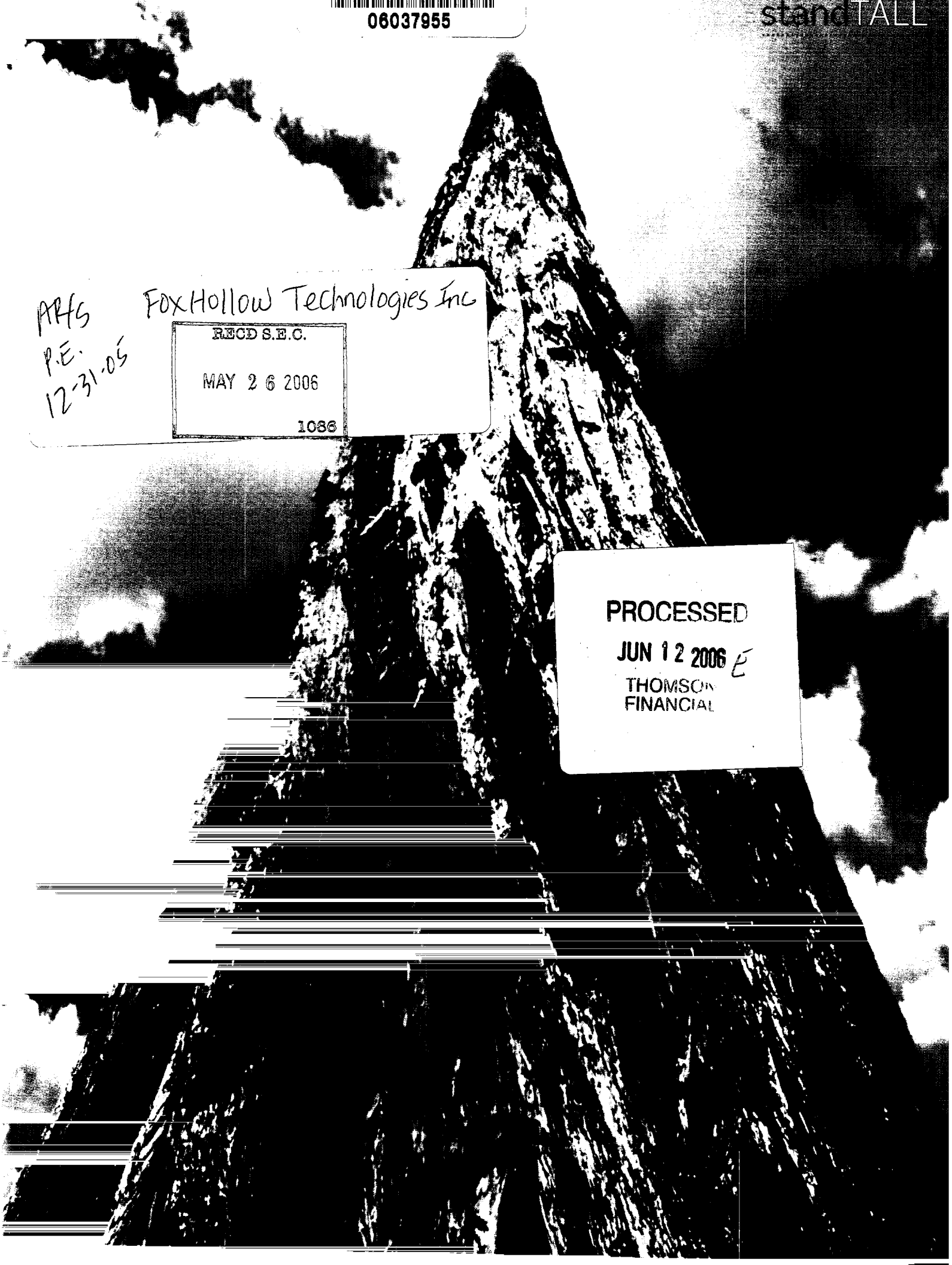
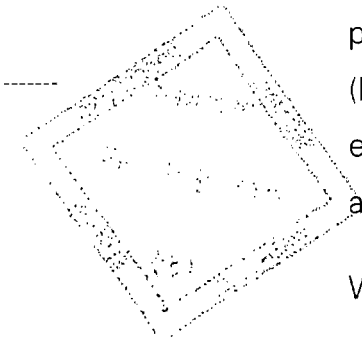




Every year, an estimated 150,000 lower limb amputations are performed in the U.S. due to severe peripheral arterial disease (PAD). Beyond the traumatic nature of the procedure itself, each amputation immediately disables a once-active person and irrevocably changes their life forever.

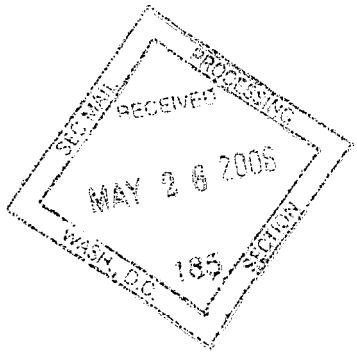
We believe there's another way.

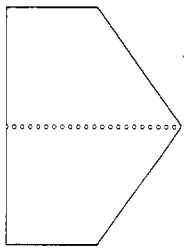
FoxHollow is single-mindedly dedicated to ensuring that some day, the number of PAD-related amputations will be 0.

How? By removing the plaque blocking the leg arteries and restoring needed blood flow to the limb. By alleviating the severe leg pain and limited mobility that often result from these blockages. By teaching thousands of physicians how to recognize PAD symptoms, and providing the technology to enable earlier intervention for the 12 million patients in the U.S. with PAD.

And, by believing that we can change the way cardiovascular disease is treated. **Forever.**

# This is our Stand.



**Chuck and Marilyn Mason**

Chuck Mason and his wife Marilyn love to dance, but when one half of the dance duo was diagnosed with PAD, the music stopped. 74-year-old Chuck Mason was afflicted with debilitating leg pain as a result of his disease. He couldn't walk without pain much less dance. Mr. Mason learned of the SilverHawk device through a local news article and eventually had plaque removed from both legs, restoring blood flow to the blocked areas. Now, he's back to walking, dancing and sweeping his wife off her feet.

# Stand together.

Peripheral arterial disease is significantly underdiagnosed. Its symptoms are often mistakenly attributed to just "getting old." As a result, hundreds of thousands of people resign themselves – unnecessarily – to watching their grandkids play instead of playing with them. To walking a block instead of a mile. To golfing 9 holes instead of 18. Chuck Mason, pictured left, was one of these people.

PAD occurs when arteries in the leg become narrowed or blocked by plaque, which decreases blood flow to the lower leg, feet and toes. If left untreated, PAD can cause severe leg pain and lead to gangrene, tissue loss, and ultimately, amputation.

**Symptoms of PAD include**

- Dull cramping pain in the hips, thighs, calves or buttocks during exercise or rest
- Numbness or tingling in the legs, feet or toes
- Changes in skin temperature or color

People with diabetes and those who have coronary artery disease are at particularly high risk for PAD. Additional risk factors include smoking and age. Approximately 30% of all diabetics and 20% of the population over 70 is thought to have PAD. Additionally, 40% of patients with coronary artery disease have PAD.

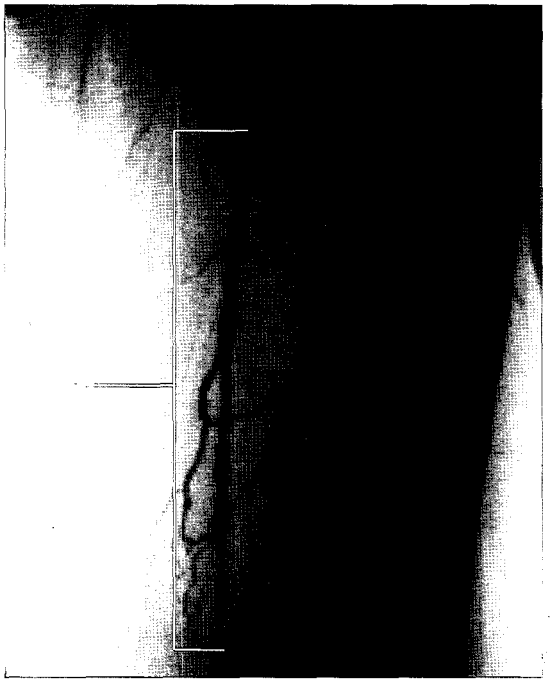
# Stand for change.

For decades, bypass surgery has been the de facto treatment for blockages in the leg arteries. Bypass surgery is typically very invasive, often requiring a leg-long incision and a long recuperation period.

We believe there is a better way.

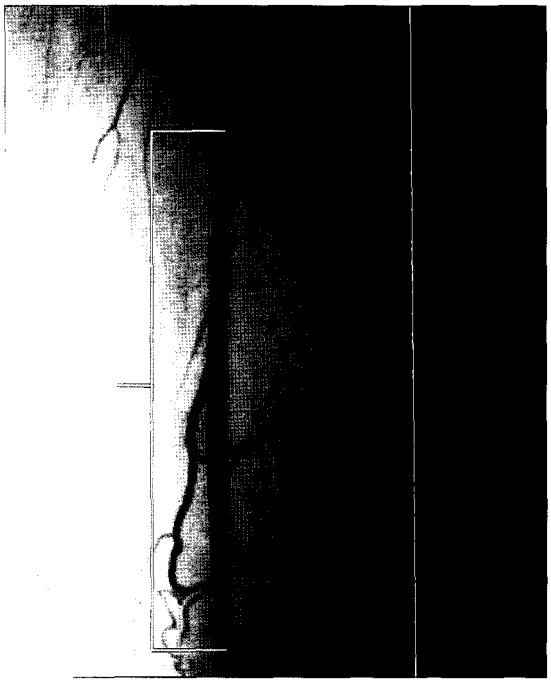
Plaque excision is a minimally invasive method of removing the plaque which clogs the leg arteries. It is performed through a tiny puncture site in the groin and typically takes no more than an hour or two. Using a tiny rotating blade, the SilverHawk™ System shaves away the plaque and stores it in the tip of the device where it can be removed when the device is withdrawn.

In 2005, FoxHollow introduced three new products that enabled physicians to more effectively remove various types of plaque which clog the leg arteries. Active research and development efforts are focused on a number of trailblazing technologies such as NightHawk™, a plaque excision device with an embedded fiber-optic camera to provide real-time visualization of the plaque being removed from the artery.



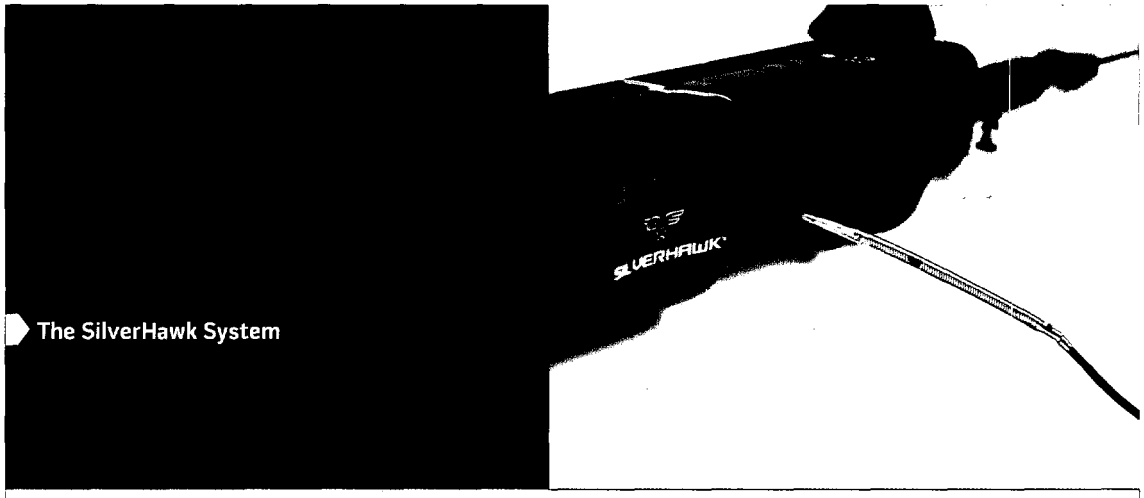
**Angiogram A**

Pre-SilverHawk angiogram
showing limited blood flow through the artery.



**Angiogram B**

Post-SilverHawk angiogram
showing restored blood flow through the artery.




**The SilverHawk System**


Avoiding amputations, one patient at a time.

# Stand firm.

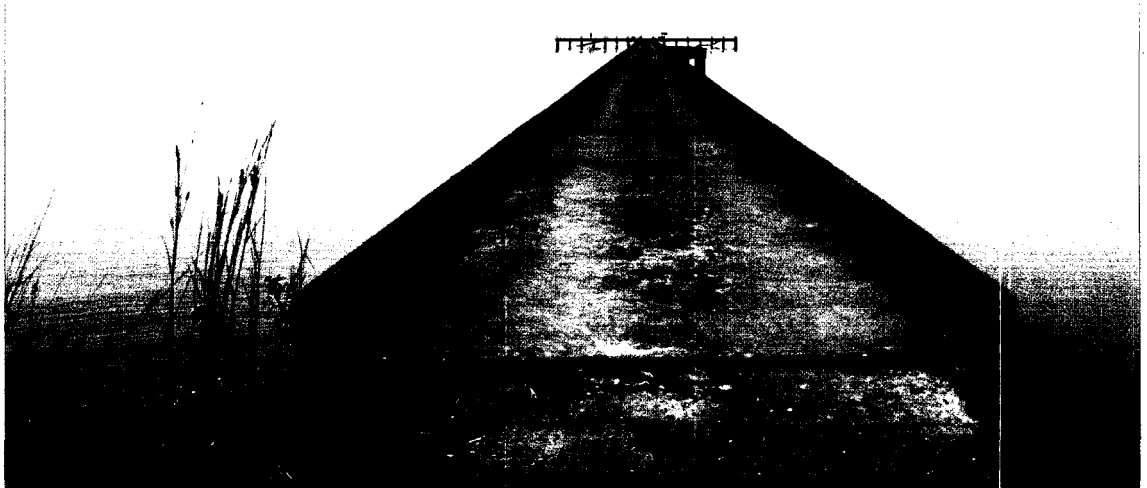
Patients who need and want treatment, deserve it.

To help those who are in need, but lack the resources to get care, FoxHollow has established the StandTALL program. SilverHawk catheters are donated at no cost for non-insured patients with PAD both abroad and here in the U.S. FoxHollow is partnering with trained SilverHawk users in the U.S. who travel to developing countries to provide medical treatment. This approach gives patients access both to no-cost devices and to physicians who are skilled experts in plaque excision.

# Stand for a cure.

SilverHawk's ability to remove plaque from the arteries opens up an entirely new field of research... gene expression and protein profiling of atherosclerosis.

In 2005, we established a new division of the company, **FHT Biologics**, and signed a wide-ranging research agreement with Merck & Co., Inc. Together with Merck, we are working toward the identification of novel biomarkers in the plaque removed by SilverHawk. Uncovering predictive biomarkers ultimately will enable physicians to understand and treat each patient's vascular disease on the basis of their own biological profile. FHT Biologics is also working toward the development of a new drug evaluation platform that will help accelerate new compound assessment and drug therapies.



Very little is known about the biological differences between patients who have cardiovascular disease. What is needed is a deeper understanding of how and why cardiovascular disease progresses, and exactly how an individual patient's gene profile affects that process.

Identifying specific biological markers in the plaque that can predict one patient's outcomes versus another will transform the way we develop and prescribe cardiovascular diagnostics and drugs. Treatment can then be based on a patient's individual biology instead of a broad set of symptoms shared by millions of other people.

This approach is not new. The diagnosis and treatment of cancer has involved genomic profiling for years. Why not vascular disease? Because finding biomarkers first requires a sample of the disease, and until the introduction of SilverHawk, it was not possible to directly sample live atherosclerotic tissue.

After removing plaque from a patient's artery to restore blood flow and alleviate leg pain, the material collected by the SilverHawk device then serves as a biopsy sample, and is sent for genomic and proteomic analysis as part of several different Merck-FoxHollow clinical trials underway. Early research has shown that the plaque samples are rich with information about the disease process. Findings from these studies already have revealed important genetic variations between various patient populations.

Chillicothe, OH

Conway, SC

Toledo, OH

Conroe, TX

Houston, TX

Charlotte, NC

Warren, MI

New Orleans, LA

Fort Walton Beach, FL

Harper Woods, MI

New York, NY

Buffalo, NY

Sacramento, CA

Yuma, AZ

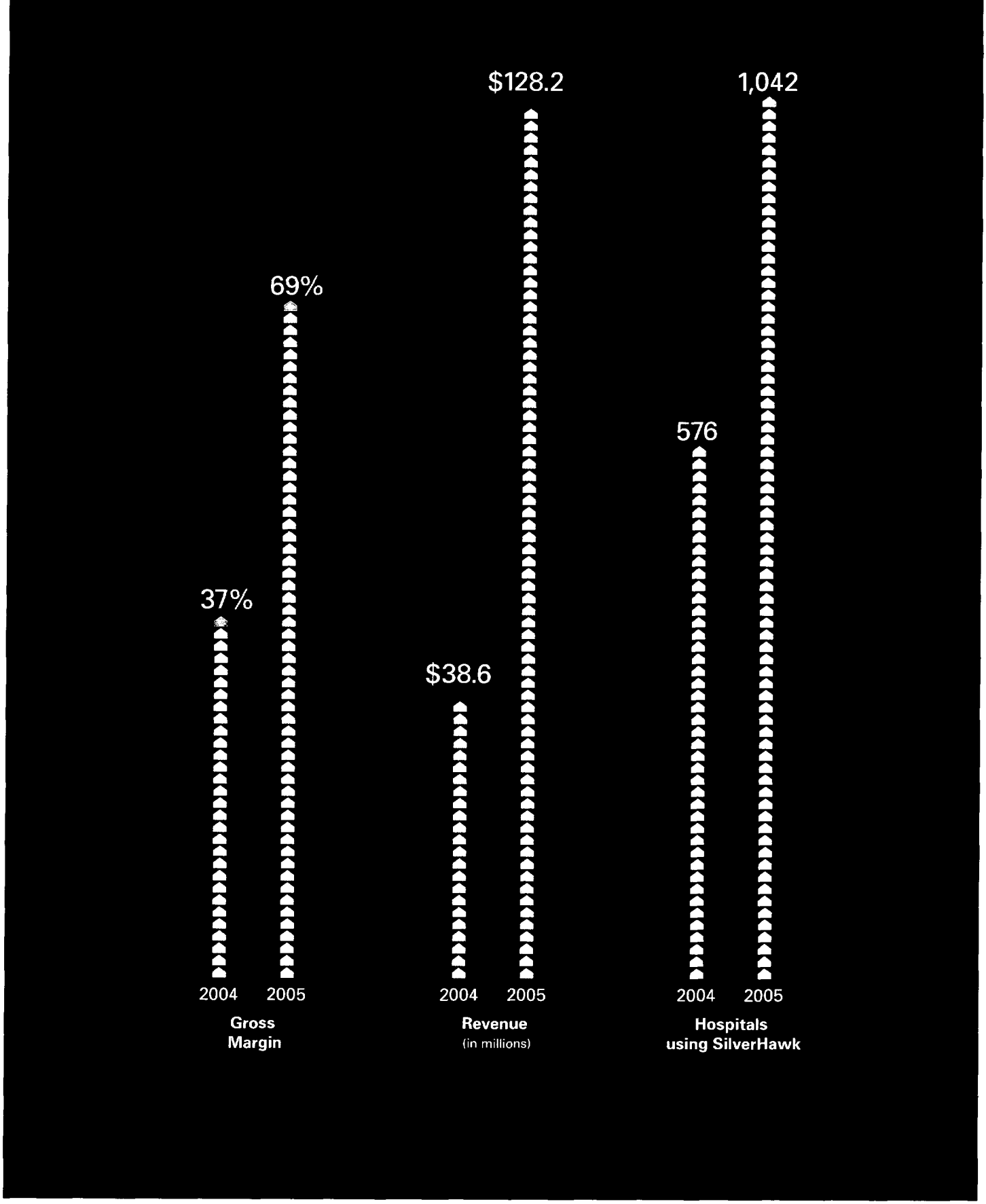
Chicago, IL

Columbus, OH

**FoxHollow Family Album**

Patients across the country treated with SilverHawk

# StandTALL.


37%
69%
2004
2005
Gross Margin
$38.6
$128.2
2004
2005
Revenue
(in millions)
576
1,042
2004
2005
Hospitals using SilverHawk

**NOTICE OF**
**2006 ANNUAL MEETING OF STOCKHOLDERS**
**TO BE HELD ON June 28, 2006**

*To our Stockholders:*

You are cordially invited to attend the 2006 Annual Meeting of Stockholders of FoxHollow Technologies, Inc. ("*FoxHollow*"). The meeting will be held at our principal executive offices located at 740 Bay Road, Redwood City, California 94063-2469 on Wednesday, June 28, 2006, for the following purposes:

1. To elect one Class II director to serve for a three-year term that expires at the 2009 Annual Meeting of Stockholders and until his successor has been duly elected and qualified;

2. To ratify the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2006; and

3. To transact such other business as may properly come before the Annual Meeting, including any motion to adjourn to a later date to permit further solicitation of proxies, if necessary, or before any adjournment thereof.

The foregoing items of business are more fully described in the proxy statement accompanying this Notice.

The meeting will begin promptly at 9:00 a.m., local time, and check-in will begin at 8:30 a.m., local time. Only holders of record of shares of FoxHollow common stock (Nasdaq: FOXH) at the close of business on May 10, 2006 will be entitled to notice of, and to vote at, the meeting and any postponements or adjournments of the meeting.

For a period of at least 10 days prior to the meeting, a complete list of stockholders entitled to vote at the meeting will be available and open to the examination of any stockholder for any purpose in connection with the Annual Meeting during normal business hours at our principal executive offices located at 740 Bay Road, Redwood City, California 94063-2469.

By order of the Board of Directors,

By: /s/ John B. Simpson
John B. Simpson
*Interim Chief Executive Officer*

Redwood City, California
May 22, 2006

**YOUR VOTE IS IMPORTANT!**

**REGARDLESS OF WHETHER YOU PLAN TO ATTEND THE MEETING, PLEASE PROMPTLY VOTE BY USING THE INTERNET OR BY TELEPHONE, IN EACH CASE AS INSTRUCTED ON THE ENCLOSED PROXY CARD, OR COMPLETE, SIGN, DATE, AND RETURN THE ENCLOSED PROXY CARD IN THE ACCOMPANYING POSTAGE-PAID ENVELOPE. NO ADDITIONAL POSTAGE IS NECESSARY IF THE PROXY IS MAILED IN THE UNITED STATES OR CANADA. YOU MAY REVOKE YOUR PROXY AT ANY TIME BEFORE IT IS VOTED AT THE MEETING.**

## TABLE OF CONTENTS

FOXHOLLOW

**PROXY STATEMENT**
**FOR**
**2006 ANNUAL MEETING OF STOCKHOLDERS**
**TO BE HELD ON June 28, 2006**

The Board of Directors of FoxHollow Technologies, Inc., a Delaware corporation, is soliciting the enclosed proxy from you. The proxy will be used at our 2006 Annual Meeting of Stockholders to be held on Wednesday, June 28, 2006, beginning at 9:00 a.m., local time, at our principal executive offices located at 740 Bay Road, Redwood City, California 94063-2469, 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*", "*FoxHollow*" and our "*Company*" each refer to FoxHollow Technologies, Inc.; the term "*Board*" means our Board of Directors; the term "*proxy materials*" means this proxy statement, the enclosed proxy card and our Annual Report, which you should read together with our Form 10-K for the year ended December 31, 2005, filed with the U.S. Securities and Exchange Commission on March 7, 2006; as amended on March 10, 2006; and the term "*Annual Meeting*" means our 2006 Annual Meeting of Stockholders.

We are sending these proxy materials on or about May 22, 2006 (the "*Proxy Date*"), to all stockholders of record at the close of business on May 10, 2006 (the "*Record Date*").

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

***Why am I receiving these proxy materials?***

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 May 10, 2006. 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.

***What is the purpose of the annual meeting?***

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 report on the performance of our Company and respond to questions from stockholders.

***Who is entitled to attend the meeting?***

You are entitled to attend the meeting *only* if you were a FoxHollow stockholder (or joint holder) of record as of the close of business on May 10, 2006, 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.

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

***Who is entitled to vote at the meeting?***

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

***How many shares must be present or represented to conduct business at the meeting (that is, what constitutes a quorum)?***

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.

***What items of business will be voted on at the meeting?***

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

1. the election of the nominee to serve as Class II director on our Board; and
2. the ratification of the appointment of our independent registered public accounting firm for the 2006 fiscal year.

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 intends to present or knows of that others will present at the meeting is as 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?***

Our Board recommends that you vote your shares "FOR" the director nominee and "FOR" the ratification of independent registered public accounting firm for the 2006 fiscal year.

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

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

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, Mellon Investor Services LLC, you are considered, 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 FoxHollow 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.

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

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. FoxHollow 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 annual meeting by telephone, by calling 1-866-540-5760 and following the simple recorded instructions, twenty-four hours a day, seven days a week, at any time prior to 11:59 p.m. on June 27, 2006, the day before the annual meeting. Alternatively, as a stockholder of record, you may vote via the Internet at any time prior to 11:59 p.m. on June 27, 2006, the day before the annual meeting, by going to *http://www.proxyvoting.com/foxh* and following the instructions 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 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.

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

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.***

***Can I change my vote?***

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.

***Is my vote confidential?***

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 FoxHollow 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 FoxHollow management.

***What vote is required to approve each item and how are votes counted?***

The vote required to approve each item of business and the method for counting votes is set forth below:

**Election of Director.** A director nominee receiving a majority of the affirmative "FOR" votes at the meeting (a plurality of votes cast) will be elected to serve as the Class II director. You may vote either "FOR" or "WITHHOLD" your vote for the director nominee. A properly executed proxy marked "WITHHOLD" with respect to the election of the director will not be voted with respect to the director indicated, although it will be counted for purposes of determining whether there is a quorum.

**Ratification of Independent Registered Public Accounting Firm.** For the ratification of the appointment of our independent registered public accounting firm, the affirmative "FOR" vote of a majority of the shares represented in person or by proxy and entitled to vote on the item will be required for approval. You may vote "FOR," "AGAINST" or "ABSTAIN" for these items of business. If you "ABSTAIN," your abstention has the same effect as a vote "AGAINST."

If you provide specific instructions with regard to certain items, your shares will be voted as you instruct on such items. If you sign your proxy card or voting instruction card without giving specific instructions, your shares will be voted in accordance with the recommendations of the Board ("FOR" our Company's nominee to the Board and "FOR" ratification of the independent registered public accounting firm, and in the discretion of the proxy holders on any other matters that properly come before the meeting).

***What is a "broker non-vote"?***

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. The election of directors and the ratification of the appointment of independent registered public accounting firm are considered routine matters. Therefore, if you do not otherwise instruct your broker, the broker may turn in a proxy card voting your shares

"FOR" our Company's nominee to the Board and "FOR" ratification of the independent registered public accounting firm. 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.

***How are "broker non-votes" counted?***

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.

***How are abstentions counted?***

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 (other than the election of directors), 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.

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

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. If you grant a proxy, the persons named as proxy holders, Sanford Fitch (a Director and Chairman of our Audit Committee) and Matthew B. Ferguson (our Chief Financial Officer), will have the discretion to vote your shares on any additional matters properly presented for a vote at the meeting. If, for any unforeseen reason, our nominee is not available as a candidate for director, the persons named as proxy holders will vote your proxy for such other candidate or candidates as may be nominated by our Board.

***Who will serve as inspector of election?***

We expect a representative of Mellon Investor Services LLC, our transfer agent, to tabulate the votes and act as inspector of election at the meeting.

***What should I do in the event that I receive more than one set of proxy/ voting materials?***

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 FoxHollow proxy card and voting instruction card that you receive to ensure that all your shares are voted.

***Who is soliciting my vote and who will bear the costs of this solicitation?***

Your vote is being solicited on behalf of the Board of our Company, and our Company will bear the entire cost of solicitation of proxies, including preparation, assembly, printing and mailing of this proxy statement. In addition to these mailed proxy materials, our directors, officers and employees may also solicit proxies in person, by telephone, by electronic mail or by other means of communication. Directors, officers and employees will not be paid any additional compensation for soliciting proxies. We may reimburse brokerage firms, banks and other agents for

the cost of forwarding proxy materials to beneficial owners. We may also engage the services of a professional proxy solicitation firm to aid in the solicitation of proxies from certain brokers, bank nominees and other institutional owners. Our costs for such services, if retained, will not be material.

***Where can I find the voting results of the meeting?***

We intend to announce preliminary voting results at the meeting and publish final results in our quarterly report on Form 10-Q for the second quarter of fiscal 2006.

***What is the deadline to propose actions for consideration at next year's annual meeting of stockholders or to nominate individuals to serve as directors?***

As a stockholder, you may be entitled to present proposals for action at a future meeting of stockholders, including director nominations.

**Stockholder Proposals:** For a stockholder proposal to be considered for inclusion in the FoxHollow proxy statement for the annual meeting to be held in 2007, the written proposal must be received by the Secretary of FoxHollow at our principal executive offices no later than January 22, 2007. If the date of next year's annual meeting is moved more than 30 days before or after the anniversary date of this year's annual meeting, the deadline for inclusion of proposals in our proxy statement is instead a reasonable time before we begin to print and mail next year's proxy materials. Such proposals also 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
FoxHollow Technologies, Inc.
740 Bay Road
Redwood City, California 94063-2469

**Nomination of Director Candidates:** You may propose director candidates for consideration by our Board. Any such recommendations should include the nominee's name and qualifications for Board membership and should be directed to the Secretary of FoxHollow at the address of our principal executive offices set forth above. In addition, our Bylaws permit stockholders to nominate directors for election at an annual meeting of stockholders. To nominate a director, the stockholder must provide the information required by the Bylaws of FoxHollow, as well as a statement by the nominee consenting to being named as a nominee and to serve as a director if elected. In addition, the stockholder must give timely notice to the Secretary of FoxHollow in accordance with the provisions of our Bylaws, which require that the notice be received by the Secretary of FoxHollow no later than January 22, 2007.

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

## STOCK OWNERSHIP

### Security Ownership of Certain Beneficial Owners and Management

The following table provides information relating to the beneficial ownership of FoxHollow common stock as of April 1, 2006, 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 on page 23 (our Interim Chief Executive Officer and former Chief Executive Officer and our four 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 or shared voting power or investment power and any shares that the individual has the right to acquire within 60 days of April 1, 2006 through the exercise of any stock option or other right. The number and percentage of shares beneficially owned is computed on the basis of 24,916,717 shares of FoxHollow common stock outstanding as of April 1, 2006. Shares of our common stock that a person has the right to acquire within 60 days of April 1, 2006 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 which an address is not otherwise provided is c/o FoxHollow Technologies, Inc., 740 Bay Road, Redwood City, California 94063-2469.

| | Beneficial Ownership | | |
|---|---|---|---|
| Beneficial Owner | Shares | Options Exercisable Within 60 Days | Approximate Percent Owned |
| Entities affiliated with Capital Research & Management Company [1]<br>333 South Hope Street<br>55th Floor<br>Los Angeles, CA 90071 | 2,580,000 | — | 10.9% |
| Entities affiliated with FMR Corp. [2]<br>82 Devonshire Street<br>Boston, MA 02109 | 2,253,899 | — | 9.5 |
| Persons and Entities affiliated with Palo Alto Investors, LLC [3]<br>470 University Avenue<br>Palo Alto, CA 94301 | 1,445,766 | — | 6.1 |
| **Named Executive Officers and Directors** | | | |
| John B. Simpson, Ph.D., M.D. [4] | 5,973,355 | — | 24.0 |
| Douglas S. Rohlen | 419,908 | 41,666 | 1.8 |
| Matthew B. Ferguson | 217,686 | 10,000 | * |
| David L. Martin [5] | 52,447 | — | * |
| Robert W. Thomas [6] | 3,766 | 349,795 | 1.4 |
| William H. Hoffman [7] | 3,571 | — | * |
| Ryan D. Drant | 515 | 15,000 | * |

| Beneficial Owner | Beneficial Ownership | | |
|---|---|---|---|
| | Shares | Options Exercisable Within 60 Days | Approximate Percent Owned |
| Jeffrey B. Child | 1,500 | — | * |
| Sanford Fitch | 18,750 | — | * |
| Tomoaki Hinohara, M.D. | 15,961 | 21,250 | * |
| Myrtle S. Potter | — | — | * |
| All executive officers and directors as a group (11 persons) | 6,707,459 | 437,711 | 28.2 |

* Indicates ownership of less than 1%.

(1) Based on information reported on a Schedule 13G jointly filed by Capital Research & Management Company and SMALLCAP World Fund, Inc. with the SEC on January 10, 2006. Includes 1,285,000 shares held by SMALLCAP World Fund, Inc. Capital Research & Management Company is an investment advisor to various investment companies, including SMALLCAP World Fund, Inc.

(2) Based on information reported on a Schedule 13G/A jointly filed by FMR Corp. and Edward C. Johnson III with the SEC on March 10, 2006. Includes 2,152,099 shares held by Fidelity Management & Research Company ("Fidelity"), an investment advisor to various investment companies (the "Fidelity Funds") and a wholly-owned subsidiary of FMR Corp. Edward C. Johnson III, Chairman of FMR Corp. and FMR Corp., through its control of Fidelity and the Fidelity Funds each has sole power to dispose of the shares held by the Fidelity Funds. Neither Edward C. Johnson III nor FMR Corp. has the sole power to vote or direct the voting of the shares owned directly by the Fidelity Funds, which power resides with the Fidelity Funds' Boards of Trustees. Fidelity executes the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. Also includes 65,300 shares owned by Strategic Advisers, Inc., a wholly-owned subsidiary of FMR Corp and 36,500 shares over which Edward C. Johnson III has sole voting and dispositive power.

(3) Based on information reported on a Schedule 13G jointly filed by Palo Alto Investors, Palo Alto Investors, LLC and William L. Edwards with the SEC on February 14, 2006. Palo Alto Investors, Palo Alto Investors, LLC and William L. Edwards share voting and dispositive power with respect to these shares. Palo Alto Investors is the manager of Palo Alto Investors, LLC. Mr. Edwards is the controlling shareholder and President of Palo Alto Investors.

(4) Includes 204,733 shares held by FoxHollow, a California Limited Partnership. Dr. Simpson disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein. Also includes 517,990 shares held in a trust for the benefit of Dr. Simpson's son of which Dr. Simpson serves as a trustee. Dr. Simpson disclaims beneficial ownership of these shares.

(5) Based on information available to us as of the last day of Mr. Martin's employment in February 2006.

(6) Based on information available to us as of the last day of Mr. Thomas' employment in January 2006. Includes 1,875 shares held in a trust for the benefit of Mr. Thomas' daughter over which Mr. Thomas has no voting or dispositive power. Mr. Thomas disclaims beneficial ownership of these shares.

(7) Based on information available to us as of the last day of Mr. Hoffman's employment in February 2006.

**Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors, officers and beneficial owners of more than *10%* of our common stock to file reports of ownership and reports of changes in ownership with the SEC. 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 reporting persons that no Forms 3, 4 or 5 were required of such persons, we believe that during our fiscal year ended December 31, 2005, all reports were timely filed, with the exceptions noted herein.

One amended Form 3 report was filed by the Simpson Family Trust on August 3, 2005 to report indirect beneficial ownership of an aggregate of 2,107,623 shares of our common stock held directly by De Novo Ventures I, L.P. and De Novo (Q) Ventures I, L.P. that was omitted from the Form 3 report filed by the Simpson Family Trust on October 26, 2004.

