
ARIS

P.E.
12-31-05

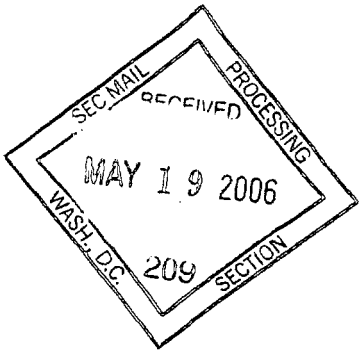
"I never thought my migraines and my heart were connected.

My life is completely different now. I feel like a new person."

*–Alison Doughty, suffered migraines for 30 years*

*Connections*






# NMT Medical, Inc.

**At the Heart of Brain Attacks**
**Annual Report 2005**

Uncovering clinical connections between previously unrelated conditions requires **vision, courage, and perseverance.**

## Connections

Connections can lead to novel treatment approaches for patients who need new hope. NMT Medical is making the connections, conducting the research, and enabling the technologically advanced treatments that get to the heart of brain attacks.

NMT Medical is establishing these connections in the emerging field of PFO closure. PFO, or Patent Foramen Ovale, is a heart defect that allows venous blood to enter the arterial circulation of the brain before being filtered or managed by the lungs. It may be connected to a host of brain attacks, including migraine, stroke, and transient ischemic attack (TIA).

## *Living Connections*

From the age of 5, Liz Norwood suffered debilitating migraine attacks that incapacitated her for up to eight hours at a time. Blurred vision, nausea, and loss of speech accompanied severe throbbing headaches, disrupting everything from simple social plans to major career decisions. "Every single day of my life, the first thing on my mind was, 'Can I see okay? Am I going to have a migraine?' It was a constant fear."

For the approximate 10% of the population who suffers from them, migraine attacks are devastating. Despite a wide range of pharmaceutical options, there is no cure. Many patients report that pharmaceutical options simply don't work, or merely delay the onset of an attack.

PFO closure may offer new hope to some of these patients. In the recent NMT Medical MIST (Migraine Intervention with STARFlex® Technology) study conducted in the United Kingdom, participants who received the STARFlex® implant experienced a significant reduction in migraine burden, measured by the number of attacks multiplied by the length in hours.

"I feel a sense of freedom and confidence now," Liz says. "The change has been absolutely fantastic. I still pinch myself every day."

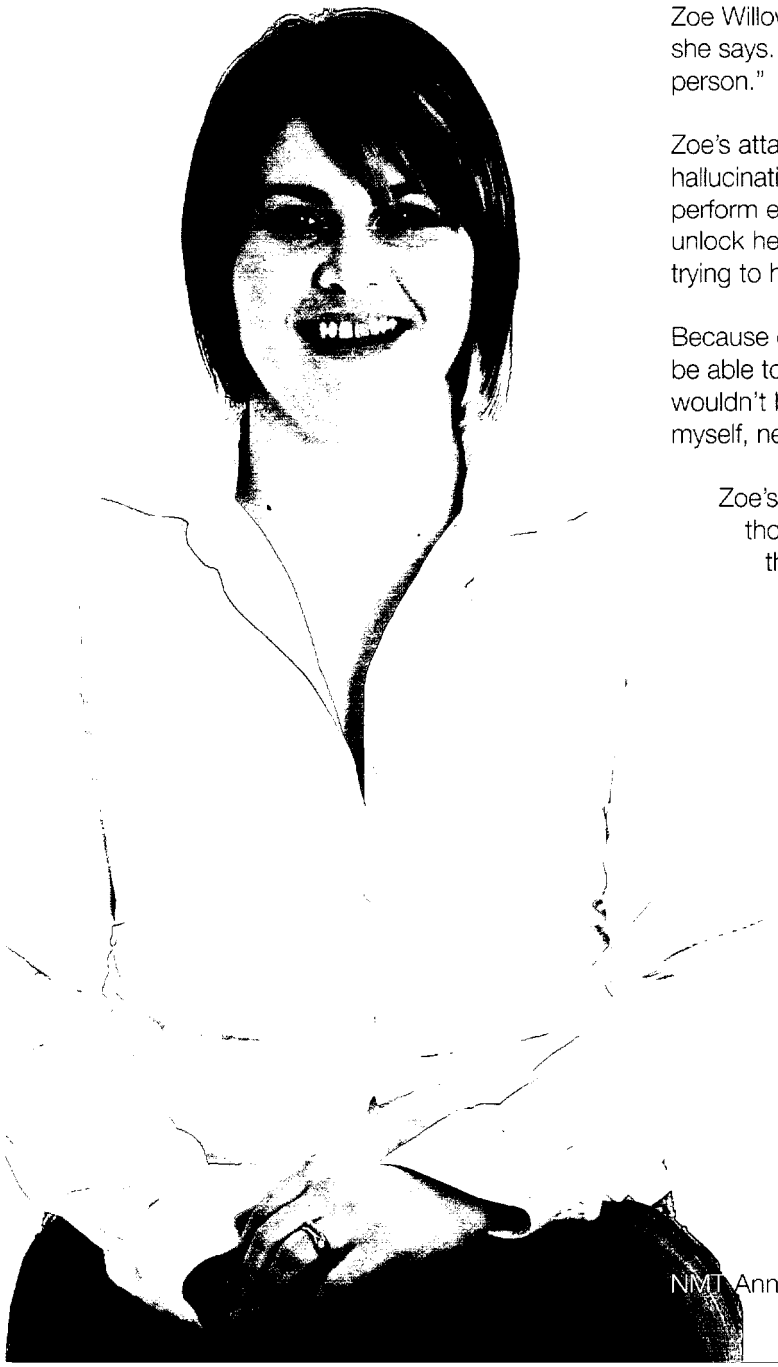
"When you have children dependent on you, migraine has a massive impact.

**I didn't want their childhood memories to be me constantly being sick."** *–Liz Norwood*

"People at my new job have never known me to have a migraine. It isn't even an issue. I'm a totally different person."

*–Zoe Willows*

## *Living Connections*



Zoe Willows, another trial participant, agrees. "It's unbelievable," she says. "I never thought it would happen. I'm a totally different person."

Zoe's attacks, which began when she was 6 years old, caused hallucinations and disorientation that made it difficult for her to perform even the simplest functions. She recalls being unable to unlock her own front door for a family member who was trying to help her during an attack.

Because of her migraine severity, she feared that she wouldn't be able to realize her dream of having a family. "I thought I wouldn't be able to cope," she says. "I couldn't take care of myself, never mind children."

Zoe's response in the MIST trial has enabled her to put those fears aside. "Now I can think about it and know that I'll be fine. It's quite exciting."

For Alison Doughty, another trial participant whose attacks ceased after her PFO closure, freedom from migraines is allowing her to have a lot more fun with her 9- and 12-year-old children.

"I used to always have to cancel things," she says. "My little boy got very upset. He'd say, 'Oh mommy, please don't get sick.' Now I'm just a normal mom doing normal things with them. It's wonderful."

"I feel so much better now. I don't live in fear of a migraine coming on all the time."

*–Jean Richards*

MIST trial participants who experienced migraine relief say the benefits extend well beyond family life. Jean Richards feels better about her job now that she doesn't need to burden co-workers by calling in sick. "I hated letting people down," she says. "If I knew we were short-staffed, I felt I was letting my colleagues down when I had a migraine. I can do so much more now."

While much work remains to be done, these stories demonstrate that for certain patients, PFO closure has a powerful impact on their migraine attacks.

"For the first time, we can see trends in a prospective study to suggest that PFO closure may be an effective way to treat certain types of migraine," says Andrew Dowson, MD, co-primary investigator of MIST with Peter Wilmhurst, MD. "A reduction in migraine burden may allow a patient to gain more control and lead a more fulfilling and productive life. The key now will be establishing the criteria that will help to determine which patients should be referred to the interventional cardiologist for further treatment."

Trial participants have made it clear that the researchers are doing vitally important work. "It would be fantastic if this could be seen as an actual treatment," says Liz. "I feel very grateful, very lucky that I was a part of the trial, and that it worked so well for me."

"The ability to treat migraine patients having a PFO and who are unresponsive to current medical therapy could have tremendous impact. MIST, MIST II, and MIST III trials will provide answers."

*–Stewart Tepper, MD*
*New England Center for Headache*

## Clinical Connections

When clinical connections are made, the critical challenge for researchers is to explore them fully in the quest to advance the most effective treatment options.

With the connection between PFO and brain attacks becoming established, NMT Medical continues to lead the field by delivering technologies to enable PFO closure to treat stroke, migraine, and transient ischemic attack (TIA).

***The PFO-Stroke Connection***

NMT Medical's ongoing CLOSURE I randomized trial is evaluating the safety and efficacy of the STARFlex® septal closure system versus best medical therapy in patients with stroke or TIA due to presumed paradoxical embolism through a PFO. CLOSURE I was the first PFO-stroke trial approved in the United States.

The PFO allows venous blood, which may contain embolic material, to flow or shunt into the arterial circulation and bypass the filtering potential of the lungs. If the embolic material were to reach the brain and block a cerebral artery, a stroke or TIA could occur.

Because PFO may be the most common risk factor of stroke for patients under 55, this trial has great significance. CLOSURE I is the largest prospective, multi-center, randomized, controlled trial of its kind and is expected to enroll approximately 1,600 patients at up to 100 leading stroke and interventional cardiology centers in the United States.

***The PFO-Migraine Connection***

Evidence of a PFO-migraine connection has been building in the medical community for years. A high incidence of PFO among migraine sufferers, as well as other reported links between the two conditions, led researchers to theorize that biological substances usually cleared by the lungs could escape through a PFO, potentially triggering a migraine.

Last year, NMT Medical's MIST (Migraine Intervention with STARFlex® Technology) study broke ground as the first prospective, randomized, double-blinded study to evaluate the PFO-migraine connection. The study brought together neurologists, headache specialists, and interventional cardiologists to collaboratively address the cardiac sources of migraine attacks for the first time.

"Our patients need more rapid, complete and natural sealing of septal defects than current methods. BioSTAR™ is a remarkable solution."

*–Michael Mullen, MD*
*Royal Brompton Hospital*

Preliminary MIST results showed a statistically significant treatment effect and shed new light on the question of which migraine sufferers might benefit from cardiac intervention.

The PFO-migraine connection revealed itself in the earliest stages of the study. Of 432 migraine with aura subjects screened for a PFO, over 60% had a right to left shunt, a defect that allows venous blood to flow into the arterial circulation, bypassing the lungs. Of those subjects, almost 40% had moderate or large PFO, six times greater than in the general population.

MIST, conducted in the United Kingdom, was designed with a primary endpoint derived from several observational studies and the only published data available at that time: a 40% elimination in migraine at six months in the treatment arm. That outcome was not seen in the MIST results. Preliminary MIST data did, however, show a statistically significant treatment effect and a promising trend to support PFO closure with STARFlex® as a treatment option for certain types of migraine. There was an approximate 37% reduction in migraine burden in patients treated with STARFlex® and a 17% reduction in those who received a sham procedure and no implant. The variance appears to increase over time.

In addition, 42% of patients who received STARFlex® had a 50% reduction in migraine days compared with only 23% of patients in the control group.