One amended Form 4 report was filed by Rita Lynn Simpson on December 2, 2005 to report indirect beneficial ownership of 12,863 shares of our common stock that was omitted from the Form 4 reports filed by Ms. Simpson between June 2, 2005 and December 1, 2005.

One amended Form 4 report was filed by John B. Simpson on December 2, 2005 to report indirect beneficial ownership of 12,863 shares of our common stock that was omitted from the Form 4 reports filed by Dr. Simpson between June 2, 2005 and December 1, 2005.

One amended Form 4 report was filed by Robert W. Thomas on December 5, 2005 to report the purchase of 1,891 shares of our common stock under our Employee Stock Purchase Plan that occurred on November 1, 2005 and was omitted from the Form 4 report filed by Mr. Thomas on November 3, 2005.

One amended Form 4 report was filed by Matthew B. Ferguson on December 12, 2005 to report the purchase of 1,271 shares of our common stock under our Employee Stock Purchase Plan that occurred on November 1, 2005 and was omitted from the Form 4 report filed by Mr. Ferguson on November 10, 2005.

One late Form 4 report was filed by Leslie L. Trigg on February 15, 2006 to report the exercise of an option to purchase 6,000 shares of our common stock that occurred on December 31, 2005.

## CORPORATE GOVERNANCE AND BOARD MATTERS

### Director Independence

Our Board of Directors consists of six directors. Our Company's directors are John B. Simpson, Ryan D. Drant, Jeffrey B. Child, Sanford Fitch, Tomoaki Hinohara and Myrtle S. Potter. Ryan D. Drant has decided not to stand for reelection in the 2006 Annual Meeting of Stockholders. Our Board has determined that each of the directors other than John B. Simpson, our Company's Founder and Interim Chief Executive Officer is independent under the listing standards established by the rules of the Nasdaq Stock Market, Inc. ("Nasdaq").

### Committees of the Board of Directors

The Board of Directors has three standing committees: the Audit Committee, the Compensation Committee and the Nominating and Governance Committee. From time to time, our Board may also create various ad hoc committees for special purposes. The membership during the last fiscal year and the function of each of the committees are described below.

| Name of Director | Audit Committee | Compensation Committee | Nominating and Corporate Governance Committee |
|---|---|---|---|
| John B. Simpson | — | — | — |
| Ryan D. Drant | X | X | X |
| Jeffrey B. Child | X | X(*) | — |
| Sanford Fitch | X(*) | — | X |
| Tomoaki Hinohara | — | X | X |
| Myrtle S. Potter | — | — | — |
| ***Number of Meetings Held During the Last Fiscal Year*** | 8 | 4 | 2 |

X = Committee member
* = Chairman of Committee

*Audit Committee.* The Audit Committee oversees our Company's accounting and financial reporting processes and the audits of its financial statements. In this role, the Audit Committee monitors and oversees the integrity of the Company's financial statements and related disclosures, the qualifications, independence, and performance of the Company's independent auditor, the performance of our Company's internal auditing function, and our Company's compliance with applicable legal requirements and its business conduct policies. Our Board has determined that each member of the Audit Committee meets the independence and financial literacy requirements of the Nasdaq rules and the independence requirements of the SEC. Our Board has determined that Sanford Fitch continues to qualify as an "audit committee financial expert," as defined in SEC rules. The Audit Committee has a written charter, which was adopted by our Board in July 2004. The report of the Audit Committee appears beginning on page 14 of this proxy statement.

*Compensation Committee.* The Compensation Committee administers our Company's equity compensation plans, determines the compensation for our Company's executive officers, and recommends to our Board appropriate compensation for our President and Chief Executive Officer. The Compensation Committee has a written charter, which was adopted by our Board in July 2004. The report of the Compensation Committee appears beginning on page 15 of this proxy statement.

*Nominating and Governance Committee.* The Nominating and Governance Committee assists our Board in ensuring that it is properly constituted and conducts itself appropriately in carrying out its duties and meeting its fiduciary obligations, and that our Company has, and follows, appropriate corporate governance standards. Our Board has determined that each member of the Nominating and Governance Committee is independent as defined in the Nasdaq rules. The Committee is responsible for developing and recommending to our Board the

governance principles applicable to our Company; overseeing the evaluation of our Board and management of our Company; recommending to our Board director nominees for each committee; and assisting our Board in identifying prospective director nominees and determining the director nominees for election at annual meetings of stockholders of our Company. Our Company does not pay any third party to identify, evaluate, or assist in identifying or evaluating potential nominees. The Nominating and Corporate Governance Committee has a written charter, which was adopted by our Board in July 2004.

**Meetings Attended by Directors**

The Board of Directors held nine meetings during 2005. The Audit Committee and the Compensation Committee held eight and four meetings, respectively, during 2005. The Nominating and Corporate Governance Committee held two meetings during 2005. During the last year, no incumbent director attended fewer than 75% of the meetings of the Board of Directors and its committees on which he or she served that were held during the period in which he or she was a director. The Company encourages, but does not require, members of our Board to attend the annual stockholders meeting. Five out of the six directors then in office attended the 2005 annual meeting of stockholders.

After our initial public offering in October 2004, the independent directors began having meetings following the regularly scheduled board meetings at which only they were present. The meetings of the independent directors typically will continue to take place in connection with the regularly scheduled meetings of the full Board. The independent directors may meet at such other times as they deem necessary or appropriate. The independent directors held three separate meetings during 2005.

**Consideration of Director Nominees**

*Stockholder Nominations and Recommendations.* As described above in the Question and Answer section of this proxy statement under "What is the deadline to propose actions for consideration at next year's annual meeting of stockholders or to nominate individuals to serve as directors?," our Bylaws set forth the procedure for the proper submission of stockholder nominations for membership on our Board. In addition, the Nominating and Corporate Governance Committee may consider properly submitted stockholder recommendations (as opposed to formal nominations) for candidates for membership on the Board. A stockholder may make such a recommendation by submitting the following information to our Secretary at 740 Bay Road, Redwood City, California 94063-2469: the candidate's name, home and business contact information, detailed biographical data, relevant qualifications, professional and personal references, information regarding any relationships between the candidate and FoxHollow within the last three years and evidence of ownership of FoxHollow stock by the recommending stockholder.

*Director Qualifications.* Members of the Board should have the highest professional and personal ethics and values, and conduct themselves in a manner consistent with our Code of Business Conduct and Ethics. While the Committee has not established specific minimum qualifications for director candidates, the Committee believes that candidates and nominees must reflect a Board that is comprised of directors who (i) are predominantly independent, (ii) are of high integrity, (iii) have qualifications that will increase overall Board effectiveness, and (iv) meet other requirements as may be required by applicable rules, such as financial literacy or financial expertise with respect to audit committee members.

*Identifying and Evaluating Director Nominees.* Typically new candidates for nomination to our Board are suggested by existing directors or by our executive officers, candidates may come to the attention of our Board through professional search firms, stockholders or other persons. The Committee shall carefully review the qualifications of any candidates who have been properly brought to its attention. Such review may, in the Committee's discretion, include a review solely of information provided to the Committee or may also include discussions with persons familiar with the candidate, an interview with the candidate or other actions that the Committee deems proper. The Committee shall consider the suitability of each candidate, including the current

members of the Board, in light of the current size and composition of the Board. In evaluating the qualifications of the candidates, the Committee considers many factors, including, issues of character, judgment, independence, age, expertise, diversity of experience, length of service, other commitments and the like. The Committee evaluates such factors, among others, and does not assign any particular weighting or priority to any of these factors. Candidates properly recommended by stockholders are evaluated by the independent directors using the same criteria as other candidates.

**Director Compensation**

Our non-employee directors are reimbursed for their out-of-pocket expenses incurred in connection with attending board and committee meetings. We have in the past granted directors options to purchase our common stock pursuant to the terms of our 1997 Stock Plan, which has been replaced with our 2004 Equity Incentive Plan. Our 2004 Equity Incentive Plan provides for the automatic grant of options to our non-employee directors. Each non-employee director appointed to the Board will automatically receive an initial option to purchase 15,000 shares upon such appointment. At the first meeting of the Board following each annual meeting of our stockholders, each non-employee director who has been a director for at least six months automatically receives an option grant for 12,500 shares of our common stock except for the lead independent director who receives an option grant for 15,000 shares. All options granted under the automatic grant provisions have a term of 10 years and an exercise price equal to the fair market value on the date of grant. Each option to purchase 15,000 shares becomes exercisable as to one-third of the shares upon each one year anniversary of the vesting commencement date, provided the non-employee director remains a director on such dates. Each option to purchase 12,500 shares becomes 100% vested and fully exercisable as to all shares, one year from the date of grant, provided the non-employee director remains a director on such date. In addition, we paid to Sanford Fitch a retainer of $12,000 in 2005 for his services as a board member, a committee member and chairman of the Audit Committee. Beginning in the second quarter of 2006, we will pay each of our non-employee directors an annual retainer of $20,000 and an annual retainer of $12,000 for each of the chairpersons of our Compensation Committee and our Audit Committee and for our lead independent director, in consideration for their services provided in those respective roles.

**Code of Business Conduct and Ethics**

FoxHollow is 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. 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 an Exhibit to our 2004 Annual Report on Form 10-K filed with the SEC on March 28, 2005 and is available on our Company's website at www.foxhollowtech.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.

**Compensation Committee Interlocks and Insider Participation**

No member of our Compensation Committee nor any executive officer of FoxHollow has a relationship that would constitute an interlocking relationship with executive officers or directors of another entity. No Compensation Committee member is an officer or employee of FoxHollow.

**Certain Relationships and Related Party Transactions**

We describe below transactions and series of similar transactions that have occurred since January 1, 2005 to which we were a party in which:

- the amounts involved exceeded or will exceed $60,000; and

- a director, executive officer, holder of more than 5% of our common stock or any member of their immediate families had or will have a direct or indirect material interest.

On January 18, 2006, Dr. Simpson signed an offer letter that sets forth his compensation as Interim Chief Executive Officer. Our Company will pay him a monthly salary of $25,000, compensation equivalent to that paid to Dr. Simpson under his consulting agreement dated May 21, 2004, which terminated upon Dr. Simpson assuming his new role as Interim Chief Executive Officer.

We also entered into an agreement with JBS Consulting, LLC ("JBS Consulting") and an agreement with JBS Consulting and Dr. Simpson, both effective as of September 1, 2005, regarding the use of a private aircraft owned by JBS Consulting for company business related travel by our directors, officers and employees. Dr. Simpson is the president and managing officer of JBS Consulting. Pursuant to these agreements, JBS Consulting will be reimbursed for the cost of first class airfare for all flights in connection with company business related travel by Dr. Simpson and the cost of coach airfare for all flights in connection with company business related travel by other directors, officers, and employees.

**Family Relationships**

Douglas S. Rohlen, President of Strategic Operations, is the brother-in-law of Matthew B. Ferguson, our Chief Financial Officer, and the son-in-law of Dr. John B. Simpson, our Interim Chief Executive Officer. There are no other family relationships among any of our directors or executive officers.

**Communications with the Board of Directors**

Stockholders wishing to communicate with the Board or with an individual Board member concerning FoxHollow may do so by writing to the Board or to the particular Board member, and mailing the correspondence to Attn: Board of Directors, c/o Secretary, FoxHollow Technologies, Inc., 740 Bay Road, Redwood City, California 94063-2469. The envelope should indicate that it contains a stockholder communication. All such stockholder communications will be forwarded to the director or directors to whom the communications are addressed.

## REPORT OF THE AUDIT COMMITTEE

*The material in this section is not deemed filed with the SEC and is not incorporated by reference in any filing of our Company under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date of this Proxy Statement and irrespective of any general incorporation language in those filings.*

The Audit Committee of the Board of Directors is comprised solely of independent directors (as defined by Nasdaq rules) all of whom were all appointed by the Board. The Audit Committee operates pursuant to a written charter which it reassesses on an annual basis. Under the Charter, the Audit Committee has authority to retain outside legal, accounting or other advisors as its deems necessary to carry out its duties and to require FoxHollow to pay for such expenditures. The purpose of the Audit Committee is to provide general oversight of FoxHollow's financial reporting, integrity of financial statements, internal controls and internal audit functions.

The Audit Committee has responsibility for the appointment, compensation, retention and oversight of FoxHollow's independent registered public accounting firm. The Audit Committee monitors FoxHollow's external audit process, including auditor independence matters, the scope and fees related to audits, and the extent to which the independent registered public accounting firm may be retained to perform non-audit services. The Audit Committee also reviews the results of the external audit work with regard to the adequacy and appropriateness of FoxHollow's financial, accounting and internal controls over financial reporting. In addition, the Audit Committee generally oversees FoxHollow's internal compliance programs. The function of the Audit Committee is not intended to duplicate or to certify the activities of management and the independent registered public accounting firm, nor can the Audit Committee certify that the independent registered public accounting firm is "independent" under applicable rules. The Audit Committee members are not professional accountants or auditors.

The Audit Committee provides counsel, advice and direction to management and the independent registered public accounting firm on matters for which it is responsible based on the information it receives from management and the independent registered public accounting firm and the experience of its members in business, financial and accounting matters.

FoxHollow's management is responsible for the preparation and integrity of its financial statements, accounting and financial reporting principles, and internal controls and procedures designed to ensure compliance with accounting standards, applicable laws and regulations.

In this context, the Audit Committee hereby reports as follows:

1. The Audit Committee has reviewed and discussed the audited financial statements for 2005 with FoxHollow's management.

2. The Audit Committee has discussed with the independent registered public accounting firm the matters required to be discussed by SAS 61 (Codification of Statements on Auditing Standard, AU 380), SAS 99 (Consideration of Fraud in a Financial Statement Audit) and Securities and Exchange Commission rules discussed in Final Releases Nos. 33-8183 and 33-8183a.

3. The Audit Committee has received written disclosures and a letter from the independent registered public accounting firm, PricewaterhouseCoopers LLP, required by Independence Standards Board Standard No. 1 (Independence Standards Board Standard No. 1, "Independence Discussions with Audit Committee") and has discussed with PricewaterhouseCoopers LLP their independence.

4. Based on the review and discussion referred to above, the Audit Committee recommended to the Board, and the Board has approved, that the audited financial statements be included in FoxHollow's Annual Report on Form 10-K for the fiscal year ended December 31, 2005.

The foregoing report is provided by the undersigned members of the Audit Committee.

Sanford Fitch
Ryan D. Drant
Jeffrey B. Child

## REPORT OF THE COMPENSATION COMMITTEE

*The material in this section is not deemed filed with the SEC and is not incorporated by reference in any filing of our Company under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date of this Proxy Statement and irrespective of any general incorporation language in those filings.*

The Compensation Committee of the Board is responsible for overseeing our compensation programs, which includes review and approval of base salaries for executive officers and administration of our incentive compensation programs. Our compensation programs are designed to provide a competitive level of total compensation and to link our performance and stockholder return to incentive and equity ownership programs.

### Compensation Philosophy

Our overall executive compensation philosophy is as follows:

1) Provide competitive levels of total compensation to attract and retain executives who are critical to our long-term success;

2) Combine base salary, bonus and stock option awards to motivate all of our employees;

3) Align the financial interest of executives and stockholders through equity-based plans; and

4) Provide a total compensation program that recognizes individual roles, responsibilities and performance within our organization as compared to the success of the overall business.

### Compensation Program

The Compensation Committee establishes and reviews general policies relating to compensation and benefits of our employees and is responsible for reviewing and recommending to the Board the specific compensation and benefits for our Chief Executive Officer, Chief Operating Officer, President of Strategic Operations and Chief Financial Officer and for establishing the general guidelines for compensation and benefits for each of our executive officers and directors. The Compensation Committee is also responsible for the administration of the 2004 Equity Incentive Plan, the 2004 Employee Stock Purchase Plan and the 1997 Stock Plan. The major components of executive compensation are base salary, potential cash bonus, and potential long-term compensation through stock options. The Compensation Committee considers the total current and potential long-term compensation of each executive officer in establishing each element of compensation. The determination as to whether these individual performance objectives and corporate performance targets have been met and the amount of the bonus to be paid to each individual executive officer will be made by the Compensation Committee.

*Base Salary.* In setting compensation levels for the Chief Executive Officer, Chief Operating Officer, President of Strategic Operations and Chief Financial Officer, and providing guidelines for other executive officers, the Compensation Committee reviews competitive information relating to compensation levels for comparable positions at medical device, biotech and other high technology companies. In addition, the Compensation Committee retains a compensation consulting firm to assist it in developing salary strategies and providing data on compensation levels at other relevant companies. Base salary compensation for individual officers may vary as a result of individual performance, salary relative to equity and critical nature of the position relative to our success.

*Bonus.* The Compensation Committee oversees the administration of bonus plans as adopted from time to time. In February 2006, the Compensation Committee met and approved a bonus plan for certain executive officers and approved a 2006 Bonus Plan (the "*Bonus Plan*") that includes annual target bonus levels for these executive officers. Under the Bonus Plan, the target bonuses for the Chief Operating Officer, Chief Financial

Officer, and the President of Strategic Operations are based on the achievement of certain corporate performance targets tied to the Company's revenue, net income excluding stock based compensation charges and clinical development. The target bonus amounts for each of these executive officers is $225,000. Target bonus payments are based on the achievement of 100% of corporate performance targets. The target bonus amounts for our Vice President of Clinical Affairs, Vice President of Quality and Regulatory Affairs and Vice President of Marketing is $75,000. The target bonus amount for our Vice President of Sales is $200,000. Target bonuses under the Bonus Plan for these vice presidents are based on i) certain individual performance objectives tailored to each executive officer's role in the Company and (ii) certain corporate performance targets tied to the Company's revenue, net income excluding stock based compensation charges and clinical development. Target bonus payments for these vice presidents are based on the achievement of 100% of both individual performance objectives and corporate performance targets. In the event our Company exceeds certain revenue and other performance criteria, a bonus will be capped at 125% of the individual's target bonus. Payments under the Bonus Plan will be paid following the end of the 2006 calendar year based upon audited results of the financial statements.

*Long-Term Incentives.* The Compensation Committee believes that stock-based performance compensation arrangements are essential in aligning the interests of management and the stockholders in enhancing the value of our equity. Our 2004 Equity Incentive Plan provides for the issuance of stock options to our officers and employees to purchase shares of our common stock at an exercise price equal to the fair market value of such stock on the date of grant. Stock options are granted to our executive officers and other employees both as a reward for past individual and corporate performance and as an incentive for future performance. FoxHollow also maintains a 2004 Employee Stock Purchase Plan that provides employees with the opportunity to purchase shares of our common stock.

**2005 Compensation for the Former Chief Executive Officer**

In determining an appropriate recommendation to the Board for Mr. Thomas' salary for 2005, the Compensation Committee considered and also engaged a compensation consulting group to compare competitive compensation data for chief executive officers of similar companies within the medical device industry, taking into account their past experience, performance and knowledge. The Compensation Committee considered Mr. Thomas' qualification, knowledge and experience and his individual performance at FoxHollow in establishing his 2005 compensation. For 2005, Mr. Thomas' base salary was $300,000. The Chief Executive Officer performance-based cash bonus plan was based upon achievement of revenue and other performance criteria being met, as determined by the Compensation Committee. The total target awards under the Chief Executive Officer plan were weighted approximately 45% for the achievement of the Company performance goals. Mr. Thomas and the Company had achieved each of the targets and he received a cash performance bonus for 2005 of $352,875.

**Director Compensation**

The Compensation Committee is also responsible for reviewing and recommending the appropriate level of compensation for our directors. After a review of comparable medical device and biotech companies and following consideration of advice provided by the compensation consulting firm we retained, the Committee established the compensation for each director, the chairperson of our committees and the lead independent director.

**Section 162(m) of the Internal Revenue Code Limitations on Executive Compensation**

Section 162(m) of the United States Internal Revenue Code of 1986, as amended may limit our ability to deduct for United States federal income tax purposes compensation paid to either our Chief Executive Officer or to any of our four other highest paid executive officers in any one fiscal year that is, for each such person, in excess of $1,000,000. None of our executive officers received any such compensation in excess of this limit during fiscal year 2005. Grants under the 2004 Equity Incentive Plan are not subject to the deduction limitation, including the option grant limitations described below.

In order to preserve our ability to deduct the compensation income associated with options granted to such executive officers pursuant to Section 162(m) of the Code, our 2004 Equity Incentive Plan provides that no optionee may be granted option(s) to purchase more than 1,750,000 shares of our common stock in any one fiscal year; provided that in connection with an optionee's initial service, an optionee may be granted an option to purchase up to 2,500,000 shares of our common stock.

The foregoing report is provided by the undersigned members of the Compensation Committee.

Ryan D. Drant
Jeffrey B. Child
Tomoaki Hinohara, M.D.

## PROPOSAL ONE—ELECTION OF DIRECTOR

### Classes of the Board of Directors

Our Amended and Restated Certificate of Incorporation provides that our Board shall be divided into three classes designated as Class I, Class II and Class III, respectively, with the classes of directors serving for staggered three-year terms. Our Board currently consists of six directors, divided among the three classes as follows: one Class I director, Dr. Tomoaki Hinohara whose term will expire in 2008; two Class II directors, Ryan D. Drant and Jeffrey B. Child, whose terms will expire at our Annual Meeting of Stockholders to be held in 2006; and three Class III directors, Dr. John B. Simpson, Sanford Fitch, and Myrtle S. Potter whose terms expire at our Annual Meeting of Stockholders to be held in 2007. Under our Amended and Restated Certificate of Incorporation and Bylaws, there is currently one vacancy for a Class I director.

The names of the each member of the Board, the class in which they serve, their ages as of April 1, 2006, principal occupation and length of service on the Board are as follows:

| Name | Term Expires | Age | Position | Director Since |
|---|---|---|---|---|
| **Class I Directors** | | | | |
| Tomoaki Hinohara, M.D. [1][3] | 2008 | 55 | Director of Cardiac Catherization Laboratory, Sequoia Hospital | 1997 |
| **Class II Directors** | | | | |
| Ryan D. Drant [1][2][3] | 2006 | 35 | General Partner, New Enterprise Associates | 1998 |
| Jeffrey B. Child [1][2] | 2006 | 46 | Chief Financial Officer of a Family Office of an Unaffiliated Third Party | 2005 |
| **Class III Directors** | | | | |
| John B. Simpson, M.D. | 2007 | 62 | Founder, Interim Chief Executive Officer | 1996 |
| Sanford Fitch [2][3] | 2007 | 65 | Former Vice President of Finance and Chief Financial Officer at Alvesta | 2004 |
| Myrtle S. Potter | 2007 | 47 | Former President, Commercial Operations, Genentech, Inc. | 2005 |

(1) Member of the Compensation Committee
(2) Member of the Audit Committee
(3) Member of Nominating and Governance Committee

### Director Nominee

The Board and the Nominating and Governance Committee has nominated Jeffrey B. Child for re-election as Class II director. Ryan D. Drant has decided not to stand for re-election.

*Jeffrey B. Child* has served as a member of our Board since June 2005. Since July 2004, Mr. Child has served as the Chief Financial Officer of a family office of an unaffiliated third party. From February 1999 through June 2003, Mr. Child served as a Managing Director, U.S. Equity Capital Markets at Banc of America Securities LLC. Prior to that time, he served as a Managing Director in the Healthcare Group at Banc of America Securities. Mr. Child currently serves on the board of directors of AMERIGROUP Corporation, a multi-state managed healthcare company. Mr. Child holds a B.S. in Chemical Engineering from the University of California at Davis and an M.B.A. from the University of Pennsylvania.

If elected, Mr. Child will hold office as a Class II director until our Annual Meeting of Stockholders to be held in 2009, and until his respective successor is elected and qualified or until his earlier death, resignation or removal.

**Board of Directors' Recommendation**

**THE BOARD OF DIRECTORS RECOMMENDS THAT YOU VOTE FOR THE NOMINEE FOR CLASS II DIRECTOR LISTED ABOVE.**

**Directors Whose Terms Extend Beyond the 2006 Annual Meeting**

*Sanford Fitch* has served as a member of our Board since May 2004. From March 2001 to December 2002, Mr. Fitch served as Vice President of Finance and Chief Financial Officer at Alvesta, a fiber optic component manufacturing company. From March 2000 to December 2000, Mr. Fitch served as Senior Vice President of Finance and Chief Financial Officer at Cruel World, an Internet-based recruiting company. From 1994 to 1998, Mr. Fitch served as Senior Vice President of Finance and Operations and Chief Financial Officer at Conceptus, a manufacturer of contraceptive medical devices. From 1991 to 1994, Mr. Fitch served as Vice President of Finance and Administration and Chief Financial Officer at SanDisk, a manufacturer of flash memory products. Mr. Fitch currently serves on the board of IRIDEX, a manufacturer of medical laser systems. Mr. Fitch holds a B.S. in Chemistry and an M.B.A. from Stanford University.

*John B. Simpson, Ph.D., M.D.* founded our Company in September 1996 and has served as our Interim Chief Executive Officer since January 2006. Dr. Simpson has served as a member of our Board since September 1996. From May 2004 to December 2005, Dr. Simpson also served as a consultant to our Company and from October 1996 to July 1997, Dr. Simpson served as our President. Since March 2000, Dr. Simpson has served in various positions at De Novo Ventures, a venture capital fund, including Managing Director and Clinical Director. Since 1983, Dr. Simpson has been a Partner at Cardiovascular Medicine and Coronary Interventions, a cardiology physician group. Prior to founding our Company, Dr. Simpson founded several other interventional cardiology companies, including Perclose, a manufacturer of femoral artery access site closure devices, Devices for Vascular Intervention, a manufacturer of atherectomy devices, and Advanced Cardiovascular Systems, a manufacturer of balloon angioplasty devices. Dr. Simpson is a Professor of Clinical Medicine at Stanford University. Dr. Simpson holds a B.S. in Agriculture from Ohio State University, an M.D. from the Duke University School of Medicine and an M.S. and a Ph.D. in Biomedical Science from the University of Texas.

*Tomoaki Hinohara, M.D.* has served as a member of our Board since March 1997. Since July 1988, Dr. Hinohara has been a partner at Cardiovascular Medicine and Coronary Interventions. Since 1992, Dr. Hinohara has been the Director of the Cardiac Catherization Laboratory at Sequoia Hospital. Dr. Hinohara holds an M.D. from Keio University.

*Myrtle S. Potter* has served as a member of our Board since November 2005. Since August 2005, Ms. Potter has been a consultant with Myrtle Potter Consulting. From May 2000 to August 2005, Ms. Potter held senior management positions at Genentech, a biotechnology company, including President and Executive Vice President of Commercial Operations and Chief Operating Officer. Prior to joining Genentech, Ms. Potter held the positions of President of U.S. Cardiovascular/Metabolics from November 1998 to May 2000, Senior Vice President of Sales, U.S. Cardiovascular/Metabolics from March 1998 to October 1998, Group Vice President of Worldwide Medicines Group from February 1997 to February 1998 and Vice President of Strategy and Economics, U.S. Pharmaceutical Group from April 1996 to January 1997 at Bristol-Myers Squibb, a pharmaceutical company. Previously, Ms. Potter held the position of Vice President of the Northeast Region Business Group at Merck & Co, a pharmaceutical company, from October 1993 to March 1996. Ms. Potter serves on the board of directors of Amazon.com, an online shopping company. Ms. Potter holds a B.A. in Political Science from the University of Chicago.

## PROPOSAL TWO—RATIFICATION OF APPOINTMENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Audit Committee of the Board has selected PricewaterhouseCooopers LLP as the independent registered public accounting firm to perform the audit of our Company's financial statements for the fiscal year ending December 31, 2006. PricewaterhouseCoopers audited our Company's financial statements for 2005 and 2004. PricewaterhouseCoopers is an independent registered public accounting firm.

The Board is asking the stockholders to ratify the selection of PricewaterhouseCoopers as our Company's independent auditor for 2006. Although not required by law, the rules of Nasdaq, or our Company's Bylaws, the Board is submitting the selection of PricewaterhouseCoopers to the stockholders for ratification as a matter of good corporate practice. Even if the selection is ratified, the Audit Committee in its discretion may select a different independent registered public accounting firm at any time during the year if it determines that such a change would be in the best interests of our Company and our stockholders.

Representatives of PricewaterhouseCoopers are expected to be present at the meeting. They will have an opportunity to make a statement if they desire to do so and will be available to respond to appropriate questions from our Company's stockholders.

### Board of Directors' Recommendation

**THE BOARD OF DIRECTORS RECOMMENDS THAT YOU VOTE FOR THE RATIFICATION OF THE SELECTION OF PRICEWATERHOUSECOOPERS AS OUR COMPANY'S INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FOR 2006.**

### Audit and Non-Audit Services

The Audit Committee is directly responsible for the appointment, compensation, and oversight of our Company's independent registered public accounting firm. In addition to retaining PricewaterhouseCoopers to audit our Company's financial statements for 2005, the Audit Committee retained PricewaterhouseCoopers to provide other auditing and advisory services in 2005. The Audit Committee understands the need for PricewaterhouseCoopers to maintain objectivity and independence in its audits of our Company's financial statements. As a result, the Audit Committee recommended and the Board approved the use of another independent registered public accounting firm for certain tax services going forward. The Audit Committee has reviewed all non-audit services provided by PricewaterhouseCoopers in 2005 and has concluded that the provision of such services was compatible with maintaining PricewaterhouseCoopers' independence in the conduct of its auditing functions.

To help ensure the independence of the independent registered public accounting firm, the Audit Committee has adopted a policy for the pre-approval of all audit and non-audit services to be performed for our Company by the independent registered public accounting firm. Pursuant to this policy, all audit and non-audit services to be performed by the independent auditor 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.

The aggregate fees billed by PricewaterhouseCoopers for audit and non-audit services provided to our Company in 2005 and 2004 were as follows:

| Service Category | 2005 | 2004 |
|---|---|---|
| Audit Fees | $442,955 | $792,400 |
| Audit-Related Fees | — | — |
| Tax Services Fees | 24,900 | 15,000 |
| All Other Fees | 18,500 | — |
| **Total** | $486,355 | $807,400 |

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 included in our 2005 Annual Report on Form 10-K filed with the SEC on March 7, 2006, as amended on March 10, 2006, 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.

All of the services provided by PricewaterhouseCoopers described in the table above were approved by the Audit Committee.

## EXECUTIVE OFFICERS AND EXECUTIVE COMPENSATION

### Executive Officers and Senior Management

Set forth below is certain information concerning the executive officers and other senior management of the Company as of April 1, 2006.

| Name | Age | Position |
|---|---|---|
| John B. Simpson | 62 | Founder, Interim Chief Executive Officer and Director |
| Matthew B. Ferguson | 38 | Chief Financial Officer |
| Ronald T. Steckel | 53 | Chief Operating Officer |
| Douglas S. Rohlen | 38 | President of Strategic Operations |
| Suzon D. Lommel | 48 | Vice President of Quality and Regulatory Affairs |
| Richard J. Zimmer | 43 | Vice President of Sales |
| Angela B. Soito | 38 | Vice President of Clinical Affairs |
| Leslie L. Trigg | 35 | Vice President of Marketing |

*John B. Simpson, Ph.D., M.D.* founded our Company in September 1996 and has served as our Interim Chief Executive Officer since January 2006. Dr. Simpson has served as a member of our Board since September 1996. From May 2004 to December 2005, Dr. Simpson also served as a consultant to our Company and from October 1996 to July 1997, Dr. Simpson served as our President. Since March 2000, Dr. Simpson has served in various positions at De Novo Ventures, a venture capital fund, including Managing Director and Clinical Director. Since 1983, Dr. Simpson has been a Partner at Cardiovascular Medicine and Coronary Interventions, a cardiology physician group. Prior to founding our Company, Dr. Simpson founded several other interventional cardiology companies, including Perclose, a manufacturer of femoral artery access site closure devices, Devices for Vascular Intervention, a manufacturer of atherectomy devices, and Advanced Cardiovascular Systems, a manufacturer of balloon angioplasty devices. Dr. Simpson is a Professor of Clinical Medicine at Stanford University. Dr. Simpson holds a B.S. in Agriculture from Ohio State University, an M.D. from the Duke University School of Medicine and an M.S. and a Ph.D. in Biomedical Science from the University of Texas.

*Matthew B. Ferguson* has served as our Chief Financial Officer since January 2004. From July 2002 to January 2004, Mr. Ferguson served as our Vice President of Finance and Business Development. From February 1998 to January 2002, Mr. Ferguson held several positions at ChannelPoint, a developer of e-commerce software for the insurance industry, including Director of Finance, Director of Corporate Development and Director of Sales Operations. Mr. Ferguson holds a B.S. in Civil Engineering from Stanford University, an M.S. in Mechanical Engineering from the University of Pennsylvania and an M.B.A. from the University of California at Berkeley.

*Ronald T. Steckel* has served as our Chief Operating Officer since January 2006. From July 2004 to December 2005, Mr. Steckel served as our Senior Vice President of Operations and Research and Development. From March 2003 to January 2004, Mr. Steckel served as the Vice President of Operations at Bacchus Vascular, a manufacturer of catheter-based products. From June 1998 to September 2002, Mr. Steckel held several

positions at RITA Medical Systems, a manufacturer of tumor ablation devices, including Vice President of Operations and Senior Vice President of Operations. Mr. Steckel holds a B.S. in Biology from Blackburn University and an M.B.A. from Lake Forest College.

*Douglas S. Rohlen* has served as our President of Strategic Operations since January 2006. From May 2004 to December 2005, Mr. Rohlen served as our Vice President of Corporate Development and Investor Relations and as our Director of Business Development. From 2001 to 2004, Mr. Rohlen served as President and Chief Executive Officer of Olive Hill Development, a land development company. From 2000 to 2001, Mr. Rohlen served as a project consultant at Massachusetts General Hospital. From 1999 to 2000, Mr. Rohlen held the position of Director of Business Development at LuMend Corporation, a privately-held company that develops chronic total occlusion products in the treatment of peripheral vascular disease which was recently acquired by Cordis Corporation. In 1999, Mr. Rohlen served as Entrepreneur in Residence at Alta Partners, a venture capital firm. Mr. Rohlen holds a B.A. in History from Stanford University and an M.B.A. from Harvard Business School.

*Suzon D. Lommel* has served as our Vice President of Quality and Regulatory Affairs since November 2002. From June 2001 to October 2002, Ms. Lommel served as our Director of Quality and Regulatory Affairs. From March 2000 to June 2001, Ms. Lommel served as the Director of Regulatory and Clinical Affairs/Quality Assurance at Advanced Stent Technology, a manufacturer of stents. From February 1996 to March 2000, Ms. Lommel held several positions at Boston Scientific, a developer of medical devices, including Senior Quality Engineer, Manager of Compliance and International Regulatory Affairs and Director of Quality Assurance and Regulatory Affairs. Ms. Lommel holds an Associate Degree in Physics from Moorpark College.

*Richard J. Zimmer* has served as our Vice President of Sales since January 2006. From October 2003 to December 2005, Mr. Zimmer held several positions with our Company including District Sales Manager, National Training Manager, Regional Sales Manager, Sales Director of Biologics Division, and Director of Sales. From November 2002 to September 2003, Mr. Zimmer held sales, sales management, and sales training positions with EV-3, a multi-specialty medical device company. From October 2001 to October 2002, Mr. Zimmer held sales and sales management positions and focused on integration of the Intra-Therapeutics product line with Sulzer Medica, a maker of orthopedics devices. From April 1989 to October 2001, Mr. Zimmer held sales, sales training, and market development positions at Intra-Therapeutics, a peripheral stent company, and Mallinckrodt Medical, a multi-specialty imaging medical device company. Mr. Zimmer holds a B.A. in Government from Southeastern Louisiana University.

*Angela B. Soito* has served as our Vice President of Clinical Affairs since January 2003. From May 2002 to December 2002, Ms. Soito provided consulting services to our Company regarding clinical affairs. From August 1998 to January 2002, Ms. Soito held several positions at Pro•Duct Health, a manufacturer of medical products for early breast cancer detection, including Manager and Director and Vice President of Regulatory Affairs and Quality Assurance. Ms. Soito holds a B.S. in Biochemistry from the University of California at Davis and a J.D. from John F. Kennedy University.

Leslie L. Trigg has served as our Vice President of Marketing since April 2004. From March 2003 to March 2004, Ms. Trigg provided consulting services to our Company regarding marketing matters. From December 2001 to September 2002, Ms. Trigg served as a Business Unit Director at Cytyc, a manufacturer of devices for use in medical diagnostic applications in the field of women's health. From July 2000 to November 2001, Ms. Trigg served as the Director of Market Development at Pro•Duct Health. From June 1998 to July 2000, Ms. Trigg served as Senior Global Product Manager at Guidant, a manufacturer of medical devices. Ms. Trigg holds a B.S. in Communication Studies from Northwestern University and an M.B.A. from the University of California at Berkeley.

## Executive Compensation

The following table sets forth summary compensation information for 2005, 2004 and 2003 for our Company's Interim Chief Executive Officer, former Chief Executive Officer and each of the four other most highly compensated executive officers of our Company who were serving in such capacities as of December 31, 2005. 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% of their total annual compensation.

### SUMMARY COMPENSATION TABLE

| Name and Position | Year | Annual Compensation | | Long Term Compensation Awards | All Other Compensation ($) |
|---|---|---|---|---|---|
| | | Salary ($) | Bonus ($) | Securities Underlying Options (#) | |
| John B. Simpson | 2005 | 300,000 (1) | — | — | — |
| Interim Chief Executive Officer | 2004 | 183,333 (2) | — | — | — |
| | 2003 | — | — | 175,000 | — |
| Robert W. Thomas | 2005 | 300,000 | 352,875 | 35,000 | — |
| Former President and Chief Executive Officer (3) | 2004 | 275,000 | 250,000 | 499,571 | — |
| | 2003 | 263,077 | — | 425,000 | — |
| Matthew B. Ferguson | 2005 | 201,623 | 120,625 | 30,000 | — |
| Chief Financial Officer | 2004 | 194,400 | 125,000 | 102,414 | — |
| | 2003 | 186,932 | — | 87,500 | — |
| Douglas S Rohlen | 2005 | 165,625 | 200,000 | 125,000 | — |
| President of Strategic Operations | 2004 | 100,000 (4) | — | 18,750 | — |
| David L. Martin | 2005 | 225,000 | 292,000 | 10,000 | — |
| Former Chief Operating Officer (5) | 2004 | 175,000 | 265,000 | 257,987 | — |
| | 2003 | 163,782 | 60,000 | 247,500 | — |
| William H. Hoffman | 2005 | 200,000 | — | 10,000 | 259,246 (7) |
| Former Vice President of Sales (6) | 2004 | 150,000 | 78,000 | 129,548 | 306,784 (7) |
| | 2003 | 46,600 | — | 62,500 | 48,800 (7) |

(1) Consists of consulting fees paid to Dr. Simpson.

(2) Dr. Simpson's consulting arrangement with us began on May 21, 2004 at an annual rate of $300,000.

(3) Mr. Thomas' employment ended in January 2006.

(4) Mr. Rohlen's employment began in May 2004 at an annual salary of $150,000.

(5) Mr. Martin's employment began in January 2003 at an annual salary of $175,000. Mr. Martin's employment ended in February 2006.

(6) Mr. Hoffman's employment began in July 2003 at an annual salary of $100,000. Mr. Hoffman's employment ended in February 2006.

(7) Consists of sales commissions.

### Option Grants in 2005

The table below sets forth information concerning the stock options grants in 2005 to the executive officers named in the Summary Compensation Table and the potential realizable value of such stock options at assumed annual rates of stock price appreciation for the ten-year terms thereof.

| | Number of Securities Underlying Options Granted (#)[1] | % of Total Options Granted to Employees in Fiscal Year | Exercise Price ($/SH) | Expiration Date | Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term ($) | |
|---|---|---|---|---|---|---|
| | | | | | 5% | 10% |
| John B. Simpson | — | — | — | — | — | — |
| Robert W. Thomas | 35,000 | 2.7% | $28.20 | 1/31/15 | $ 620,719 | $1,573,024 |
| Matthew B. Ferguson | 30,000 | 2.3% | 28.20 | 1/31/15 | 532,045 | 1,348,306 |
| Douglas S. Rohlen | 125,000 | 9.8% | 28.20 | 1/31/15 | 2,216,854 | 5,617,942 |
| David L. Martin[2] | 10,000 | 0.8% | 28.20 | 1/31/15 | 177,348 | 449,435 |
| William H. Hoffman[3] | 10,000 | 0.8% | 28.20 | 1/31/15 | 177,348 | 449,435 |

(1) These options vest at a rate of 25% of the shares after one year from January 1, 2005 and 1/48th per month thereafter, subject to acceleration of vesting upon a change in control.

(2) The shares underlying the unvested portion of this option as of Mr. Martin's last day of employment were returned to our 2004 Equity Incentive Plan and are no longer exercisable by Mr. Martin.

(3) The shares underlying the unvested portion of this option as of Mr. Hoffman's last day of employment were returned to our 2004 Equity Incentive Plan and are no longer exercisable by Mr. Hoffman.

### Stock Option Exercises and Values for 2005

The table below sets forth information concerning the number of stock options exercised in 2005 and the value realized upon their exercise by the executive officers named in the Summary Compensation Table and the number and value of their unexercised stock options at December 31, 2005.

| | Shares Acquired Upon Exercise (#) | Value Realized ($) | Number of Securities Underlying Unexercised Options at December 31, 2005 (#) | | Value of Unexercised In-the-Money Options at December 31, 2005 ($)[1] | |
|---|---|---|---|---|---|---|
| | | | Vested | Unvested | Vested | Unvested |
| John B. Simpson | — | — | — | — | — | — |
| Robert W. Thomas | 28,700 | 1,299,007 | 489,322 | 410,299 | $14,233,819 | $11,115,712 |
| Matthew B. Ferguson | — | — | — | 30,000 | — | 47,700 |
| Douglas S. Rohlen | — | — | — | 125,000 | — | 198,750 |
| David L. Martin[2] | 193,000 | 8,800,010 | 66,086 | 211,401 | 1,947,554 | 5,951,187 |
| William H. Hoffman[3] | 21,900 | 913,192 | 64,500 | 115,648 | 1,770,741 | 2,897,084 |

(1) The fair market value of a share of our common stock at the close of business on December 31, 2005, was $29.79.

(2) All shares underlying unvested options held by Mr. Martin on his last day of employment were returned to our 2004 Equity Incentive Plan and are no longer exercisable by Mr. Martin.

(3) All shares underlying unvested options held by Mr. Hoffman on his last day of employment were returned to our 2004 Equity Incentive Plan and are no longer exercisable by Mr. Hoffman.

### Change in Control Arrangements

Employment at our Company is at will. We have entered into agreements with each of our employees at the level of vice president or above under which the vesting of options granted to these employees will accelerate upon a change in control. Under these agreements, on a change in control, these employees will immediately vest in 50% of the unvested shares underlying options then held by them, and in 50% of shares previously purchased

by these employees that we are then entitled to repurchase. In addition, the shares underlying options held by these employees that remain subject to vesting will vest fully over the 12 months following a change in control, and our right to repurchase any shares previously purchased by the employee will lapse over 12 months following a change in control, so long as the employee continues to be employed by us or any successor entity, at a rate of one-twelfth of the shares subject to vesting or to our right to repurchase per month.

Under these agreements, a covered employee that is terminated without cause within 12 months of a change in control, will, in most circumstances, be eligible for a severance package under which: (i) 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, (ii) the employee will be paid an amount equal to the employee's base salary for 12 months, if the employee is our Chief Executive Officer, Chief Operating Officer, President of Strategic Operations or Chief Financial Officer, or otherwise six months, and (iii) certain health coverage and benefits for that employee will be reimbursed for up to six months.

### Separation Agreement

On January 3, 2006, we entered into a Separation Agreement and Release (the "*Separation Agreement*") with Robert W. Thomas, our former President and Chief Executive Officer. The terms of the Separation Agreement were disclosed on, and filed as an exhibit to, our Current Report on Form 8-K filed with the SEC on January 9, 2006 the contents of which are incorporated by reference herein.

### Equity Compensation Plan Information

The following table provides certain information with respect to the Company's equity compensation plans in effect as of December 31, 2005.

| Plan Category | Number of securities to be issued upon exercise of outstanding options (a) | Weighted-average exercise price of outstanding options (b) | Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c) [1] |
|---|---|---|---|
| Equity compensation plans approved by stockholders: | 4,055,484 | $12.41 | 322,641 |
| Equity compensation plans not approved by security holders | — | — | — |
| **Total** | 4,055,484 | $12.41 | 322,641 |

[1] On January 1, 2006, the number of shares available for issuance was automatically increased by 1,693,132 shares.

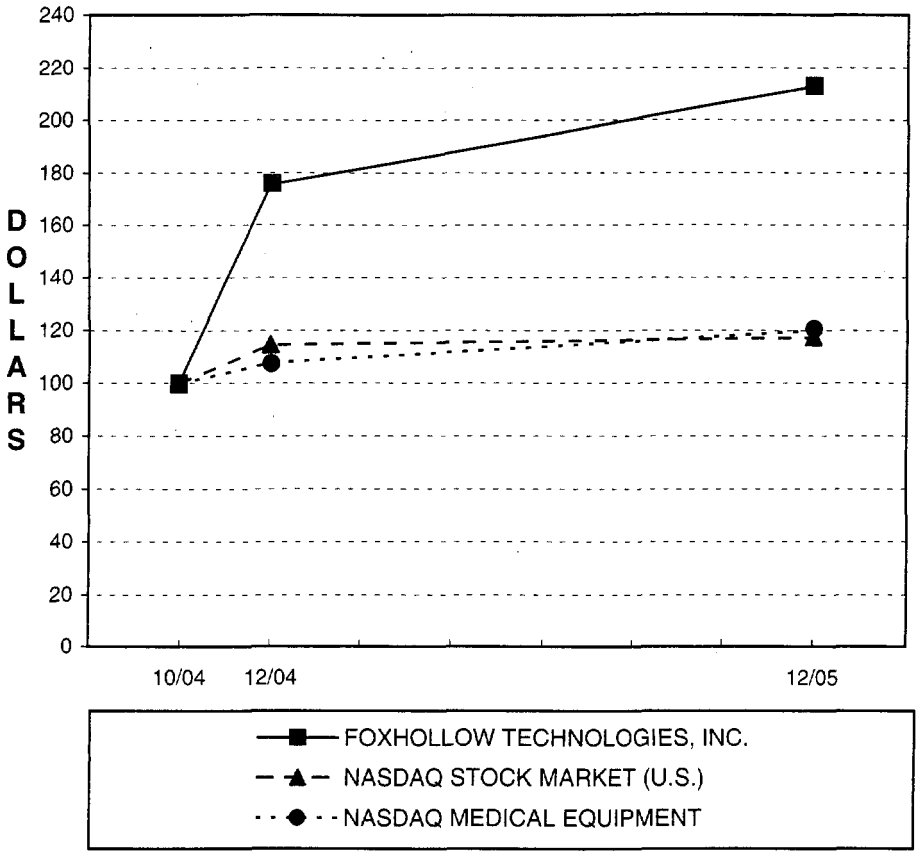
## STOCK PERFORMANCE GRAPH

*The material in this section is not deemed filed with the SEC and is not incorporated by reference in any filing of our Company under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date of this Proxy Statement and irrespective of any general incorporation language in those filings.*

The following graph compares the cumulative total stockholder return on our common stock with the cumulative total return of the Nasdaq Market, U.S. Index and the Nasdaq Medical Equipment Index for the period beginning on October 28, 2004, our first day of trading after our initial public offering, and ending on December 31, 2005.

**COMPARISON OF 14 MONTH CUMULATIVE TOTAL RETURN***

AMONG FOXHOLLOW TECHNOLOGIES, INC., THE NASDAQ STOCK MARKET (U.S.) INDEX AND THE NASDAQ MEDICAL EQUIPMENT INDEX




* $100 invested on 10/28/04 in stock or on 9/30/04 in index-including reinvestment of dividends. Fiscal year ending December 31.

## OTHER MATTERS

We are not aware of any other business to be presented at the meeting. As of the date of this proxy statement, no stockholder had advised us of the intent to present any business at the meeting. Accordingly, the only business that our Board intends to present at the meeting is as set forth in this proxy statement.

If any other matter or matters are properly brought before the meeting, the proxies will use their discretion to vote on such matters in accordance with their best judgment.

By order of the Board of Directors,

/s/ John B. Simpson

John B. Simpson
*Interim Chief Executive Officer*

Redwood City, California
May 22, 2006

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


# FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2005

or

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

Commission File Number 000-50998

# FOXHOLLOW TECHNOLOGIES, INC.

**(Exact name of Registrant as specified in its charter)**

| **Delaware** | **94-3252085** |
|---|---|
| **(State of incorporation)** | **(I.R.S. Employer Identification No.)** |

**740 Bay Road**
**Redwood City, California 94063-2469**
***(Address of principal executive offices, including Zip Code)***

**(650) 421-8400**
**(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:** |
|---|---|
| **None** | **N/A** |

**Securities registered pursuant to Section 12(g) of the Act:**
**Common Stock, $0.001 par value**
**(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 ☐ No ☒

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 ☐ No ☒

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 ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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 or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (check one):
Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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

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 June 30, 2005 (which is the last business day of registrant's most recently completed second fiscal quarter), as reported on the Nasdaq National Market was approximately $439.5 million. 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 February 10, *2006, the Registrant had 24,802,995 shares of Common Stock outstanding.*

## DOCUMENTS INCORPORATED BY REFERENCE

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

**FOXHOLLOW TECHNOLOGIES INC.**
**FISCAL YEAR 2005 FORM 10-K ANNUAL REPORT**
**TABLE OF CONTENTS**

## PART 1

*This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. These statements include, but are not limited to, those concerning the following: our intentions, beliefs and expectations regarding our future success and results; the timing and success of our clinical trials and regulatory submissions; our belief that our cash and cash equivalents will be sufficient to satisfy our anticipated cash requirements; our operating results; our expectations regarding our revenues and customers; and our distributors and statements regarding market penetration and expansion efforts. Forward-looking statements are subject to risks and uncertainties that could cause actual results and events to differ materially. For a detailed discussion of these risks and uncertainties, see the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Form 10-K. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-K.*

### ITEM 1. BUSINESS

#### Overview

We design, develop, manufacture and sell medical devices primarily for the treatment of peripheral artery disease. PAD results from the accumulation of plaque in arteries, most commonly occurring in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. Left untreated, PAD increases the risk of heart attack, stroke, amputation or death. Our first product, the SilverHawk Plaque Excision System, is a minimally-invasive, disposable catheter system that treats PAD by removing plaque in order to reopen narrowed or blocked arteries. In June 2003, the FDA granted us 510(k) clearance to market the SilverHawk in the United States for treatment of atherosclerosis in the peripheral vasculature. We commenced full commercial introduction of the SilverHawk in the United States in January 2004. We were incorporated in Delaware in September 1996 as ArterRx, Inc. We changed our name to FoxHollow Technologies in October 1996.

PAD affects approximately 12 million people in the United States. PAD becomes more common with age and affects approximately 20% of the U.S. population over 70. Growth in the prevalence of diabetes and obesity, which are risk factors for PAD, is also contributing to an increase in the prevalence of PAD. PAD is currently underdiagnosed and undertreated. There are approximately 2.5 million people in the United States diagnosed with PAD. We believe that several factors are contributing to a growing diagnosed patient population, including increasing public and physician awareness, evolving physician practice patterns, and increasing diagnostic screening for PAD. Treatment for the approximately 2.5 million people in the United States diagnosed with PAD depends on the severity of the disease. Physicians typically treat patients with mild to moderate PAD through non-invasive management, including lifestyle changes and drug treatment, and, if symptoms worsen, they may recommend interventional procedures, including angioplasty and stenting, or surgical procedures, including bypass grafting and amputation.

The SilverHawk represents a new approach to the treatment of PAD that we believe offers significant benefits. Unlike most treatments for PAD that leave plaque behind, the SilverHawk is designed for removal of plaque from artery walls with minimal vascular trauma. Use of the SilverHawk does not involve stretching of the artery walls that can lead to dissection or perforation.

We market the SilverHawk through our direct sales force in the United States primarily to interventional cardiologists, as well as to vascular surgeons and interventional radiologists. Reimbursement claims for the SilverHawk procedure are typically submitted by the hospital and physician to Medicare or other third-party payors using established billing codes for atherectomy procedures. For the year ended December 31, 2005, we sold over 49,000 devices, and ended the year with more than 1,000 current hospital customers in the United States.

We have also entered into a Collaboration and License Agreement with Merck & Co. Inc., (the "Merck Collaboration Agreement") through which we agreed with Merck to collaborate on the analysis of atherosclerotic plaque removed from patient arteries with the goal of identifying new biomarkers for atherosclerotic disease progression. The Merck Collaboration Agreement provides for a research collaboration of up to three years and

consists of an initial one-year research term that Merck may, at its discretion, extend for one or two additional years. As part of this research collaboration, we will provide Merck with exclusive access to existing atherosclerotic plaque samples collected from patients having vascular disease using the SilverHawk Plaque Excision System as well as new samples to be collected pursuant to agreed upon protocols and criteria. We may derive further revenue from Merck for milestone payments based on the progress of clinical development of any pharmaceutical or diagnostic products arising from work under the research collaboration, as well as royalties on sales of any such products.

**Industry Background**

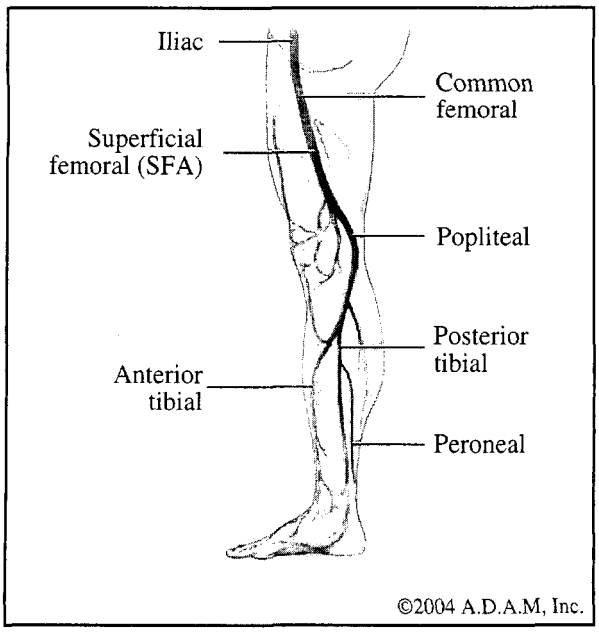
***Cardiovascular Disease***

Cardiovascular disease refers to diseases of the heart and blood vessels located throughout the body. The most common cause of cardiovascular disease is atherosclerosis, or "hardening of the arteries." Atherosclerosis is a complex, progressive and degenerative condition resulting from the build-up of cholesterol and other obstructive materials, known as plaque, on the walls of arteries. The accumulation of plaque narrows the interior of arteries, thereby reducing blood flow. In addition, plaque may rupture and trigger a blood clot that can further narrow or block an artery. A significant reduction in blood flow can deprive tissue and organs of oxygen that may lead to tissue damage, stroke or heart attack.

Plaque occurs in several different forms and may be located throughout the arterial system. Plaque varies in composition, with portions that are hard and brittle, referred to as calcified plaque, and other portions that are fatty or fibrous. Plaque lesions can be long or short, focused or diffuse and can form in all types of arteries, including straight or curved arteries of varying diameters. Atherosclerosis in the arteries that supply the heart muscle with blood causes coronary artery disease, and atherosclerosis outside of the heart and brain causes PAD.

***Peripheral Artery Disease***

PAD, also known as peripheral vascular disease, is most common in the arteries of the pelvis and legs. The legs receive their supply of blood through the femoral arteries, which originate at the groin. The superficial femoral artery, or SFA, extends from the upper thigh to the knee. At the knee, the SFA becomes the popliteal artery, which branches into arteries that supply blood to the lower leg and foot. Arteries above the knee are generally long, straight and relatively wide, while arteries below the knee are shorter and branch into arteries that are progressively smaller in diameter.



Plaque build-up in the leg arteries reduces blood flow to the surrounding tissue, causing claudication, the most common early symptom of PAD. Claudication refers to pain, cramping or tiredness in the leg or hip muscles while walking. Symptoms may progress to include numbness, tingling or weakness in the leg and, in severe cases, burning or aching pain in the foot or toes while resting.

As PAD progresses, additional signs and symptoms occur, including loss of hair on the legs, cooling or color changes in the skin of the legs or feet, and sores on the legs and feet that do not heal. If untreated, PAD may lead to critical limb ischemia, or CLI, a condition where there is not enough oxygenated blood being delivered to the limb to keep the tissue alive. As reported in *Endovascular Today* in February 2004, up to 30% of the people diagnosed with PAD suffer from CLI. If untreated, CLI often leads to large non-healing ulcers, infections, gangrene and eventually limb amputation or death.

Primary risk factors associated with PAD are diabetes and smoking. Other significant risk factors include advanced age, high cholesterol, high blood pressure, obesity and physical inactivity. A family history of cardiovascular disease may also put individuals at higher risk for PAD. According to the *Clinical Cardiology Review* in 2002, 40% of people with coronary artery disease also suffer from PAD.

**Market Overview**

PAD affects approximately 12 million people in the United States, according to the December 2003 American Diabetes Association Consensus Statement. PAD becomes more common with age and, according to the American Heart Association, affects approximately 20% of the U.S. population over 70. Those with diabetes or who are obese are at increased risk of PAD. In 2002, the ADA estimated that there were 18 million U.S. adults with diabetes, with approximately 1.3 million new cases of diabetes diagnosed each year. According to the Centers for Disease Control, there were over 44 million obese adults in the United States in 2001, which reflects a 74% increase since 1991. These demographic trends are contributing to an increase in the prevalence of PAD.

Of the PAD population, there are only approximately 2.5 million people diagnosed in the United States, according to the Society of Interventional Radiology. Underdiagnosis is due in large part to the fact that over one-half of the PAD population does not display symptoms of the disease. In addition, others dismiss their symptoms as part of the normal aging process or attribute them to another cause. Approximately one-third of those with PAD have claudication, according to the ADA Consensus Statement. As PAD worsens, patients may eventually develop CLI. We believe approximately 750,000 people in the United States suffer from CLI. We believe that the following factors are contributing to a growing diagnosed PAD patient population:

- **Increased Awareness.** Recent emphasis on PAD education from medical associations, insurance companies and online medical communities, as well as publication in medical journals such as the 2001 PARTNERS study in the *Journal of the American Medical Association*, is increasing public and physician awareness of PAD risk factors, symptoms and treatment options. The "Legs for Life" campaign screens more than 40,000 people for PAD each year, of which nearly 29% are at moderate to high risk of lower extremity PAD. The ADA recommends that all diabetics over the age of 50 be screened for PAD.
- **Evolving Physician Practice Patterns.** Given that many patients with coronary artery disease also have PAD, we believe that interventional cardiologists and vascular surgeons are increasingly screening patients for both diseases. As a consequence, we believe that physicians are diagnosing more cases of PAD. In addition, heightened awareness of PAD, its symptoms and treatment options is leading to increased referrals from general practitioners, podiatrists who treat patients with pain and lesions in the feet that may be caused by PAD, and nephrologists and endocrinologists, who treat diabetics often experiencing complications resulting from PAD.
- **Increased PAD Screening.** The PARTNERS study advocated increased PAD screening by primary care physicians using an ankle-brachial index, or ABI, a simple technique that compares blood pressure in a patient's foot to blood pressure in the patient's arm to determine how well blood is flowing to the foot. In addition to the ABI, physicians are increasingly using established techniques, such as angiography and ultrasound, to either diagnose or confirm diagnosis of PAD.

**Conventional Means of Treatment and Their Limitations**

Treatment for the approximately 2.5 million people in the United States diagnosed with PAD depends on the severity of the disease. Physicians typically treat patients with mild to moderate PAD through non-invasive management, including lifestyle changes and drug treatment, and, if symptoms worsen, may recommend interventional or surgical procedures. Some patients who initially are diagnosed with severe PAD are treated immediately through interventional or surgical procedures.

*Non-Invasive Management*

Approximately 2.1 million cases of diagnosed PAD in the United States are considered mild to moderate, according to the Society of Interventional Radiology. For this population, lifestyle changes and drug treatment may slow or reverse the progression of PAD. Lifestyle changes include improving diet, exercising regularly and quitting smoking. Although these adjustments can be effective, many people are unable to maintain this new lifestyle. In addition to lifestyle changes, physicians often prescribe medications that increase blood flow but do not treat the underlying obstruction. Pletal, the most commonly prescribed medication for claudication, should not be taken if the patient also has heart disease, which often exists in PAD patients. In addition, doctors often prescribe cholesterol-lowering drugs and drugs for high blood pressure. Patients generally need to take the prescribed drugs for the rest of their lives. According to the American Academy of Family Physicians, 20% to 30% of patients who are non-invasively managed for claudication develop more severe symptoms that require intervention.

*Interventional Procedures*

When PAD progresses beyond claudication, physicians may advise intervention, often beginning with minimally-invasive procedures. Based on publicly available information, we believe that there were approximately 400,000 endovascular procedures for the treatment of PAD in 2000, and that the number of procedures is growing annually. Angioplasty and stenting are the most commonly performed minimally-invasive interventional treatments.

- **Angioplasty.** In angioplasty, a catheter with a balloon tip is inserted into the blocked or narrowed part of the artery over a previously positioned guide wire that directs the catheter to the affected area. The balloon is then inflated, compressing the plaque and stretching the artery wall. No plaque is removed. Angioplasty generally has lower success rates treating arterial obstructions that are longer than four to six centimeters. Accordingly, stand-alone angioplasty has had limited success in the large arteries of the legs because many of the affected arteries have diseased segments that are longer than four to six centimeters. In addition, angioplasty is not well suited to treat highly calcified lesions, lesions concentrated on one side of the artery wall, or lesions that occur at bifurcations, all common manifestations of PAD in the leg. Angioplasty is also not well suited to treat lesions below the knee, because these arteries are small, diffusely diseased, and less tolerant of dissections than larger arteries.

  There are several complications associated with the use of angioplasty in the peripheral arteries. The inflation of the balloon stretches the artery walls, which may result in dissections. Additionally, lesions from the superficial femoral artery, or SFA, through the popliteal arteries treated with angioplasty only remain open, or patent, in approximately 60% of all cases one year following the procedure, according to a 2000 Transatlantic Inter-Society Consensus study, or TASC. The TASC study also noted that complications occurred in roughly 10% of all angioplasty procedures with approximately half resulting in major complications, leading to more intensive care, prolonged hospitalization, permanent adverse injury or death.

- **Stenting.** Stenting is performed in tandem with angioplasty in the majority of interventional procedures. Stents are tubular frames, generally made of metal that are positioned within a lesion, expanded into position and left in the artery to prevent the artery from collapsing. According to Frost & Sullivan, an industry research group, there were approximately 194,000 peripheral stent procedures performed in the United States in 2002.

Use of stents in the legs has been problematic due to restenosis and stent-fracture rates. Lesions treated with bare metal stents only remain patent in approximately two-thirds of all cases one year following the procedure, according to the TASC study. Longer lesions treated with stents close up, or restenose, more frequently than shorter lesions, which makes stents less effective for use in leg arteries than in coronary arteries since leg lesions typically are longer. Additionally, stents tend to fracture due to the torquing, bumping and stretching of arteries caused by leg movement. In cases where restenosis occurs within the stent, physicians are left with limited treatment alternatives because there are no approved treatments for peripheral in-stent restenosis.

- **Other Interventional Treatments.** Other PAD interventional treatments include: laser therapy, which uses a laser to reduce plaque to relatively small particles; drug-eluting stents, where a stent is coated with a slow-to-moderate release drug formulation intended to reduce restenosis; and vascular cryotherapy, where an angioplasty balloon is inflated with nitrous oxide in an attempt to reduce inflammation caused by treatment of the lesion. In the case of laser therapy, the process usually only creates narrow openings in the artery and typically must be used in conjunction with other therapies, such as angioplasty or stenting. Drug-eluting stents are currently under investigation for peripheral use in the United States. Vascular cryotherapy was commercially launched in 2003 and its effectiveness has not been validated. Other interventional devices include cutting balloons and rotoblators, which have limited application and are used infrequently.

*Surgical Procedures*

Surgery is used when non-invasive management or interventional procedures have failed or if the patient is diagnosed when PAD has progressed to an advanced state.

- **Bypass Surgery.** In bypass surgery, the surgeon reroutes blood around a lesion using a vessel from another part of the body or a tube made of synthetic fabric. Bypass surgery is not advisable for some patients because of the inherent risks of surgery, the symptoms are not deemed to be critical enough to warrant such an intervention, or the existence of other diseases. Bypass surgery has a high risk of procedure-related complications from blood loss, post-procedural infection or reaction to general anesthesia and may require patients to remain hospitalized for several days. Despite these limitations, bypass surgery below the knee remains the most widely practiced method of improving blood flow to a threatened limb and accounts for 75% of all leg procedures in patients with diabetes, according to the American Diabetes Association, or ADA, Consensus Statement. Based on publicly available information, we believe that there were approximately 145,000 peripheral bypass procedures in the United States in 2000.
- **Endarterectomy.** Endarterectomy involves the surgical removal of plaque. While endarterectomy is sometimes used, the procedure is highly invasive and subjects the patient to the same procedural risks and complications as bypass surgery. Endarterectomy is rarely used below the knee because the arteries below the knee are generally too small to accommodate the procedure.
- **Amputation.** If critical limb ischemia, or CLI, progresses to an advanced state, physicians may amputate all or a portion of the limb. According to the ADA Consensus Statement, within six months of the onset of CLI, 30% of patients require amputation. The ADA Consensus Statement also notes that approximately half of all patients with CLI in one leg will also develop it in the other leg. PAD results in approximately 150,000 amputations per year in the United States.

**The FoxHollow Solution—The SilverHawk Plaque Excision System**

Our SilverHawk Plaque Excision System represents a new approach to the treatment of PAD that we believe offers significant benefits. The SilverHawk is a minimally-invasive, single-use catheter system designed for rapid removal of plaque from artery walls with minimal vascular trauma. We believe that the principal benefits of the SilverHawk are:

- **Safety.** The SilverHawk is designed not to stretch or damage the artery walls, which can lead to dissection or perforation. We believe that the safety of the SilverHawk measured by low rates of

perforation and dissection is supported by results from the treatment of 1,517 lesions in 728 patients recorded in our TALON registry. In data presented in October 2005, there were dissections and perforations in less than 5% and 1%, respectively, of these lesions treated post-SilverHawk. The SilverHawk procedure is minimally-invasive and typically performed under local anesthesia; therefore, it does not have many of the risks associated with more invasive surgeries and general anesthesia. We have not conducted, and do not have any current plans to conduct, studies designed to directly compare the safety of the SilverHawk against alternative procedures, such as angioplasty, stenting or bypass grafting. However, we do intend to conduct a study directly comparing the safety and efficacy of the SilverHawk procedure to current drug therapy.

- **Efficacy.** Unlike most treatments for PAD that leave plaque behind, the SilverHawk removes plaque. The SilverHawk has removed over 700 milligrams of plaque in a single procedure, with an average of approximately 100 milligrams per procedure. We believe that excising plaque without causing stretch injury to the artery wall may minimize restenosis and the need for reintervention. We also believe that the efficacy of the SilverHawk, measured by low twelve-month reintervention rates is supported by the results of three single site studies as well as our TALON registry. Reintervention rates usually increase over time, and generally two-year rates will be substantially higher than one-year rates. We plan to conduct additional studies designed to measure restenosis rates or patency rates after treatment with the Silverhawk. See "—*Clinical Studies—Postmarketing Studies—Single Center Clinical Experience.*"

- **Treats Difficult to Treat Lesions.** The SilverHawk enables physicians to remove plaque from long, calcified and bifurcated lesions in a wide variety of locations, including arteries below the knee. Approximately one-third of SilverHawk procedures to date have been performed below the knee, an area where lesions have traditionally gone untreated until they require bypass surgery or amputation. Certain treatment locations, such as arteries below the knee or above the leg, are not suited for physicians with limited experience using the device.

- **Utilizes Familiar Techniques.** The SilverHawk procedure employs techniques similar to those used in angioplasty, which are familiar to the approximately 10,000 interventional cardiologists, vascular surgeons and interventional radiologists in the United States who are generally trained in endovascular techniques. This significantly increases the number of physicians who are able to perform the procedure compared to surgical alternatives that must be performed by highly-trained vascular surgeons. In addition, we designed the SilverHawk to be easy to use. The SilverHawk operates with one switch that controls all device functionality, and has a unique torque shaft designed for a one-to-one correlation between the handle and the tip, providing physicians with precise control of the position of the cutting blade.

- **Cost and Time Efficient.** A single SilverHawk device can be used to treat multiple and long lesions where more than one stent might otherwise be required. Compared to surgical alternatives, the SilverHawk procedure reduces cost by allowing physicians to treat patients in a catheterization lab instead of an operating room, decreasing the length of hospitalization and reducing complications.

- **Leaves Treatment Options Open.** Physicians can, and sometimes do, use adjunctive angioplasty and stenting during a SilverHawk procedure. When the SilverHawk procedure is performed without adjunctive procedures, future treatment options remain available in the event that restenosis does occur and reintervention is required. The SilverHawk procedure does not require a foreign body, such as a stent, to be left in the artery.

- **Captures and Removes Plaque.** The patient and the physician get immediate feedback by seeing the volume of plaque removed, visibly reinforcing the benefits of the procedure. The removed plaque often is collected and will be used in research to identify markers of atherosclerotic disease.

Treating certain lesions may require the use of more than one SilverHawk model, which would increase the cost of the procedure. Risks of using the SilverHawk peripherally include the risks that are common to use of interventional devices, including infection, perforation or dissection of the artery wall, internal bleeding, limb

loss and death. In the United States, the SilverHawk is approved for use in the peripheral vasculature but is not approved for use in the carotid or coronary arteries. This means that our product may not be marketed or advertised in the United States for use in the heart, brain or in specific peripheral anatomy without additional clearances from the FDA. Use of the SilverHawk in the coronary arteries has led to serious adverse events, including perforations, emergency bypass surgery, stroke, heart attack and patient death. In the United States, the SilverHawk is contraindicated, and should therefore not be used, for in-stent restenosis and for use in the carotid arteries. Within the peripheral vascular system, we do not recommend the SilverHawk for use in renal or iliac arteries.