Additional, important analysis from the MIST study is still underway and is expected to be published later this year. Moving forward, NMT Medical will incorporate the promising MIST findings into MIST II, a U.S.-based study, and MIST III, an 18-month follow-up to MIST.

With MIST II, NMT Medical was the first company to enroll patients in a PFO-migraine IDE (investigational device exemption) study approved by the FDA. More than 40 leading migraine specialists and interventional cardiologists are participating. The goal is to establish the criteria to determine which patients should be referred to an interventional cardiologist for further treatment. For the 28 million Americans who suffer from migraines, that information may constitute the most significant development in migraine treatment in over a decade.

"The next treatment frontier in interventional cardiology is structural heart repair. New biological platforms that leverage the body's regenerative capabilities will be integral to these efforts. BioTREK™ is a promising technology."

*–Aaron Kaplan, MD*
*Dartmouth-Hitchcock Medical Center*

## Technology Connections

Innovation requires leadership. To succeed on the front lines of discovery, innovators have to have vision, courage, and perseverance. NMT Medical's research team developed the first, early design septal closure devices implanted in humans nearly 20 years ago. More than 20,000 PFO closures have been successfully completed with NMT Medical's more recent generation implants, CardioSEAL® and STARFlex®. NMT Medical research continues to advance this important and rapidly evolving field.

In January, the Company received a Phase I grant from the National Institutes of Health (NIH) Small Business Technology Transfer Program to evaluate the new BioTREK™ septal closure technology.

BioTREK™ strives for the most natural, rapid, and complete PFO closure using a unique biosynthetic material that relies on the body's regenerative capability to restore function naturally, leaving nothing behind. It is expected to complement NMT Medical's existing technologies, creating an exceptionally promising and well-protected pipeline.

BioTREK™ is NMT Medical's second biological technology. The first, BioSTAR™, is currently being studied in the BEST study (BioSTAR™ Evaluation STudy) in the U.K., and is expected to receive CE mark approval for European commercialization later this year. BioSTAR™ combines bioabsorbable collagen matrix technology with NMT Medical's proven STARFlex® technology. Once implanted, BioSTAR™ creates a bioscaffold that promotes native tissue deposition. During that biological closure process, the collagen matrix dissolves, leaving behind natural tissue that completely covers the STARFlex® alloy framework. Like BioTREK™, BioSTAR™ has the potential to deliver and localize biological response modifiers (drugs, genes, cells, and other materials) that may further enhance PFO closure outcomes.

***Biological Closure with BioSTAR™***


*Courtesy of Michael Mullen, MD*
*Consultant Cardiologist, Royal Brompton Hospital, London, United Kingdom*

The BioSTAR™ implant being evaluated in the BEST study releases the anticoagulant heparin over time, potentially minimizing device thrombus, a potential risk with all intra-cardiac devices.

Being first and innovating has other advantages. NMT Medical has the broadest patent portfolio in septal closure in the world, with 18 issued patents and more than 60 applications in process.

## *Advancing Connections*

With five PFO-related clinical trials underway, NMT Medical is committed to maintaining its technology and clinical research leadership position in the emerging arena of PFO closure. Through leading clinical trials and technology, the company is uncovering new connections and changing perceptions about brain attacks and their treatment.

By continuing to develop the most innovative closure technologies, **NMT Medical remains at the heart of brain attacks.**

## *Connections*

To our patients, clinical partners, employees and investors,

For NMT Medical, 2005 was a year of strengthening connections. We completed enrollment in MIST (Migraine Intervention with STARFlex® Technology), to investigate the connection between a common heart defect and some migraine attacks. More recently we reported preliminary results of that landmark clinical trial. The results confirmed, for the first time in a prospective study, that the connection exists. While MIST did not demonstrate the cessation of migraine headaches observed in earlier retrospective studies it did show a significant treatment benefit for some migraine sufferers like the young women featured in this year's annual report.

While we believe that MIST has validated positive clinical outcomes to closing a PFO, a great deal of work is ahead of us. MIST generated a tremendous amount of valuable data that still requires further analysis. Publication of the full data is expected to take place later in 2006.

The data from MIST will also provide the Company with important information to share with the Food and Drug Administration (FDA) to modify and strengthen the previously approved MIST II study which has started enrollment in the United States. Compared to MIST, MIST II is a larger PFO-migraine study with longer follow up and is expected to build upon what we learned with MIST. We remain very committed and very excited about the evolving PFO-migraine opportunity.

Other important milestones were achieved in 2005. In June, we received approval for BEST (BioSTAR™ Evaluation STudy) and in November we completed enrollment. BioSTAR™ represents the first of a new generation of biological closure technologies that NMT Medical is innovating. Once implanted, BioSTAR™ creates a bioscaffold that promotes native tissue deposition. During that biological closure process the bioabsorbable collagen matrix used in BioSTAR™ dissolves, leaving behind natural tissue.

The collagen material also has the potential to deliver biological response modifiers (genes, drugs, cells and other materials) that may further enhance PFO closure outcomes. The BioSTAR™ implant evaluated in the BEST study incorporates a heparin substrate that elutes over time. This feature is designed to minimize device thrombus, a potential risk with all current intra-cardiac implants.

Our clinical research team sees BioSTAR™ as a potentially better solution than current methods of septal repair, with a more rapid, complete and natural outcome. We currently expect BioSTAR™ to be commercially available in Europe by year-end.

Earlier this year, the Company announced it had received a Phase I grant from the National Institutes of Health (NIH) Small Business Technology Transfer Program to fund a pre-clinical research program for yet another innovative biological closure platform. Called BioTREK™, the technology incorporates a unique biosynthetic material that uses the body's own regenerative capability to restore function naturally. Like BioSTAR™, BioTREK™ has the ability to deliver biological response modifiers to potentially enhance results.

"We entered 2005 with the objective to confirm the Company's clinical and technology leadership in the emerging PFO opportunity. We believe we have achieved that objective."

Along with MIST, MIST II and BEST, NMT Medical has received approval for and is enrolling patients in MIST III, an important continuation study of MIST patients. CLOSURE I, our U.S.-based clinical trial to evaluate the effectiveness of our STARFlex® PFO closure technology in preventing stroke and transient ischemic attack (TIA), continues enrollment. Through our clinical trial investments, NMT Medical remains committed to being the first company to provide migraine and stroke patients with proven, safe and effective PFO-related treatment options.

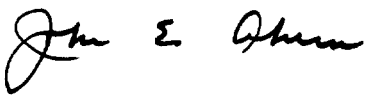
On the technology front, NMT Medical continues to extend its competitive advantage in PFO closure technology. With BioSTAR™ and BioTREK™ the Company advances its biological closure platform and builds upon the existing base of over 20,000 PFO closure procedures completed with STARFlex® and CardioSEAL®.

During 2005, the Company carefully managed operating costs and inventories, funded our ongoing clinical trials and technology development activities, and strengthened our patent portfolio. Total revenues for the year were approximately $23.9 million or about 11% over 2004. We ended the year with approximately $31.5 million in cash. We continue to have no debt.

Looking forward, as a leader NMT Medical remains committed to building the emerging PFO opportunity for stroke and migraine, to innovating better ways to close the PFO defect and to helping patients achieve better lives.

On an ending note, we would like to thank Alison Doughty, Liz Norwood, Zoe Willows and Jean Richards for sharing their remarkable stories in this year's annual report. These four brave women, along with 143 other equally courageous study subjects, participated in the groundbreaking MIST clinical trial and have helped us make the clinical connections that are paving the way to a new era in migraine headache research.

Sincerely,



**John E. Ahern**
President, Chief Executive Officer and Chairman

## *Financials*

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

## FORM 10-K

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

☒ 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

For the transition period from _____ to _____.
Commission File No. 000-21001

## NMT MEDICAL, INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

| Delaware | 95-4090463 |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |

27 Wormwood Street, Boston, Massachusetts 02210
(Address of Principal Executive Offices, Including Zip Code)

Registrant's telephone number, including area code: (617) 737-0930

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:
None

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:
Common Stock, $.001 par value per share
Preferred Stock Purchase Rights
(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 Securities Exchange Act of 1934 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 filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer (as defined in Exchange Act Rule 12b-2).

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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

The aggregate market value of the registrant's Common Stock held by non-affiliates on June 30, 2005 was $94,894,050 based on the last reported sale price of registrant's Common Stock on The NASDAQ National Market on that date. For these purposes, the registrant deemed its affiliates to include its directors and officers and each person who owned 10% or more of the outstanding Common Stock of the registrant.

As of March 6, 2006, there were 12,623,446 shares of the registrant's Common Stock, $.001 par value, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2005. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

# PART I

**Forward-Looking Statements**

In addition to historical information, this Annual Report on Form 10-K contains forward-looking statements that involve assumptions, risks and uncertainties that could cause our actual results to differ materially. Factors that might cause or contribute to such differences include, but are not limited to, those discussed in the section entitled "Risk Factors". When used in this report, the words "expects", "could", "would", "may", "anticipates", "intends", "plans", "believes", "targets", "estimates", and similar expressions, as well as statements regarding our focus for the future, are generally intended to identify forward-looking statements.

## ITEM 1. BUSINESS

### INTRODUCTION

**General**

We are an advanced medical technology company that designs, develops, manufactures and markets proprietary implant technologies that allow interventional cardiologists to treat cardiac sources of migraine headaches, stroke and other potential brain attacks through minimally invasive, catheter-based procedures. We are investigating the potential connection between a common cardiac defect called a patent foramen ovale ("PFO") and brain attacks such as migraine headaches, stroke, and transient ischemic attacks ("TIA"). A PFO can allow venous blood, unfiltered and unmanaged by the lungs, to directly enter the arterial circulation of the brain, possibly triggering a cerebral event or brain attack. In utero, the PFO is an opening in the atrial wall that allows the mother's oxygenated blood to support the fetus. At birth, or usually by age one, the PFO completely closes, preventing venous blood and arterial blood from mixing. We believe that up to 25% of the population has a PFO that does not fully seal and most will never even know that they have this defect.

We are a leader in designing and developing implants to seal the PFO defect in a minimally invasive, catheter-based procedure performed by an interventional cardiologist. Globally, more than 20,000 PFOs have been closed using our proprietary, minimally invasive, catheter-based implant technology.

We are a Delaware corporation that was founded in 1986, with executive offices located at 27 Wormwood Street, Boston, Massachusetts 02210-1625, and our telephone number is (617) 737-0930. We maintain a website with the address www.nmtmedical.com. We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the U.S. Securities and Exchange Commission. We also make available on our website our proxy statements for our annual meetings of stockholders, initial reports of ownership and reports of changes in ownership of our common stock required to be filed pursuant to Section 16(a) of the Exchange Act, the charters for our audit committee, joint compensation and options committee, and nominating and corporate governance committee, and our code of business conduct and ethics, and such information is available in print to any stockholder of NMT Medical who requests it.

**Migraine Opportunity**

Several recent research studies have suggested that patients who have a PFO may suffer from severe migraines. Some doctors have observed that after PFO closure to prevent recurrent stroke, patients who had previously suffered from migraines unexpectedly reported that their attacks either stopped completely or improved in terms of frequency and/or severity. In order to help confirm the clinical relevancy of this apparent connection between migraine and PFOs, in late 2004, we received approval to commence the first prospective, randomized, double-blinded, controlled clinical study in the United Kingdom using our existing proprietary STARFlex® septal repair technology. This clinical study, named MIST (Migraine Intervention with STARFlex® Technology), completed enrollment of 147 patients in July 2005, with follow-up evaluation over the following six-month period. We currently anticipate that results from MIST will be announced on March 13, 2006.

We also received conditional approval from the U.S. Food and Drug Administration ("FDA") of an investigational device exemption ("IDE") to initiate enrollment in our pivotal PFO/migraine clinical study in the United States. The study, named MIST II, will evaluate the safety and effectiveness of our proprietary STARFlex® implant technology for the treatment and prevention of migraine headaches in patients who have a PFO. MIST II is a prospective, randomized, multi-center, double-blinded, controlled clinical study designed to randomize approximately 600 migraine patients with a PFO to either PFO closure with our STARFlex® technology or a control arm. MIST II incorporates our new enhanced implant delivery system that is now commercially available in Europe. More than twenty U.S. research centers have committed to participate in MIST II, and enrollment began in January

2006. We currently anticipate that enrollment in MIST II will be completed in early 2007. Patient follow-up is one year, after which the data will be collected and analyzed. It is currently our plan to file for a PFO pre-market approval ("PMA") with the FDA in 2008.

In October 2005 regulatory authorities in the United Kingdom granted approval to commence our MIST III clinical trial. We began enrollment in MIST III, a study in which control patients from the original MIST study, who did not receive the STARFlex® implant, have the option to receive an implant after they have been unblinded as part of the MIST study. These patients will follow the identical protocol as in MIST after which they will be followed for an additional 18 months. In addition, as part of MIST III, migraine patients with a PFO who did receive a STARFlex® implant in MIST will also be followed for an additional 18 months.

We believe our initial target population for PFO closure with our proprietary technology to be approximately 5% of all migraine sufferers worldwide, or more than 4.5 million people. This is based on statistics from the World Health Organization and the American Council for Headache Evaluation that the prevalence of migraines in the United States, Europe and Japan is approximately 10% of the general population. Also, published medical research indicates that approximately 20% of migraine sufferers have migraine with aura, often referred to as the classic migraine, and up to 50% of those suffering from migraine with aura are unresponsive to current medications. Within that patient subset, the prevalence of PFO is estimated to be 50%, or twice what would be expected in a normal population.

If the MIST trial is successful in demonstrating that PFO closure with STARFlex® helps to remove a risk factor contributing to certain migraine attacks, we believe that it would represent a potential breakthrough treatment for patients currently not responding to other therapies. Based upon our current direct sales force, our planned additional investments in that strategy and potential demand for our proprietary technology, we believe that we could gain a portion of this large market opportunity.

**Stroke Opportunity**

Stroke is the third leading cause of death in the United States, and for some young adults, a PFO may be the primary cause or risk factor of embolic stroke. When intracardiac pressures are increased (for example, by strenuous activities, lifting or straining), the PFO may open and allow blood flow to move, or shunt, from one atrial chamber (the right/venous) to the other (left/arterial). On occasion, emboli present in venous blood, which are normally filtered through the lungs, can now cross through the PFO into the arterial side, travel to the brain and block essential blood flow. The result may be a stroke, causing potential loss of speech, vision and movement, and even death. Each year, approximately 750,000 Americans suffer a new or recurrent stroke and 500,000 Americans experience a TIA. For these people, who risk embolic stroke each year because of their PFO, traditional therapeutic options have been lifetime medication or heart surgery. We believe that PFO closure using our proprietary implant technologies is an alternative treatment for a certain subset of patients and is another potentially large market opportunity for us.

In 2003 we commenced CLOSURE I under an FDA-approved IDE comparing our STARFlex® cardiac septal repair implant with medical therapy in preventing recurrent stroke and TIA. CLOSURE I is a randomized, controlled trial currently designed to enroll 1,600 patients at approximately 100 leading stroke and interventional cardiology centers in the United States and Canada, with follow-up evaluation over a two-year period. Patient enrollment in CLOSURE I has progressed much slower than anticipated. Presently, we are working with our consultants, regulatory bodies and investigators to develop a course of action that will enable us to complete CLOSURE I enrollment. We now believe that study changes, acceptable to the FDA, the investigators and us, are necessary in order to successfully complete this study. Until these changes are approved, it is difficult to estimate a completion date. It is currently anticipated that when completed, study data from CLOSURE I will be used to support a PFO PMA application.

**Regulatory Factors**

In the United States, the FDA classifies septal repair implant devices as Class III medical devices, which require a PMA to be marketed. Under the FDA's Humanitarian Device Exemption ("HDE") regulations, medical devices that provide safe treatment for limited populations of patients can be granted approval by the FDA based upon more limited clinical experience than is required for a full PMA. Specifically, an HDE application must include safety data, but need not contain the results of clinical investigations demonstrating that the device is effective for its intended use. An approved HDE authorizes marketing of a humanitarian use device, a device that treats or diagnoses a disease or condition that affects fewer than 4,000 individuals in the United States per year. We currently sell our CardioSEAL® product in the United States under an HDE granted in 2000 by the FDA for treating PFO patients with recurrent paradoxical stroke who have failed conventional drug therapy such as Coumadin®. The FDA approved a selling price of $5,500 for each device in the U.S. We also sell our CardioSEAL® product in the United States under a PMA for patients with a ventricular septal defect ("VSD") who have high surgical risk factors.

The European Union has promulgated rules governing the marketing and sale of medical products in the countries of the European Union. These products must receive a Conformité Europeene ("CE") Mark indicating that the manufacturer has conformed to all of the obligations required by the legislation. The CardioSEAL® and STARFlex® implants have been sold in Europe since they received the CE Mark.

We also re-sell third party products for use with our CardioSEAL® and STARFlex® implant devices, specifically vascular sizing balloons and sheaths. Sales of our proprietary implant technologies, including these ancillary third party products, in the United States and Europe account for substantially all of our current product sales.

**Our Strategy**

Our primary strategic objectives include:

- gaining additional acceptable clinical data from MIST that demonstrates positive clinical efficacy of PFO closure in certain migraine patients;
- completing the study enrollment for MIST II and MIST III;
- receiving a CE Mark for BioSTAR™, our new bioabsorbable, biological closure technology; and
- making significant progress with CLOSURE I patient enrollment.

If the results of our MIST, MIST II, and MIST III studies confirm a PFO/migraine connection, we currently believe that PFO closure for migraine would represent a substantial and more immediate revenue growth opportunity for us as compared to PFO closure for stroke. With a strong balance sheet, including approximately $31.5 million of cash, equivalents, and marketable securities at December 31, 2005, and anticipated revenue growth from outside the United States, we currently believe that we have the available financial resources to complete these regulatory and clinical activities and to continue our focus on technological improvements to our products and intellectual property positions.

## PRODUCTS

In February 1996, we acquired the exclusive rights to the CardioSEAL® cardiac septal repair implant from InnerVentions, Inc., a licensee of the Children's Medical Center Corporation ("CMCC"), also known as Children's Hospital Boston. In connection with this acquisition, we acquired all of the existing development, manufacturing, testing equipment, patent licenses, know-how and documentation necessary to manufacture cardiac septal repair implant devices. Under the license agreements, as amended, we pay royalties to CMCC on all commercial sales of our cardiac septal repair products. We sell CardioSEAL® in the United States, Canada and Europe. We sell STARFlex® in Europe. We also re-sell third party products for use with the CardioSEAL® and STARFlex® implant devices, specifically vascular sizing balloons and sheaths. Since the second half of 2002, following completion of the transitional manufacturing agreement related to the sale of our former vena cava filter product line to C.R. Bard, Inc. ("Bard"), our cardiac septal repair implants have accounted for substantially all of our product sales. The aggregate of these product sales accounted for 80.8%, 79.8% and 93.3% of our total revenues for the years ended December 31, 2005, 2004 and 2003, respectively.

Cardiac septal repair implant devices are used for the repair of intracardiac shunts that result in abnormal blood flow through the chambers of the heart. Common cardiac septal defects include PFO, VSD and atrial septal defects ("ASD"). PFO, the most common of these defects, has been implicated as (i) a possible factor in certain migraine headaches; and (ii) a possible cause of embolic stroke, for which other current treatments include lifelong anticoagulation therapy or open heart surgery. These treatments may present significant risks to the embolic stroke patient with a PFO. We believe that our catheter-based cardiac septal repair implant technologies may provide a minimally invasive and less costly treatment alternative. We estimate that the worldwide market potential for our cardiac septal repair implant technologies is more than 4.5 million procedures for migraine headaches and approximately 750,000 procedures annually for stroke and TIA. In addition, we believe that congenital heart defects, such as ASD and VSD, account for approximately 30,000 procedures.

In the United States, we received FDA approval to market our septal repair implant devices under HDE regulations for three indications. Our first HDE approval was granted in September 1999 for nonsurgically closing fenestrated fontans. Following the FDA's grant of a PMA for a competitive device for this indication, this HDE was withdrawn. Our second HDE approval, also in September 1999, was granted for closing VSD in patients with high surgical risk factors. We received a PMA for this indication in December 2001 and, accordingly, this HDE approval was no longer necessary and was withdrawn. Our third HDE approval, granted in February 2000, provided for the use of CardioSEAL® in treating PFO patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through a PFO who have failed conventional drug therapy such as Coumadin®. CMCC worked with us to generate the clinical data necessary for our HDE and PMA applications and approvals. HDE regulations for the remaining PFO indication allow for the treatment of up to 4,000 patients per year. The FDA approved a selling price of $5,500 for each device in the U.S.

In 1998, we introduced design enhancements to the CardioSEAL® cardiac septal repair device, the STARFlex®, which incorporates a self-centering system. This system allows the implant to self-adjust to variations in the anatomy of a septal defect without deforming the septum or interfering with heart valve function. This feature accommodates easier implantation and the closure of larger defects than would otherwise be possible. Commercialization began in Europe following the awarding of the CE Mark for STARFlex® in September 1998. During 2000, we introduced the QuickLoad enhancement to the entire CardioSEAL® product family, providing a more ergonomic implant loading system. In 2001, two additional STARFlex® sizes for treatment of larger defects were awarded the CE Mark. During 2003, we introduced in Europe the Rapid Transport™ System ("RTS"), which allows the interventional cardiologist to more easily implant the STARFlex® device.

BioSTAR™ is our bioabsorbable PFO implant and the first biological closure technology. The extracellular biomaterial in BioSTAR™ enhances cell growth, promoting more rapid and complete sealing of the PFO defect. Over time, the BioSTAR™

material is replaced by the body's own native tissue. During 2005, we completed our clinical trial known as "BEST" (BioSTAR™ Evaluation STudy), and we anticipate receiving a CE Mark by the end of 2006.