**Business Strategy**

Our goal is to be the leading provider of medical devices for the treatment of atherosclerosis. The key elements of our strategy include:

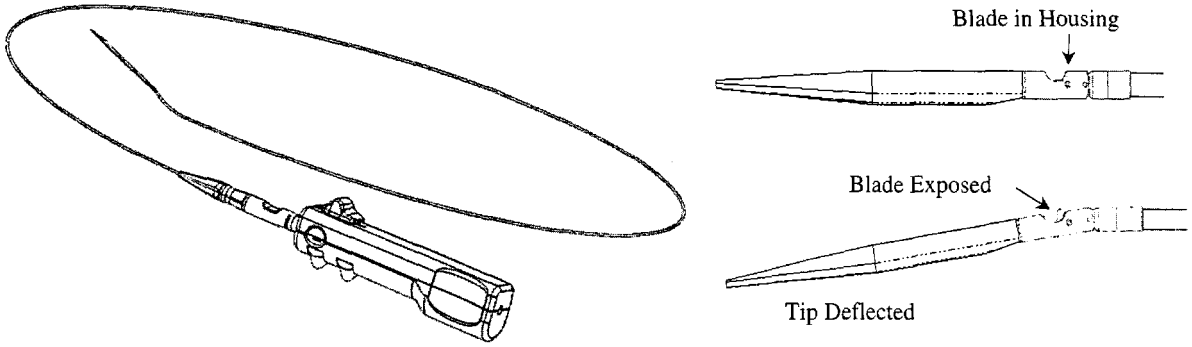
- **Drive Adoption of the SilverHawk within the Physician Community.** We plan to drive adoption of the SilverHawk by marketing it as an alternative means of treatment, as well as for patients that have previously gone untreated. Our initial focus is to target and increase usage among treating physicians with high patient volumes. Over time, we will broaden our focus to target the wider physician base of potential SilverHawk users. Peer-to-peer selling by early adopters and physician referrals are integral to our strategy.
- **Penetrate the PAD Market with an Expanded U.S. Direct Sales Force.** We are expanding our U.S. direct sales force to further penetrate the PAD market. Our sales force has increased from 69 direct sales representatives on December 31, 2004 to 206 on December 31, 2005, and we expect to continue to grow our sales force. Since use of the SilverHawk does not require additional training for physicians, our sales force can focus on selling the clinical benefits of the SilverHawk and encouraging physician use.
- **Acquire or Partner with Complementary Businesses.** We believe that we will be able to leverage our technology, existing sales infrastructure, manufacturing capability and reputation within the physician community to introduce new products and technologies. We intend to supplement our internal development efforts through selective licenses, alliances or acquisitions of complementary products, technologies or businesses that will further enhance our presence in interventional medicine.
- **Improve the SilverHawk's Capabilities and Features.** We focus our research and development efforts on technology enhancements that make the SilverHawk more effective in excising plaque in difficult to treat areas. We are developing smaller devices capable of treating lesions in smaller arteries located in the lower legs and feet, as well as devices that will be more effective in treating calcified lesions. We are focusing on onboard imaging developments that will allow physicians to view plaque excision on a real-time basis, making improvements to catheters that will dramatically reduce procedure time and on the development of new catheters to adequately address patient needs below the knee.
- **Leverage Broadly Applicable Proprietary Technology to Expand into New Markets.** We intend to leverage the SilverHawk to treat coronary artery disease. We believe that the adaptability and flexibility of the SilverHawk will provide substantial benefits in treating difficult to treat plaque lesions in the coronary arteries. In addition, the SilverHawk's ability to remove plaque allows for the opportunity to analyze tissue and research the factors contributing to cardiovascular disease.
- **Plaque Analysis Partnership.** The plaque excised during a Silverhawk procedure may be used to study cardiovascular disease at a biological level. In September 2005, we entered into the Merck Collaboration Agreement through which we agreed with Merck to collaborate on the analysis of atherosclerotic plaque removed from patient arteries with the goal of identifying new biomarkers for atherosclerotic disease progression. The Merck Collaboration Agreement provides for a research collaboration of up to three years and consists of an initial one-year research term that Merck may, at its discretion, extend for one or two additional years. As part of this research collaboration, we will provide Merck with exclusive access to existing atherosclerotic plaque samples collected from patients having vascular disease using the SilverHawk Plaque Excision System as well as new samples to be collected pursuant to agreed upon

protocols and criteria. We may derive further revenue from Merck for milestone payments based on the progress of clinical development of any pharmaceutical or diagnostic products arising from work under the research collaboration, as well as royalties on sales of any such products.

- **Expand Manufacturing Capacity and Reduce Costs.** We intend to leverage our development and manufacturing experience to achieve large-scale production of the SilverHawk while maintaining high quality standards and regulatory compliance. In September 2005, we consolidated manufacturing operations into our Redwood City, California, building, which serves as our headquarters. This 60,000 square foot facility represents a three-fold increase over our previous facility, resulting in expanded production area and clean room space and enhanced research and development labs. In addition, we plan to continue to actively pursue manufacturing efficiencies and cost reductions that we expect will result in lower manufacturing cost per device.

**The SilverHawk Product**

The SilverHawk is a single-operator, hand-held device that removes plaque from arteries. The SilverHawk has two primary components, consisting of a low profile catheter connected to a battery-driven control unit, both of which are disposable.




The SilverHawk's catheter consists of a flexible shaft designed to track over a previously positioned guide wire, allowing for a minimally-invasive procedure. We offer eight different SilverHawk catheters of various diameters and tip lengths to accommodate differing artery sizes and amounts of plaque.

At the leading end of the catheter is a motor-driven cutting blade within a platinum tubular housing. The cutting blade rotates at approximately 8,000 revolutions per minute and is made of carbide, which is significantly stronger than stainless steel, enabling it to cut through heavily calcified lesions.

The cutter height is fixed to achieve consistent cut depth in order to create a smooth surface. The cutter housing contains a mechanism that causes the tip of the catheter to deflect, which in turn pushes the blade against the lesion without requiring an inflated balloon to anchor the device. Since the cutting blade does not use a balloon, long lesions can be treated efficiently by continuously advancing the device along the entire length of the lesion. The SilverHawk's unique torque shaft is designed for one-to-one correlation between the handle and the tip, allowing physicians to precisely control the cutting blade's position.

The catheter tip consists of a hollow nose cone located in front of the cutter housing that is designed to collect plaque. Depending on the size of the nose cone, it can collect up to approximately 100 milligrams of plaque before it must be removed and emptied. The control unit contains a battery-driven motor that drives the rotation of the cutting blade. A thumb-switch controls all functionality of the SilverHawk. Retracting the switch prepares the device for plaque excision by simultaneously turning on the motor, opening the cutter window, exposing the cutting blade and deflecting the tip. Advancing the switch closes the cutter window and returns the blade into its housing, straightening the tip and turning off the motor.

## The SilverHawk Procedure

The SilverHawk treatment procedure is typically performed under local anesthesia in a catheterization lab, and less frequently performed under general anesthesia in an operating room. The procedure involves the following steps:

- **Introducer Sheath Insertion and Angiogram.** With the patient under anesthesia, the physician inserts the introducer sheath, or plastic tube, and guide wire to gain access to the target artery using standard endovascular techniques. An angiogram is then performed by injecting contrast dye into the artery while x-ray pictures are taken, allowing the physician to locate lesions that need treatment. To prevent the possibility of air embolus, the sheath should be aspirated before angiography.
- **Removal of Plaque Using SilverHawk.** The SilverHawk is advanced over the guide wire to the target lesion. The physician then uses the on/off switch on the handle to deflect the tip and activate the cutting blade. With the blade spinning, the SilverHawk is slowly advanced across the lesion, "shaving" plaque from a portion of the artery with each advancement. Each lesion is typically treated with several cuts. The excised tissue is captured and stored in the nose cone of the device. After each cutting pass, the motor is deactivated and the catheter is either re-positioned for additional treatment or removed from the artery. The device can be rotated to different quadrants of the artery to achieve uniform plaque excision. When the nose cone is filled with plaque, the catheter is removed from the patient. After emptying the plaque from the chamber, the catheter can be re-inserted to treat additional areas in the same patient.
- **Assessment and Sheath Removal.** An angiogram typically follows the procedure to assess the extent of plaque removal. The guide wire and introducer sheath are removed, and the access artery is closed.

The entire procedure takes approximately 90 minutes, of which on average 30 minutes is spent using the SilverHawk. Typically, the patient is kept overnight in a hospital for observation.

## Clinical Studies

### *Premarketing Trials*

***Peripheral.*** We have conducted clinical trials to demonstrate the safety and efficacy of the SilverHawk in treating PAD. Our first study was a 105-patient clinical trial in Europe, which began in January 2002. The purpose of the trial was to collect data to submit to the FDA in support of 510(k) clearance for use of the SilverHawk in the peripheral vasculature and to support a European submission. We collected acute and 30-day follow-up data and received our CE Mark to market in Europe in May 2003 and our 510(k) clearance in the United States in June 2003. Our 510(k) clearance is for the treatment of atherosclerosis of the peripheral vasculature. This means that our product may not be marketed in the United States for use in the heart, brain or in specific peripheral anatomy without additional clearances from the FDA. In the United States, the SilverHawk is contraindicated for in-stent restenosis and for use in the carotid arteries.

***Coronary.*** In February 2002, we commenced a European safety study in order to obtain a CE Mark for use of the SilverHawk in coronary arteries. We enrolled and treated 146 patients and obtained the right to affix the CE Mark to the SilverHawk for coronary use in October 2002. In October 2004, we received regulatory approval in Europe for use of the SilverHawk to treat in-stent restenosis in coronary arteries.

In October 2002, we initiated a trial to support FDA approval of the SilverHawk for use in the coronary arteries. The trial was designed to treat advanced bifurcation lesions, which form in locations where arteries branch. We enrolled 172 out of a planned 250 patients at 15 sites before voluntarily placing the trial on hold in December 2003. Prior to placing the trial on hold, we experienced 37 serious adverse events in treating 28 patients, including 10 perforations, two cases of emergency bypass surgery, three cases of stroke, 14 cases of heart attack and eight patient deaths. We have made several design modifications to the coronary versions of our devices, and we have submitted an application to the FDA for a new Investigational Device Exemption, or IDE. The FDA has responded to our IDE application, and we now expect that further modifications to our devices will be necessary

before the new trial can be started in the U.S. to evaluate the safety and efficacy of the SilverHawk in the coronary arteries. We cannot predict when the trial will be initiated, the outcome of such a trial or whether the results will adequately demonstrate the safety and efficacy of the SilverHawk for use in coronary arteries.

***Postmarketing Studies***

Postmarketing studies are conducted to provide data regarding disease treatment outcomes. These studies often collect acute, procedural, safety and long-term efficacy data. Acute data from postmarketing studies on treatments for PAD often describe the amount of blockage caused by plaque, or stenosis, immediately pre- and post-procedure, as well as on procedure-related injuries, such as perforations, dissections and embolizations. Long-term efficacy data collected weeks, months or years after a procedure can be measured in terms of restenosis, patency or reintervention rates. Restenosis rates measure the number of lesions that have renarrowed in a group of treated lesions over a defined period of time. Patency rates are generally negatively correlated with restenosis rates and measure the number of lesions in a group of treated lesions that remain open following treatment over a defined period of time. Typically, an artery is considered "restenosed" once it is narrowed by 50% or more and an artery is considered "patent" if it has renarrowed by less than 50%. Some studies measure patency by techniques, such as an ankle-brachial index, or ABI, that do not quantify the amount of plaque build-up in the artery. Consequently, not all patency rates can be equated to the exact inverse of restenosis rates. Reintervention, or revascularization, rates measure the number of treated lesions that have required retreatment within a defined period of time. Reintervention is typically performed when arteries restenose, and thus is a related indicator of restenosis and patency.

Studies are subject to a number of factors that can influence results, making it difficult to draw general conclusions. PAD studies have historically involved very few patients, with even fewer patients available for long-term follow up and analysis. Moreover, restenosis and patency can be measured in a variety of ways. For example, the amount of plaque accumulation may be measured with varying degrees of accuracy by an ABI examination, duplex ultrasound or angiography. Additionally, the rate of plaque build-up and the need for reintervention may be influenced by factors unrelated to the method of treatment, such as the type of artery in which the lesion is located or a patient's overall health. Among a small number of treated patients, these factors can influence the meaningfulness of clinical study results. Consequently, findings from one study should not be used to predict limitations or benefits of a particular means of treatment.

We plan to conduct additional studies designed to measure restenosis rates or patency rates after treatment with the SilverHawk. However, we have not conducted and we do not have any current plans to conduct randomized studies comparing the use of the SilverHawk with the use of other interventional therapies such as balloon angioplasty and stenting. It would be expensive for us to compensate the site and the patient for these types of studies, which requires follow-up testing at six-month intervals using an angiography, ultrasound or ABI test. In addition, it would be difficult for us to find a comparable procedure to randomize against. Reintervention data has been gathered through our TALON registry, but we cannot provide any assurance that the data collected is compelling to the medical community because it may not be scientifically meaningful and does not directly compare the outcomes of the SilverHawk procedure to the outcomes from alternative procedures. Clinical studies that have been conducted with the SilverHawk, as well as clinical experiences recorded in the TALON registry, have involved procedures performed by physicians who are technically-proficient and high-volume users of the SilverHawk. Consequently, both short and long-term results reported in these studies and the TALON registry may be significantly more favorable than typical results of practicing physicians, which could negatively impact rates of adoption of the SilverHawk.

We plan to launch two new clinical studies related to the use of the SilverHawk in treating PAD. The first will be a 100-patient registry reviewed by independent physicians for acute safety and long term outcomes data. The study will include six and 12-month follow up of patients to evaluate patency in a controlled population of patients and lesions. Study enrollment is expected to start in the second quarter of 2006, with six-month data expected in the first quarter of 2007. The second study will be a randomized trial comparing outcomes in patients

treated with the SilverHawk versus those treated with Pletal for PAD. Enrollment of the study is expected to be completed by the end of 2006, with initial data expected by mid-2007.

***TALON Registry.*** We completed enrollment in a registry called TALON with participating sites to track outcomes of patients whose legs have been treated with the SilverHawk. We voluntarily initiated this registry following our FDA clearance. The primary purpose of the registry was to capture acute data, tissue specimens and short and long-term data on reintervention rates. The TALON registry was open to all physicians at participating sites that are willing and able to collect compliant data. Each participating physician must commit to enrolling all SilverHawk patients and tracking them to obtain follow-up data to reflect the average patient's experience. Participating TALON sites must secure IRB approval and patients' informed consent prior to site initiation and patient enrollment. The protocol establishes the objectives of the study, requires the device to be used for its intended use in peripheral arteries and requires the collection of blood and tissue for subsequent analysis. Following a SilverHawk procedure, a case report form is completed to record certain acute and post-procedure data and patients are requested to return to the center at six and twelve-month intervals to ensure that post-procedure data can be recorded. We believe that currently fewer than 5% of all SilverHawk procedures are performed at TALON sites. This prospective, noncontrolled, nonrandomized registry commenced enrollment in September 2003. The registry will be closed at the end of 2006.

In data presented in October 2005, we had seventeen U.S. sites participating in the TALON registry. Sites participating in the TALON registry typically have a high-volume practice, employ highly-skilled practitioners, have the staff available to collect follow-up data and are interested in publishing clinical results. Due to these criteria, the clinical results collected by the TALON registry may be significantly more favorable than typical results of practicing physicians. Data on 1,517 lesions in 728 patients were reported in the registry. In a subset of these lesions, 402 lesions were treated with the SilverHawk and adjunctive therapy, such as angioplasty or stenting. Lesions above the knee accounted for approximately 74% of the lesions treated, with lesions below the knee accounting for the remainder. The 1,115 lesions treated with the SilverHawk alone were on average 86% stenosed prior to the procedure and 11% stenosed immediately following the procedure, as measured by visual angiography. The 402 lesions treated with the SilverHawk and adjunctive therapy were on average 91% stenosed prior to the procedure, 31% stenosed immediately following treatment with the SilverHawk and 11% stenosed post-adjunctive therapy, as measured by visual angiography. In this patient cohort, no major device-related complications have been reported and there were dissections and perforations in less than 5% and 1% of the lesions treated post-SilverHawk, 8% and 0% of lesions treated post-adjunctive therapy and 0% and 1% of the lesions treated post-procedure, respectively. In the data presented in October 2005, 12-month follow-up results were included for 659 lesions treated in 336 patients. Physicians reported retreatment of 138 lesions, or 21%, within the twelve months following initial treatment. Short-term and 12-month follow-up data may not predict the long-term efficacy of the SilverHawk.

The TALON registry is also designed to provide histological data on plaque excised from patients. Removed plaque can also be used to research novel and existing markers that may be predictive of restenosis and PAD risk.

We estimate that there are approximately twenty-one physicians at TALON sites who use the SilverHawk, eleven of whom are our consultants. Similarly, nearly all of the physicians who have contributed to the TALON registry are also consultants to our company, and have been compensated for their consulting services with both cash and stock or cash alone. These consulting arrangements do not cover participation in the TALON registry. Physicians are not compensated for their participation in our TALON registry other than nominal reimbursement paid to partially offset the costs incurred due to participation in the registry and collection of long-term follow-up data.

***Single-Center Clinical Experience.*** Two abstracts describing single-center clinical experiences using the SilverHawk with 12-month follow up were presented in October 2005 at the Transcatheter Cardiovascular Therapeutics conference. The first abstract reports on SilverHawk treatments conducted on 251 limbs between September 2003 and May 2005 on 324 lesions within the superficial femoral artery, or SFA. Treated lesions ranged from 2 to 36 centimeters in length, averaging 15.3 centimeters. The SilverHawk was used alone to treat

all of these lesions. There were no device-related complications, embolisms or thrombosis reported. Twelve-month follow up data on 102 lesions examined through angiography showed an approximately 16% restenosis rate.

The second abstract reports on the treatment of 386 leg lesions, located above and below the knee, in 220 patients between June 2003 and January 2005. The SilverHawk was used as a standalone therapy in 78% of lesions. Adjunctive treatments such as angioplasty were used to treat 13.4% of lesions, and stents were placed in 8.6% of lesions. There were no major complications and no embolisms reported. Twelve-month follow-up data on 104 lesions which had been collected using duplex ultrasound or ABI, indicated a patency rate of 86%. For these treatments, patency rates were measured as the percentage of patients who did not undergo a repeat procedure during the follow-up period.

In addition to these two abstracts, four additional abstracts were presented by physicians at the October 2005 Transcatheter Cardiovascular Therapeutics conference. These four abstracts also involved single-center clinical experience with the SilverHawk, examining immediate procedural results. These abstracts reported on the procedural safety and efficacy of the SilverHawk.

We did not conduct any of these single-center studies, and we were not involved in gathering or analyzing the data. Four of the seven principal physicians involved in these six studies are consultants to our company who have been compensated for their consulting services in cash and stock or cash alone. These consulting arrangements do not include conducting these studies or publishing this data, but rather evaluating new product development, preparing individual patient studies, and delivering presentations at medical meetings.

***Studies to Support Biologics Programs.*** We have several registries underway to collect tissue specimens for collaborative research work. The samples collected under these study protocols are focused on particular patient and lesion groups. The primary purpose of these registries is to evaluate the gene and protein profiles of the collected specimens. Data from these studies will be used to establish its utility as a significant research tool. In the first quarter of 2006, we plan to initiate a multi-center, randomized, double-blind placebo controlled study to evaluate the effect of certain approved drugs on the gene and protein profiles of excised plaque.

**Sales and Marketing**

We market and sell the SilverHawk through a direct sales force in the United States. As of December 31, 2005, we had 246 employees in our sales organization, including 206 direct sales representatives and 40 members of sales management including our vice president of sales. We expect to continue to grow our sales force. Our sales force is organized by geographic sales territories, and each territory is managed by a district sales manager, or direct sales representative, who acts as the primary customer contact. Our regional sales managers supervise the district sales managers and also focus on maintaining key customer relationships. We plan to continue to increase the size of our sales organization to expand our customer base and to increase utilization of the SilverHawk by our more than 1,000 U.S. hospital customers. While we sell directly to hospitals, interventional physicians typically drive the purchasing decision.

Our initial sales and marketing effort has primarily targeted high volume practitioners among the approximately 4,000 U.S. interventional cardiologists. We also market to the approximately 2,100 vascular surgeons and 4,000 interventional radiologists practicing in the United States. We have targeted interventional cardiologists because they generally have experience with similar catheter-based procedures, such as angioplasty. In addition, there is a high correlation between coronary artery disease and PAD. Consequently, cardiologists are well positioned to screen for, and often do screen for, PAD in patients experiencing coronary symptoms, resulting in diagnosis and treatment of patients who might otherwise go undiagnosed. We believe that these physicians are early adopters of new technologies, are rapidly adopting new PAD treatments like the SilverHawk, and are increasingly retaining patients for treatment after diagnosis, rather than referring them to other specialists. Although we believe the majority of SilverHawk procedures are performed by interventional cardiologists, usage by vascular surgeons increased significantly during the last year, and we expect this trend to continue in the future.

Physician referrals and peer-to-peer selling are critical elements of our sales strategy. Our sales force helps interventional physicians develop referral networks to supplement their existing patient populations. Potential referrals come from general practitioners, podiatrists, nephrologists and endocrinologists. Although we do not market the SilverHawk for off-label uses, interventional physicians may use the SilverHawk off-label outside the peripheral vasculature in coronary and carotid arteries. In addition, off-label use for in-stent restenosis has occurred and is likely to continue. If the FDA concludes that we promote our device for such off-label uses or that our promotional activities otherwise fail to comply with the FDA's regulations or guidelines, we may be subject to warning letters from, or other enforcement action by, the FDA.

From the full commercial introduction of the SilverHawk in January 2004, through December 31, 2005, we recorded $163.9 million of product revenue. For the years ended December 31, 2005, 2004, and 2003, our net product revenues were $125.4 million, $38.6 million, and $2.6 million, respectively.

We have operated mainly in the United States, and 100%, 99% and 88% of our sales were made in U.S. dollars for the years ended December 31, 2005, 2004 and 2003, respectively. International sales in 2005 did not account for a significant portion of total sales, and we do not expect them to account for a significant portion of sales in the foreseeable future. We do not have a direct sales force outside of the United States. As of December 31, 2005, we had four distribution agreements in place in four countries in Europe, and one agreement in place with a distributor in Japan that is assisting us in applying for regulatory approval to market the SilverHawk in Japan.

As of December 31, 2005, our marketing department consisted of 15 employees who report to a vice president of marketing. Our marketing program focuses on:

- developing relationships with key opinion leaders;
- facilitating regional marketing programs;
- educating physicians regarding the proper use and application of the SilverHawk; and
- supporting physicians' efforts to enhance referral opportunities.

We primarily target our marketing efforts to practitioners through marketing materials, medical conferences and journals. We also host seminars where industry leaders discuss case studies and treatment techniques using the SilverHawk. In addition, our direct sales force uses peer-reviewed publications, cost-benefit data and case studies in the selling process.

**Competition**

We believe that the SilverHawk competes primarily on the basis of:

- its ability to treat PAD safely and effectively;
- predictable clinical performance;
- ease of use;
- price;
- adequate third-party reimbursement; and
- brand and name recognition.

We believe that we compete favorably with respect to these factors, although there can be no assurance that we will be able to continue to do so in the future or that new devices that perform better than the SilverHawk will not be introduced. We believe that our continued success depends on our ability to:

- continue to innovate and maintain scientifically advanced technology;
- enhance the capability of the SilverHawk;

- demonstrate the clinical safety and efficacy of the SilverHawk through clinical studies;
- attract and retain skilled scientific and sales personnel;
- obtain patents or other protection for our products;
- obtain and maintain regulatory approvals;
- manufacture the SilverHawk in commercial quantities; and
- successfully market and sell the SilverHawk.

Our industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Many of our competitors have significantly greater financial and human capital resources than we do and have established reputations with our target customers, as well as worldwide distribution channels that are more effective than ours. These competitors include Abbott Laboratories, Boston Scientific, Cook, Guidant, Johnson & Johnson and Medtronic. We also compete against smaller manufacturers including, among others: ev3, a manufacturer of peripheral vascular stents; Spectranetics, a manufacturer of excimer lasers for the treatment of coronary artery disease and PAD and W. L. Gore, (Medical Products Division), a manufacturer of endoprostheses stent-grafts. There are also several other companies that provide products used by surgeons in peripheral bypass procedures. In addition, we compete against existing drug therapy treatments manufactured by many major pharmaceutical companies, including Otsuka Pharmaceutical, the manufacturer of Pletal.

Because of the size of the peripheral and coronary market opportunities, competitors and potential 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 cardiovascular disease 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 the SilverHawk. To compete effectively, we have to demonstrate that our products are attractive alternatives to other devices and treatments by differentiating our products on the basis of safety, efficacy, performance, ease of use, brand and name recognition, reputation and price. We have encountered and expect to continue to encounter potential customers who, due to existing relationships with our competitors, are committed to or prefer the products offered by these competitors. We expect that competitive pressures may result in price reductions and reduced margins over time for our products. The SilverHawk may be rendered obsolete or uneconomical by technological advances developed by one or more of our competitors.

**Manufacturing**

We manufacture the SilverHawk with components supplied by vendors and with parts manufactured in-house. The components manufactured in-house include the cutter driver assembly and the ramp that elevates the cutter to a fixed height against the lesion. The remaining components are purchased from outside manufacturers. We then assemble, test, package, and ship finished product to a contract sterilization facility. The sterilization facility sends samples to an independent laboratory to test for sterility.

Purchased components for the SilverHawk are available from more than one supplier, with four exceptions. We rely on one vendor for our torque shaft, one vendor for our cutting blade motor, one vendor for our cutter assembly, and one vendor for our tip housing. These components are critical to the SilverHawk and there are few alternative sources of supply for them. We do not carry a significant inventory of these components. Establishing additional or replacement suppliers for any of the components used in the SilverHawk, if required, may not be accomplished quickly and could involve significant additional costs. We have entered into supply agreements with the providers of the lubricating coating for our catheters, the tip housing, and the cutter assembly. Our other suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, any of the other components used in our devices. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components would limit our ability to manufacture our product and could have a material adverse effect on our business, financial condition and results of operations.

Order quantities and lead times for components purchased from outside suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times for components may vary significantly depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the components and subassemblies. To date, we have not experienced significant delays in obtaining any of our components or subassemblies.

To meet the growing demand for the SilverHawk, in the third quarter of 2005, we consolidated manufacturing operations into our Redwood City, California, building, which serves as our headquarters. This 60,000 square foot facility represents a three-fold increase over our previous facility. This expansion of our manufacturing facility has resulted in expanded production area and clean room space and enhanced research and development labs. The completion of the facility expansion increases our production capacity from approximately 15,000 to 25,000 units per quarter. Manufacturers often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we are unable to manufacture the SilverHawk to keep up with demand, we would not meet expectations for the growth of our business.

Our operations are subject to regulatory requirements relating to the environment, waste management and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal and remediation of hazardous substances. We cannot ensure that we will not incur material costs or liability in connection with our operations, or that our past or future operations will not result in claims or injury by employees or the public. Environmental laws and regulations could also become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. Our leased Redwood City facility was formerly occupied by Rohm & Haas and Occidental Chemical Company and contains residual contamination in soil and groundwater from these past industrial operations. Rohm & Haas and Occidental Chemical Company previously performed soil remediation on the property under the supervision of the California Regional Water Quality Control Board. Rohm & Haas has indemnified the owner of the Bay Road facility and its tenants against costs associated with the residual contamination.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Health Services, or CDHS. We and our component suppliers are required to manufacture our products in compliance with the FDA's Quality System Regulation, or QSR. The QSR regulates extensively the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. The FDA enforces the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. We were inspected by the FDA in September 2004, and two minor observations were noted. We corrected the observations, and they were verified by the FDA. Our failure or the failure of our component suppliers to maintain compliance with the QSR requirements could result in the shutdown of our manufacturing operations or the recall of our products, which would have a material adverse effect on our business. In the event that one of our suppliers fails to maintain compliance with our quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We also could be subject to injunctions, product seizure, and civil or criminal penalties. In addition, we are subject to inspection by the FDB to determine our compliance with the QSR and other regulations. We have been previously inspected by the CDHS, and no significant findings were made, although observations were noted. Our responses to these observations have been accepted by the FDB and CDHS, and we believe that we are in substantial compliance with the QSR. We have opted to maintain quality assurance and quality management certifications to enable us to market our products in the member states of the European Union, the European Free Trade Association and countries which have entered into Mutual Recognition Agreements with the European Union. Our Redwood City facility is ISO 9001 and EN 13485:2003 certified. We cannot assure you that we comply with all applicable manufacturing regulations.

**Third-Party Reimbursement**

Payment for patient care in the United States is generally made by third-party payors, including private insurers and government insurance programs, such as Medicare and Medicaid. The Medicare program, the largest single

payor in the United States, is a federal governmental health insurance program administered by the Centers for Medicare and Medicaid Services, or CMS, and covers certain medical care expenses for eligible elderly and disabled individuals, and individuals with end-stage renal disease. Because a large percentage of the population for which the SilverHawk procedure is used includes Medicare beneficiaries, and private insurers may follow the coverage and payment policies of Medicare, Medicare's coverage and payment policies are significant to our operations.

Medicare pays hospitals for inpatient or outpatient services under prospective payment systems, or a pre-determined payment amount. These payment amounts differ for inpatient and outpatient procedures. We receive payment from the hospital for our product, and Medicare reimburses the hospital under these reimbursement systems for its operating costs, consisting of the costs of admitting and treating the patient, including the purchase of our product. The physician who performs the procedure is reimbursed separately under the Medicare physician fee schedule. Claims for the SilverHawk procedure are typically submitted by the hospital and physician to Medicare or other health insurers using established billing codes, including Current Procedural Terminology, or CPT, billing codes maintained by the American Medical Association. The billing codes identify the procedures performed and are relied upon to determine third-party payor payment amounts.

Existing Category 1 CPT billing codes describe atherectomy procedures and have been used by hospitals and physicians to submit claims for payment for the SilverHawk procedure. Third-party payment amounts for hospitals and physicians can vary substantially depending on the payors' coverage and reimbursement policies. Market acceptance of our products is dependent on adequate payment levels from such payors.

In 2005, national average Medicare hospital payment rates for atherectomy procedures were $1,789 for outpatient services, $7,160 for inpatient stays without complications and comorbidities, and $11,927 for inpatient stays with complications and comorbidities. The new rates recently issued for 2006 are $2,515 for outpatient services, $7,437 for inpatient stays without complications and comorbidities, $15,949 for inpatient stays with complications and comorbidities with major cardiovascular diagnosis, and $10,676 for inpatient stays with complications and comorbidities without major cardiovascular diagnosis. These figures are inclusive of supplies such as the SilverHawk; additional reimbursement for the device is not available. These amounts can vary substantially by geographical region and by facility. Payment rates of other third-party payors may be consistent with Medicare rates, or they may be higher or lower, depending on their particular reimbursement methodology. Because of the wide variability, it is not possible to identify an average rate for other third-party payors.

**Research and Development**

As of December 31, 2005, we had 20 employees in our research and development department, 15 of who report to a senior vice president of operations and research development and 5 who report to a vice president of business development. The major focus of this group is to leverage our existing technology platform for new applications. We are developing smaller devices to optimize treatment of smaller arteries located in the feet, as well as coronary arteries. Future research and development efforts will involve continued enhancements to and cost reductions for the SilverHawk. We will also explore the development of other products that can be derived from our core technology platform and intellectual property. Currently, the three major areas of technological focus for the research and development department are onboard imaging developments that will allow physicians to view plaque excision on a real-time basis, improvements to catheters that will dramatically reduce procedure time, and new catheters to adequately address patient needs below the knee. Our research and development team works together with our sales and marketing organizations to set development priorities and to beta test new product variations based on communicated customer needs. The feedback received from beta testing is incorporated into successive design iterations until a new product is ready for release. Research and development expenses were $10.3 million, $6.2 million and $5.8 million for the fiscal years ended December 31, 2005, December 31, 2004, and December 31, 2003, respectively.

**Patents and Proprietary Technology**

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, 2005, we had 8 issued U.S. patents primarily covering the cutting blade and tissue excision. In addition, as of December 31, 2005, we had 19 pending U.S. patent applications and 6 pending foreign patent applications. We intend to file for additional patents to strengthen our intellectual property rights.

We have a master license agreement with SurModics for the right to coat our catheters with certain proprietary coating materials. We pay SurModics a royalty on sales of the SilverHawk that are treated with these coatings. We have the right to terminate this license voluntarily upon 90 days' notice, and SurModics has the right to terminate for material breach of the license or nonpayment of royalties. The license expires at the later of the expiration of the last to expire of the SurModics' patents or 15 years following the first commercial sale of the SilverHawk.

All employees and technical consultants are required to execute confidentiality agreements in connection with their employment and consulting relationships with us. We also require them to agree to disclose and assign to us all inventions conceived in connection with the relationship. We cannot provide any assurance that employees and consultants will abide by the confidentiality or assignment terms of these agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of the SilverHawk or obtain and use information that we regard as proprietary.

Our patent applications may not result in issued patents, and we cannot assure you that any patents that have issued or might issue will protect our intellectual property rights. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. We cannot be certain that the steps we have taken will prevent the misappropriation of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

Occasionally, we may learn about patents owned by third parties that appear to have claims relevant to the SilverHawk. In particular, we are aware of patent families related to catheter positioning and atherectomy, or plaque removal, owned or licensed by Guidant. With regard to the atherectomy patents, one of our founders, Dr. John Simpson, founded a company prior to founding our company that developed an atherectomy device that is currently sold by Guidant, and he is a listed inventor on several patents covering that device. Those patents are now also held by Guidant. Because of a doctrine known as "assignor estoppel," if any of Dr. Simpson's earlier patents are asserted against us by Guidant, we may be prevented from asserting an invalidity defense regarding those patents, and our defense may be compromised. Guidant has significantly greater financial resources than we do to pursue patent litigation and can assert these patent families against us at any time.

An adverse determination in litigation or interference proceedings to which we may become a party relating to any of the above patents or any other patents could subject us to significant liabilities to Guidant or other third parties or require us to seek licenses from Guidant or other third parties. Furthermore, if we are found to willfully infringe these patents, we could, in addition to other penalties, be required to pay treble damages. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign the SilverHawk to avoid infringement. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling the SilverHawk, which would have a significant adverse impact on our business.

**Government Regulation**

The SilverHawk is a medical device subject to extensive and rigorous regulation by the FDA, as well as other federal and state regulatory bodies in the United States and comparable authorities in other countries. We currently market our product in the United States under a 510(k) clearance for treatment of atherosclerosis in the peripheral vasculature. This means that our product may not be marketed for use in the heart or brain, or in specific peripheral anatomy, without additional clearances from the FDA. In the United States, the SilverHawk is contraindicated for in-stent restenosis and for use in the carotid arteries. We will be required to submit and obtain premarket approval of the SilverHawk for use in treating coronary lesions prior to marketing our device for this indication. The premarket approval, or PMA, submission will require clinical data supporting the safe and effective use of the device in coronary indications. We cannot assure you that we will successfully complete a clinical trial in coronary artery disease patients or will submit and obtain approval for the SilverHawk for use in treating coronary lesions. The FDA regulations govern the following activities that we perform, or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

- product design, development and manufacture;
- product safety, testing, labeling and storage;
- premarketing clearance or approval;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, reporting of deaths or serious injuries and medical device reporting.

***The FDA's Premarket Clearance and Approval Requirements.*** Unless an exemption applies, each medical device we wish to distribute commercially in the United States will require either prior 510(k) clearance or a PMA from the FDA. Medical devices are classified into one of three classes—Class I, Class II, or Class III—depending on the degree or risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Devices deemed to pose lower risks are placed in either Class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempted from this requirement. 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. The SilverHawk is a Class II device.

***510(k) Clearance Pathway.*** When a 510(k) clearance is required, we must submit a premarket notification to the FDA demonstrating that our proposed device is substantially equivalent to a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA application. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance often takes significantly longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously-cleared device or use, the FDA will place the device, or the particular use, into Class III.