## ROYALTY INCOME

*Vena Cava Filters*

In November 2001, we sold our former vena cava filter product line, including the Recovery™ Filter ("RNF") and Simon Nitinol Filter ("SNF") products, to Bard for $27 million in cash and up to an additional $7 million in cash tied to certain performance and delivery milestones. We continued to manufacture the filter products for Bard through June 2002 and, upon final transfer of manufacturing to Bard, received a $4 million milestone payment on September 30, 2002. In January 2003, we received the final $3 million milestone payment as a result of Bard's receipt of FDA approval for the commercial sale and use of its RNF product as of December 31, 2002. Commencing in 2003, we earned royalties from Bard on its sales of the vena cava filter products. Through 2007, the Bard royalty rate applicable to RNF product sales is substantially higher than the royalty rate applicable to SNF products, after which time the lower royalty rate applies to all products. These royalties are recorded net of certain royalties that we continue to pay to the original inventor under the terms of our agreements with Bard.

*Stents*

In November 1994, we licensed to Boston Scientific Corporation ("BSC") the exclusive worldwide rights to develop, manufacture, market and distribute products utilizing our stent technology. BSC is not prohibited from selling competing stents and has established a broad-based stent program. Pursuant to the license agreement, we earn sales royalties and, if applicable, manufacturing cost reduction incentives.

Net royalty income accounted for 19.2%, 19.5% and 6.0% of our total revenues for the years ended December 31, 2005, 2004 and 2003, respectively.

## CLINICAL TRIALS

Based on statistics from the World Health Organization and the American Council for Headache Evaluation, the prevalence of migraines in the United States, Europe and Japan is approximately 10% of the general population. Also, published medical research indicates that approximately 20% of migraine sufferers have migraine with aura, often referred to as the classic migraine, and up to 50% of those suffering from migraine with aura are unresponsive to current medications. Within that patient subset, the prevalence of PFO is estimated to be 50%, or twice what would be expected in a normal population. If the MIST trial is successful in demonstrating that PFO closure with STARFlex® shuts down a process that may be triggering or contributing to certain migraine attacks, it would represent a potential breakthrough treatment for patients currently not responding to other therapies. Based on our current implant selling price and the initial target population, which represents more than 4.5 million migraine sufferers, we could potentially gain a portion of this large market opportunity.

*MIST*

In November 2004, we received approval in the United Kingdom for MIST (Migraine Intervention with STARFlex® Technology), the first prospective, randomized, double-blinded study to evaluate the effectiveness of transcatheter closure of a PFO, using our proprietary STARFlex® septal repair technology, in the treatment and prevention of migraine headaches. MIST, a multi-center study involving approximately 16 centers, enrolled 147 migraine patients with aura, who have a PFO and who were randomized to either PFO closure with our STARFlex® implant or a control arm. The study was designed by a scientific advisory board comprised of some of the top European and North American migraine specialists and interventional cardiologists. The MIST study's patient recruitment process was supported by the Migraine Action Association (MAA), a migraine headache advocacy group representing more than 14,000 members in the United Kingdom. Total costs of this trial, including third party contracts and agreements with clinical sites and other service providers, are currently estimated to be in the range of $4.0 to $4.5 million. Of this total, approximately $3.0 million and $900,000 were incurred during 2005 and 2004, respectively. We currently estimate 2006 costs to be approximately $300,000. It is currently anticipated that results from this study will be announced on March 13, 2006.

*MIST II*

In September 2005, we received conditional approval from the FDA of an IDE to initiate enrollment in our pivotal PFO/migraine clinical study, named MIST II. MIST II is a prospective, randomized, multi-center, controlled study. The double-blinded trial is designed to randomize approximately 600 migraine patients who have a PFO to either PFO closure with our STARFlex® implant or a control arm. More than twenty U.S. research centers have committed to participate in MIST II, and enrollment began in January 2006. Patient follow-up will be over a one year period. We currently anticipate utilizing our newest, most technologically advanced delivery system in our MIST II IDE study. We currently project the costs of this clinical study to be in the range of $16 to $20 million through 2008. Of this total, approximately $300,000 was incurred during 2005, and we currently estimate 2006 costs to be approximately $14 million.

*MIST III*

In October 2005, we received approval from the regulatory authorities in the United Kingdom to begin enrollment in MIST III. In MIST III, control patients from the original MIST study, those who did not receive the STARFlex® implant, have the option to receive an implant after they have been unblinded as part of the MIST study. These patients will follow the identical protocol as in MIST after which they will be followed for an additional 18 months. In addition, migraine patients with a PFO who did receive a STARFlex® implant in MIST will be followed for an additional 18 months. We currently estimate the cost of MIST III to be approximately $1.2 million through 2007.

*BEST*

In June 2005, we received approval in the United Kingdom for BEST (BioSTAR™ Evaluation STudy), a multi-center study designed to evaluate our new BioSTAR™ PFO closure technology, the first in-human use of a bioabsorbable collagen matrix incorporated on our STARFlex® platform. BioSTAR™ is designed to optimize the biological response by promoting quicker healing and device endothelialization. Patient enrollment was initiated in July 2005 and completed during the fourth quarter 2005. The goal of our BEST study is to secure European commercial approval for our novel BioSTAR™ technology through the CE Mark process, which we anticipate receiving by the end of 2006. We currently estimate total costs of this study, including third party contracts and agreements with clinical sites and other service providers, to be in the range of $1.2 to $1.5 million. Of this total, approximately $900,000 was incurred in 2005 and we currently estimate 2006 costs to be approximately $400,000.

*CLOSURE I*

In April 2002, we filed a PMA application with the FDA for the use of our STARFlex® implant device for PFO closure in certain high risk patient populations, including the population currently served by the HDE PFO approval, using a subset of the data we used to obtain our VSD PMA in December 2001. At a September 2002 meeting of the Circulatory Systems Devices Panel of the FDA, the panel did not recommend approval of this PMA. Working closely with the FDA and experts from the neurology and interventional cardiology communities, we submitted to the FDA the clinical trial design for our PFO IDE. The trial, named CLOSURE I, for which we received IDE approval from the FDA in June 2003, is a prospective, multi-center, randomized, controlled clinical trial designed to evaluate the safety and efficacy of our STARFlex® septal closure system versus medical therapy in patients who have had a stroke and/or a TIA due to a presumed paradoxical embolism through a PFO. The trial is expected to enroll approximately 1,600 patients at approximately 100 leading stroke and interventional cardiology centers in the United States, with half receiving a STARFlex® implant and the other half receiving drug therapy. Patients will be evaluated periodically over a two-year period, during which time, safety and efficacy data, including recurrent event rates (i.e., stroke and/or TIA), will be collected for all patients. Patient enrollment in CLOSURE I has progressed much slower than anticipated. At the present time, we are working with our consultants, regulatory bodies and investigators to develop a course of action that will enable us to complete the CLOSURE I enrollment. We now believe that study changes, acceptable to the FDA, the investigators and us, are necessary in order to successfully complete this study. Until these changes are approved, it is difficult to estimate the completion date. It is currently anticipated that when completed, study data from CLOSURE I will be used to support a PFO PMA application. For more information concerning FDA regulations applicable to CLOSURE I, see the section of this Annual Report on Form 10-K entitled "Business—Government Regulation".

We have committed significant financial and personnel resources to the execution of our CLOSURE I clinical trial. Including contracts with third party providers, agreements with participating clinical sites, internal clinical department costs and manufacturing costs of the STARFlex® devices to be implanted, total costs are currently estimated to be approximately $24 million through completion of the trial and submission to the FDA. Of this total, approximately $3.2 million, $3.7 million and $2.5 million were incurred during 2005, 2004 and 2003, respectively. We currently project 2006 costs to approximate $4.0 to $4.5 million, largely dependent upon the rate of patient enrollment.

We do not charge for the products implanted in any of the aforementioned clinical trials.

## RESEARCH AND DEVELOPMENT

Our research and development organization included 32 persons as of December 31, 2005, with departmental groups dedicated to product development, regulatory and clinical affairs, and quality assurance. Total company-sponsored research and development expenses were approximately $15.4 million, $9.0 million, and $7.0 million for the years ended December 31, 2005, 2004, and 2003, respectively. We do not have any customer-sponsored research and development activities. Of these totals, approximately $7.5 million, $4.6 million and $2.5 million for the years ended December 31, 2005, 2004 and 2003, respectively, were clinical trials costs.

### Product Development

BioSTAR™ is our bioabsorbable PFO implant and the first biological closure technology. The extracellular biomaterial in BioSTAR™ enhances cell growth, promoting more rapid and complete sealing of the PFO defect. Over time, the BioSTAR™ material is replaced by the body's own native tissue. During 2005, we completed enrollment in our BEST clinical trial and we currently anticipate receiving a CE Mark by the end of 2006.

We are continuing to develop our advanced biological closure technology called BioTREK™. BioTREK™ represents our second biological closure technology and follows our BioSTAR™ implant technology. BioTREK™ incorporates a unique biosynthetic material that uses the body's own regenerative capability to restore function naturally. We believe that BioTREK™ will provide a more natural, biological closure of structures within the heart, such as the PFO. Under a Phase I grant recently received from the National Institutes of Health (NIH), specifically a Small Business Technology Transfer Program grant from the National Heart, Lung and Blood Institute, we have initiated preclinical evaluation of BioTREK™. Additionally, the research and development group continues to invest in strengthening our intellectual property assets in all aspects of PFO closure.

### Regulatory and Clinical Affairs

In June 2005, we completed patient enrollment in our MIST (Migraine Intervention with STARFlex® Technology) clinical study. The study, the first of its kind, enrolled 147 migraine headache patients at 16 participating centers in the United Kingdom. MIST is designed to evaluate the effectiveness of our proprietary STARFlex® implant technology in the treatment of these patients. Patients were randomized to the STARFlex® implant or a control arm. It is currently anticipated that results from this study will be announced on March 13, 2006.

In September 2005, we received conditional approval from the FDA of an IDE to initiate enrollment in our pivotal MIST II PFO/migraine clinical study. This study will evaluate the safety and effectiveness of our proprietary STARFlex® implant technology for the treatment and prevention of migraine headaches in patients who have a PFO. MIST II is a prospective, randomized, multi-center, double-blinded, controlled clinical study designed to randomize approximately 600 migraine patients with a PFO to either PFO closure with our STARFlex® technology or a control arm. MIST II incorporates our new enhanced implant delivery system that is now commercially available in Europe. More than twenty U.S. research centers have committed to participate in MIST II, and enrollment began in January 2006. We currently anticipate that enrollment in MIST II will be completed in early 2007. Patient follow-up is one year, after which the data will be collected and analyzed. It is currently our plan to file for a PFO PMA in 2008.

In October 2005 regulatory authorities in the Untied Kingdom granted approval to commence MIST III. We began enrollment in MIST III, a study in which control patients from the original MIST study, who did not receive the STARFlex® implant, have the option to receive an implant after they have been unblinded as part of the MIST study. These patients will follow the identical protocol as in MIST after which they will be followed for an additional 18 months. In addition, as part of MIST III, migraine patients who had a PFO and who received a STARFlex® implant in MIST will also be followed for an additional 18 months.

A significant accomplishment for us in 2005 was completing patient enrollment in our BEST clinical trial during the fourth quarter 2005. The goal of our BEST study is to secure European commercial approval for our novel BioSTAR™ technology through the CE Mark process, which we anticipate receiving by the end of 2006. Additionally, we managed ongoing enrollment in the VSD PMA post-market registry for the CardioSEAL® septal repair implants.

In 2006, in addition to our ongoing MIST, MIST II, MIST III and CLOSURE I trials, we intend to focus on the following projects: (i) securing CE Mark approval for BioSTAR™, our next generation STARFlex® cardiac septal repair implant incorporating the enhanced tissue scaffold; (ii) securing FDA approval, and implementation of, CLOSURE I study amendment(s); and (iii) submitting QuickLoad plus supplements on VSD PMA.

### Quality Assurance

Our quality assurance group is responsible for product inspection and release, and for ensuring company-wide compliance with U.S. and international quality system regulations. Quality assurance also manages our field quality and international regulatory approval activities.

## MARKETING AND SALES STRATEGY

We market CardioSEAL® through our direct sales force to customers in the United States and Canada and market CardioSEAL® and STARFlex® directly in key European markets and through select distributors in other parts of Europe. As of December 31, 2005, worldwide sales and marketing personnel consisted of 20 persons, of which 12 are in various locations in the United States and 8 were based in Europe. Our European employees are based in Germany, France and the United Kingdom. During 2006, we plan to expand our presence in Ireland, Benelux, Scandinavia and Spain.

Traditionally, the neurologist and the interventional cardiologist have not collaborated on patient diagnosis or treatment. We believe that the PFO/migraine and PFO/stroke connections have changed that relationship. To further facilitate what we believe to be an emerging solution to these brain attacks associated with both migraine and stroke, we have focused added resources on enhancing the referral process and helping neurologists and interventional cardiologists form the partnerships needed to diagnose and treat PFO. These are often the most challenging aspects of introducing a new technology and promoting a new therapeutic concept. We have sponsored joint meetings in both Europe and the United States that brought together the interventional

cardiology and stroke neurology communities on the subject of prevention and treatment of cardiac sources of migraine headache and stroke.

We use a variety of marketing and education programs to create ongoing awareness and demand for our CardioSEAL® and STARFlex® products. In addition to active participation in numerous cardiology related symposia and exhibitions in the United States and Europe, we work closely with our leading customers to promote multi-disciplinary dialogue and education, especially between the interventional cardiology and neurology communities.

## CUSTOMERS

Our customers are generally hospitals, clinics and other healthcare centers. In order for our U.S. customers to purchase the CardioSEAL® products under our PFO HDE, they must obtain Institutional Review Board ("IRB") approval. It is not necessary for our U.S. customers to obtain IRB approval to purchase CardioSEAL® products for VSD closure, as we have received a PMA for this indication. At December 31, 2005, we had approximately 280 active customers worldwide to which we sell our CardioSEAL® and STARFlex® products directly.

No customer accounted for greater than 10% of product sales in any of the three years in the period ended December 31, 2005.

## MANUFACTURING

We manufacture the CardioSEAL® and STARFlex® cardiac septal repair implants at our headquarters in Boston, Massachusetts, which includes a Class 10,000 cleanroom. We have received ISO 13485 certification, on adherence to established standards in the areas of quality assurance and manufacturing process control, and we have also received permission to affix the CE Mark to our products. We believe that our current manufacturing facilities are sufficient to accommodate potential increases in demand for our products.

## COMPETITION

Four companies, AGA Medical Corp. ("AGA"), W. L. Gore & Associates, Inc., Cardia, Inc. ("Cardia"), and St. Jude Medical, Inc., have developed or acquired technologies that may compete with our proprietary technologies. These companies sell their products in Europe and other international markets, and AGA also sells products in the United States. We believe that these competitors are conducting, or are planning to conduct, clinical trials in the United States and Europe. Additionally, more than 40 other companies or individuals have intellectual property in the field of septal closure including devices, radiofrequency welding, suturing, abrasion, adhesives and other approaches.

We believe that the CardioSEAL® and STARFlex® implants have a distinct advantage over other PFO closure devices. CardioSEAL® has the longest clinical use history, a highly conformable, atraumatic design, a tissue scaffold proven to promote endothelialization, and a low septal profile and low metal surface area. Additionally, STARFlex® has a self-adjusting PFO-compatible centering mechanism which provides exceptionally high closure rates. The Rapid Transport™ delivery system provides for simplicity by reducing the number of steps for implantation. We further believe that our new bioabsorbable devices, BioSTAR™ and BioTREK™, will provide even more biological response by promoting quicker healing and device endothelialization, improving both PFO closure rate and patient safety.

We have initiated patent infringement claims against each of AGA and Cardia. See Item 3 (legal proceedings).

## PATENTS AND PROPRIETARY TECHNOLOGY

We seek to protect our technology through the use of patents, trademarks and trade secrets. We are the owner or licensee of 18 issued United States patents, and corresponding foreign patents, relating to our cardiac septal repair implant devices, stents, distal (embolic) protection, anastomosis devices, nitinol radiopaque markers and other related inventions. In addition, we have 47 pending utility patent applications and 14 provisional patent applications in the areas of distal protection and intracardiac repair, including implants, delivery systems and accessory products. The existing patents expire at various dates ranging from 2011 to 2021. The patents related to our anastomosis devices, which are minimally invasive means of attaching vascular grafts, expire from 2016 to 2017 and the patent for our radiopaque markers, which allow catheters to be more visible under x-ray, expires in 2014. The patents for our distal protection system expire in 2021, the patent for our nitinol septal repair device expires in 2016, and the patent for our superelastic hinge joint, a novel concept with applicability to both implants and delivery systems, expires in 2017. The expiration dates of our patents relating to our stents range from 2012 to 2017. In addition, we are the exclusive licensee under certain patents, expiring from 2011 to 2016, relating to the CardioSEAL® and STARFlex® cardiac septal repair implants, delivery systems and methods for repairing cardiac and vascular defects. We also hold a perpetual license to certain technology used in nitinol septal repair devices.

We also rely on trade secrets and technical know-how in the development and manufacture of our devices, which we seek to protect, in part, through confidentiality agreements with our employees, consultants and other parties. We have ten trademarks, four of which are registered with the United States Patent and Trademark Office (see the following table).

| Trademark | Jurisdiction | Status | Renewal Date |
|---|---|---|---|
| STARFlex® | United States | Registered | Aug 2012 |
| STARFlex® | Canada | Registered | Sep 2020 |
| STARFlex® | European Community | Registered | Feb 2011 |
| STARFlex® | Japan | Registered | Jun 2014 |
| NMT Medical® | United States | Registered | Apr 2011 |
| CardioSEAL® | United States | Registered | Jan 2008 |
| Rapid Transport™ | European Community | Registered | Aug 2013 |
| BioSTAR™ | European Community | Registered | Apr 2014 |
| BioSTAR™ | Japan | Registered | Oct 2015 |
| Gator™ | European Community | Registered | Apr 2014 |
| Elegant Solutions® | United States | Registered | Aug 2009 |
| Rapid Transport™ | Canada | Pending | — |
| BioSTAR™ | United States | Allowed | Mar 2006 |
| Gator™ | United States | Allowed | Mar 2006 |
| Getting To The Heart Of Brain Attacks™ | United States | Published | — |
| At The Heart of Brain Attacks™ | United States | Published | — |
| At The Heart of Brain Attacks™ | Canada | Pending | — |
| At The Heart of Brain Attacks™ | European Community | Pending | — |
| BioTREK™ | United States | Pending | — |
| BioTREK™ | Canada | Pending | — |
| BioTREK™ | European Community | Pending | — |
| BioTREK™ | Japan | Approved for Registration | — |

## LICENSED TECHNOLOGY; ROYALTY OBLIGATIONS

*Cardiac Septal Repair Implants*

In connection with our cardiac septal repair implants, we have an exclusive worldwide license from CMCC under United States patents entitled "Occluder and Method for Repair of Cardiac and Vascular Defects" (U.S. Patent No. 5,425,744), "Occluder for Repair of Cardiac and Vascular Defects" (U.S. Patent No. 5,451,235) and "Self-Centering Umbrella-Type Septal Closure Device" (U.S. Patent No. 5,709,707) and the respective corresponding foreign patents, patent applications and associated know-how. The license agreement, as amended, provides for royalty payments to CMCC of 10.5% of commercial net sales of our CardioSEAL® and STARFlex® septal repair implant devices. Royalties continue until the end of the term of the patents, which range from 2014 to 2016. We also have a royalty-free, worldwide sublicense under the U.S. patent entitled "System for the Percutaneous Transluminal Front-End Loading Delivery and Retrieval of a Prosthetic Occluder" (U.S. Patent No. 5,649,950) and its corresponding foreign patents and associated know-how. The sublicense is exclusive in the field of the repair of atrial septal defects and nonexclusive in certain other fields. We have also obtained an exclusive worldwide license from Lloyd A. Marks, M.D. under the United States patent entitled "Aperture Occlusion Device" (U.S. Patent No. 5,108,420). The license agreement with Dr. Marks provides for royalty payments, subject to certain annual minimums, based on net sales of nitinol septal repair implants that are covered by the patent, which expires in 2011. There have been no sales by us of covered nitinol septal repair implants to date.

*Vena Cava Filters*

Under the terms of the 2001 sale of our former vena cava filter product line to Bard, we continue to make royalty payments to the estate of the inventor of these products based upon net sales by Bard of its SNF and RNF products. Commencing in 2003, these royalty expenses are reported in our consolidated financial statements as a reduction of royalties that we earn from Bard.

*Stents*

We pay a royalty equal to 2.5% of net royalties received from BSC to a former employee of ours and joint inventor of our stent technology.

## GOVERNMENT REGULATION

The manufacture and sale of medical devices intended for commercial distribution are subject to extensive governmental regulations in the United States. Medical devices are regulated in the United States by the FDA under the Federal Food, Drug, and Cosmetic Act (the "FDC Act") and require pre-market clearance, unless exempt, or PMA prior to commercial distribution. In addition, certain material changes or modifications to medical devices are also subject to FDA review and clearance or approval. Pursuant to the FDC Act, the FDA regulates the research, testing, manufacture, safety, labeling, storage, record keeping, advertising, and distribution of medical devices in the United States. Noncompliance with applicable requirements can result in failure of the government to grant pre-market clearance or approval for devices, withdrawal of approvals, total or partial suspension of production, banning devices or imposing restrictions on sale, distribution or use, fines, injunctions, civil penalties, recall or seizure of products, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the purchase price of any device manufactured or distributed that presents an unreasonable health risk.

Generally, before a new device can be introduced into the market in the United States, the manufacturer or distributor must obtain FDA clearance of a pre-market notification ("510(k)") submission, unless exempt, or approval of a PMA. Medical devices are classified into one of three classes on the basis of the level of control deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to the least regulatory control (general controls), and generally are exempt from the 510(k) requirement. Devices that cannot be classified as Class I because the general controls are insufficient to provide reasonable assurance of safety and effectiveness, and for which there is sufficient information to establish special controls (e.g., performance standards or guidelines) are Class II devices. Class II devices, unless exempt, can be marketed with a cleared 510(k). Specifically, if a medical device manufacturer, (or any other person required to submit a 510(k) under 21 CFR Part 807), can establish that a device is "substantially equivalent" to a legally marketed Class I or Class II device, or to a Class III device for which the FDA does not require an approved PMA, the manufacturer may seek clearance from the FDA to market the device by filing a 510(k). The 510(k) needs to be supported by appropriate data establishing the claim of substantial equivalence to the satisfaction of the FDA. The FDA charges a fee for 510(k) reviews unless an exemption or waiver applies. The 510(k) must be submitted 90 days before the marketing of the device. The FDA will issue an order determining that the device is substantially equivalent or not substantially equivalent, or may request additional information. There can be no assurance that the FDA review process will not involve delays or that such clearance will be granted on a timely basis, if at all.