***Premarket Approval Pathway.*** A PMA application must be submitted to the FDA if the device cannot be cleared through the 510(k) process. The PMA application process is much more demanding than the 510(k) premarket notification process. A PMA application must be supported by extensive data, including but not limited to technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA application is submitted and the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will accept the application for review. The FDA has 180 days to review an "accepted" PMA application, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. New PMA applications or PMA application supplements are required for significant modification to the manufacturing process, labeling and design of a device that is approved through the premarket approval process. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application and may not require as extensive clinical data or the convening of an advisory panel.

***Clinical Trials.*** Clinical trials are almost always required to support an FDA premarket application and are sometimes required for 510(k) clearance. In the United States, these trials generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, at the clinical trial sites. Our clinical trials must be conducted under the oversight of an IRB at the relevant clinical trial sites and in accordance with the FDA regulations, including but not limited to those relating to good clinical practices. We are also required to obtain patients' informed consent that complies with both the FDA requirements and state and federal privacy regulations. We, the FDA or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and efficacy of the device, may not be equivocal or may otherwise not be sufficient to obtain approval of the product. Similarly, in Europe the clinical study must be approved by the local ethics committee and in some cases, including studies with high-risk devices, by the Ministry of Health in the applicable country.

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

- The FDA's Quality System Regulation, or QSR, which requires 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 uncleared, unapproved or off-label uses;
- clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;
- medical device reporting, or MDR, 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 effectiveness data for the device.

After a device receives 510(k) clearance or a PMA, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any

such decision and can disagree with a manufacturer's determination. We have modified various aspects of our SilverHawk since receiving regulatory clearance, but we believe that new 510(k) clearances are not required for these modifications. If the FDA disagrees with our determination not to seek a new 510(k) clearance or PMA, the FDA may retroactively require us to seek 510(k) clearance or premarket approval. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or premarket approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines, penalties and warning letters.

The MDR regulations require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. For the fourth quarter of 2005, the FDA has received seventeen medical device reports associated with procedures where the SilverHawk was used. These filings included one death resulting when a device used during a contra-indicated in-stent procedure became trapped in an iliac stent resulting in perforation, one report that the SilverHawk would not cut through a stent which was contra-indicated in the instructions for use, six reports of intervention due to nose cone separation resulting from wire wrap and use of smaller labeled sheaths, three reports of emboli resulting from tip volumes that exceeded the instructions for use, one report related to procedural thrombosis, one report of treatment of compartment syndrome caused by use of a device larger than the vessel being treated, one report of off-label coronary perforation which was corrected by placement of a covered stent, one report of a peripheral perforation, one report of an aneurysm noted months post-procedure and one report of embolization during off-label treatment of a PolyTetraFluoroEthylene or PTFE graft.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Health Services, or CDHS. 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 CDHS, or FDB, to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. We were inspected by FDA in September 2004, and two minor observations were noted. We corrected the observations, and they were verified by the FDA. In the past, our current facility has been inspected extensively by FDB, and observations were noted. There were no findings that involved a material violation of regulatory requirements. Our responses to these observations have been accepted by FDB and CDHS, and we believe that we are in substantial compliance with the QSR.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

We will be required to submit an application for and obtain a PMA for the SilverHawk for use in treating coronary lesions. The PMA submission will require clinical data supporting the safe and effective use of the device in coronary indications. We cannot assure you that we will successfully complete a clinical trial in coronary artery disease patients or will submit and obtain approval for the SilverHawk for use in treating coronary lesions.

***Fraud and Abuse.*** We may directly or indirectly be subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the federal healthcare program 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, arranging for or recommending a good or service, for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General, or OIG, has issued 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 element of a safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

***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 the FDA clearance or approval, and the requirements may be different.

The primary regulatory environment in Europe is that of the European Union, which has adopted numerous directives and has 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 directives and, accordingly, can be commercially distributed throughout the member states of the European Union, and other countries that comply with or mirror these directives. 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 notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's device. Such an assessment is required in order for a manufacturer to commercially distribute the product throughout these countries. ISO 9001 and ISO 13845 certifications are voluntary harmonized standards. Compliance establishes the presumption of conformity with the essential requirements for a CE Marking. We have the authorization to affix the CE Mark to the SilverHawk and to commercialize the device in the European Union for both peripheral and coronary indications. At this time discussions are underway to initiate appropriate trials to commence the process to obtain commercial approvals in Japan; however, no Japanese approval is anticipated before late 2008.

**Employees**

As of December 31, 2005 we had 542 employees, including 159 employees in manufacturing, 246 employees in sales, 16 in marketing, 51 employees in clinical, regulatory and quality assurance, 50 employees in general and administrative, and 20 employees in research and development. We believe that our future success will depend on our continued ability to attract, hire and retain qualified personnel. None of our employees are represented by a labor union or are parties to a collective bargaining agreement, and we believe our employee relations are good.

**Available Information**

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

You may also find on our website at http://www.foxhollowtech.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. Our charter for our Audit, Compensation and Nominating and Corporate Governance Committees and our Code of Ethics are available on our website. In the event that we grant a waiver under our Code of Ethics, to any of our officers and directors, we will publish it on our website.

## ITEM 1A. RISK FACTORS

### Factors Affecting Future Operating Results

**We are going through a period of transition while we search for a new chief executive officer and if the interim management structure that we have established does not stabilize our company, there may be internal disruption and our stock price and revenues may decline as a result.**

In December 2005 our president and chief executive officer retired from our company and in February 2006 our vice president of sales resigned. During this period of transition, we chose to replace our chief operating officer, install our founder Dr. John Simpson as interim chief executive officer, and create a leadership committee consisting of our new chief operating officer, our chief financial officer and our president of strategic operations. In the event that this management structure does not stabilize our company, other officers and employees may choose to leave the company and our revenues and stock price may decline as a result.

We are actively searching for a new chief executive officer but we can provide no assurance that we will locate a qualified candidate. We have engaged a qualified executive search firm but finding a new chief executive officer that holds the qualifications that we are searching for may take time. Even if we locate a well-qualified individual it may be difficult to convince the candidate to work at a company where the founder and single largest shareholder is actively engaged in the company. At the conclusion of our search, we may decide that none of the external candidates possess the appropriate qualifications and recommend an internal candidate for the position of chief executive officer. During the executive search period, we will undergo a period of uncertainty that may disrupt our business and delay strategic transactions which may in turn affect the execution of our operating plan.

**We may become involved in litigation as a result of the changes that have taken place and any lawsuit may further depress the price of our stock.**

We may be sued by former employees in connection with their departure or by our stockholders who have suffered losses during this period of transition. In the event we are sued we intend to defend ourselves vigorously which may result in costly litigation. We retain employment practices liability and director and officer liability insurance but there can be no guarantee that such insurance will cover the claims that are made or will insure us fully for all losses on covered claims. Any such litigation may distract our management and consume resources that would otherwise have been directed toward achieving our operating plan and generating increased revenue, which may further cause a decline in our stock price.

**We depend on a single product, the SilverHawk. If the SilverHawk fails to gain or loses market acceptance, our business will suffer.**

The SilverHawk is our only product, and we are wholly dependent on it. We expect that sales of the SilverHawk in the United States will account for a substantial portion of our revenue for the foreseeable future. Because of its fairly recent commercial introduction, the SilverHawk has limited product and brand recognition. We do not know if the SilverHawk will be successful over the long term. Market acceptance of the SilverHawk may be hindered if physicians are not presented with compelling data from long-term studies of the safety and efficacy of the SilverHawk compared against alternative procedures, such as angioplasty, stenting or bypass grafting. We have no current plans to conduct such comparative studies. In addition, demand for the SilverHawk may decline

or may not increase as quickly as we expect. Failure of the SilverHawk to significantly penetrate current or new markets would negatively impact our business, financial condition and results of operations.

**There exists limited long-term data regarding the safety and efficacy of the SilverHawk. Future long-term data may not be positive or consistent with data currently available, which would affect the rate at which our device is adopted.**

The SilverHawk is a novel product, and our success depends on its acceptance by the medical community as safe and effective. Important factors upon which the efficacy of the SilverHawk will be measured are long-term data on the rate of restenosis, or plaque regrowth following our procedure, and the corresponding duration of patency, or openness of the artery. Because our technology is relatively new in the treatment of PAD, to date there have been a limited number of single-center, clinical experiences with limited patient populations that have measured short-term restenosis and patency rates up to one year following treatment. None of these studies were conducted by us. We plan to conduct studies designed to measure restenosis rates or patency rates after treatment with the SilverHawk. These studies may be expensive and time consuming and the results may not prove favorable for the SilverHawk device.

Our TALON registry may produce limited subset data regarding restenosis and patency rates, but such an evaluation is not mandated by the registry protocol. Another important factor that physicians will consider is the rate of reintervention, or retreatment, following the SilverHawk procedure. In data presented in October 2005, we announced consistent reintervention data on a much larger group of patients from the TALON registry. We cannot provide any assurance that the data collected will be compelling to the medical community, because it may not be scientifically meaningful and may not demonstrate that the SilverHawk is an attractive procedure when compared against data from alternative procedures. In addition, the long-term effects of the SilverHawk procedure are not known.

The results of limited long-term data and of short-term clinical experience of the SilverHawk do not necessarily predict long-term clinical benefit. Restenosis rates usually increase over time, and typically two-year restenosis rates are substantially higher than one-year results. We believe that physicians will compare the rates of long-term restenosis and reintervention for the SilverHawk procedure against alternative procedures, such as angioplasty, stenting and bypass grafting. If long-term rates of restenosis and reintervention do not meet physicians' expectations, the SilverHawk may not become widely adopted and physicians may recommend alternative treatments for their patients. Other significant factors that physicians will consider include acute safety data on complications that occur during the SilverHawk procedure. If the results obtained from any future clinical studies or clinical or commercial experience indicate that the SilverHawk is not as safe or effective as other treatment options or as prior short-term or long-term data would suggest, adoption of our product may suffer and our business would be harmed.

Even if we believe the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with our device will vary. Clinical studies conducted with the SilverHawk, as well as clinical experience recorded in the TALON registry, have involved procedures performed by physicians who are technically-proficient and high-volume users of the SilverHawk. Consequently, both short and long-term results reported in these studies and the TALON registry may be significantly more favorable than typical results of practicing physicians, which could negatively impact rates of adoption of the SilverHawk.

**We depend on skilled and experienced personnel to operate our business effectively. If we are unable to recruit, hire and retain these employees, our ability to manage and expand our business will be harmed, which would impair our future revenue and profitability.**

Our success largely depends on the skills, experience and efforts of our officers and other key employees. Any of our officers and other key employees may terminate their employment at any time. We recently had our president and chief executive officer retire from our company and our vice president of sales resign. In addition, during this

period of transition, we decided to replace our chief operating officer. The further loss of any of our senior management team could harm our business. Our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. We may not be able to meet our future hiring needs or retain existing personnel. We will face particularly significant challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees. Failure to attract and retain personnel, particularly technical and sales and marketing personnel, would harm our ability to compete effectively and grow our business. The announcement of the loss of one of our key employees could further negatively affect our stock price.

**We have a limited history of operations and a history of net losses that may prevent us from achieving or maintaining profitability.**

We have a limited history of operations upon which you can evaluate our business. In particular, we incurred net losses of $11.6 million in 2005, $29.9 million in 2004 and $14.3 million in 2003. As of December 31, 2005, we had an accumulated deficit of $85.1 million. We commenced full commercial sales of the SilverHawk in January 2004, and our short commercialization experience makes it difficult for us to predict future performance. Our failure to accurately predict financial performance may lead to volatility in our stock price. In addition, we expect our operating expenses will increase as we expand our business to meet anticipated growing demand for the SilverHawk and devote substantial resources to our sales force expansion, sales and marketing programs and research and development activities. Our failure to achieve and sustain profitability would negatively impact the market price of our common stock.

**Our future growth depends on physician adoption of the SilverHawk, which requires physicians to change their screening and referral practices.**

Although there is a significant correlation between PAD and coronary artery disease, many physicians do not routinely screen for PAD while screening for coronary artery disease. We target our sales efforts to interventional cardiologists and vascular surgeons because they are often the primary care physicians diagnosing and treating both coronary artery disease and PAD. However, the initial point of contact for many patients may be general practitioners, podiatrists, nephrologists or endocrinologists, each of whom commonly treats patients experiencing complications resulting from PAD. If we do not educate referring physicians about PAD in general and the existence of the SilverHawk in particular, they may not refer patients to interventional cardiologists, vascular surgeons or interventional radiologists for the SilverHawk procedure, and those patients may instead be surgically treated or treated with an alternative interventional procedure. If we are not successful in educating physicians about screening for PAD or about referral opportunities, our ability to increase our revenue may be impaired.

**Our ability to market the SilverHawk in the United States is limited to use in peripheral vessels, and if we want to expand our marketing claims, we will need to file for additional FDA clearances or approvals and conduct further clinical trials, which would be expensive and time-consuming and may not be successful.**

We have FDA clearance in the United States for treatment of atherosclerosis in the peripheral vasculature. This general clearance restricts our ability to market or advertise the SilverHawk for any specific indication within the peripheral arteries, which limits our ability to market the SilverHawk and could affect our growth. Off-label use of the SilverHawk outside the peripheral vasculature, in coronary and carotid arteries, has occurred and is likely to continue. In addition, off-label use for treatment of in-stent restenosis has occurred and is likely to continue. While off-label uses of medical devices are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications regarding such off-label use. We may not actively promote or advertise the SilverHawk for off-label uses. In addition, we cannot make comparative claims regarding the use of the SilverHawk against any alternative treatments without conducting head-to-head comparative clinical studies, which would be expensive and time consuming. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to FDA warnings or enforcement action.

If we want to market the SilverHawk in the United States for use in coronary or carotid arteries, we will need to conduct further clinical trials and obtain premarket approval from the FDA. We previously began a clinical trial in support of FDA approval for use of the SilverHawk in the coronary arteries. Based on 172 patients treated in this trial, we experienced 37 serious adverse events in treating 28 patients, including 10 perforations, two cases of emergency bypass surgery, three cases of stroke, 14 cases of heart attack and eight patient deaths. We voluntarily halted enrollment so that we could incorporate safety and design improvements into our coronary product. We believe that these serious adverse events resulted from a number of factors, including the patients' overall poor health, the complexity of treating the bifurcated lesions called for under the trial protocol, and the application of our device in the coronary arteries, which are extremely small and constantly move as the heart beats. We have made several design modifications to the coronary versions of our devices, and we have submitted an application to the FDA for a new Investigational Device Exemption, or IDE. The FDA has responded to our IDE application, and we now expect that further modifications to our devices will be necessary before the new trial can be started in the U.S. to evaluate the safety and efficacy of the SilverHawk in the coronary arteries. We cannot predict when the trial will be initiated, the outcome of such a trial or whether the results will adequately demonstrate the safety and efficacy of the SilverHawk for use in coronary arteries.

**If we make acquisitions or divestitures, we could encounter difficulties that harm our business.**

We may acquire companies, products or technologies that we believe to be complementary to the present or future direction of our business. If we engage in such acquisitions, we may have difficulty integrating the acquired personnel, financials, operations, products or technologies. Acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees, increase our expenses, subject us to liabilities, and increase our risk of litigation, all of which could harm our business. If we use cash to acquire companies, products or technologies, it may divert resources otherwise available for other purposes. If we use our common stock to acquire companies, products or technologies, our stockholders may experience substantial dilution.

**If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.**

The growth that we have experienced, and in the future may experience, provides challenges to our organization, requiring us to rapidly expand our sales personnel and manufacturing operations. Our sales force has increased from 69 direct sales representatives on December 31, 2004 to 206 on December 31, 2005, and we expect to continue to grow our sales force and invest aggressively in expanded sales and marketing activities. We also continue to expand our manufacturing operations. Rapid expansion in personnel means that less experienced people may be producing and selling our product, which could result in unanticipated costs and disruptions to our operations. If we cannot scale and manage our business appropriately, our anticipated growth may be impaired and our financial results will suffer.

**We have limited experience manufacturing the SilverHawk in commercial quantities, which could adversely impact our business.**

Because we have only limited experience in manufacturing the SilverHawk in commercial quantities, we may encounter unforeseen situations that would result in delays or shortfalls. For example, in June 2004, we initiated a voluntary recall of two lots of the SilverHawk due to the possibility of improper sterilization at one of two approved sterilization facilities. We may encounter difficulties and delays in manufacturing the SilverHawk for the following additional reasons:

- we are in the process of significantly expanding our manufacturing operations, and our production processes may have to change to accommodate this growth;
- key components of the SilverHawk are currently provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components;

- to increase our manufacturing output significantly, we will have to attract and retain qualified employees, who are in short supply, for the assembly and testing operations; and
- all of our manufacturing occurs at a single facility and if we were to lose availability of this facility due to earthquake, fire, natural disaster or other disruptions, our operations would be significantly impaired.

If our manufacturing operations are unable to meet demand for the SilverHawk, our revenue could be impaired, market acceptance for the SilverHawk could be adversely affected, and our customers might instead purchase our competitors' products. Additionally, although we maintain business interruption insurance, there can be no assurance that the proceeds of such insurance would be sufficient to offset any loss that we might incur or that we would be able to retain our customer base if operations were disrupted.

**We depend on third-party vendors in our manufacturing operations, making us vulnerable to supply shortages and price fluctuations that could harm our business.**

We currently rely on third-party vendors for the manufacture of most of the components used in the SilverHawk. Our reliance on these vendors subjects us to a number of risks that could impact our ability to manufacture our product and harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's variation in a component;
- price fluctuations due to a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- delays in delivery by our suppliers due to changes in demand from us or their other customers.

Any significant delay or interruption in the supply of components, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and harm our business.

**We depend on single and limited source suppliers for some of the SilverHawk components, and if any of those suppliers are unable or unwilling to produce these components or supply them in the quantities that we need, we would experience manufacturing delays as a result.**

We rely on single and limited source suppliers for several of our components. For example, we rely on one vendor for our torque shaft, one vendor for our cutting blade motor, one vendor for our cutter assembly, and one vendor for our tip housing. These components are critical to the SilverHawk and there are few alternative sources of supply for them. We do not carry a significant inventory of these components. Identifying and qualifying additional or replacement suppliers for any of the components used in the SilverHawk, if required, may not be accomplished quickly or at all and could involve significant additional costs. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components used to manufacture the SilverHawk would limit our ability to manufacture our product and could therefore have a material adverse effect on our business, financial condition and results of operations.

**The use, misuse or off-label use of the SilverHawk may result in injuries that lead to product liability suits, which could be costly to our business.**

We neither provide training for physicians nor require that physicians be trained in the use of the SilverHawk by a third party because we market primarily to physicians who are skilled in the interventional techniques required

to use our device. Although the SilverHawk is cleared by the FDA for the treatment of atherosclerosis in the peripheral vasculature, we have indicated through our marketing efforts that certain treatment locations, such as arteries below the knee or above the leg, are not suited for physicians with limited experience using the device. There may be increased risk of injury if such physicians attempt SilverHawk procedures in peripheral arteries in these areas of the body. Not requiring training specific to the use of our device in various parts of the body may expose us to greater risk of product liability if injuries occur during the SilverHawk procedure. If demand for the SilverHawk continues to grow, less skilled surgeons will likely use the device, potentially leading to more injury and an increased risk of product liability.

The use or misuse of the SilverHawk in the peripheral and coronary arteries has in the past resulted, and may in the future result, in complications, including damage to the treated artery, internal bleeding, limb loss and death, potentially leading to a product liability claim. The SilverHawk is not FDA-cleared or approved for treatment of carotid arteries, which are arteries leading to the brain, coronary arteries, or in-stent restenosis in the United States. Our sales force does not promote the product for off-label uses, and our U.S. instructions for use specify that the SilverHawk is not intended for use in the coronary arteries or carotid arteries. However, we cannot prevent a physician from using the SilverHawk for these off-label applications. The application of the SilverHawk to coronary arteries, as opposed to peripheral arteries, is more likely to result in complications that have serious consequences. For example, if excised plaque were not captured properly in our device, it could be carried by the bloodstream to a narrower location, blocking a coronary artery, leading to a heart attack, or blocking an artery to the brain, leading to a stroke. We have had three reported incidents of stroke in our halted coronary trial, which may have been caused by excised arterial plaque entering the bloodstream. If the SilverHawk is defectively designed, manufactured or labeled, contains defective components or is misused, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us.

**We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and, if we are unable to fully comply with such laws, could face substantial penalties.**

Our operations may be directly or indirectly affected by various broad state and federal healthcare fraud and abuse laws, including the federal Anti-Kickback Statute, which prohibit any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing or arranging for an item or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. If our past or present operations, including our consulting arrangements with physicians who use our product, are found to be in violation of these laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare and Medicaid program participation. If enforcement action were to occur, our business and financial condition would be harmed.

**We compete against companies that have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration or improved operating results.**

We compete against very large and well-known stent and angioplasty device manufacturers, including Abbott Laboratories, Boston Scientific, Cook, Guidant, Johnson & Johnson and Medtronic. We also compete against smaller manufacturers, including, among others: ev3, a manufacturer of peripheral vascular stents and angioplasty devices; Spectranetics, a manufacturer of excimer lasers for the treatment of coronary artery disease and PAD; and W. L. Gore, (Medical Products Division), a manufacturer of endoprostheses stent-grafts. There are also several other companies that provide products used by surgeons in peripheral bypass procedures. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of mild to moderate PAD. Many of our competitors have significantly greater financial and human capital resources than we do and have established reputations, as well as worldwide distribution channels that are more effective than ours.

Competition with these companies could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations.

Our ability to compete effectively depends on our ability to distinguish our company and the SilverHawk from our competitors and their products, and includes such factors as:

- the SilverHawk's ability to treat PAD safely and effectively;
- predictable clinical performance;
- ease of use;
- price;
- adequate third-party reimbursement; and
- brand and name recognition.

Our competitors with greater financial resources could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing product, which may cause our revenue to decline and would harm our business.

**Our ability to compete also depends on our ability to innovate successfully. If our competitors can compete directly against us or demonstrate the safety and efficacy of other methods of treating PAD, our revenue may decline.**

The market for medical devices is highly competitive, dynamic, and marked by rapid and substantial technological development and product innovations. There are few barriers that would prevent new entrants or existing competitors from developing products that compete directly with ours. Demand for the SilverHawk could be diminished by equivalent or superior products and technologies offered by competitors. For example, drug-eluting stents have been developed for treating coronary artery disease and have been rapidly adopted. Cook is currently conducting clinical trials for the use of drug-eluting stents and Edwards is conducting clinical trials for the use of non-drug-eluting stents in the peripheral vasculature, each of which, if successful, may impact future SilverHawk sales. We are also aware of at least two other companies, Cardiovascular Systems, Inc. and Pathway Medical, developing plaque-removal devices intended for the treatment of PAD. If we are unable to innovate successfully or if new competitors emerge, the SilverHawk could become obsolete, and our revenue would decline as our customers purchase our competitors' products.

We do not currently have a vice president of research and development and rely significantly on our interim chief executive officer for guidance and direction regarding the development of new products and improvements to existing products. We may choose to acquire complementary products and technologies to augment the number of our product offerings and add to the diversity of the SilverHawk system. Any acquisitions that we make may divert management's attention from our core programs and may consume necessary resources without generating significant additional revenue.

**We may in the future be a party to patent litigation and administrative proceedings that could be costly and could interfere with our ability to sell the SilverHawk.**

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. We may become a party to patent infringement claims and litigation or interference proceedings declared by the U.S. Patent and Trademark Office to determine the priority of inventions. The defense and prosecution of these matters are both costly and time consuming. Additionally, we may need to commence proceedings against others to enforce our patents, to protect our trade secrets or know-how or to determine the enforceability, scope and validity of the proprietary rights of others. These proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel.

An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities or injunctions which would require us to seek licenses. In addition, if we are found to willfully infringe third-party patents, we could be required to pay treble damages in addition to other penalties. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign the SilverHawk to avoid infringement. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling the SilverHawk, which would have a significant adverse impact on our business.

**We are aware of patents held by Guidant that may be asserted against us in litigation that could be costly and could limit our ability to sell the SilverHawk.**

We are aware of patent families related to catheter positioning and atherectomy, or plaque removal, owned or licensed by Guidant. With regard to atherectomy patents, one of our founders, Dr. John Simpson, founded a company prior to founding our company that developed an atherectomy device that is currently sold by Guidant, and he is a listed inventor on several patents covering that device. Those patents are now held by Guidant. Guidant's device is currently marketed and sold for use in coronary arteries. We are not currently aware of any claims Guidant has made or intends to make against us. Because of a doctrine known as "assignor estoppel," if any of Dr. Simpson's earlier patents are asserted against us by Guidant, we may be prevented from asserting an invalidity defense regarding those patents, and our defense may be compromised. Guidant has significantly greater financial resources than we do to pursue patent litigation and can assert these patent families against us at any time. Adverse determinations in such litigation could prevent us from manufacturing or selling the SilverHawk, which would have a significant adverse impact on our business. Guidant is currently being acquired by Boston Scientific Corporation which could, upon an assignment of the aforementioned Guidant patents, assert the same assignor estoppel defenses which were previously available to Guidant.

**Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.**

We rely on patents, trade secret laws and confidentiality agreements to protect our technology and products. Our pending patent applications may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Any patents we have obtained or will obtain in the future might be invalidated or circumvented by third parties. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase a SilverHawk device and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. If our intellectual property is not adequately protected against competitors' products and methods, our competitive position could be adversely affected, as could our business.

**The Merck Collaboration Agreement may not result in revenue beyond the initial payment we received and many of the factors affecting the likelihood of generating any such revenue are not within our control.**

The Merck Collaboration Agreement may be terminated by Merck at any time in its sole discretion. Additionally, even if extended beyond the initial one year term, the payments may be reduced if we do not meet certain milestones or if Merck elects to waive its exclusivity rights. As a result, any additional payments for our services

to Merck pursuant to the Merck Collaboration Agreement may be reduced or eliminated. Also, the additional revenue from Merck for milestone payments based on the progress of clinical development of certain pharmaceutical and diagnostic products arising from work under the research collaboration, as well as royalties on sales of any such products, are substantially or entirely based on Merck's efforts under this Agreement. The development of Merck's drug therapies from our collaboration are long-term projects with significant research, clinical, development, and execution risks. As a result, the achievement of the milestones and any sales of a product may not happen for many years, or may not happen at all, and we may not realize additional revenue from the Merck Collaboration Agreement.

**If we fail to obtain and maintain necessary regulatory clearances or approvals for the SilverHawk, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations would be harmed.**

The SilverHawk is a medical device that is subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. Government regulations specific to medical devices are wide-ranging and govern, among other things:

- product design, development and manufacture;
- product safety, testing, labeling and storage;
- premarketing clearance or approval;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, reporting of deaths or serious injuries and medical device reporting.

Before a new medical device or a new use of, or claim for, an existing product can be marketed in the United States, a company must first apply for and receive either 510(k) clearance or premarketing approval from the FDA, unless an exemption applies. Either process can be expensive, lengthy and unpredictable. Although we have obtained 510(k) clearance to market the SilverHawk for treatment of atherosclerosis in the peripheral vasculature, our clearance can be revoked if safety or efficacy problems develop. We voluntarily suspended our U.S. clinical trial for the use of the SilverHawk in coronary arteries. To market the SilverHawk in the United States for this use, we must successfully complete a clinical trial, submit a premarket approval application to the FDA and obtain premarket approval. Therefore, even if we believe we have successfully developed the SilverHawk for use in the coronary arteries, we may not be permitted to market our device for this indication in the United States for a number of years, if at all. Delays in obtaining approval could adversely affect our future growth.

We are also subject to medical device reporting regulations that require us to report to the FDA if our product causes or contributes to a death or serious injury or malfunctions. For the fourth quarter of 2005, the FDA has received seventeen medical device reports associated with procedures where the SilverHawk was used. These filings included one death resulting when a device used during a contra-indicated in-stent procedure became trapped in an iliac stent resulting in perforation, one report that the SilverHawk would not cut through a stent which was contra-indicated in the instructions for use, six reports of intervention due to nose cone separation resulting from wire wrap and use of smaller sheaths recommended by the instructions for use, three reports of emboli resulting from tip volumes that exceeded the instructions for use, one report related to procedural thrombosis, one report of treatment of compartment syndrome caused by use of a device larger than the vessel being treated, one report of off-label coronary perforation which was corrected by placement of a covered stent, one report of a peripheral perforation, one report of an aneurysm noted months post-procedure and one report of embolization during off-label treatment of a PolyTetraFluoroEthylene or PTFE graft.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new products; new intended uses of, or modifications to, existing products;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition would be harmed.

**Modifications to the SilverHawk may require new 510(k) clearances or premarket approvals or may require us to recall or cease marketing the SilverHawk until clearances are obtained.**

Modifications to the SilverHawk may require new 510(k) clearances or premarket approvals or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, the SilverHawk in a timely fashion, or at all. Delays in obtaining required future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to the SilverHawk in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the SilverHawk as modified, which could harm our operating results and require us to redesign the SilverHawk. In these circumstances, we may be subject to significant enforcement actions.

**If we or our suppliers fail to comply with the FDA's Quality System Regulation, our manufacturing operations could be delayed and SilverHawk sales could suffer.**

Our manufacturing processes and those of our suppliers are required to comply with the FDA's Quality System Regulation, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of the SilverHawk. We are also subject to similar state requirements and licenses. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. We were inspected by the FDA in late 2004, and two minor observations were noted. We corrected the observations, and they were verified by the FDA. If we fail a Quality System inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse Quality System inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our product and cause our revenue to decline.

**The SilverHawk has been and may in the future be subject to product recalls that could harm our reputation.**

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. In June 2004, we initiated a voluntary recall of two lots of the SilverHawk due to the possibility of improper sterilization. We continue to use both the testing facility and sterilization facility involved in the recall. In October 2004, we received a formal closure notice from the FDA regarding the recall. Additional recalls of the SilverHawk would divert managerial and financial resources, harm our reputation with customers and have an adverse effect on our financial condition and results of operations. A recall announcement would negatively affect our stock price.

**Changes in coverage and reimbursement for procedures using the SilverHawk could affect the adoption of the SilverHawk and our future revenue.**

Currently, the SilverHawk procedure is typically reimbursed by third-party payors, including Medicare and private healthcare insurance companies, under existing atherectomy codes. These payors may adversely change their coverage and reimbursement policies, as well as payment amounts. Also, healthcare reform legislation or regulation may be proposed or enacted in the future, which may adversely affect such policies and amounts. We cannot predict whether and to what extent existing coverage and reimbursement will continue to be available. If physicians, hospitals and other providers are unable to obtain adequate coverage and reimbursement for the SilverHawk procedure, they are less likely to use it and our business would be adversely impacted.

**The expense and potential unavailability of insurance coverage for our company or our customers could adversely affect our ability to sell the SilverHawk, which would harm our business.**

We may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry and reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and adversely affecting our financial condition and operating results.

Some of our customers and prospective customers may have difficulty in procuring or maintaining liability insurance to cover their operation and use of the SilverHawk. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using the SilverHawk and potential customers may opt against purchasing the SilverHawk due to the cost or inability to procure insurance coverage.

**Compliance with environmental laws and regulations could be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability.**

Our manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state and local environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances. Our research and development and manufacturing operations produce biological waste materials, such as human and animal tissue, and waste solvents, such as isopropyl alcohol. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Compliance with these laws and regulations may be expensive and non-compliance could result in substantial liabilities. In addition, our manufacturing operations may result in the release, discharge, emission or disposal of hazardous substances that could cause us to incur substantial liabilities, including costs for investigation and remediation. Our leased Redwood City

facility was formerly occupied by Rohm & Haas and Occidental Chemical Company and contains residual contamination in soil and groundwater from these past industrial operations. Rohm & Haas and Occidental Chemical Company previously performed soil remediation on the property under the supervision of the California Regional Water Quality Control Board. Rohm & Haas has indemnified the owner of the Bay Road facility and its tenants against costs associated with the residual contamination, but there can be no assurance that this indemnification will be adequate to cover the extent of the liability. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

**Our directors, officers, affiliates 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 February 1, 2006, our directors, officers, affiliates and principal stockholders each holding more than 5% of our common stock collectively will control approximately 48% of our outstanding common stock, assuming the exercise of all options held by such persons. As a result, these stockholders, if they act together, would be able to exercise significant control over 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, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

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

Our amended and restated certificate of incorporation and bylaws and Delaware law contain provisions that might enable our management to resist a takeover. These provisions include:

- a classified board of directors;
- advance notice requirements to stockholders for matters to be brought at stockholder meetings;
- a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws; and
- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer.

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

**The cost of public company compliance with the securities laws and regulations is substantial and recently enacted and proposed changes to these laws and regulations will further increase our general and administrative expenses.**

The cost of complying with the reporting requirements under the Securities and Exchange Act of 1934 are substantial. In addition, the Sarbanes-Oxley Act of 2002, along with other recent and proposed rules from the SEC and Nasdaq, have required further legal and financial compliance costs, and made some corporate actions more difficult. For example, compliance with the internal control requirements of Sarbanes-Oxley Section 404 requires us to commit significant resources to document and review the adequacy of our internal controls. While we are expending significant resources in developing the required documentation and testing procedures required by Section 404, we can provide no assurance as to conclusions by our external auditors with respect to the

effectiveness of our internal controls over financial reporting. If we are unable to comply with the requirements of Section 404, we will have to issue a report that our internal controls are not effective, which could cause the market price of our stock to decline.

In addition, the changes in securities laws and regulations may make it more difficult and more expensive for us to maintain directors and officers liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These developments also could make it more difficult for us to attract and retain qualified executive officers and members of our board of directors, particularly with regard to our audit committee.

**Recent changes in the required accounting treatment for stock options will have a material negative impact on our financial statements and may affect our stock price.**

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("SFAS") No. 123(R), "Share-Based Payment," pursuant to which we must measure all stock-based compensation awards, including grants of employee stock options, using a fair value-based method and record such expense in our financial statements. This requirement to expense stock-based compensation awards is to take effect for public companies for annual periods beginning after June 15, 2005, thus we are required to adopt this standard commencing January 1, 2006. Currently, we disclose such expenses on a pro forma basis in the notes to our financial statements, but we do not record a charge for employee stock option expense in the financial statements. The inclusion of employee stock-option expense in accordance with SFAS No. 123(R) will cause our reported earnings to decrease, which may affect our stock price.

**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 and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem 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

In June 2004, we moved our principal executive offices and our administrative, sales and marketing operations to a 61,000 square foot facility located at 740 Bay Road, Redwood City, California. We have leased this facility through September 2011 with an option to renew through 2016. In September 2005, we consolidated our research and development and manufacturing operations into our Bay Road facility. In November 2005, we entered into a noncancelable operating lease for our new 124,000 square foot Mountain View facility. We have leased this facility through December 31, 2016, with the first payment scheduled to commence on January 1, 2007. We believe that our premises are adequate for our needs for the foreseeable future.

## ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material litigation.

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

None.

## PART II

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

We had our initial public offering on October 28, 2004. Our Common Stock is traded on the Nasdaq National Market under the symbol "FOXH". The following table sets forth the high and low closing sales price of our common stock for the periods indicated.

| | Price Range | |
|---|---|---|
| | High | Low |
| Fiscal 2005: | | |
| First Quarter | $30.91 | $23.91 |
| Second Quarter | 40.11 | 25.60 |
| Third Quarter | 53.70 | 38.00 |
| Fourth Quarter | 53.73 | 29.79 |
| Fiscal Year | 53.73 | 23.91 |
| Fiscal 2004: | | |
| Fourth Quarter (from Oct. 28, 2004) | $28.00 | $20.45 |

As of February 23, 2006, the closing price of our Common Stock on the Nasdaq National Market was $27.77 per share, and the number of stockholders of record was approximately 7,800.

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

On October 28, 2004, we completed the initial public offering of our common stock by selling 4.5 million shares at $14.00 per share. Additionally, on October 29, 2004, the underwriters exercised their over-allotment option to purchase 675,000 shares at $14.00 per share. Proceeds from the offering after deducting underwriting discounts and commissions of $5.1 million, but before expenses were $67.4 million. The managing underwriters of the offering were J.P. Morgan Securities, Inc., Piper Jaffray & Co., Thomas Weisel Partners, LLC and William Blair & Company, LLC. All of the net proceeds from the initial public offering were spent as of the second quarter of 2005.

## ITEM 6. SELECTED FINANCIAL DATA

The following tables reflect selected financial data derived from our financial statements for each of the last five years. The statement of operations data for the years ended December 31, 2005, 2004 and 2003, and the balance sheet data as of December 31, 2005 and 2004 are derived from our audited financial statements included in this report. The statement of operations data for the years ended December 31, 2002 and 2001, and the balance sheet data as of December 31, 2003, 2002 and 2001 are derived from our audited financial statements not included in this report. Historical results are not necessarily indicative of future results. The selected financial data set forth below should be read in conjunction with our financial statements, the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report.

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2005 | 2004 | 2003 | 2002 | 2001 |
| | (in thousands, except per share data) | | | | |
| **Statement of Operations Data:** | | | | | |
| Revenue: | | | | | |
| Product | $125,362 | $ 38,552 | $ 2,585 | $ 12 | $ — |
| Research collaboration | 2,794 | — | — | — | — |
| Net revenue | 128,156 | 38,552 | 2,585 | 12 | — |
| Costs and expenses: | | | | | |
| Product (1) | 39,335 | 24,144 | 4,503 | 95 | — |
| Research collaboration | 614 | — | — | — | — |
| Research and development (1) | 10,321 | 6,191 | 5,785 | 6,570 | 4,360 |
| Selling, general and administrative (1) | 91,396 | 38,465 | 6,792 | 1,548 | 989 |
| Total costs and expenses | 141,666 | 68,800 | 17,080 | 8,213 | 5,349 |
| Loss from operations | (13,510) | (30,248) | (14,495) | (8,201) | (5,349) |
| Interest and other income | 1,945 | 376 | 183 | 73 | 210 |
| Interest and other expense | (46) | (3) | (35) | (78) | (278) |
| Net loss | (11,611) | (29,875) | (14,347) | (8,206) | (5,417) |
| Dividend related to beneficial conversion feature of convertible preferred stock (2) | — | (15,977) | (24) | — | — |
| Net loss attributable to common stockholders | $(11,611) | $(45,852) | $(14,371) | $(8,206) | $(5,417) |
| Basic and diluted net loss per common share | $ (0.51) | $ (10.52) | $ (24.69) | $(15.00) | $(10.28) |
| Basic and diluted weighted-average number of shares used in per common share calculations | 22,975 | 4,359 | 582 | 547 | 527 |

(1) Includes the following stock-based compensation charges:

| | | | | | |
|---|---|---|---|---|---|
| Costs and expenses: | | | | | |
| Product | $ 550 | $ 727 | $ 95 | $ — | $ — |
| Research and development | 1,056 | 605 | 232 | 1 | — |
| Selling, general and administrative | 5,471 | 5,494 | 1,109 | 4 | 1 |
| | $ 7,077 | $ 6,826 | $ 1,436 | $ 5 | $ 1 |

(2) In connection with the issuance of preferred stock in 2004, we recorded a non-cash charge representing the deemed dividend relating to the intrinsic value of the beneficial conversion feature of the preferred stock. See Note 9 of the notes to our financial statements.

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2005 | 2004 | 2003 | 2002 | 2001 |
| | (in thousands) | | | | |
| **Balance Sheet Data:** | | | | | |
| Cash, cash equivalents and investments | $ 59,915 | $70,393 | $ 7,511 | $ 1,086 | $ 6,765 |
| Working capital | 74,758 | 77,606 | 7,366 | (1,575) | 6,294 |
| Total assets | 108,205 | 90,836 | 11,416 | 1,988 | 7,587 |
| Convertible preferred stock | — | — | 49,998 | 27,374 | 27,374 |
| Total stockholders' equity (deficit) | 83,764 | 81,673 | (41,109) | (28,230) | 7,022 |

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

### Introduction

Management's discussion and analysis of financial condition and results of operations, or MD&A, is provided as a supplement to the accompanying financial statements and footnotes contained in Item 8 of this report and to provide an understanding of our results of operations, financial condition, and changes in financial condition. This discussion contains forward-looking statements. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's results, levels of activity, performance or achievement to be materially different from any future results, levels of activity, performance or achievements expressed or implied in or contemplated by the forward-looking statements. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of selected factors, including those set forth in this section. MD&A is organized as follows:

- *Company description.* This section provides a general description and history of our business, including details regarding our organization and customer base and capsule financial information regarding our results of operations.
- *Results of operations.* This section provides our analysis and outlook for the significant line items on our statements of operations.
- *Stock-based compensation.* This section provides the method and financial reporting of our accounting for stock options granted to employees and to non-employees.
- *Liquidity and capital resources.* This section provides an analysis of our liquidity and cash flows, as well as a discussion of our commitments that existed as of December 31, 2005.
- *Recent accounting pronouncements.* This section describes the issuance and effects of new accounting pronouncements.
- *Critical accounting policies and estimates.* This section discusses those accounting policies that both are considered important to our financial condition and results of operations and require us to exercise subjective or complex judgments in their application. In addition, all of our significant accounting policies, including our critical accounting policies, are summarized in Note 2 to our financial statements.
- *Factors affecting future operating results.* This section discusses the most significant factors that could affect our future financial results. The factors discussed in this section are in addition to factors that may be described in the MD&A captions discussed above and elsewhere in this report.

**Company Description.** We design, develop, manufacture and sell medical devices primarily for the treatment of peripheral artery disease. PAD results from the accumulation of plaque in arteries, most commonly occurring in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. Left untreated, PAD increases the risk of heart attack, stroke, amputation or death. Our first product, the SilverHawk Plaque Excision System, is a minimally-invasive catheter system that treats PAD by removing plaque in order to reopen narrowed or blocked arteries. The SilverHawk consists of two primary components, a low profile catheter connected to a battery-driven control unit, both of which are disposable. In June 2003, the U.S. Food and Drug Administration, or FDA, granted us 510(k) clearance to market the SilverHawk in the United States for treatment of atherosclerosis in the peripheral vasculature, which includes arteries outside the heart and brain.

From our inception in 1996 until July 2003, our operations consisted primarily of start-up activities, including developing the SilverHawk, recruiting personnel and raising capital. We received clearance from the FDA to market the SilverHawk for treatment of atherosclerosis in the peripheral vasculature in June 2003. In July 2003, we began to build our U.S. direct sales organization and initiated sales of the SilverHawk to several large medical

centers in the United States. In January 2004, we commenced full commercial introduction of the SilverHawk in the United States. The SilverHawk is not approved in the United States for use in the coronary or carotid arteries. We received our CE Mark to market the SilverHawk for coronary applications in October 2002 for peripheral applications in May 2003, and for the treatment of in-stent restenosis in the coronary arteries in October 2004. We began commercial sales in Europe in November 2002. To date, our sales outside of the United States have been limited, and we expect our international sales to remain limited for the foreseeable future.

We are expanding our direct sales force in the United States to further penetrate the PAD market. We have increased our sales force from 69 direct sales representatives on December 31, 2004 to 206 on December 31, 2005, and we expect to continue to grow our sales force. We market the SilverHawk through our direct sales force in the United States primarily to interventional cardiologists, as well as to vascular surgeons and interventional radiologists. As of December 31, 2005 we had over 1,000 active hospital customers in the United States. No single customer accounted for more than 5% of our net revenue in the year ended December 31, 2005. Reimbursement claims for the SilverHawk procedure are typically submitted by the hospital and physician to Medicare or other third-party payors using established billing codes for atherectomy procedures.

We manufacture the SilverHawk with parts manufactured in-house and components supplied by vendors, which we then assemble, test and package. We offer eight different SilverHawk models of various catheter diameters and tip lengths to accommodate differing artery sizes and amounts of plaque.

In September 2005, we consolidated our research and development and manufacturing operations into our Redwood City, California, building, which serves as our headquarters. This 60,000 square foot facility represents a three-fold increase over our previous facility. This expansion of our manufacturing facility has resulted in expanded production area and clean room space and enhanced research and development labs. The completion of the facility expansion increases our production capacity from approximately 15,000 to 25,000 units per quarter.

In September 2005, we entered into a Collaboration and License Agreement with Merck & Co. Inc., the "Merck Collaboration Agreement" through which we agreed with Merck to collaborate on the analysis of atherosclerotic plaque removed from patient arteries with the goal of identifying new biomarkers for atherosclerotic disease progression. The Merck Collaboration Agreement provides for a research collaboration of up to three years and consists of an initial one-year research term that Merck may, at its discretion, extend for one or two additional years. As part of this research collaboration, we will provide Merck with exclusive access to existing atherosclerotic plaque samples collected from patients having vascular disease using the SilverHawk Plaque Excision System as well as new samples to be collected pursuant to agreed upon protocols and criteria. Upon execution of the Merck Collaboration Agreement, we received an initial cash payment of $9 million to cover costs associated with our responsibilities and for the rights granted to Merck during the initial year of the research collaboration. We may also be entitled to additional payments of at least $7 million and up to $31 million over the following two years, if Merck elects to extend the research collaboration beyond its initial one-year term and/or exercise an option to maintain exclusive access to our atherosclerotic plaque samples. We may derive further revenue from Merck for milestone payments based on the progress of clinical development of any pharmaceutical or diagnostic products arising from work under the research collaboration, as well as royalties on sales of any such products.

For the year ended December 31, 2005, we generated net revenue of $128.2 million and a net loss of $11.6 million. As of December 31, 2005, our accumulated deficit was $85.1 million. We have not been profitable since inception. As of December 31, 2005, our cash, cash equivalents and investments balances were $59.9 million. On October 28, 2004, the Company completed an initial public offering of 4.5 million shares of its common stock, additionally, on October 29, 2004, the underwriters of the offering exercised their over-allotment option to purchase 675,000 shares. Proceeds from the offering after deducting underwriting discounts and commissions but before expenses were $67.4 million.

## Results of Operations

### *Years Ended December 31, 2005, 2004 and 2003*

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts (in thousands) and as percentages of net revenue:

| | Year Ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2005 | | 2004 | | 2003 | |
| | Amount | % of Net Revenue | Amount | % of Net Revenue | Amount | % of Net Revenue |
| Revenue: | | | | | | |
| Product | $125,362 | 98% | $ 38,552 | 100% | $ 2,585 | 100% |
| Research collaboration | 2,794 | 2% | — | 0% | — | 0% |
| Net revenue | 128,156 | 100% | 38,552 | 100% | 2,585 | 100% |
| Costs and expenses: | | | | | | |
| Product (1) | 39,335 | 31% | 24,144 | 63% | 4,503 | 174% |
| Research collaboration | 614 | 0% | — | 0% | — | 0% |
| Research and development (1) | 10,321 | 8% | 6,191 | 16% | 5,785 | 224% |
| Selling, general and administrative (1) | 91,396 | 71% | 38,465 | 100% | 6,792 | 263% |
| Total costs and expenses | 141,666 | 110% | 68,800 | 179% | 17,080 | 661% |
| Loss from operations | (13,510) | -10% | (30,248) | -79% | (14,495) | -561% |
| Interest and other income | 1,945 | 1% | 376 | 1% | 183 | 7% |
| Interest and other expense | (46) | 0% | (3) | 0% | (35) | -1% |
| Net loss | $(11,611) | -9% | $(29,875) | -78% | $(14,347) | -555% |

(1) Includes the following stock-based compensation charges:

| | | | |
|---|---|---|---|
| Costs and expenses: | | | |
| Product | $ 550 | $ 727 | $ 95 |
| Research and development | 1,056 | 605 | 232 |
| Selling, general and administrative | 5,471 | 5,494 | 1,109 |
| | $ 7,077 | $ 6,826 | $ 1,436 |

***Revenue:***

Our revenue consists of two components: product and research collaboration.

***Product.*** Product revenue is derived from sales of the SilverHawk plaque excision system. Product revenue was $125.4 million for the year ended December 31, 2005 as compared to $38.6 million and $2.6 million for the years ended December 31, 2004 and 2003, respectively. The increase of $86.8 million from 2004 to 2005 was attributable to an increase in the number of SilverHawk devices sold and a 30% increase in the average sales price per unit. The increase of $36.0 million from 2003 to 2004 was attributable to an increase in the number of SilverHawk devices sold and a 40% increase in the average sales price per unit. The increase in the number of devices sold was primarily attributable to an increase in the number of hospital customers purchasing our devices as we expanded our sales force. We expect our product revenue to increase as we continue to expand our sales force to increase penetration of existing customer accounts and to penetrate new customer accounts.

***Research collaboration.*** Research collaboration revenue is derived from the Merck Collaboration Agreement. Research collaboration revenue was $2.8 million for the year ended December 31, 2005 as compared to $0 for the years ended December 31, 2004 and 2003. The $2.8 million of revenue was recognized in connection with delivery of tissue samples under the agreement. The agreement provides for an initial payment of $9.0 million

which covers costs associated with the Company's responsibilities and for the rights granted to Merck during the initial year of the research collaboration. The initial payment was classified as deferred revenue and the Company will recognize revenue as it fulfills its obligations and delivers tissue samples. We expect our research collaboration revenue to increase as we continue to deliver tissue samples and recognize the remaining deferred revenue balance of $6.2 million.

***Costs and Expenses:***

Our costs and expenses consist of four components: product, research collaboration, research and development, and selling, general and administrative.

***Product.*** Product costs consists primarily of material, labor and overhead costs. Product costs were $39.3 million for the year ended December 31, 2005 as compared to $24.1 million and $4.5 million for the years ended December 31, 2004 and 2003, respectively. The increase was primarily attributable to the increase in the number of SilverHawk devices sold. As a percentage of net revenue, product costs were 31% in the year ended December 31, 2005 as compared to 63% and 174% for the years ended December 31, 2004 and 2003, respectively. Primary factors that contributed to the decrease in product costs as a percentage of net revenue included an increase in the average sales price per unit, continued improvements related to the absorption of manufacturing overhead costs associated with increased production volumes, improved purchasing efficiencies of supplies and materials, and improved labor and manufacturing efficiencies. We expect product costs will increase in absolute dollars but decrease as a percentage of product revenue as we implement cost reduction initiatives and benefit from economies of scale.

***Research Collaboration.*** Research collaboration expenses consist of costs associated with procurement and delivery of tissue samples under the Merck Collaboration Agreement. Research collaboration expenses were $614,000 for the year ended December 31, 2005 as compared to $0 for the years ended December 31, 2004 and 2003. We expect that research collaboration costs will increase in absolute dollars and as a percentage of research collaboration revenue as we continue to expand our efforts to collaborate on the analysis of atherosclerotic plaque removed from patient arteries.

***Research and Development.*** Research and development expenses consist primarily of costs associated with personnel, materials, and clinical studies within our product development, regulatory and clinical organizations. Research and development expenses were $10.3 million for the year ended December 31, 2005 as compared to $6.2 million and $5.8 million for the years ended December 31, 2004 and 2003, respectively. The increase of $4.1 million from 2004 to 2005 was primarily attributable to a $3.7 million increase in personnel-related costs resulting from additional hiring of research and development and regulatory and clinical personnel associated with the launch of new devices and new clinical studies, a $451,000 increase in stock-based compensation and a $166,000 increase in travel and related expenses attributable to research and development activities, offset by a $522,000 decrease in materials costs used in product development. The increase of $0.4 million from 2003 to 2004 was primarily attributable to a $462,000 increase in personnel-related costs resulting from additional hiring of research and development and regulatory and clinical personnel and a $373,000 increase in stock-based compensation, offset by a $300,000 decrease in materials costs used in product development and an $82,000 decrease in expenses related to clinical trials. As a percentage of net revenue, research and development expenses were 8% in the year ended December 31, 2005, as compared to 16% and 224% for the years ended December 31, 2004 and 2003, respectively. We expect research and development expenses to increase in absolute terms and increase as a percentage of net revenue as we explore new technologies and commence new clinical trials.

***Selling, General and Administrative.*** Selling, general and administrative expenses consist primarily of employment costs for sales, marketing and administrative personnel, and costs associated with participation in medical conferences, physician symposia and promotional activities. Selling, general and administrative expenses were $91.4 million for the year ended December 31, 2005 as compared to $38.5 million and $6.8 million for the years ended December 31, 2004 and 2003, respectively. The increase of $52.9 million from 2004 to 2005 was primarily attributable to a $38.0 million increase in personnel costs related to additional hiring of

sales and marketing personnel, a $5.3 million increase in travel and related expenses attributable to selling and marketing activities and a $3.2 million increase in marketing and promotional activities. The increase of $31.7 million from 2003 to 2004 was primarily attributable to a $20.8 million increase in personnel costs primarily related to additional hiring of sales and marketing personnel, a $4.4 million increase in stock-based compensation, a $2.6 million increase in travel and related expenses attributable to selling and marketing activities and an $800,000 increase in marketing and promotional activities. As a percentage of net revenue, selling, general and administrative expenses in the year ended December 31, 2005 were 71% as compared to 100% and 263% for the years ended December 31, 2004 and 2003, respectively. We expect selling, general and administrative expenses to increase in absolute terms as we expand our sales and marketing efforts and incur additional administrative costs, but to decrease as a percentage of net revenue as we leverage our existing selling, general and administrative infrastructure.

***Interest and Other Income.*** Interest and other income were $1.9 million for the year ended December 31, 2005 as compared to $376,000 and $183,000 for the years ended December 31, 2004 and 2003, respectively. The increase of $1.5 million from 2004 to 2005 is primarily attributable to higher interest rates and higher average cash, cash equivalents and investment balances that increased primarily as a result of cash received from financing activities and cash received from the Merck Collaboration Agreement. The increase in interest and other income of $193,000 from 2003 to 2004 is primarily attributable to higher average cash, cash equivalents and investment balances that increased as a result of cash received from our initial public offering.

***Interest and Other Expense.*** Interest and other expense were $46,000 for the year ended December 31, 2005 as compared to $3,000 and $35,000 for the years ended December 31, 2004 and 2003, respectively. The increase of $43,000 from 2004 to 2005 is primarily attributable to losses on disposal of property and equipment. The decrease of $32,000 from 2003 to 2004 is primarily attributable to the reduction in outstanding notes payable and convertible promissory note balances.

***Beneficial Conversion Feature.*** The issuance of Series D and Series E convertible preferred stock resulted in a deemed dividend associated with the beneficial conversion feature, calculated in accordance with Emerging Issues Task Force No. 00-27, *"Application of Issue No. 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratio," to Certain Convertible Instruments,"* based on the conversion price and fair value of the common stock on the date of issuance. Accordingly, we recognized $16.0 million and $24,000 as a charge to additional paid-in-capital to account for the deemed dividend on the convertible preferred stock as of the issuance date in 2004 and 2003, respectively. The amount of the deemed dividend related to the beneficial conversion feature was recorded upon issuance of the convertible preferred stock, as the convertible preferred stock could have been converted to common stock by the holder at any time.

## Stock-Based Compensation

We record deferred stock-based compensation for financial reporting purposes as the difference between the exercise price of options granted to employees and directors and the estimated fair value of our common stock at the time of grant. Deferred stock-based compensation is amortized on a straight-line basis to cost of product, research and development expenses and selling, general and administrative expenses. Deferred stock-based compensation recorded through December 31, 2005 was $19.8 million, net of stock option cancellations, with accumulated amortization of $10.7 million. The remaining $9.1 million will be amortized over the vesting periods of the options, generally four years from the date of grant (assuming no additional cancellations). We currently expect to record amortization expense for deferred stock-based compensation as follows:

| For the Year Ended December 31, | Amount |
|---|---|
| 2006 | $4.7 million |
| 2007 | $3.7 million |
| 2008 | $0.7 million |

Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. The amount of stock-based compensation expense to be recorded in future periods may decrease if unvested options are cancelled. Our stock-based compensation expenses will fluctuate as the fair market value of our common stock fluctuates. We recorded $2.4 million, $1.8 million and $447,000 in stock-based compensation expense for non-employees in the years ended December 31, 2005, 2004, and 2003, respectively.

### Liquidity and Capital Resources

On October 28, 2004, the Company completed an initial public offering of 4.5 million shares of its common stock. Additionally, on October 29, 2004, the underwriters of the offering exercised their over-allotment option of 675,000 shares. Proceeds from the offering after deducting underwriting discounts and commissions but before expenses were $67.4 million. From inception through June 2004, we raised $78.3 million through private sales of convertible preferred stock. As of December 31, 2005, we had $24.2 million of cash and cash equivalents, $35.7 million of investments, and working capital of $74.8 million.

### Contractual Obligations

The following table discloses aggregate information about our contractual obligations and the periods in which payments are due as of December 31, 2005:

| | Payments Due by Period (in thousands) | | | | | | |
|---|---|---|---|---|---|---|---|
| **Contractual Obligations** | **Total** | **2006** | **2007** | **2008** | **2009** | **2010** | **After 2010** |
| Operating leases | $44,820 | $ 889 | $4,656 | $4,582 | $4,678 | $4,789 | $25,226 |
| Royalty obligation | 83 | 83 | — | — | — | — | — |
| Purchase agreement | 5,657 | 2,829 | — | 2,828 | — | — | — |
| | $50,560 | $3,801 | $4,656 | $7,410 | $4,678 | $4,789 | $25,226 |

The long-term commitments under operating leases shown above consist of payments related to our real estate lease in Redwood City expiring August 2011, our real estate lease in Menlo Park expiring May 2007, and our real estate lease in Mountain View that expires on December 31, 2016, with the first payment scheduled to commence on January 1, 2007 (see Note 7).

For 2006 and each year thereafter, the quarterly minimum patent royalty obligation equals the prior year's minimum royalty adjusted by a percentage equal to the percentage change in the consumer price index for the prior calendar year as reported by the U.S. Department of Labor. Unless terminated earlier, the term of the royalty obligation will continue until the expiration of the last to expire patent that covers that licensed product in such country or for a period of 15 years following commercial sales, whichever is longer.

In March 2005, the Company entered into a purchase agreement with one of its suppliers for certain manufacturing components used in the Company's devices. Under the terms of this agreement, the Company will be required to make payments to the supplier for differences between actual purchase quantities and the minimum purchase quantities defined in the agreement.

***Net Cash Used in Operating Activities.*** Net cash used in operating activities was $8.5 million for the year ended December 31, 2005 as compared to $30.2 million for the year ended December 31, 2004 and $12.5 million for the year ended December 31, 2003. Net cash used in 2005 was primarily attributable to net loss of $11.6 million and increases in inventory and accounts receivable balances of $9.4 million and $14.8 million, respectively, as we increased our net revenue, partially offset by adjustments for non-cash charges related to stock-based compensation of $7.1 million, depreciation and amortization of $3.3 million and increases in accrued liabilities and accounts payable of $9.4 million due to our increased operating expenses, and a $6.2 million increase in deferred revenue. Net cash used in 2004 was primarily attributable to a net loss of $29.9 million and

increases in inventory and accounts receivable balances of $7.2 million and $7.1 million, respectively, as we increased our net revenue, partially offset by adjustments for non-cash charges related to stock-based compensation of $6.8 million, depreciation and amortization of $1.4 million and increases in accrued liabilities and accounts payable of $6.0 million due to our increased operating expenses. Net cash used in 2003 was primarily attributable to a net loss of $14.3 million and increases in inventory and accounts receivable balances of $1.3 million and $893,000, respectively, as we increased our net revenue, partially offset by adjustments for non-cash charges related to stock-based compensation of $1.4 million, depreciation and amortization of $585,000 and increases in accrued liabilities and accounts payable of $2.0 million due to our increased operating expenses.

***Net Cash Provided by (Used in) Investing Activities.*** Net cash used in investing activities was $1.1 million for the year ended December 31, 2005 as compared to $41.5 million for the year ended December 31, 2004 and net cash provided by investing activities of $5.1 million for the year ended December 31, 2003. For 2005 and 2004, net cash used in investing activities was attributable to purchases of investments and acquisition of property and equipment, offset by sales or maturities of investments. For 2003, net cash provided by investing activities was attributable to sales and maturities of investments, offset by purchases of investments and acquisition of property and equipment.

***Net Cash Provided by Financing Activities.*** Net cash provided by financing activities was $6.3 million for the year ended December 31, 2005 as compared to $96.6 million and $9.0 million for the years ended December 31, 2004 and 2003, respectively. For 2005, net cash provided by financing activities was attributable to proceeds from issuance of common stock related to stock option exercises and issuance of common stock relating to our employee stock purchase plan, offset by repurchases of common stock. For 2004, net cash provided by financing activities was attributable to proceeds from issuance of common stock associated with our initial public offering, issuance of convertible preferred stock and issuance of common stock related to stock option exercises. For 2003, net cash provided by financing activities was attributable to proceeds from issuance of convertible preferred stock and issuance of common stock related to stock option exercises.

Our future capital requirements depend on numerous factors. These factors include but are not limited to the following:

- revenue generated by sales of the SilverHawk;
- costs associated with our sales and marketing initiatives and manufacturing activities;
- rate of progress and cost of our research and development activities;
- costs of obtaining and maintaining FDA and other regulatory clearances of the SilverHawk;
- effects of competing technological and market developments;
- size, number and timing of acquisitions and other strategic transactions; and
- revenue generated by the Merck Collaboration Agreement and its possible renewal beyond the initial one-year term.

***Off-Balance-Sheet Arrangements.*** As of December 31, 2005, we did not have any significant off-balance-sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

***Summary.*** We believe that our current cash, cash equivalents and investments, along with the cash we expect to generate from operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. If these sources of cash are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Additional financing may not be available at all, or in amounts or on terms acceptable to us. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned research and development and selling and marketing efforts.

We expect to increase capital expenditures consistent with our anticipated growth in manufacturing, infrastructure and personnel. We also may increase our capital expenditures as we expand our product lines or invest to address new markets.

**Inflation**

Inflation has not had a significant impact on our operations over the past three years and we do not expect it to have a significant impact on our results of operations or financial condition in the foreseeable future.

**Recent Accounting Pronouncements**

In November 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 151, "Inventory Costs, an amendment of ARB No. 43, Chapter 4," ("SFAS 151"). SFAS 151 amends APB No. 43, Chapter 4, to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges. In addition, SFAS No. 151 requires that allocation of fixed production overhead to the cost of conversion be based on the normal capacity of the production facilities. The provisions of SFAS No. 151 are effective for fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151 is not expected to have a material impact on the Company's financial statements.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Non-monetary Assets, an amendment of APB Opinion No. 29," ("SFAS No. 153"). SFAS 153 addresses the measurement of exchanges of non-monetary assets and redefines the scope of transactions that should be measured based on the fair value of the assets exchanged. SFAS No. 153 is effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS No. 153 is not expected to have a material impact on the Company's financial statements.

In December 2004, the FASB issued SFAS No. 123(R), "Share-Based Payment" (revised 2004), ("SFAS No. 123(R)"). SFAS No. 123(R) requires companies to measure all stock-based compensation awards, including grants of employee stock options, using a fair value method and record such expense in the financial statements. In addition, the adoption of SFAS No. 123(R) requires additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. SFAS No. 123(R) as amended, is now effective for public companies for annual, rather than interim, periods that begin after June 15, 2005, which will require the Company to adopt this standard commencing January 1, 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin ("SAB") No. 107, "TOPIC 14: Share-based payment." SAB No. 107 addresses the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides views regarding the valuation of share-based payment arrangements for public companies. SAB No. 107 was effective immediately.

We plan to adopt SFAS 123(R) using the modified prospective method, under which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123(R) for all share-based payments granted after the effective date and (b) based on the previous requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123(R) that remain unvested on the effective date. The amounts disclosed within our footnotes are not necessarily indicative of the amounts that will be expensed upon the adoption of SFAS 123(R). Compensation expense calculated under SFAS 123(R) may differ from amounts currently disclosed within our footnotes based on changes in the fair value of our common stock, changes in the number of options granted or the terms of such options, and changes in interest rates or other factors. Upon adoption of SFAS 123(R), we plan to use the Black-Scholes model to value the compensation expense associated with employee stock options and stock purchases under our employee stock purchase plan. We have completed our assessment of the impact of adopting these new standards. We expect this standard to have a significant impact on the statements of operations and statements of cash flows.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections," ("SFAS No. 154") which establishes, unless impracticable, retrospective application as the required method for reporting a change

in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. The statement provides guidance for determining whether retrospective application of a change in accounting principle is impracticable. The statement also addresses the reporting of a correction of an error by restating previously issued financial statements. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 is not expected to have a material impact on the Company's financial statements.

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses, and disclosures of contingent assets and liabilities at the date of the financial statements. On a periodic basis, we evaluate our estimates, including those related to accounts receivable, inventories, warranty reserve, income taxes and deferred stock-based compensation. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

***Revenue Recognition.*** The Company generates revenue from the sale of SilverHawk devices and through plaque analysis related to the Merck Collaboration Agreement. The Company recognizes product revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, "Revenue Recognition." SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; title has transferred; the fee is fixed and determinable; and collectibility is reasonably assured. Transfer of title and risk of ownership generally occurs when the product is shipped to the customer or when the customer receives the product, depending on the nature of the arrangement. The Company does not offer any rights of return for product sales to direct and indirect customers. The Company recognizes revenue related to the Merck Collaboration Agreement in accordance with Emerging Issues Task Force Issue No. 00-21 ("EITF 00-21"), Accounting for Revenue Arrangements with Multiple Deliverables. The Merck Collaboration Agreement provides for an initial payment which covers costs associated with the Company's responsibilities and for the rights granted to Merck during the initial year of the research collaboration which was classified as deferred revenue. The Company recognizes revenue as it fulfills its obligations and delivers tissue samples under the Merck Collaboration Agreement.

***Accounts Receivable.*** We perform periodic credit evaluations of our customers and adjust credit limits based upon payment history and the customer's current creditworthiness, as determined by our review of current credit information. We monitor collections and payments from our customers and maintain an allowance for doubtful accounts based upon our historical experience and any specific customer collection issues that we have identified. While our credit losses have historically been within our expectations and the allowance established, we may not continue to experience the same credit loss rates that we have in the past.

***Warranty Reserve.*** We provide for the estimated cost of product warranties at the time revenue is recognized. As we sell new products to our customers, we must exercise considerable judgment in estimating the expected failure rates. Should actual product failure rates, material usage or service delivery costs differ from our estimates, revisions to the estimated warranty liability would be required.

***Inventories.*** We state our inventories at the lower of cost or market, computed on a standard cost basis, which approximates actual cost on a first-in, first-out basis and market being determined as the lower of replacement cost or net realizable value. Standard costs are monitored on a quarterly basis and updated as necessary to reflect changes in raw material costs and labor and overhead rates. Inventory reserves are established when conditions

indicate that the selling price could be less than cost due to physical deterioration, usage, obsolescence, reductions in estimated future demand and reductions in selling prices. Inventory reserves are measured as the difference between the cost of inventory and estimated market value. Inventory reserves are charged to cost of product and establish a lower cost basis for the inventory. We balance the need to maintain strategic inventory levels with the risk of obsolescence due to changing technology and customer demand levels. Unfavorable changes in market conditions may result in a need for additional inventory reserves that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins.

***Accounting for Income Taxes.*** Our income tax policy records the estimated future tax effects of temporary differences between the tax bases of assets and liabilities and amounts reported in the accompanying balance sheets, as well as operating loss and tax credit carry forwards. We have recorded a full valuation allowance to reduce our deferred tax asset. Based on available objective evidence, it is more likely than not that the deferred tax asset will not be realized. In the event that we were to determine that we would be able to realize our deferred tax assets in the future, an adjustment to the deferred tax asset would increase net income in the period such determination was made.

***Stock-Based Compensation.*** We have stock option plans to reward our employees and directors. We account for these plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25 and related interpretations and apply the disclosure provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, as amended by SFAS No. 148. We have recorded stock-based compensation based upon the difference between the estimated fair value of common stock on the date of grant and the option exercise price. The fair value of the common stock for options granted between January 1, 2003 and the completion of our initial public offering was originally estimated by our board of directors, with input from management. We did not obtain contemporaneous valuations by an unrelated valuation specialist. Subsequently, we reassessed the valuations of common stock relating to grants of options during the 22 month period preceding the completion of our initial public offering. As disclosed more fully in Note 11 of the notes of our financial statements, we granted stock options and restricted preferred stock with exercise prices ranging from $0.32 to $11.68 during the 22 month period. In addition, we determined that the fair value of our common stock increased from $2.56 to $11.32 per share during that period. We estimated the fair value of our common stock based upon several factors, including progress and milestones attained in our business, sales of convertible preferred stock, changes in valuations of existing comparable public companies and the valuation we expected to obtain in our initial public offering. We amortize employee and director stock-based compensation on a straight-line basis over the vesting terms of the underlying options. We issue stock options to non-employees, generally for services, which we account for under the provisions of SFAS No. 123 and Emerging Issues Task Force, or EITF, Abstract No. 96-18. These options are valued using the Black-Scholes option valuation model and are subject to periodic adjustment as the underlying options vest.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to interest rate risk at December 31, 2005 is related primarily to our investment portfolio. Our investment portfolio includes fixed rate debt instruments of high quality US government and corporate issuers. A change in prevailing interest rates may cause the fair value of our investments to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing rate rises, the fair value of the principal amount of our investment will probably decline. To minimize this risk, investments are generally held to maturity and the weighted average duration of our investments is 6 months or less. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments.