Class III is the most stringent regulatory category for devices. The FDA places devices in Class III if insufficient information exists to determine that the application of general controls or special controls are sufficient to provide reasonable assurance of safety and effectiveness, and the devices are life-sustaining or life-supporting, or of substantial importance in preventing the impairment of human health, or present a potential, unreasonable risk of illness or injury. Most Class III devices require clinical testing to ensure safety and effectiveness, and an approved PMA, prior to marketing and distribution. Class III devices that require an approved PMA to be marketed are devices that were regulated as new drugs prior to May 28, 1976 (transitional devices), devices not found substantially equivalent to devices marketed prior to May 28, 1976, and Class III pre-amendment devices which were introduced into the U.S. market before May 28, 1976 and which by regulation require a PMA. Pre-amendment devices are classified automatically by statute into Class III without any FDA rulemaking process, and may be marketed with a 510(k) until the FDA issues a final classification regulation requiring the submission of a PMA. The FDA is directed by statute to either down-classify pre-amendment Class III devices to Class I or II, or to publish a classification regulation retaining the device in Class III. In reclassifying these devices, the FDA considers data, including adverse safety and effectiveness information, submitted by manufacturers of pre-amendment Class III devices for which no final regulation has been issued. If the FDA calls for a PMA for a pre-amendment Class III device, a PMA must be submitted for the device even if it has already received 510(k) clearance. If the FDA down-classifies a pre-amendment Class III device to Class I or Class II, a PMA application is not required. Post-amendment Class III devices that are substantially equivalent to pre-amendment Class III devices, and for which a regulation calling for an approved PMA has not been published, can be marketed with a 510(k). A PMA application must be supported by extensive data, including preclinical and clinical trial data, to prove the safety and effectiveness of the device. The FDA charges a fee for PMA reviews unless an exemption or waiver applies. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) codified the FDA's modular review approach, whereby applicants are allowed to submit discrete sections of the PMA for review after completion. Under the FDC Act, the FDA must review PMAs within 180 days. There can, however, be no assurance that the FDA review process will not involve delays or that PMA approvals will be granted on a timely basis, if at all.

If human clinical trials of a device are required, and if the device presents a "significant risk", the manufacturer of the device is required to file an IDE application with the FDA prior to commencing clinical trials. The IDE application must be supported by data, typically the results of animal and, possibly, mechanical testing. If the IDE application is approved by the FDA, human clinical trials may begin at a specific number of investigational sites with a maximum number of patients, as approved by the FDA. Sponsors of clinical trials may charge for an investigational device provided that such costs do not exceed the amount necessary to recover the costs of manufacture, research, development and handling of the investigational device. The clinical trials must be

conducted under the auspices of an independent IRB established pursuant to FDA regulations. If one or more IRBs determine that a clinical trial involves a "nonsignificant risk" device, the investigation is considered to have an approved IDE if certain conditions are met, including, for example, IRB approval of the investigation and compliance with informed consent requirements. The sponsor of a study involving a nonsignificant risk device does not need to obtain FDA approval of an IDE application before beginning the study.

After approval or clearance of a device, numerous regulatory requirements apply. These include establishment registration and device listing as well as requirements relating to labeling and corrections and removals reporting. The FDA also requires that all device manufacturers comply with the Quality System Regulation ("QSR"). Under the QSR, manufacturers must comply with various control requirements pertaining to all aspects of the manufacturing process, including requirements for design and processing controls, packaging, storage, labeling, and recordkeeping, including maintaining complaint files. The FDA enforces these requirements through periodic inspections of the medical device manufacturing facilities.

Under the Medical Device Reporting regulation, manufacturers or importers must inform the FDA whenever information reasonably suggests that one of their devices may have caused or contributed to a death or serious injury, or has malfunctioned, and, if the malfunction were to recur, the device would be likely to cause or contribute to a death or serious injury. These reports are publicly available and, therefore, can become a basis for private tort suits, including class actions.

With the passage of the Safe Medical Devices Act of 1990, Congress sought to improve the framework to regulate medical devices. Congress recognized that for diseases and conditions affecting small populations, a device manufacturer's research and development costs could exceed its market returns, thereby making development of such devices unattractive. The HDE regulations were created to provide an incentive for development of devices to be used in the treatment of diseases or conditions affecting small numbers of patients. Under the HDE regulations, medical devices that provide safe treatment and that are intended to treat and diagnose conditions that affect fewer than 4,000 individuals in the United States per year, may be approved on more limited clinical experience than that required for a PMA. The HDE application is exempt from the effectiveness requirement of a PMA, and the FDA reviews it within 75 days of receipt of the application. One of the criteria that must be satisfied in order for a device to obtain marketing approval under the HDE regulation is that there is no comparable device, other than another Humanitarian Use Device ("HUD") approved under the HDE regulation, or a device being studied under an approved IDE, available to treat or diagnose the disease or condition.

From time to time, legislation is drafted and introduced in Congress that could significantly affect the statutory provisions governing the approval, manufacture, and marketing of medical devices in the U.S. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect business operations and/or products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance, or interpretations will be changed, and what the impact of such changes, if any, may be.

The current regulatory environment in Europe for medical devices differs from that in the United States. Countries in the European Union ("EU") have promulgated rules, which provide that medical products may not be marketed and sold commercially in the countries in the European Economic Area unless they receive a CE Mark. The letters "CE", an abbreviation of a French phrase "Conformité Europeene", indicates that the manufacturer has conformed to all of the obligations required by the legislation. All of our current products have received approval for CE Marking. Non-EU members, such as Switzerland, have adopted internal regulations that in most instances mirror the requirements established in the neighboring European Union.

## THIRD PARTY REIMBURSEMENT

Health care providers in the United States, such as hospitals and physicians, that purchase medical devices, such as the products manufactured or licensed by us, generally rely on third party payors, principally Medicare, Medicaid and private health insurance plans, to reimburse all or part of the costs and fees associated with our devices. Major third party payors reimburse inpatient medical treatment, including all operating costs and all furnished items or services, including devices such as ours, at a prospectively fixed rate based on the diagnosis-related group ("DRG") that covers such treatment as established by the Federal Health Care Financing Administration ("HCFA"). For interventional procedures, the fixed rate of reimbursement is based on the procedure or procedures performed and are unrelated to the specific devices used in that procedure. If a procedure is not covered by a DRG, certain third party payors may deny reimbursement. Alternatively, a DRG may be assigned that does not reflect the costs associated with the use of our devices, resulting in under-reimbursement. If, for any reason, our products were not to be reimbursed by third party payors, our ability to sell the products may be materially adversely affected.

Mounting concerns about rising health care costs may cause more restrictive coverage and reimbursement policies to be implemented in the future. Several states and the federal government are investigating a variety of alternatives to reform the health care delivery system and to further reduce and control health care spending. These reform efforts include proposals to limit spending on health care items and services, limit coverage for new technology and limit, or control directly, the price health care providers and drug and device manufacturers may charge for their services and products. We believe that U.S. health care providers currently are reimbursed for the cost of purchasing our CardioSEAL® septal repair implants used in HDE and PMA procedures. In the international market, reimbursement by private third party medical insurance providers, including

governmental insurers and providers, varies from country to country. In certain countries, our ability to achieve significant market penetration may depend upon the availability of third party governmental reimbursement. Our independent distributors, and the health care providers to whom such distributors sell, obtain any necessary reimbursement approvals.

The CardioSEAL® septal repair implant was awarded a Medicare billing pass-through code in September 2000 and has a favorable medical policy position from the national Blue Cross Blue Shield Association. A specific American Medical Association procedure code (CPT) for catheter closure of atrial and ventricle level shunts has been issued and became effective March 1, 2003. The assigned CPT codes cover procedures using our CardioSEAL® cardiac septal repair implants for closure of certain categories of VSD and PFO defects.

Our MIST II and CLOSURE I trials are being conducted under FDA approved IDEs with Category B HCFA status, meaning usage under the trial is eligible for Medicare coverage.

### FINANCIAL INFORMATION ABOUT GEOGRAPHIC AREAS

Please see Notes 2(l) and 12 of Notes to Consolidated Financial Statements for certain of our financial information concerning geographic areas.

### PRODUCT LIABILITY AND INSURANCE

Our business involves the risk of product liability claims. We maintain product liability insurance with coverage limits of $10 million per occurrence on a claims made basis, with a maximum $10 million aggregate per policy year, and an umbrella policy of $8 million.

### EMPLOYEES

As of December 31, 2005, we had 94 full-time employees. We believe that we maintain good relations with our employees.

## ITEM 1A. RISK FACTORS

The following important factors, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this Annual Report on Form 10-K and presented elsewhere by us from time to time.

**WE MAY FACE UNCERTAINTIES WITH RESPECT TO THE EXECUTION, COST AND ULTIMATE OUTCOME OF MIST.**

In November 2004, we received approval to initiate our MIST clinical study in the United Kingdom. This study is designed to evaluate the effectiveness of transcatheter closure of a PFO in the treatment and prevention of migraine headaches. Patient enrollment was completed in early July 2005, with follow-up evaluations over a six-month period. We currently estimate the total costs of MIST, including third party contracts, agreements with clinical sites and other service providers, to be approximately $4.0 to $4.5 million. We cannot be certain that this prospective, randomized, controlled study will confirm clinical relevance between PFO and migraine headaches or that it will demonstrate the effectiveness of our proprietary technology in treating this condition. Even if we achieve positive results, we cannot be certain of the timing or the costs of obtaining required FDA approvals in order to market our STARFlex® technology in the U.S. to treat migraines. It is currently anticipated that results from this study will be announced on March 13, 2006.

**SUBSTANTIALLY ALL OF OUR REVENUES ARE DERIVED FROM SALES OF ONE PRODUCT LINE.**

We derive a substantial portion of our ongoing revenues from sales of our CardioSEAL® and STARFlex® products. In the United States, the FDA limits sales under our existing PFO HDE to 4,000 CardioSEAL® implant units per year. As demand for, and costs associated with, these products fluctuates, including the potential impact of our non-revenue producing PFO IDE clinical trials on product sales, our financial results on a quarterly or annual basis may be significantly impacted. Accordingly, events or circumstances adversely affecting the sales of either of these products would directly and adversely impact our business. These events or circumstances may include reduced demand for our products, lack of regulatory approvals, product liability claims and/or increased competition.

**CIRCUMSTANCES COULD CAUSE THE LOSS OF OUR HDE APPROVAL FOR USE OF CARDIOSEAL® IN TREATING PFO PATIENTS.**

All of our U.S. commercial sales of CardioSEAL® are made pursuant to either: (a) the PMA granted by the FDA in December 2001 covering the VSD indication or (b) the HDE granted by the FDA in February 2000 covering the PFO indication. In 2005, approximately 50% of our U.S. implant sales were made under the PFO HDE. If our PFO HDE were to be deactivated by the FDA, whether due to issuance of a PMA to one of our competitors or otherwise, such a loss of our PFO HDE would potentially cause a very material reduction in U.S. sales, resulting in significant operating losses based upon our current operational

structure. Under these circumstances, and in the absence of substantial sources of new financing, our future prospects would be severely limited, including our ability to complete the CLOSURE I clinical trial that is required to apply for a PFO PMA to treat cardiac sources of stroke.