We have operated mainly in the United States, and 100%, 99% and 88% of our sales were made in U.S. dollars for the years ended December 31, 2005, 2004 and 2003, respectively. To date, we have not had any material exposure to foreign currency rate fluctuations.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

### FOXHOLLOW TECHNOLOGIES, INC.
### INDEX TO FINANCIAL STATEMENTS

## FOXHOLLOW TECHNOLOGIES, INC.

## BALANCE SHEETS
**(in thousands, except share and per share amounts)**

| | December 31, 2005 | December 31, 2004 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 24,249 | $ 27,506 |
| Short-term investments | 35,666 | 42,887 |
| Accounts receivable, net of allowance for doubtful accounts of $1,002 in 2005 and $324 in 2004 | 21,831 | 7,666 |
| Inventories | 15,607 | 7,619 |
| Prepaid expenses and other current assets | 1,846 | 1,091 |
| Total current assets | 99,199 | 86,769 |
| Property and equipment, net | 8,442 | 3,506 |
| Other assets | 564 | 561 |
| Total assets | $108,205 | $ 90,836 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,072 | $ 3,757 |
| Accrued liabilities | 11,163 | 5,406 |
| Deferred revenue | 6,206 | — |
| Total liabilities | 24,441 | 9,163 |
| Commitments and Contingencies (Note 7) | | |
| Stockholders' equity: | | |
| Common stock: $0.001 par value; 50,000,000 shares authorized: Issued and outstanding: 23,855,326 and 22,259,586 at December 31, 2005 and 2004, respectively | 24 | 22 |
| Additional paid-in capital | 178,011 | 169,389 |
| Deferred stock-based compensation | (9,066) | (14,202) |
| Other comprehensive loss | (99) | (41) |
| Accumulated deficit | (85,106) | (73,495) |
| Total stockholders' equity | 83,764 | 81,673 |
| Total liabilities and stockholders' equity | $108,205 | $ 90,836 |

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

## FOXHOLLOW TECHNOLOGIES, INC.

## STATEMENTS OF OPERATIONS
**(in thousands, except share and per share amounts)**

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Revenue: | | | |
| Product | $125,362 | $ 38,552 | $ 2,585 |
| Research collaboration | 2,794 | — | — |
| Net revenue | 128,156 | 38,552 | 2,585 |
| Costs and expenses: | | | |
| Product (1) | 39,335 | 24,144 | 4,503 |
| Research collaboration | 614 | — | — |
| Research and development (1) | 10,321 | 6,191 | 5,785 |
| Selling, general and administrative (1) | 91,396 | 38,465 | 6,792 |
| Total costs and expenses | 141,666 | 68,800 | 17,080 |
| Loss from operations | (13,510) | (30,248) | (14,495) |
| Interest and other income | 1,945 | 376 | 183 |
| Interest and other expense | (46) | (3) | (35) |
| Net loss | (11,611) | (29,875) | (14,347) |
| Dividend related to beneficial conversion feature of convertible preferred stock | — | (15,977) | (24) |
| Net loss attributable to common stockholders | $(11,611) | $(45,852) | $(14,371) |
| Net loss per common share: | | | |
| Basic and diluted | $ (0.51) | $ (10.52) | $ (24.69) |
| Weighted-average number of shares used in per common share calculations: | | | |
| Basic and diluted | 22,975 | 4,359 | 582 |

(1) Includes the following stock-based compensation charges:

| | | | |
|---|---|---|---|
| Costs and expenses: | | | |
| Product | $ 550 | $ 727 | $ 95 |
| Research and development | 1,056 | 605 | 232 |
| Selling, general and administrative | 5,471 | 5,494 | 1,109 |
| | $ 7,077 | $ 6,826 | $ 1,436 |

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

## FOXHOLLOW TECHNOLOGIES, INC.

## STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
### (in thousands, except share amounts)

| | Common Stock | | Additional Paid-In Capital | Deferred Stock-Based Compensation | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total Stockholders' (Deficit)/ Equity |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | | |
| **Balances at December 31, 2002** | **571,262** | **$ 1** | **$ 1,042** | **$ —** | **$—** | **$(29,273)** | **$(28,230)** |
| Exercise of common stock options | 37,833 | — | 32 | — | — | — | 32 |
| Beneficial conversion feature related to issuance of Series D convertible preferred stock | — | — | 24 | — | — | — | 24 |
| Deemed dividend related to beneficial conversion feature related to issuance of Series D convertible preferred stock | — | — | (24) | — | — | — | (24) |
| Deferred stock-based compensation | — | — | 4,662 | (4,662) | — | — | — |
| Stock-based compensation | — | — | 447 | — | — | — | 447 |
| Amortization of deferred stock-based compensation | — | — | — | 989 | — | — | 989 |
| Components of other comprehensive loss: | | | | | | | |
| Net loss | — | — | — | — | — | (14,347) | (14,347) |
| Comprehensive loss | | | | | | | (14,347) |
| **Balances at December 31, 2003** | **609,095** | **$ 1** | **$ 6,183** | **$ (3,673)** | **$—** | **$(43,620)** | **$(41,109)** |
| Exercise of common stock options | 733,533 | 1 | 361 | — | — | — | 362 |
| Beneficial conversion feature related to issuance of Series E convertible preferred stock | — | — | 15,977 | — | — | — | 15,977 |
| Deemed dividend related to beneficial conversion feature related to issuance of Series E convertible preferred stock | — | — | (15,977) | — | — | — | (15,977) |
| Deferred stock-based compensation in connection with a deemed dividend related to the issuance of Series E convertible restricted preferred stock | — | — | 766 | (766) | — | — | — |
| Deferred stock-based compensation | — | — | 15,063 | (15,063) | — | — | — |
| Stock-based compensation | — | — | 1,818 | — | — | — | 1,818 |
| Amortization of deferred stock-based compensation in connection with a deemed dividend related to the issuance of Series E convertible restricted preferred stock | — | — | — | 756 | — | — | 756 |
| Reversal of deferred stock-based compensation in connection with a deemed dividend related to the issuance of Series E convertible restricted preferred stock | — | — | (9) | 9 | — | — | — |
| Amortization of deferred stock-based compensation | — | — | — | 4,252 | — | — | 4,252 |
| Reversal of deferred stock-based compensation due to option cancellations | — | — | (283) | 283 | — | — | — |
| Common stock issued in connection with initial public offering | 5,175,000 | 5 | 65,734 | — | — | — | 65,739 |
| Conversion of convertible preferred stock | 15,557,097 | 15 | 79,499 | — | — | — | 79,514 |
| Exercise of warrants | 184,861 | — | 257 | — | — | — | 257 |
| Components of other comprehensive loss: | | | | | | | |
| Changes in unrealized gains/(losses) on investments | — | — | — | — | (41) | — | (41) |
| Net loss | — | — | — | — | — | (29,875) | (29,875) |
| Comprehensive loss | | | | | | | (29,916) |
| **Balances at December 31, 2004** | **22,259,586** | **$ 22** | **$169,389** | **$(14,202)** | **$ (41)** | **$(73,495)** | **$ 81,673** |
| Exercise of common stock options | 1,257,075 | 2 | 2,107 | — | — | — | 2,109 |
| Issuance of common stock under employee stock purchase plan | 338,665 | — | 4,574 | — | — | — | 4,574 |
| Stock-based compensation | — | — | 2,360 | — | — | — | 2,360 |
| Amortization of deferred stock-based compensation | — | — | — | 4,717 | — | — | 4,717 |
| Reversal of deferred stock-based compensation due to option cancellations | — | — | (419) | 419 | — | — | — |
| Components of other comprehensive loss: | | | | | | | |
| Changes in unrealized gains/(losses) on investments | — | — | — | — | (58) | — | (58) |
| Net loss | — | — | — | — | — | (11,611) | (11,611) |
| Comprehensive loss | | | | | | | (11,669) |
| **Balances at December 31, 2005** | **23,855,326** | **$ 24** | **$178,011** | **$ (9,066)** | **$ (99)** | **$(85,106)** | **$ 83,764** |

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

## FOXHOLLOW TECHNOLOGIES, INC.

### STATEMENTS OF CASH FLOWS
### (in thousands)

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| **Cash flows from operating activities:** | | | |
| Net loss | $(11,611) | $(29,875) | $(14,347) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Interest expense related to warrants and accrued interest converted into convertible preferred stock | — | — | 17 |
| (Gain)/Loss on disposal of property and equipment | (15) | — | 3 |
| Allowance for doubtful accounts | 678 | 285 | 39 |
| Depreciation and amortization | 3,299 | 1,354 | 585 |
| Amortization of deferred stock-based compensation | 4,717 | 5,008 | 989 |
| Stock-based compensation expense | 2,360 | 1,818 | 447 |
| Provision for excess and obsolete inventories | 3,922 | 826 | 142 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (14,843) | (7,085) | (893) |
| Inventories | (11,910) | (7,222) | (1,303) |
| Prepaid expenses and other current assets | (755) | (798) | (184) |
| Other assets | (3) | (462) | (9) |
| Accounts payable | 3,315 | 2,198 | 1,139 |
| Accrued liabilities | 6,109 | 3,761 | 858 |
| Deferred revenue | 6,206 | — | — |
| Net cash used in operating activities | (8,531) | (30,192) | (12,517) |
| **Cash flows from investing activities:** | | | |
| Acquisition of property and equipment | (8,378) | (3,436) | (1,383) |
| Proceeds from disposal of property and equipment | 158 | — | — |
| Sales or maturities of investments | 52,977 | 19,467 | 18,277 |
| Purchases of investments | (45,814) | (57,521) | (11,783) |
| Net cash provided by (used in) investing activities | (1,057) | (41,490) | 5,111 |
| **Cash flows from financing activities:** | | | |
| Proceeds from initial public offering, net | — | 65,739 | — |
| Proceeds from issuance of convertible preferred stock, net | — | 29,532 | 8,925 |
| Repurchase of convertible preferred stock | — | (17) | — |
| Proceeds from exercise of options to purchase common stock | 1,778 | 1,050 | 32 |
| Proceeds from issuance of common stock under the Employee Stock Purchase Plan | 4,574 | — | — |
| Repurchase of common stock | (21) | (10) | — |
| Exercises of warrants | — | 257 | — |
| Net cash provided by financing activities | 6,331 | 96,551 | 8,957 |
| Net increase (decrease) in cash and cash equivalents | (3,257) | 24,869 | 1,551 |
| Cash and cash equivalents, beginning of period | 27,506 | 2,637 | 1,086 |
| Cash and cash equivalents, end of period | $ 24,249 | $ 27,506 | $ 2,637 |
| **Supplemental disclosure of noncash investing and financing activities:** | | | |
| Preferred stock converted to common upon initial public offering | $ — | $ 79,514 | $ — |
| Issuance of convertible preferred stock in exchange for marketable securities | — | — | 11,369 |
| Changes in net unrealized gains/(losses) on investments | (58) | (41) | — |
| Deferred stock-based compensation | — | 15,537 | 4,662 |
| Reversal of deferred stock-based compensation | (419) | — | — |
| Conversion of promissory notes and accrued interest into convertible preferred stock | — | — | 2,331 |
| Dividend related to beneficial conversion feature of convertible preferred stock | — | 15,977 | 24 |
| Vesting of restricted stock | 368 | 1,372 | — |

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

## FOXHOLLOW TECHNOLOGIES, INC.

## NOTES TO FINANCIAL STATEMENTS

### NOTE 1—THE COMPANY:

FoxHollow Technologies, Inc. (the "Company") designs, develops, manufactures and sells medical devices primarily for the treatment of peripheral artery disease ("PAD"). PAD results from the accumulation of plaque in the arteries. The Company sells the SilverHawk Plaque Excision System ("SilverHawk"), a minimally-invasive single-use catheter system designed for removal of plaque from arteries. Plaque removal re-opens previously narrowed arteries, allowing increased blood flow to tissue and organs. In June 2003, the U.S. Food and Drug Administration ("FDA") granted 510(k) clearance to market the SilverHawk for treatment of atherosclerosis in the peripheral vasculature. In September 2005, the Company entered into a Collaboration and License Agreement with Merck & Co., Inc. (the "Merck Collaboration Agreement"), pursuant to which the Company and Merck agreed to collaborate on the analysis of atherosclerotic plaque removed from patient arteries. The Company was incorporated in the state of Delaware on September 24, 1996. On October 28, 2004, the Company completed an initial public offering of 4.5 million shares of its common stock at $14.00 per share. Additionally, on October 29, 2004, the underwriters exercised their over-allotment option to purchase 675,000 shares at $14.00 per share. Proceeds from the offering after deducting underwriting discounts and commissions but before expenses were $67.4 million.

### NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

#### Reclassification

Certain amounts in the prior year financial statements have been reclassified to conform to the current year's presentation.

#### 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 and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### Cash and Cash Equivalents

The Company considers all highly-liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2005 and 2004, the Company's cash and cash equivalents were held in financial institutions in the United States and consist of deposits in money market funds and U.S., government securities, which were unrestricted as to withdrawal or use.

#### Restricted Cash

At December 31, 2005 and 2004, restricted cash of $564,000 and $561,000, respectively, represent certificates of deposit held with financial institutions as security deposits for the Company's corporate credit card and building lease. These balances are included in other assets.

#### Investments

The Company classifies all investments as "available-for-sale." Such investments are recorded at fair value and unrealized gains and losses are recorded as a separate component of stockholders' equity (deficit) until realized. Realized gains and losses on the sale of all such securities are reported in net loss, computed using the specific

identification cost method. The Company places its investments primarily in U.S. Government securities, corporate bonds and commercial paper. Unrealized gains and losses on such investments are reported as a separate component of stockholders' equity (deficit).

**Fair Value of Financial Instruments**

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

**Concentration of Credit Risk and Other Risks and Uncertainties**

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents, investments and accounts receivable. The Company's cash, cash equivalents and investments are deposited with two major banks in the United States. The Company is exposed to credit risk in the event of default by these financial institutions for amounts in excess of Federal Deposit Insurance Corporation insured limits. Management believes that the Company's investments in cash, cash equivalents and investments are financially sound and have minimal credit risk. The Company's accounts receivable are derived from revenue earned from customers primarily located in the United States. The Company performs ongoing credit evaluations of its customers' financial condition and generally requires no collateral from its customers.

Prior to the receipt of FDA clearance in June 2003, the Company derived all of its revenue and related accounts receivable balances from sales to the Company's international distributors. No customer accounted for more than 10% of the Company's net revenue for the years ended December 31, 2005 and 2004. For the year ended December 31, 2003, Distributor A accounted for 13% of the Company's net revenue. At December 31, 2005 and 2004, no customer accounted for more than 10% of the Company's accounts receivable.

The Company's products require clearances from the FDA and international regulatory agencies prior to commercialized sales. The SilverHawk has received FDA clearance for treatment of atherosclerosis in the peripheral vasculature. There can be no assurance that the Company's future products will receive required clearances. If the Company was denied such clearances or such clearances were delayed, it could have a materially adverse impact on the Company.

The Company relies on sole-source suppliers to manufacture some of the components used in its product. The Company's manufacturers and suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, including the FDA's Quality System Regulation, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet demand.

**Inventories**

Inventories are stated at the lower of cost or market, cost being determined on a standard cost basis (which approximates actual cost on a first-in, first-out basis) and market being determined as the lower of replacement cost or net realizable value.

**Property and Equipment**

Property and equipment are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the related assets, which are generally two to three years for all property and equipment categories. Amortization of leasehold improvements is computed using the straight-line method over the shorter of the

remaining lease term or the estimated useful life of the related assets. Upon sale or retirement of assets, the costs and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in the statement of operations.

**Impairment of Long-Lived Assets**

In accordance with the provisions of Statement of Financial Accounting Standards Board ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-lived Assets," the Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Under SFAS No. 144, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. The Company considers various valuation factors, principally discounted cash flows, to assess the fair values of long-lived assets. Through December 31, 2005, there have been no such impairments.

**Comprehensive Income (Loss)**

Comprehensive income (loss) generally represents all changes in stockholders' equity (deficit) except those resulting from investments or contributions by stockholders. The Company's unrealized gain (loss) on investments represents the only component of other comprehensive loss that is excluded from the Company's net loss and has been reflected in the statement of stockholders' equity (deficit).

**Revenue Recognition**

The Company generates revenue from the sale of SilverHawk devices and through plaque analysis related to the Merck Collaboration Agreement. The Company recognizes product revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, "Revenue Recognition." SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; title has transferred; the fee is fixed and determinable; and collectibility is reasonably assured. Transfer of title and risk of ownership generally occurs when the product is shipped to the customer or when the customer receives the product, depending on the nature of the arrangement. The Company does not offer any rights of return for product sales to direct and indirect customers. The Company recognizes revenue related to the Merck Collaboration Agreement in accordance with Emerging Issues Task Force Issue No. 00-21 ("EITF 00-21"), Accounting for Revenue Arrangements with Multiple Deliverables. The Merck Collaboration Agreement provides for an initial payment which covers costs associated with the Company's responsibilities and for the rights granted to Merck during the initial year of the research collaboration which was classified as deferred revenue. The Company recognizes revenue as it fulfills its obligations and delivers tissue samples under the Merck Collaboration Agreement.

**Warranties**

The Company maintains a warranty allowance for the estimated amount of repairs or replacement cost of all products which are found to be defective. Provisions for warranty are provided for in the same period that the related product sales are recorded. The amount of allowance is based upon analyses of historical repairs and replacements, known improvements in design and changes in reliability. Although the Company believes it has the ability to reasonably estimate warranty expenses, unforeseeable changes in factors impacting the estimate for warranty could occur and such changes could cause a material change in the Company's warranty accrual

estimate. Such a change would be recorded in the period in which the change was identified. Changes in the Company's warranty liability during the fiscal years ended December 31, 2005 and 2004 were as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2005 | 2004 |
| Balance at January 1 | $ 207 | $ 52 |
| Add: Accruals for warranties | 818 | 1,063 |
| Less: Cost of replacements | (808) | (908) |
| Balance at December 31 | $ 217 | $ 207 |

**Deferred Revenue**

In September 2005, the Company entered into the Merck Collaboration Agreement, pursuant to which the Company and Merck agreed to collaborate on the analysis of atherosclerotic plaque removed from patient arteries with the goal of identifying new biomarkers of atherosclerotic disease progression. Certain payments made by Merck to the Company thereunder must be recognized as revenue on a deferred basis. Upon execution of the Merck Collaboration Agreement, the Company received initial cash payments of $9 million to cover costs associated with the Company's responsibilities and for the rights granted to Merck during the initial year of the research collaboration. The Company recognized $2.8 million as revenue for the year ended December 31, 2005 and will continue to recognize revenue as it fulfills its obligations and delivers tissue samples under the Merck Collaboration Agreement.

**Research and Development Expenditures**

Costs related to research, design and development of products are charged to research and development expense as incurred.

**Advertising Costs**

Advertising costs are included in selling, general and administrative expenses and are expensed as incurred. Advertising costs were $1.3 million, $556,000 and $113,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

**Income Taxes**

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the difference is expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

**Segments**

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. All long-lived assets are maintained in the United States.

### Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by giving effect to all potential dilutive common shares, including options, common stock subject to repurchase, common stock issued under the employee stock purchase plan, warrants and convertible preferred stock. A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per common share follows (in thousands):

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Numerator: | | | |
| Net loss | $(11,611) | $(29,875) | $(14,347) |
| Dividend related to beneficial conversion feature of convertible preferred stock | — | (15,977) | (24) |
| Net loss attributable to common stockholders | $(11,611) | $(45,852) | $(14,371) |
| Denominator: | | | |
| Weighted-average common shares outstanding | 23,483 | 4,709 | 582 |
| Less: Weighted-average unvested common shares subject to repurchase | (508) | (350) | — |
| Weighted-average number of common shares outstanding used in computing basic and diluted net loss per common share | 22,975 | 4,359 | 582 |

The following outstanding options, convertible preferred stock, common stock issued under the employee stock purchase plan, and warrants were excluded from the computation of diluted net loss per common share for the periods presented because including them would have had an antidilutive effect (in thousands):

| | December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Convertible preferred stock | — | — | 10,409 |
| Options to purchase common stock | 4,107 | 4,246 | 2,396 |
| Warrants to purchase convertible preferred stock | — | — | 336 |
| | 4,107 | 4,246 | 13,141 |

### Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees" and its interpretations and complies with the disclosure provisions of SFAS No. 123, "Accounting for Stock-Based Compensation." Under APB Opinion No. 25, compensation expense is based on the difference, if any, on the date of the grant between the fair value of the Company's stock and the exercise price. Employee stock-based compensation is amortized on a straight-line basis over the vesting period of the underlying options. SFAS No. 123 defines a "fair value" based method of accounting for an employee stock option or similar equity investment.

The following table illustrates the effect on net loss if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation arrangements (in thousands, except per share data):

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Net loss attributable to common stockholders, as reported | $(11,611) | $(45,852) | $(14,371) |
| Add: Employee stock-based compensation included in reported net loss | 4,717 | 4,252 | 989 |
| Deduct: Employee total stock-based compensation determined under fair value method | (14,792) | (4,254) | (1,042) |
| Pro forma net loss attributable to common stockholders | $(21,686) | $(45,854) | $(14,424) |
| Net loss attributable to common stockholders per common share, basic and diluted: | | | |
| As reported | $ (0.51) | $ (10.52) | $ (24.69) |
| Pro forma | $ (0.94) | $ (10.52) | $ (24.78) |

The above pro forma effects on net loss may not be representative of the effects on future results as options granted typically vest over several years and additional grants are expected to be made in future years.

Prior to the Company's initial public offering, the fair value for each option grant was determined using the minimum value method. Volatility and dividend yield are not factors in the Company's minimum value calculation. No dividend yield was assumed as the Company has not paid dividends and has no intentions to do so. In accordance with the provisions of SFAS No. 123, the fair value of each option is estimated using the following assumptions:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Weighted-average risk-free interest rate | 3.90% | 3.36% | 2.59% |
| Expected life (in years) | 4 | 4 | 4 |
| Dividend yield | — | — | — |
| Volatility | 75 - 81% | 75% | 0% |

The grant date weighted-average fair value per share of options granted during the years ended December 31, 2005, 2004 and 2003 was $19.75, $8.38, and $2.96, respectively.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force ("EITF") Issue No. 96-18, "Accounting for Equity Instruments that Are Issued to other Than Employees for Acquiring, or in conjunction with Selling Goods, or Services," which require that such equity instruments are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest.

**Recent Accounting Pronouncements**

In November 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 151, "Inventory Costs, an amendment of ARB No. 43, Chapter 4,

("SFAS 151"). SFAS No. 151 amends APB No. 43, Chapter 4, to clarify that abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) should be recognized as current period charges. In addition, SFAS No. 151 requires that allocation of fixed production overhead to the cost of conversion be based on the normal capacity of the production facilities. The provisions of SFAS No. 151 are effective for fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151 is not expected to have a material impact on the Company's financial statements.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Non-monetary Assets, an amendment of APB Opinion No. 29," ("SFAS No. 153"). SFAS No. 153 addresses the measurement of exchanges of non-monetary assets and redefines the scope of transactions that should be measured based on the fair value of the assets exchanged. SFAS No. 153 is effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS No. 153 is not expected to have a material impact on the Company's financial statements.

In December 2004, the FASB issued SFAS No. 123(R), "Share-Based Payment" (revised 2004), ("SFAS No. 123(R)"). SFAS No. 123(R) requires companies to measure all stock-based compensation awards, including grants of employee stock options, using a fair value method and record such expense in the financial statements. In addition, the adoption of SFAS No. 123(R) requires additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. SFAS No. 123(R) as amended, is now effective for public companies for annual, rather than interim, periods that begin after June 15, 2005, which will require the Company to adopt this standard commencing January 1, 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin ("SAB") No. 107, "TOPIC 14: Share-based payment." SAB No. 107 addresses the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides views regarding the valuation of share-based payment arrangements for public companies. SAB No. 107 was effective immediately.

We plan to adopt SFAS 123(R) using the modified prospective method, under which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123(R) for all share-based payments granted after the effective date and (b) based on the previous requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123(R) that remain unvested on the effective date. The amounts disclosed within our footnotes are not necessarily indicative of the amounts that will be expensed upon the adoption of SFAS 123(R). Compensation expense calculated under SFAS 123(R) may differ from amounts currently disclosed within our footnotes based on changes in the fair value of our common stock, changes in the number of options granted or the terms of such options, and changes in interest rates or other factors. Upon adoption of SFAS 123(R), we plan to use the Black-Scholes model to value the compensation expense associated with employee stock options and stock purchases under our employee stock purchase plan. We have completed our assessment of the impact of adopting these new standards. We expect this standard to have a significant impact on the statements of operations and statements of cash flows.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections," ("SFAS No. 154") which establishes, unless impracticable, retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. The statement provides guidance for determining whether retrospective application of a change in accounting principle is impracticable. The statement also addresses the reporting of a correction of an error by restating previously issued financial statements. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 is not expected to have a material impact on the Company's financial statements.

## NOTE 3—INVESTMENTS:

Investments consisted of the following (in thousands):

| | Cost Basis | Unrealized Gains | Unrealized Losses | Fair Value |
|---|---|---|---|---|
| **At December 31, 2005** | | | | |
| US Government securities (maturities less than one year) | $17,685 | $— | $(74) | $17,611 |
| Corporate bonds (maturities less than one year) | 18,080 | — | (25) | 18,055 |
| Total | $35,765 | $— | $(99) | $35,666 |

| | Cost Basis | Unrealized Gains | Unrealized Losses | Fair Value |
|---|---|---|---|---|
| **At December 31, 2004** | | | | |
| US Government securities (maturities less than one year) | $32,306 | $ 1 | $(21) | $32,286 |
| Corporate bonds (maturities less than one year) | 10,622 | 7 | (28) | 10,601 |
| Total | $42,928 | $ 8 | $(49) | $42,887 |

The Company has not experienced any significant realized gains or losses on its investments in the periods presented in the statements of operations.

## NOTE 4—BALANCE SHEET DETAIL:

### Inventories

Inventories consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2005 | 2004 |
| Raw materials | $ 9,808 | $4,833 |
| Work in process | 896 | 1,366 |
| Finished goods | 4,903 | 1,420 |
| | $15,607 | $7,619 |

### Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2005 | 2004 |
| Computer equipment | $ 4,102 | $ 1,846 |
| Machinery and equipment | 5,451 | 3,365 |
| Office furniture and fixtures | 1,210 | 652 |
| Leasehold improvements | 4,532 | 1,431 |
| | 15,295 | 7,294 |
| Less: Accumulated depreciation and amortization | (6,853) | (3,788) |
| | $ 8,442 | $ 3,506 |

**Accrued Liabilities**

Accrued liabilities consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2005 | 2004 |
| Salaries and related expense | $ 7,820 | $3,682 |
| Employee stock purchase plan withholding | 1,273 | 280 |
| Accrued warranty | 217 | 207 |
| Proceeds received on issuance of restricted common stock | 335 | 677 |
| Deferred rent | 1,108 | 324 |
| Accrued sales and use tax | 410 | 222 |
| Other | — | 14 |
| | $11,163 | $5,406 |

## NOTE 5—INCOME TAXES:

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2005 | 2004 |
| **Deferred tax assets:** | | |
| Net operating loss carryforwards | $ 25,965 | $ 18,737 |
| Research and development and other credits | 2,974 | 1,765 |
| Capitalized costs | 92 | 392 |
| Accruals and reserves | 6,802 | 966 |
| Fixed assets | 589 | 292 |
| Total deferred tax asset | $ 36,422 | $ 22,152 |
| Valuation allowance | (36,422) | (22,152) |
| **Net deferred tax asset** | $ — | $ — |

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. We have concluded that it was more likely than not that our deferred tax assets would not be realized. Accordingly, the total deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $14.3 million and $9.0 million during 2005 and 2004, respectively. Of the total valuation allowance amounts listed above, approximately $6.1 million of the valuation allowance at December 31, 2005 relates to tax benefits associated with exercises of stock options, which will reduce income taxes payable and be credited to additional paid-in capital when realized.

As of December 31, 2005, the Company had net operating loss carryforwards of approximately $67.0 million and $65.1 million available to reduce future taxable income, if any, for Federal and State income tax purposes, respectively. The net operating loss carryforwards begin to expire between 2011 and 2006 for Federal and State purposes, respectively, and fully expire in 2025 and 2015, respectively. The Company also had Federal and State research and development credit carryforwards of approximately $1.7 million and $1.8 million, respectively, at December 31, 2005. The Federal credits will expire starting in 2022 if not utilized.

Utilization of the net operating loss carryforward may be subject to an annual limitation due to the ownership percentage change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of the net operating loss before utilization.

## NOTE 6—BORROWINGS:

### Convertible Promissory Notes

In November 2002, the Company entered into convertible promissory note agreements with detachable warrants to purchase shares of Series D convertible preferred stock (See Note 9) with the Company's founder and other investors for an aggregate amount of $2.5 million. The convertible promissory notes accrued interest at 8.0% per annum. In January 2003, the outstanding notes and accrued interest of $43,000 were converted into 840,360 shares of Series D convertible preferred stock.

## NOTE 7—COMMITMENTS AND CONTINGENCIES:

### Leases

In May 2004, the Company entered into a noncancelable operating lease for its Bay Road facility that expires on August 31, 2011. The terms of the facility lease provide for rental payments on a graduated scale. The Company recognizes rent expense on a straight line basis over the lease period and has accrued the rent expense incurred but not paid. In December 2004, in conjunction with the facility lease, the Company issued a standby letter of credit which is collateralized by a certificate of deposit in the amount of $531,000, which is classified as other long term assets. In June 2005, the Company entered into a noncancelable operating lease for its Edison Way facility that expires on February 28, 2007. In November 2005, the Company entered into a noncancelable operating lease for its Stierlin Court facility that expires on December 31, 2016, with the first payment scheduled to commence on January 1, 2007. In addition to monthly base rent, the Company is subject to utility and maintenance fees. The aggregate future minimum rental payments required under the noncancelable operating leases as of December 31, 2005 are as follows (in thousands):

| Years Ending December 31, | |
|---|---|
| 2006 | $ 889 |
| 2007 | 4,656 |
| 2008 | 4,582 |
| 2009 | 4,678 |
| 2010 | 4,789 |
| Thereafter | 25,226 |
| Future minimum rental payments | $44,820 |

Rent expense was $1.0 million, $979,000 and $540,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

### Royalty Obligations

In 1999, the Company entered into a license agreement that requires minimum quarterly royalty payments to the licensor. Under the terms of the agreement, as amended in May 2002, the Company is required to make minimum annual payments of $80,000, $40,000 and $20,000 in equal quarterly installments for the years ended December 31, 2005, 2004 and 2003, respectively. For the calendar year commencing January 1, 2006, and each year thereafter, the quarterly calendar year minimum royalty shall be the prior year's minimum royalty adjusted

by a percentage equal to the percentage change in the "Consumer Price Index for All Urban Consumers" for the prior calendar year as reported by the U.S. Department of Labor. Unless terminated earlier, the term of the license agreement shall continue until the expiration of the last to expire patent that covers that licensed product in such country or for the period of fifteen years following the first bona fide commercial sales of such licensed product in such country, whichever is longer.

### Purchase Agreement

In March 2005, the Company entered into a purchase agreement with one of its suppliers for certain manufacturing components used in the Company's devices. Under the terms of this agreement, the Company will be required to make payments to the supplier for differences between actual purchase quantities and the minimum purchase quantities defined in the agreement.

### 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 future claims that may be made against the Company. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations, and accordingly, the Company has not accrued any amounts for such indemnification obligations. However, the Company may record charges in the future as a result of these potential indemnification obligations.

### Contingencies

From time to time, the Company may become involved in litigation relating to claims arising from the ordinary course of business. Management is not currently aware of any matters that will have a material adverse effect on the financial position, results of operations or cash flows of the Company.

## NOTE 8—INITIAL PUBLIC OFFERING:

On October 28, 2004, the Company completed an initial public offering of 4.5 million shares of its common stock. Additionally, on October 29, 2004, the underwriters exercised their over-allotment option of 675,000 shares. Proceeds from the offering after deducting underwriting discounts and commissions but before expenses were $67.4 million. Upon the closing of the offering, all the Company's outstanding shares of convertible preferred stock converted into 15,557,097 shares of common stock.

## NOTE 9—CONVERTIBLE PREFERRED STOCK:

Under the Company's Amended and Restated Certificate of Incorporation, as amended, the Company's convertible preferred stock is issuable in series and the Company's Board of Directors is authorized to determine the rights, preferences and terms of each series.

Upon the closing of the initial public offering, all of the Company's outstanding shares of convertible preferred stock converted into 15,557,097 shares of common stock.

### 2004 Preferred Stock Plan

In May 2004, the Company adopted the 2004 Preferred Stock Plan. The Board of Directors terminated the 2004 Preferred Stock Plan in August 2004. However, the 2004 Preferred Stock Plan will continue to govern the terms

and conditions of the outstanding awards granted thereunder. The Board of Directors has the authority to amend the 2004 Preferred Stock Plan provided such action does not impair the rights of any participant.

A total of 275,000 shares of the Series E convertible preferred stock was reserved for issuance pursuant to the 2004 Preferred Stock Plan. During 2004, the Company granted rights to purchase 222,741 shares of Series E convertible preferred stock that vest over one year. All such stock rights have been exercised resulting in the issuance of Series E restricted preferred stock. Upon the completion of the initial public offering, all remaining unvested shares of Series E restricted preferred stock, net of cancellations, were immediately vested.

**Beneficial Conversion Feature**

The issuance of Series D and Series E convertible preferred stock resulted in a deemed dividend associated with the beneficial conversion feature, calculated in accordance with EITF No. 00-27, "Application of Issue No. 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features of Contingently Adjustable Conversion Ratios" to Certain Convertible Instruments" based on the conversion price of the preferred stock into common, and the fair value of the common stock at the date of issuance. Accordingly, the Company has recognized $16.0 million and $24,000 as a charge to additional paid-in-capital to account for the deemed dividend on the redeemable convertible preferred stock as of the issuance date in 2004 and 2003, respectively. The amount of the deemed dividend related to the beneficial conversion feature was recorded upon issuance of the convertible preferred stock, as the convertible preferred stock was convertible into common stock by the holder at any time.

As described above, certain employees were granted purchase rights to acquire Series E convertible preferred stock. The difference between the purchase price and the fair value of the common stock on the date of issuance was recorded as deferred compensation and was amortized to compensation expense over the vesting period. Upon the completion of the initial public offering, any remaining unamortized deferred compensation was expensed.

**Warrants for Convertible Preferred Stock**

In connection with the convertible promissory notes issued in November 2002, the Company issued warrants to purchase 212,670 shares of Series D convertible preferred stock at an exercise price of $3.04 per share. The warrants were immediately exercisable, had a term of seven years and expire upon a change of control or upon an initial public offering of the Company's common stock. The allocated fair value of the warrants of $287,000 was calculated using the Black-Scholes pricing model with the following assumptions: fair value of the preferred stock at the date of issuance of $3.04 per share, an estimated life of seven years, an annual risk free rate of 2.21%, volatility of 75% and no future dividends. The value of these warrants was recorded as a discount against the related promissory notes and was amortized to interest expense over one year, the term of the promissory notes, using the straight line method as the difference between the effective interest method and the straight-line method was deemed to be immaterial. In January 2003, the promissory notes were converted into shares of Series D convertible preferred stock (See Note 6). Accordingly, amortization of the discount against the promissory notes ceased and the remaining unamortized discount was netted against the carrying value of the converted promissory notes.

In October 2004, prior to the initial public offering, 84,610 warrants were exercised resulting in cash proceeds totaling $257,000 and 100,251 warrants were net exercised with 27,809 warrants given up in exchange for the issuance of 184,861 shares of Series D convertible preferred stock. Simultaneously upon the closing of the initial public offering, the Series D convertible preferred shares were automatically converted into shares of common stock.

## NOTE 10—COMMON STOCK:

Each share of common stock has the right to one vote. The holders of common stock are entitled to dividends when funds are legally available and when declared by the Board of Directors, subject to the prior rights of the convertible preferred stockholders.

### 2004 Employee Stock Purchase Plan

In July 2004, the Company adopted the 2004 Employee Stock Purchase Plan. A total of 600,000 shares of common stock have been made available for sale. In addition, the 2004 Employee Stock Purchase Plan provides for annual increases in the number of shares available for issuance under the 2004 Employee Stock Purchase Plan on the first day of each fiscal year, beginning with the Company's fiscal year 2005, equal to the lesser of: 2% of the outstanding shares of the Company's common stock on the first day of the fiscal year; 1,000,000 shares; and 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 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 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 generally start on the first trading day on or after May 1 and November 1 of each year. The Company's 2004 Employee Stock Purchase Plan permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation which includes a participant's base salary, wages, overtime pay, commissions, and other compensation remuneration paid directly to the employee. A participant may purchase a maximum of 5,000 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 price is 85% of the lower of the fair market value of the Company's common stock at the beginning of an offering period or after a purchase period end. If the fair market value at the end of a purchase period is less than the fair market value at the beginning 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 payroll deductions to date. Participation ends automatically upon termination of employment with the Company. The 2004 Employee Stock Purchase Plan will automatically terminate in 2024, unless the Company terminates it sooner. As of December 31, 2005, 338,665 shares have been issued to date in connection with the 2004 Employee Stock Purchase Plan.

## NOTE 11—STOCK OPTION PLANS:

### 1997 Stock Plan

In March 1997, the Company adopted the 1997 Stock Plan under which the Board of Directors may issue incentive stock options to employees and non-qualified stock options to employees, directors and consultants. The Board of Directors has the authority to determine to whom options will be granted, the number of shares, the term and exercise price (which cannot be less than fair market value at date of grant for incentive stock options or 85% of fair market value for nonqualified stock options). If an individual owns stock representing more than 10% of the outstanding shares, the price of each share shall be at least 110% of fair market value, as determined by the Board of Directors. The options are exercisable at times and increments as specified by the Board of Directors and generally expire 10 years from the date of grant. Upon the completion of the initial public offering, the Company's 1997 Stock Plan was terminated and the Board of Directors determined not to grant any

additional awards under the 1997 Plan. However, the 1997 Plan will continue to govern the terms and conditions of the outstanding awards issued thereunder.

**2004 Equity Incentive Plan**

In July 2004, the Company adopted the 2004 Equity Incentive Plan, or the 2004 Plan, under which the Board of Directors may issue incentive stock options to employees and non-statutory stock options, restricted stock, stock appreciation rights, performance units and performance shares to employees, directors and consultants. The 2004 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year, beginning with fiscal year 2005, equal to the lesser of: 5% of the outstanding shares of the Company's common stock on the first day of the fiscal year; 2,500,000 shares; and such other amount as the Board of Directors may determine. The number of shares authorized for issuance under the 2004 Equity Incentive Plan will also be increased by any shares returned to the 1997 Stock Plan on or after the completion of the public offering as a result of the termination of options or the repurchase of unvested shares issued thereunder. There were 2,250,000 and 1,150,450 additional shares reserved for issuance in 2004 and 2005, respectively.

The Board of Directors has the authority to determine to whom options will be granted, the number of shares, the term and exercise price (which cannot be less than fair market value at date of grant for incentive stock options or 85% of fair market value for nonqualified stock options). If an individual owns stock representing more than 10% of the outstanding shares, the price of each share shall be at least 110% of fair market value, as determined by the Board of Directors. The options are exercisable at times and increments as specified by the Board of Directors, and generally expire 10 years from the date of grant.

Activity under the 1997 and 2004 Plans are as follows:

| | Shares Available for Grant | Outstanding Options | | |
|---|---|---|---|---|
| | | Number of Shares | Range of Exercise Prices | Aggregate Price |
| **Balances, December 31, 2002** | 2,112,307 | 582,474 | $ 0.40-2.16 | $ 672,000 |
| Options granted | (1,949,850) | 1,949,850 | 0.32 | 642,000 |
| Options exercised | — | (37,833) | 0.40-2.16 | (32,000) |
| Options cancelled | 148,739 | (148,739) | 0.84-2.16 | (80,000) |
| **Balances, December 31, 2003** | 311,196 | 2,345,752 | 0.32-2.16 | 1,202,000 |
| Reservation of shares | 2,250,000 | — | — | — |
| Options granted | (2,654,251) | 2,654,251 | 0.32-24.02 | 10,451,000 |
| Options exercised | — | (733,533) | 0.32-4.00 | (361,000) |
| Options cancelled | 115,678 | (115,678) | 0.32-11.68 | (204,000) |
| **Balances, December 31, 2004** | 22,623 | 4,150,792 | 0.32-24.02 | 11,088,000 |
| Reservation of shares | 1,150,450 | — | — | — |
| Options granted | (1,280,820) | 1,280,820 | 27.93-53.73 | 44,026,000 |
| Options exercised | — | (1,207,075) | 0.32-24.02 | (2,093,000) |
| Options cancelled | 169,053 | (169,053) | 0.32-50.69 | (2,691,000) |
| **Balances, Dec 31, 2005** | 61,306 | 4,055,484 | $ 0.32-53.73 | $50,330,000 |

In addition to the 1997 and 2004 Plans, in March 2003, the Company granted to a consultant a non-qualified stock option to purchase 50,000 shares of the Company's common stock at an exercise price of $0.32 per share

that vests over two years, all of which were exercised in April 2005. The Company recorded stock-based compensation based on the fair value of the stock option on the date of grant, which was calculated using the Black-Scholes option pricing model in accordance with the weighted-average assumptions disclosed further below.

The options outstanding and currently exercisable by exercise price at December 31, 2005 are as follows:

| | Options Outstanding | | | Options Exercisable | | | Options Vested | |
|---|---|---|---|---|---|---|---|---|
| Range of Exercise Price | Number Outstanding | Weighted-Average Remaining Contractual Life in Years | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Life in Years | Options Exercisable | Weighted-Average Exercise Price | Options Vested | Weighted-Average Exercise Price |
| $ 0.32 | 1,502,535 | 7.71 | $ 0.32 | 7.72 | 1,502,535 | $ 0.32 | 487,533 | $ 0.32 |
| 0.40 | 5,000 | 1.95 | 0.40 | 1.95 | 5,000 | 0.40 | 5,000 | 0.40 |
| 0.84 | 145,348 | 5.66 | 0.84 | 5.61 | 145,348 | 0.84 | 135,206 | 0.84 |
| 2.00 | 259,797 | 8.34 | 2.00 | 8.34 | 259,797 | 2.00 | 45,083 | 2.00 |
| 2.16 | 97,796 | 4.04 | 2.16 | 4.04 | 97,796 | 2.16 | 97,796 | 2.16 |
| 4.00 | 454,957 | 8.55 | 4.00 | 8.55 | 454,957 | 4.00 | 77,693 | 4.00 |
| 11.68 | 297,739 | 8.81 | 11.68 | 8.81 | 297,739 | 11.68 | 66,006 | 11.68 |
| 24.02 | 75,242 | 1.49 | 24.02 | 1.47 | 18,993 | 24.02 | 18,993 | 24.02 |
| 27.93 | 200,250 | 9.32 | 27.93 | 9.32 | 1,041 | 27.93 | 1,041 | 27.93 |
| 28.20 - 29.80 | 453,925 | 9.09 | 28.24 | 9.08 | 200 | 28.20 | 200 | 28.20 |
| 30.12 - 31.00 | 89,025 | 9.17 | 30.35 | 9.10 | 6,500 | 30.18 | 6,500 | 30.18 |
| 34.39 - 39.71 | 185,200 | 9.47 | 38.13 | — | — | — | — | — |
| 41.88 - 46.88 | 166,220 | 9.75 | 44.80 | — | — | — | — | — |
| $47.47 - 53.73 | 122,450 | 9.61 | 51.31 | — | — | — | — | — |
| | 4,055,484 | 8.13 | $12.41 | 7.74 | 2,789,906 | $ 2.62 | 941,051 | $ 2.49 |

The weighted-average exercise price of all options outstanding at December 31, 2005, 2004 and 2003 was $12.41, $2.63, and $0.51, respectively. As of December 31, 2004, 4,200,792 options were outstanding and exercisable with a weighted average exercise price of $0.79.

On May 3, 2004, the board of directors approved a resolution that allows for the early exercise of all previously granted options and all options to be granted in the future under the Company's 1997 Stock Plan. Under the terms of this amendment, option holders, upon early exercise, must sign a restricted stock purchase agreement that gives the Company the right to repurchase any unvested shares, at the original exercise price, in the event the optionees' employment terminates for any reason. The right to exercise options before they are vested does not change existing vesting schedules in any way and the early-exercised options may not be sold or transferred before they vest. The repurchase right lapses over time as the shares vest at the same rate as the original option vesting schedule. At December 31, 2005 and 2004, a total of 332,273 and 749,435 shares of common stock at an aggregate price of $335,000 and $677,000, respectively, were subject to repurchase. As such, in accordance with FASB Interpretations ("FIN") No. 44 "Accounting for Certain Transactions Involving Stock Compensation," the unvested shares as of December 31, 2005 and 2004 are not considered issued for accounting purposes and the options are deemed not to be exercised until the options vest. These options have therefore been excluded from the number of options exercised as of December 31, 2005.

**Deferred Stock-Based Compensation**

During the years ended December 31, 2004 and 2003, the Company issued options to certain employees under the 1997 Stock Plan and the 2004 Preferred Stock Plan with exercise prices below the fair market value of the

Company's common stock at the date of grant, determined with hindsight. The Company estimated the fair value of its common stock based upon several factors, including progress and milestones attained in its business, sales of convertible preferred stock, changes in valuations of existing comparable public companies and the expected valuation that the Company would obtain in an initial public offering. The Company has reviewed these key factors and events between each date and has determined that the combination of these factors and events reflect a true measurement of the Company's relative fair value over an extended period of time and believes that the fair value of its common stock is appropriately reflected using a linear progression. In accordance with the requirements of APB No. 25, the Company has recorded deferred stock-based compensation for the difference between the exercise price of the stock option and the fair market value of the Company's stock at the date of grant. This deferred stock-based compensation is amortized to expense on a straight-line basis over the period during which the Company's right to repurchase the stock lapses or the options vest, generally four years. During the years ended December 31, 2004 and 2003, the Company has recorded deferred stock-based compensation, net of cancellations, related to these options of approximately $14.8 million and $4.7 million, respectively.

The Company granted stock options to employees with exercise prices below estimated fair market value as follows:

| Grants Made During Quarter Ended | Number of Options Granted (000's) | Weighted-Average Exercise Price Per Share | Weighted-Average Fair Value Per Share | Weighted-Average Intrinsic Value Per Share |
|---|---|---|---|---|
| March 31, 2003 | 1,564 | $0.32 | $ 2.56 | $2.24 |
| June 30, 2003 | — | — | — | — |
| September 30, 2003 | 89 | 0.32 | 4.60 | 4.28 |
| December 31, 2003 | 164 | 0.32 | 6.16 | 5.84 |
| March 31, 2004 | 1,063 | 0.32 | 7.68 | 7.36 |
| June 30, 2004 | 621 | 3.44 | 9.76 | 6.32 |
| September 30, 2004 | 640 | 4.00 | 10.79 | 6.79 |

**Stock-Based Compensation**

During the years ended December 31, 2005, 2004 and 2003, the Company granted options to non-employees to purchase 12,750, 118,875, and 181,250 shares of common stock, respectively, in exchange for services, at a range of exercise prices between $0.32 and $30.35 per share. Stock-based compensation expense related to stock options granted to non-employees is recognized on a straight-line basis, as the stock options are earned. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the consulting services received. The fair value of the stock options granted is calculated at each reporting date using the Black-Scholes option pricing model as prescribed by SFAS No. 123 with the following weighted-average assumptions:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Risk-free interest rate | 4.09 - 4.51% | 3.86 - 4.62% | 3.87 - 4.58% |
| Expected life (in years) | 10 | 10 | 10 |
| Dividend yield | — | — | — |
| Expected volatility | 75 - 81% | 75% | 75% |

The stock-based compensation expense will fluctuate as the fair market value of the common stock fluctuates. In connection with the grant of stock options to non-employees, the Company recorded stock-based compensation

expense of $2.4 million, $1.8 million, and $447,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

## NOTE 12—RELATED PARTY TRANSACTIONS:

On May 21, 2004, the Company entered into a Consulting Agreement with John Simpson, Ph.D., M.D. under which Dr. Simpson provides the Company with consulting services. For services provided under the Consulting Agreement, Dr. Simpson is paid $25,000 per month. During the year ended December 31, 2005, the Company paid $300,000 under the consulting agreement. At December 31, 2005, no amounts were due or outstanding. On January 18, 2006, Dr. Simpson signed an offer letter that sets forth his compensation as Interim Chief Executive Officer, thus terminating his consulting arrangement (See Note 14).

We entered into an agreement with JBS Consulting, LLC ("JBS Consulting") and an agreement with JBS Consulting and Dr. Simpson, both effective as of September 1, 2005, regarding the use of a private aircraft owned by JBS Consulting for company business related travel by the Company's directors, officers and employees. Dr. Simpson is the president and managing officer of JBS Consulting. Pursuant to these agreements, JBS Consulting will be reimbursed for the cost of first class airfare for all flights in connection with company business related travel by Dr. Simpson and the cost of coach airfare for all flights in connection with company business related travel by other directors, officers, and employees.

## NOTE 13—EMPLOYEE BENEFIT PLANS:

In September 1997, the Company adopted its 401(k) Retirement Plan which covers substantially all employees. Eligible employees may make salary deferral (before tax) contributions up to a specified maximum. The Company, at its discretion, may make additional matching contributions on behalf of the participants in the 401(k) Retirement Plan. To date, the Company has not made any contributions to the 401(k) Retirement Plan.

## NOTE 14—SUBSEQUENT EVENTS:

In January 2006, John Simpson, Ph.D., M.D. signed an offer letter that sets forth his compensation as Interim Chief Executive Officer. The Company will pay him a monthly salary of $25,000 retroactive to his first day of employment which was January 4, 2006. His base salary may be reviewed and adjusted by the Compensation Committee of the Board of Directors from time to time. This compensation is equivalent to that paid to Dr. Simpson under his consulting arrangement, which terminated upon Dr. Simpson assuming his new role as interim Chief Executive Officer.

In January 2006, in conjunction with the Stierlin Court facility lease, the Company issued a standby letter of credit for drawings up to $500,000. This letter of credit will expire in January 2007 and will automatically extend without amendment for one year periods from the expiration date or any future expiration date, subject to cancellation by the Company.

## NOTE 15—QUARTERLY FINANCIAL DATA (UNAUDITED):

**The following tables contain selected unaudited Statement of Operations data for each quarter for 2005 and 2004 (in thousands, except per share data):**

| | Year 2005 Quarter Ended | | | |
|---|---|---|---|---|
| | Mar. 31, | June 30, | Sept. 30, | Dec. 31, |
| Revenue: | | | | |
| Product | $21,478 | $ 28,724 | $35,645 | $39,515 |
| Research collaboration | — | — | 431 | 2,363 |
| Net revenue | 21,478 | 28,724 | 36,076 | 41,878 |
| Loss from operations | (6,942) | (3,924) | (1,923) | (721) |
| Net loss | (6,523) | (3,442) | (1,486) | (160) |
| Net loss per common share: | | | | |
| Basic and diluted | $ (0.29) | $ (0.15) | $ (0.06) | $ (0.01) |
| Weighted-average number of shares used in per common share calculations: | | | | |
| Basic and diluted | 22,345 | 22,711 | 23,189 | 23,642 |

| | Year 2004 Quarter Ended | | | |
|---|---|---|---|---|
| | Mar. 31, | June 30, | Sept. 30, | Dec. 31, |
| Revenue: | | | | |
| Product | $ 4,775 | $ 7,497 | $11,581 | $14,699 |
| Research collaboration | — | — | — | — |
| Net revenue | 4,775 | 7,497 | 11,581 | 14,699 |
| Loss from operations | (6,218) | (8,837) | (7,482) | (7,711) |
| Net loss | (6,192) | (8,809) | (7,421) | (7,453) |
| Dividend related to beneficial conversion feature of convertible preferred stock | (1,780) | (14,197) | — | — |
| Net loss attributable to common stockholders | (7,972) | (23,006) | (7,421) | (7,453) |
| Net loss per common share: | | | | |
| Basic and diluted | $(12.48) | $ (29.65) | $ (6.83) | $ (0.50) |
| Weighted-average number of shares used in per common share calculations: | | | | |
| Basic and diluted | 639 | 776 | 1,087 | 14,933 |

## SCHEDULE II

## VALUATION AND QUALIFYING ACCOUNTS

**(in thousands)**

| Allowance for doubtful accounts receivable: | Balance at Beginning of Period | Additions | Deductions | Balance at End of Period |
|---|---|---|---|---|
| Year ended December 31, 2003 | $ — | $ 39 | $ — | $ 39 |
| Year ended December 31, 2004 | 39 | 285 | — | 324 |
| Year ended December 31, 2005 | $ 324 | $ 678 | $ — | $ 1,002 |

| Allowance for inventories valuation: | Balance at Beginning of Period | Additions | Deductions | Balance at End of Period |
|---|---|---|---|---|
| Year ended December 31, 2003 | $ — | $ 142 | $ — | $ 142 |
| Year ended December 31, 2004 | 142 | 968 | (142) | 968 |
| Year ended December 31, 2005 | $ 968 | $ 3,922 | $(2,557) | $ 2,333 |

| Valuation allowance for deferred tax assets: | Balance at Beginning of Period | Additions | Deductions | Balance at End of Period |
|---|---|---|---|---|
| Year ended December 31, 2003 | $12,187 | $ 951 | $ — | $13,138 |
| Year ended December 31, 2004 | 13,138 | 9,014 | — | 22,152 |
| Year ended December 31, 2005 | $22,152 | $14,270 | $ — | $36,422 |

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
FoxHollow Technologies, Inc.:

We have completed an integrated audit of FoxHollow Technologies, Inc.'s 2005 financial statements and of its internal control over financial reporting as of December 31, 2005 and audits of its 2004 and 2003 financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

***Financial statements and financial statement schedule***

In our opinion, the financial statements listed in the accompanying index present fairly, in all material respects, the financial position of FoxHollow Technologies, Inc. at December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements 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.

***Internal control over financial reporting***

Also, in our opinion, management's assessment, included in the accompanying Report of Management on Internal Control Over Financial Reporting, that the Company maintained effective internal control over financial reporting as of December 31, 2005 based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control—Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting

includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

San Jose, California
February 28, 2006

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

None.

## ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures. Based on the evaluation of our disclosure controls and procedures (as defined in the Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) required by Exchange Act Rules 13a-15(b) or 15d-15(b), our principal executive officer and principal financial officer have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed by the company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and include controls and procedures designed to ensure that information required to be disclosed by us in such reports is accumulated and communicated to our management, including the principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure..

(b) Report of management on internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States. Internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles in the United States, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions and that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2005. In making this assessment, management used the criteria set forth in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on its assessment and those criteria, management concluded that the company maintained effective internal control over financial reporting as of December 31, 2005. Management's assessment of the effectiveness of the company's internal control over financial reporting as of December 31, 2005 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included in Item 8 of this Annual Report on Form 10-K.

(c) Changes in internal control over financial reporting. There were no changes in our internal control over financial reporting that occurred during our fourth fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

(d) Certificates. Certificates with respect to disclosure controls and procedures and internal control over financial reporting under Rule 13a-14(a) of the Exchange Act are attached as exhibits 31.1 and 31.2 to this annual report on Form 10-K.

## ITEM 9B. OTHER INFORMATION

We entered into an agreement with JBS Consulting, LLC ("JBS Consulting") and an agreement with JBS Consulting and Dr. Simpson, both effective as of September 1, 2005, regarding the use of a private aircraft owned by JBS Consulting for company business related travel by the Company's directors, officers and employees. Dr. Simpson is the president and managing officer of JBS Consulting. Pursuant to these agreements, JBS Consulting will be reimbursed for the cost of first class airfare for all flights in connection with company business related travel by Dr. Simpson and the cost of coach airfare for all flights in connection with company business related travel by other directors, officers, and employees.

# PART III

## ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2006 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our 2005 fiscal year (the "2006 Proxy Statement").

## ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the 2006 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 2006 Proxy Statement.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item is incorporated by reference to the 2006 Proxy Statement.

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to the 2006 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) The financial statement schedules required by Item 15(a) are filed in Item 8 of the Annual Report on Form 10-K.

(3) Exhibits.

| Exhibit Number | Description |
|---|---|
| 3.2* | Amended and Restated Certificate of Incorporation. |
| 3.4* | Bylaws. |
| 4.2* | Amended and Restated Specimen Common Stock certificate. |
| 10.1* | Form of Indemnification Agreement for directors and executive officers. |
| 10.2* | 1997 Stock Plan. |
| 10.3* | 2004 Equity Incentive Plan. |
| 10.4* | 2004 Employee Stock Purchase Plan. |
| 10.5* | 2004 Preferred Stock Plan. |
| 10.6* | Amended and Restated Investors' Rights Agreement, dated February 24, 2004, by and among the Registrant and certain stockholders. |
| 10.7* | First Amendment to Amended and Restated Investors' Rights Agreement, dated May 21, 2004, by and among the Registrant and certain stockholders. |
| 10.10* | Office Building Lease, dated May 3, 2004, by and between the Registrant and Woodside Technology Center, LLC for office space located at 740 Bay Road, Redwood City, California. |
| 10.11†* | Master License Agreement dated August 24, 1999, by and between the Registrant and Surmodics, Inc., as amended. |
| 10.13* | Second Amendment to Amended and Restated Investors' Rights Agreement, dated October 25, 2004, by and among the Registrant and certain stockholders. |
| 10.14†** | Supplier Agreement between the Registrant and Norman Noble, Inc. dated March 25, 2005. |
| 10.15†*** | Collaboration and License Agreement between the Registrant and Merck & Co. Inc. dated September 14, 2005. |
| 10.16 | Time-sharing Agreement dated September 1, 2005, by and between the Registrant and JBS Consulting, LLC. |
| 10.17 | Reimbursement Agreement dated September 1, 2005, by and among the Registrant, John B. Simpson, and JBS Consulting, LLC. |
| 10.18 | Office Building Lease, dated November 1, 2005, by and between the Registrant and Brittania Hacienda VIII LLC for office space located at 2081 Stierlin Court, Mountain View, California. |
| 23.1 | Consent of Independent Registered Public Accounting Firm |
| 31.1 | Certification of Interim 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 Interim Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

* Incorporated by reference from our Registration Statement on Form S-1 (Registration No. 333-118191), which was declared effective on October 27, 2004.

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

** Incorporated by reference from our Form 10-Q for the quarter ended March 31, 2005 filed May 13, 2005.

*** Incorporated by reference from our Form 10-Q for the quarter ended September 30, 2005 filed November 1, 2005.

## 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 7, 2006

FoxHollow Technologies, Inc.

By: /s/ John B. Simpson
John B. Simpson
Interim 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 John B. Simpson and Matthew B. Ferguson, his or her attorney-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this annual report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute, may do or cause to be done by virtue thereof.

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

| Signature | Title | Date |
|---|---|---|
| /s/ JOHN B. SIMPSON<br>John B. Simpson | Interim Chief Executive Officer and Director (Principal Executive Officer) | March 7, 2006 |
| /s/ MATTHEW B. FERGUSON<br>Matthew B. Ferguson | Chief Financial Officer (Principal Accounting Officer) | March 7, 2006 |
| /s/ RYAN D. DRANT<br>Ryan D. Drant | Director | March 7, 2006 |
| /s/ JEFFREY B. CHILD<br>Jeffrey B. Child | Director | March 7, 2006 |
| /s/ MYRTLE S. POTTER<br>Myrtle S. Potter | Director | March 7, 2006 |
| /s/ SANFORD FITCH<br>Sanford Fitch | Director | March 7, 2006 |
| /s/ TOMOAKI HINOHARA<br>Tomoaki Hinohara | Director | March 7, 2006 |

**EXHIBIT 31.1**

## CERTIFICATION OF INTERIM CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John B. Simpson, certify that:

1. I have reviewed this annual report on Form 10-K of FoxHollow Technologies, Inc.;

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

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

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

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

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 7, 2006

By: /s/ John B. Simpson

John B. Simpson
Interim Chief Executive Officer and Director
(Principal Executive Officer)

**EXHIBIT 31.2**

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Matthew B. Ferguson, certify that:

1. I have reviewed this annual report on Form 10-K of FoxHollow Technologies, Inc.;

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

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

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

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

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 7, 2006

By: /s/ Matthew B. Ferguson

Matthew B. Ferguson
Chief Financial Officer
(Principal Accounting and Financial Officer)

**EXHIBIT 32.1**

**CERTIFICATION OF INTERIM CHIEF EXECUTIVE OFFICER**
**PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, John B. Simpson, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of FoxHollow Technologies, Inc. on Form 10-K for the fiscal year ended December 31, 2005 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of FoxHollow Technologies, Inc.

Date: March 7, 2006

By: /s/ John B. Simpson

John B. Simpson
Interim Chief Executive Officer and Director
(Principal Executive Officer)

**EXHIBIT 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**

I, Matthew B. Ferguson, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of FoxHollow Technologies, Inc. on Form 10-K for the fiscal year ended December 31, 2005 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of FoxHollow Technologies, Inc.

Date: March 7, 2006

By: /s/ Matthew B. Ferguson

Matthew B. Ferguson
Chief Financial Officer
(Principal Accounting and Financial Officer)

# Letter to shareholders:

Since the U.S. introduction of SilverHawk, an estimated 55,000 patients have had plaque removed from their legs with our device. My aunt was one of them.

Although she had suffered from leg pain for years and eventually developed a sore on her calf that just wouldn't heal, Aunt Dorothy was never diagnosed with PAD until it was almost too late. Her doctors believed that her only option was an amputation right below the knee. As an active 92-year-old who thoroughly enjoyed every minute of life, she was devastated. Fortunately, Aunt Dorothy got a second opinion. She was successfully treated in Austin, Texas with the SilverHawk and kept her leg.

For every Aunt Dorothy though, there are thousands of people across the country who either continue to suffer with debilitating leg pain or face an amputation. The 542 employees of FoxHollow will not rest until we reach each and every one of them.

The first step toward this goal is training physicians to perform plaque excision, and educating referring physicians to recognize and diagnose PAD patients so that they can be treated earlier. To accomplish these initiatives, we tripled the size of our sales force to broaden our reach and impact. We held 41 different medical education meetings across the country, which collectively drew 740 physicians. As one example of these programs, we initiated two national medical meetings focused exclusively on in-depth technique training related to the assessment, diagnosis and treatment of critical limb ischemia, which is the condition that most often leads to amputations. Over 400 physicians attended.

Education does not stop with the physicians who perform the SilverHawk procedure. In 2005, our sales force began actively calling on podiatrists. Podiatrists in the U.S. see millions of patients each year, many of whom have diabetes and are at the highest risk for PAD. We have found that connecting local podiatrists to SilverHawking physicians in their area results in real clinical benefit for the patient.

We also began efforts to educate PAD patients directly. In 2005, almost 700 stories on SilverHawk appeared in newspapers, magazines and on television across the country.

Our financial results reflect our success in rapidly increasing the awareness and adoption of SilverHawk. Our active customer base almost doubled in the year to 1,042 hospitals nationwide. As compared to 2004, FoxHollow's gross revenue grew 232% from $38.6 million to $128.2 million.

At the same time, we dramatically improved our bottom line by increasing gross margin from 37% in 2004 to 69% in 2005. As a result of this performance, the company is now approaching profitability.

We also met major milestones related to production capacity and output, which were essential in order to continue to meet growing demand. We tripled our capacity in 2005 due to productivity gains and a new clean room space, which is more than double the size of the old facility. As a result, we were able to manufacture 2.5 times the number of devices in 2005 compared to 2004.

One of the most exciting aspects of 2005 was the formal establishment of FHT Biologics and the announcement of our research agreement with Merck. The first focus of this joint effort is to identify novel gene and protein markers inside the plaque removed from the leg arteries.

Within six months of establishing our partnership, FoxHollow completed enrollment on six different research studies, which already have yielded new information about vascular disease. Perhaps the most important question to answer first was whether the plaque is information-rich. We now know that it is. Are there genomic differences between diabetics and non-diabetics? Between blockages located above the knee vs. below the knee? Between people who have new blockages and those that have recurrent blockages? Based on early scientific research of the plaque, we now know the answer to all of these questions is yes.

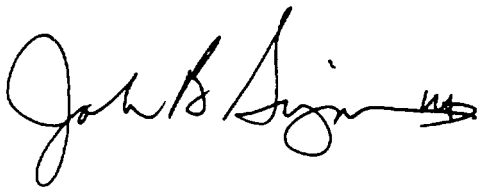
The ultimate vision behind FHT Biologics is to treat cardiovascular disease on the basis of each individual's biology, not just a set of broadly shared symptoms. By uncovering new biomarkers, we also begin the process of accelerating new drug and diagnostic development. Lastly, these markers may help us spot which types of plaque in the heart are most likely to rupture and cause fatal heart attacks. The science underlying these future discoveries is early, but extremely exciting.

FoxHollow's obsession with forward-reaching research and development extends further beyond biologics. In 2005, we launched three new devices, the MS, the LS-F and the MS-F. In addition, we met significant R&D milestones on the NightHawk, a plaque excision catheter embedded with a tiny fiber optic viewing system. The system will allow physicians to know the exact thickness of the artery wall at the site where they are excising the plaque.

A coronary version of the SilverHawk System is also in development. Because the heart continually beats during coronary artery procedures, an imaging component could significantly enhance precision. For this reason, we decided to start our coronary clinical trial after the NightHawk technology was successfully applied to the coronary device.

On Page 11 of this report, you'll find pictures of patients who have PAD. Each has a story. Each has a life. And, each of them chose to believe plaque excision could help.

Thank you for believing in us too.



John B. Simpson, Ph.D., M.D.
INTERIM CHIEF EXECUTIVE OFFICER

# Statement of Operations Data

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2005 | 2004 | 2003 | 2002 | 2001 |
| | (in thousands, except per share data) | | | | |
| Revenue: | | | | | |
| Product | $ 125,362 | $ 38,552 | $ 2,585 | $ 12 | $ — |
| Research collaboration | 2,794 | — | — | — | — |
| Net revenue | 128,156 | 38,552 | 2,585 | 12 | — |
| Costs and expenses: | | | | | |
| Product (1) | 39,335 | 24,144 | 4,503 | 95 | — |
| Research collaboration | 614 | — | — | — | — |
| Research and development (1) | 10,321 | 6,191 | 5,785 | 6,570 | 4,360 |
| Selling, general and administrative (1) | 91,396 | 38,465 | 6,792 | 1,548 | 989 |
| Total costs and expenses | 141,666 | 68,800 | 17,080 | 8,213 | 5,349 |
| Loss from operations | (13,510) | (30,248) | (14,495) | (8,201) | (5,349) |
| Interest and other income | 1,945 | 376 | 183 | 73 | 210 |
| Interest and other expense | (46) | (3) | (35) | (78) | (278) |
| Net loss | (11,611) | (29,875) | (14,347) | (8,206) | (5,417) |
| Dividend related to beneficial conversion feature of convertible preferred stock (2) | — | (15,977) | (24) | — | — |
| Net loss attributable to common stockholders | $ (11,611) | $ (45,852) | $(14,371) | $ (8,206) | $ (5,417) |
| Net loss per common share: Basic and diluted | $ (0.51) | $ (10.52) | $ (24.69) | $ (15.00) | $ (10.28) |
| Weighted-average number of shares used in per common share calculations: Basic and diluted | 22,975 | 4,359 | 582 | 547 | 527 |

(1) Includes the following stock-based compensation charges:

| | | | | | |
|---|---|---|---|---|---|
| Costs and expenses: | $ 550 | $727 | $ 95 | $ — | $ — |
| Product | 1,056 | 605 | 232 | 1 | — |
| Research and development | 5,471 | 5,494 | 1,109 | 4 | 1 |
| Selling, general and administrative | $ 7,077 | $ 6,826 | $1,436 | $5 | $ 1 |

(2) In connection with the issuance of preferred stock in 2004, we recorded a non-cash charge representing the deemed dividend relating to the intrinsic value of the beneficial conversion feature of the preferred stock.

Note: This Annual Report should be read in conjunction with the audited financial statements and the notes thereto included in the Company's Form 10-K for the year ended December 31, 2005, filed with the Securities and Exchange Commission on March 7, 2006.

# Corporate Information

## Board of Directors

**John B. Simpson, M.D**
Founder
Interim Chief Executive Officer

**Jeffrey B. Child**
Chief Financial Officer
of a Family Office of an Unaffiliated Third Party

**Ryan D. Drant**
General Partner
*New Enterprise Associates*

**Sanford Fitch**
Former Vice President of Finance
and Chief Financial Officer
*Alvesta*

**Tomoaki Hinohara, M.D.**
Director of Cardiac Catherization Laboratory
*Sequoia Hospital*

**Myrtle S. Potter**
Former President,
Commercial Operations
*Genentech, Inc.*

## Executive Officers

**John B. Simpson**
Founder,
Interim Chief Executive Officer
and Director

**Matthew B. Ferguson**
Chief Financial Officer

**Ronald T. Steckel**
Chief Operating Officer

**Douglas S. Rohlen**
President of Strategic Operations

**Suzon D. Lommel**
Vice President of Quality
and Regulatory Affairs

**Angela B. Soito**
Vice President of Clinical Affairs

**Leslie L. Trigg**
Vice President of Marketing

**Richard J. Zimmer**
Vice President of Sales

## Corporate Headquarters

740 Bay Road
Redwood City, CA 94063

Phone: 650.421.8400
Fax: 650.421.8566

www.foxhollowtech.com

## Corporate Counsel

Wilson Sonsini Goodrich & Rosati, P.C.
Palo Alto, California

## Independent Registered Public Accounting Firm

PricewaterhouseCoopers LLP
San Jose, California

## Transfer Agent and Registrar

Communications concerning stock transfer requirements, lost certificates and changes of address should be directed to:

Mellon Investor Services LLC
85 Challenger Road
Ridgefield Park, NJ 07660

800.356.2017

www.melloninvestor.com

## Annual Report on Form 10-K

A copy of the Company's Annual Report on Form 10-K as filed with the Securities and Exchange Commission is available without charge upon request to:

Investor Relations
FoxHollow Technologies, Inc.
740 Bay Road
Redwood City, CA 94063

Phone: 650.421.8449
Fax: 650.421.8566

investorrelations@foxhollowtech.com

## For further information

Visit our website at
www.foxhollowtech.com.

# Stock Market Information

## Stock Symbol

FoxHollow Technologies' common stock is traded on the Nasdaq National Market under the symbol FOXH.

## Annual Meeting

The Annual Meeting of Stockholders will be held at 9:00a.m. on June 28, 2006, at our offices located at 740 Bay Road, Redwood City, CA 94063.

## Price Range of Common Stock

Our Common Stock is traded on the Nasdaq National Market under the symbol "FOXH" since our initial public offering in October 2004. The following table sets forth the high and low closing sale prices of our common stock for the periods indicated.

| | PRICE RANGE | |
|---|---|---|
| **Fiscal 2005** | **High** | **Low** |
| 1st QTR | 30.91 | 23.91 |
| 2nd QTR | 40.11 | 25.60 |
| 3rd QTR | 53.70 | 38.00 |
| 4th QTR | 53.73 | 29.79 |
| Fiscal Year | 53.73 | 23.91 |
| **Fiscal 2004** | | |
| 4th QTR (from 10.28.04) | 28.00 | 20.45 |

## Dividends

We have not declared or paid any cash dividends on our capital stock since our inception. 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. As of April 24, 2006, there were approximately 7,200 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

## Changes/Disagreements with Accountants

None.

# Report of Independent Registered Public Accounting Firm

**To the Board of Directors and Stockholders of FoxHollow Technologies, Inc.:**

We have completed an integrated audit of FoxHollow Technologies, Inc.'s 2005 financial statements and of its internal control over financial reporting as of December 31, 2005 and audits of its 2004 and 2003 financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

**Financial Statements and Financial Statement Schedule**

In our opinion, the financial statements listed in the accompanying index present fairly, in all material respects, the financial position of FoxHollow Technologies, Inc. at December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements 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.

**Internal Control Over Financial Reporting**

Also, in our opinion, management's assessment, included in the accompanying Report of Management on Internal Control Over Financial Reporting, that the Company maintained effective internal control over financial reporting as of December 31, 2005 based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control - Integrated Framework issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP

San Jose, California
February 28, 2006

This Annual Report contains forward-looking statements within the meaning of the federal securities laws. These statements include, but are not limited to, those concerning the following: our intentions, beliefs and expectations regarding our future success and results; the timing and success of our clinical trials and regulatory submissions; our belief that our cash and cash equivalents will be sufficient to satisfy our anticipated cash requirements; our operating results; our expectations regarding our revenues and customers; and our distributors and territorial expansion efforts. Forward-looking statements are subject to risks and uncertainties that could cause actual results and events to differ materially. For a detailed discussion of these risks and uncertainties, see the "Management's Discussion and Analysis of Financial Condition and Results of Operation" section in the Company's Form 10-K for the year ended December 31, 2005, filed with the Securities and Exchange Commission on March 7, 2006. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report.