**AS A RESULT OF GOVERNMENT REGULATIONS, WE MAY EXPERIENCE LOWER SALES AND EARNINGS.**

The manufacture and sale of medical devices intended for commercial distribution are subject to extensive governmental regulations in the United States and abroad. Medical devices generally require pre-market clearance or pre-market approval prior to commercial distribution. Certain material changes or modifications to medical devices are also subject to regulatory review and clearance or approval. The regulatory approval process is expensive, uncertain and lengthy. If granted, the approval may include significant limitations on the indicated uses for which a product may be marketed. In addition, any products that we manufacture or distribute are subject to continuing regulation by the FDA. We cannot be certain that we will be able to obtain necessary regulatory approvals or clearances for our products on a timely basis or at all. The occurrence of any of the following events could have a material adverse effect on our business, financial condition and results of operations:

- delays in receipt of, or failure to receive, regulatory approvals or clearances;
- the loss of previously received approvals or clearances, including our PFO HDE;
- limitations on the intended use of a device imposed as a condition of regulatory approvals or clearances; or
- our failure to comply with existing or future regulatory requirements.

In addition, sales of medical device products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Failure to comply with foreign regulatory requirements also could have a material adverse effect on our business, financial condition and results of operations.

**WE MAY FACE UNCERTAINTIES WITH RESPECT TO THE EXECUTION, COST AND ULTIMATE OUTCOME OF MIST II.**

In September 2005, we received conditional approval from the FDA of an IDE to initiate enrollment in our pivotal PFO/migraine clinical study, named MIST II. Patient enrollment, which commenced in January 2006, is currently estimated to be completed in early 2007, with patient follow-up over a one year period. We currently project the costs of this clinical study to be in the range of $16 to $20 million through 2008. We cannot be certain that this study will confirm clinical relevance between PFO and migraine headaches or that it will demonstrate the effectiveness of our proprietary technology in treating this condition. We cannot be certain that our preliminary cost estimates for MIST II will not need to be adjusted upwards significantly. Furthermore, we cannot be certain that we will ultimately obtain a PMA from the FDA based upon the final results of this study or whether further studies might be required by the FDA before consideration of a PMA. In addition, if patient enrollment were to progress as rapidly as we experienced for our MIST UK study, we cannot be certain of the effect, if any, on the level of commercial sales of our CardioSEAL® products in the United States during the enrollment period.

**WE MAY FACE UNCERTAINTIES WITH RESPECT TO THE EXECUTION, COST AND ULTIMATE OUTCOME OF BEST.**

In June 2005, we received approval to initiate our BEST clinical study in the United Kingdom. We currently estimate total costs of this study, including third party contracts and agreements with clinical sites and other service providers, to be in the range of $1.2 to $1.5 million through early 2006. We cannot be certain that the projected costs of BEST will not need to be adjusted upwards. Furthermore, we cannot be certain that we will secure European commercial approval for our BioSTAR™ technology through the CE Mark process.

**WE MAY FACE UNCERTAINTIES WITH RESPECT TO THE EXECUTION, COST AND ULTIMATE OUTCOME OF CLOSURE I.**

Upon receipt of final FDA approval, we commenced CLOSURE I in June 2003. During the two years ended December 31, 2005, the rate of patient enrollment has been disappointing. At the present time, we are working with our consultants, regulatory bodies and investigators to develop a course of action designed to enable us to complete the CLOSURE I enrollment. We now believe that study changes, acceptable to the FDA, the investigators and us, are necessary in order to successfully complete this study. Until these changes are approved and implemented, it is difficult to estimate the completion date. It is currently anticipated that when completed, study data from CLOSURE I will be used to support a PFO PMA application. We currently estimate the total costs of CLOSURE I to be approximately $24 million through completion of the clinical trial and submission to the FDA. We have no direct experience conducting a clinical trial of this magnitude. We cannot be certain that patient enrollment will be completed at all. We cannot be certain that the projected costs of CLOSURE I will not need to be adjusted upwards, primarily related to the extended enrollment period. Furthermore, we cannot be certain that we will obtain a PMA from the FDA based upon the final results of the trial. If CLOSURE I does not result in a PMA, we may face uncertainties and/or limitations as to the continued growth of revenues of our CardioSEAL® and STARFlex® products, which may impact our profitability.

**WE MAY NEED TO RAISE DEBT OR EQUITY FUNDS IN THE FUTURE.**

In the future, considering our anticipated significant spending on clinical trials, we may require additional funds for our research and product development programs, regulatory processes, preclinical and clinical testing, sales, marketing and manufacturing infrastructure and programs and potential licenses and acquisitions. Any additional equity financing may be dilutive to our stockholders, and additional debt financing, if available, may involve restrictive covenants. Our capital requirements will depend on numerous factors, including the level of sales of our products, the progress of our research and development programs, the progress of clinical testing, the time and cost involved in obtaining regulatory approvals, the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, competing technological and market developments, developments and changes in our existing research, licensing and other relationships and the terms of any collaborative, licensing and other similar arrangements that we may establish. We do not currently have any existing line of credit arrangements, and we may not be able to obtain any such credit facilities on acceptable terms, if at all.

**WE MAY FACE UNCERTAINTIES WITH RESPECT TO COMMERCIALIZATION, PRODUCT DEVELOPMENT AND MARKET ACCEPTANCE OF OUR PRODUCTS.**

We cannot be certain that our current products, or products currently under development, will achieve or maintain market acceptance. Certain of the medical indications that can be treated by our devices can also be treated by surgery, drugs or other medical devices. Currently, the medical community widely accepts many alternative treatments, and these other treatments have a long history of use. We cannot be certain that our devices and procedures will be able to replace such established treatments or that either physicians or the medical community, in general, will accept and utilize our devices or any other medical products that we may develop. In addition, our future success depends, in part, on our ability to develop new and improved implant technology products. Even if we determine that a product candidate has medical benefits, the cost of commercializing that product candidate may be too high to justify development. In addition, competitors may develop products that are more effective, cost less or are ready for commercial introduction before our products. If we are unable to develop additional, commercially viable products, our future prospects will be limited.

**WE MAY FACE CHALLENGES IN EXECUTING OUR FOCUSED BUSINESS STRATEGY.**

As a result of the 2001 sale of our vena cava filter product line and the 2002 sale of our neurosciences business unit, we have focused our business growth strategy to concentrate on the manufacturing, marketing and selling of our cardiac septal repair implant devices. Our future sales growth and financial results depend almost exclusively upon the growth of sales of this product line. CardioSEAL® and STARFlex® product sales may not grow as quickly as we expect for various reasons, including, but not limited to, delays in receiving further FDA approvals for additional indications and product enhancements, difficulties in recruiting additional experienced sales and marketing personnel and increased competition. This focus has placed significant demands on our senior management team and other resources. Our future success will depend on our ability to manage and implement our focused business strategy effectively, including by:

- achieving successful migraine and stroke-related clinical trials;
- developing next generation product lines;
- improving our sales and marketing capabilities, including expansion in Europe;
- expanding our production capabilities;
- improving our ability to successfully manage inventory as we expand production;
- continuing to train, motivate and manage our employees; and
- developing and improving our operational, financial and other internal systems.

**WE MAY BE UNABLE TO PROTECT OUR INTELLECTUAL PROPERTY RIGHTS AND MAY FACE INTELLECTUAL PROPERTY INFRINGEMENT CLAIMS.**

Our success will depend, in part, on our ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties. We cannot be certain that:

- any of our pending patent applications or any future patent applications will result in issued patents;
- the scope of our patent protection will exclude competitors or provide competitive advantages to us;
- any of our patents will be held valid if subsequently challenged; or
- others will not claim rights in or ownership of the patents and other proprietary rights held by us.

Furthermore, we cannot be certain that others have not or will not develop similar products, duplicate any of our products or design around any patents issued, or that may be issued, in the future to us or to our licensors. Whether or not patents are issued to us or to our licensors, others may hold or receive patents which contain claims having a scope that covers products developed

by us. We could incur substantial costs in defending any patent infringement suits or in asserting any patent rights, including those granted by third parties. In addition, we may be required to obtain licenses to patents or proprietary rights from third parties. There can be no assurance that such licenses will be available on acceptable terms, if at all.

Our issued U.S. patents, and corresponding foreign patents, expire at various dates ranging from 2011 to 2021. When each of our patents expires, competitors may develop and sell products based on the same or similar technologies as those covered by the expired patent. We have invested in significant new patent applications, and we cannot be certain that any of these applications will result in an issued patent to enhance our intellectual property rights.

**WE CANNOT BE CERTAIN THAT THE RECENT TREND OF NET ROYALTY INCOME WILL CONTINUE.**

For the year ended 2005, net royalty income increased 10% compared to the year ended 2004. For the year ended 2004, net royalty income increased approximately 200% compared to the year ended 2003. As a percentage of our total revenues, net royalty income has increased from approximately 6.0% for fiscal year 2003 to approximately 19.5% and 19.2% for the fiscal years ended 2004 and 2005, respectively. These increases have been directly attributable to higher sales by Bard of its RNF product, for which Bard received FDA approval for commercial sales and use as of December 31, 2002. We cannot be certain that the recent trend of Bard's RNF sales can be sustained or even maintained at its current level. Furthermore, these sales levels could fluctuate on a quarter-to-quarter basis. We incur virtually no operating expenses related to our net royalty income and, therefore, future increases or decreases, if any, in the level of Bard's RNF sales could have a material effect on net income (loss) in future periods. In addition, commencing in 2008, the royalty rate earned on Bard's RNF sales will decrease substantially from its current rate.

**OUR LIMITED MANUFACTURING HISTORY AND THE POSSIBILITY OF NON-COMPLIANCE WITH MANUFACTURING REGULATIONS RAISE UNCERTAINTIES WITH RESPECT TO OUR ABILITY TO COMMERCIALIZE FUTURE PRODUCTS.**

We have a limited history in manufacturing our products, including our CardioSEAL® and STARFlex® cardiac septal repair implant devices, and we may face difficulties as the commercialization of our products and the medical device industry changes. Increases in our manufacturing costs, or significant delays in our manufacturing process, could have a material adverse effect on our business, financial condition and results of operations.

The FDA and other regulatory authorities require that our products be manufactured according to rigorous standards including, but not limited to, Good Manufacturing Practices and International Standards Organization ("ISO") standards. These regulatory requirements may significantly increase our production or purchasing costs and may even prevent us from making or obtaining our products in amounts sufficient to meet market demand. If we or a third-party manufacturer change our approved manufacturing process, the FDA will require a new approval before that process could be used. Failure to develop our manufacturing capabilities may mean that, even if we develop promising new products, we may not be able to produce them profitably, as a result of delays and additional capital investment costs.

**WE MAY BE UNABLE TO SUCCESSFULLY GROW OUR PRODUCT REVENUES OR EXPAND GEOGRAPHICALLY DUE TO LIMITED MARKETING AND SALES EXPERIENCE.**

Our cardiac septal repair implant devices are marketed primarily through our direct sales force. Since 2001, we have increased our combined U.S. and European sales and marketing organization headcount from 9 to 20. Due to our relatively new sales staff, and because we had marketed our initial products, such as stents and vena cava filters, through third parties, we have limited experience marketing our products directly. We are uncertain that we can successfully expand geographically in Europe or other potential markets for our products. In order to market directly the CardioSEAL® and STARFlex® septal implants and any related products, we will have to continue to develop a marketing and sales organization with technical expertise and distribution capabilities.

**WE MAY BE UNABLE TO COMPETE SUCCESSFULLY BECAUSE OF INTENSE COMPETITION AND RAPID TECHNOLOGICAL CHANGE IN OUR INDUSTRY.**

The medical device industry is characterized by rapidly evolving technology and intense competition. Existing and future products, therapies, technological approaches and delivery systems will continue to compete directly with our products. Many of our competitors have substantially greater capital resources, greater research and development, manufacturing and marketing resources and experience and greater name recognition than we do. In addition, new surgical procedures and medications could be developed that replace or reduce the importance of current or future procedures that utilize our products. As a result, any products that we develop may become obsolete before we recover any expenses incurred in connection with development of these products.

**AN ADVERSE OUTCOME IN ANY LITIGATION WE ARE CURRENTLY INVOLVED IN COULD AFFECT OUR FINANCIAL CONDITION.**

We are currently involved in the litigation of disputes as described in Item 3 Part I (Legal Proceedings). An adverse outcome in any one of these disputes could result in substantial monetary damages and or negatively impact our ability to use intellectual property and, therefore, negatively impact our financial condition or results of operations.

**PRODUCT LIABILITY CLAIMS, PRODUCT RECALLS AND UNINSURED OR UNDERINSURED LIABILITIES COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS.**

The testing, marketing and sale of implantable devices and materials carry an inherent risk that users will assert product liability claims against us or our third party distributors. In these claims, users might allege that their use of our devices had adverse effects on their health. A product liability claim or a product recall could have a material adverse effect on our business. Certain of our devices are designed to be used in life-threatening situations where there is a high risk of serious injury or death. Although we currently maintain limited product liability insurance coverage, we cannot be certain that in the future we will be able to maintain such coverage on acceptable terms, or that current insurance or insurance subsequently obtained will provide adequate coverage against any or all potential claims. Furthermore, we cannot be certain that we will avoid significant product liability claims and the attendant adverse publicity. Any product liability claim, or other claim, with respect to uninsured or underinsured liabilities could have a material adverse effect on our business.

**INTENSE INDUSTRY COMPETITION FOR QUALIFIED EMPLOYEES COULD AFFECT OUR ABILITY TO ATTRACT AND RETAIN NECESSARY, QUALIFIED PERSONNEL.**

In the medical device field, there is intense competition for qualified personnel, and we cannot be assured that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business. Both the loss of the services of existing personnel, as well as the failure to recruit additional qualified scientific, technical and managerial personnel in a timely manner, would be detrimental to our anticipated growth and expansion into areas and activities requiring additional expertise. The failure to attract and retain such personnel could adversely affect our business.

**WE FACE UNCERTAINTIES WITH RESPECT TO THE AVAILABILITY OF THIRD PARTY REIMBURSEMENT.**

In the United States, Medicare, Medicaid and other government insurance programs, as well as private insurance reimbursement programs, greatly affect revenues for suppliers of health care products and services. Such third party payors may affect the pricing or relative attractiveness of our products by regulating the maximum amount, if any, of reimbursement which they provide to the physicians and hospitals using our devices, or any other products that we may develop. If, for any reason, the third party payors decided not to provide reimbursement for our products, our ability to sell our products would be materially adversely affected. Moreover, mounting concerns about rising health care costs may cause the government or private insurers to implement more restrictive coverage and reimbursement policies in the future. In the international market, reimbursement by private third party medical insurance providers and by governmental insurers and providers varies from country to country. In certain countries, our ability to achieve significant market penetration may depend upon the availability of third party governmental reimbursement.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## ITEM 2. PROPERTIES

Our principal executive offices are located at 27 Wormwood Street, Boston, Massachusetts 02210-1625. We currently lease approximately 35,000 square feet of manufacturing, laboratory and administrative space at this facility, under leases that expire in September 2010, with one 5-year renewal option thereafter. The renewal option is subject to acceptance by the landlord.

## ITEM 3. LEGAL PROCEEDINGS

We are a party to the following legal proceedings that could have a material adverse impact on our results of operations or liquidity if there were an adverse outcome. Although we intend to pursue our rights in each of these matters vigorously, we cannot predict the ultimate outcomes. In September 2004, we and CMCC filed a civil complaint in the U.S. District Court for the District of Minnesota for infringement of a patent owned by CMCC and licensed exclusively to us. The complaint alleges that Cardia of Burnsville, Minnesota is making, selling and/or offering to sell a medical device in the United States that infringes CMCC's U.S. patent relating to a device and method for repairing septal defects. We sought an injunction from the court to prevent further infringement by Cardia, as well as monetary damages. The court has entered a pre-trial order stating that the case is to be ready for trial in the spring of 2006.

On March 22, 1999, we filed a patent infringement suit in the United States District Court for the District of Massachusetts (the "Court") against AGA alleging that AGA was infringing United States Patent No. 5,108,420 (the "'420 patent"), relating to aperture occlusion devices, to which we have an exclusive license. We sought an injunction from the Court to prevent further infringement by AGA, as well as monetary damages. On April 12, 1999, AGA served its answer and counterclaims denying liability

and alleging that we had engaged in false or misleading advertising and in unfair or deceptive business practices. AGA's counterclaims sought an injunction and an unspecified amount of damages. On May 3, 1999, we answered AGA's counterclaims denying liability. On April 25, 2001, the Court granted our motion to stay all proceedings in this matter pending reexamination of the '420 patent by the United States Patent and Trademark Office and, on December 2, 2003, the Court dismissed our claim and AGA's counterclaim without prejudice to our ability to refile suit after the conclusion of the reexamination proceedings. Although a Patent Office examiner initially rejected the claims of the '420 patent, on August 19, 2004, the Board of Patent Appeals and Interferences reversed the examiners rejection of the claims of the '420 patent and returned the reexamination for action consistent with its decision. On January 26, 2005, the Patent Office mailed a Notice of Intent to Issue a Reexamination Certificate. This reexamination certificate was issued on June 7, 2005. On October 13, 2004, AGA initiated a declaratory action in the United States District Court for the District of Minnesota seeking a declaration that the '420 patent is invalid, unenforceable, and not infringed. On December 7, 2004, we revived our original Massachusetts action by filing a complaint alleging that AGA is infringing the '420 patent. On September 1, 2005, AGA's declaratory judgment action in the United States District Court for the District of Minnesota was transferred to the District of Massachusetts. On October 13, 2005, we answered AGA's complaint in its declaratory judgment action, denying AGA's claims. On November 2, 2005, we filed an amended complaint adding the inventor of the '420 patent as a plaintiff. On November 3, 2005, AGA answered our amended complaint, denying liability and counterclaiming that the '420 patent is invalid, unenforceable, and not infringed. On November 17, 2005, we answered AGA's counterclaims by denying them.

On or about September 24, 2001, each of the three French subsidiaries of our former neurosciences business unit received a Notification of Reassessment Following Verification of the Accounts (Notification de redressements suite à une vérification de comptabilité) from the French Direction de Controle Fiscal Sud-est (Nice) ("Reassessment"). The French authorities sought back taxes, interest and penalties in excess of FF 11 million, which is the currency in which the assessment was made (approximately $2.0 million based upon the exchange rate at June 30, 2005). In connection with our sale of the neurosciences business unit to Integra LifeSciences Holding Corporation ("Integra") in July 2002, we agreed to specifically indemnify Integra against any liability in connection with these tax claims. In order to continue to appeal the Reassessment, in October 2004 we provided the French authorities with a bank guarantee on behalf of Integra Neurosciences Implants SA totaling approximately 824,000 Euros (approximately $1.0 million based upon the exchange rate at June 30, 2005). On July 6, 2005, we settled the tax claim and, pursuant to the indemnification agreement, we paid $324,267 to Integra, which amount was net of a previous deposit payment of approximately $60,000. In connection with this settlement, we recorded income from discontinued operations of $90,687 for the year ended December 31, 2005.

Other than as described above, we have no material pending legal proceedings.

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

No matters were submitted to a vote of security holders during the fourth quarter of the year ended December 31, 2005.

# PART II

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

Our common stock is quoted on The NASDAQ National Market under the symbol "NMTI". There were approximately 84 stockholders of record of our common stock on March 6, 2006, representing approximately 16,500 shareholder accounts. The following table lists the high and low sales prices for our common stock for the periods indicated.

| PERIOD | HIGH | LOW |
|---|---|---|
| 2004 | | |
| First quarter | $ 5.35 | $ 4.03 |
| Second quarter | 5.10 | 3.56 |
| Third quarter | 4.15 | 3.18 |
| Fourth quarter | 5.00 | 3.35 |
| 2005 | | |
| First quarter | $ 8.22 | $ 4.19 |
| Second quarter | 10.22 | 6.85 |
| Third quarter | 12.20 | 7.30 |
| Fourth quarter | 21.79 | 9.83 |

We did not declare or pay any cash dividends on shares of our common stock during the years ended December 31, 2005 and 2004 and do not anticipate declaring or paying cash dividends in the foreseeable future. We currently expect that we will retain any earnings for use in our business.

# ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data for each of the five years in the period ended December 31, 2005 were derived from our audited consolidated financial statements. The selected consolidated financial data set forth below should be read in conjunction with the consolidated financial statements and the Notes thereto, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the other financial information appearing elsewhere in this Annual Report on Form 10-K.

Product sales included our vena cava filter products through the November 2001 sale of that product line to Bard and the transitional manufacturing agreement with Bard that continued through the second quarter of 2002. A portion of the Bard sale proceeds in 2001 were used to repay, in full, our outstanding subordinated debt.

We sold the remainder of our former neurosciences business unit to Integra in July 2002. Accordingly, the operations of our former neurosciences business unit have been included as discontinued operations for all periods presented.

| FOR THE YEARS ENDED DECEMBER 31, | 2005 | 2004 | 2003 | 2002 | 2001 |
|---|---|---|---|---|---|
| **STATEMENT OF OPERATIONS DATA:** | | | | | |
| (In thousands, except per share data) | | | | | |
| Revenues: | | | | | |
| Product sales | $19,313 | $17,279 | $21,574 | $24,546 | $22,501 |
| Net royalty income | 4,603 | 4,181 | 1,387 | 413 | 546 |
| Total revenues | 23,916 | 21,460 | 22,961 | 24,959 | 23,047 |
| Costs and Expenses: | | | | | |
| Cost of product sales | 5,470 | 4,514 | 5,303 | 6,606 | 7,436 |
| Research and development | 15,384 | 9,004 | 6,961 | 5,544 | 3,801 |
| General and administrative | 5,344 | 5,065 | 5,546 | 5,496 | 6,080 |
| Selling and marketing | 6,340 | 5,542 | 5,614 | 5,446 | 3,619 |
| Settlement of litigation | — | — | 1,216 | — | — |
| Total costs and expenses | 32,538 | 24,125 | 24,640 | 23,092 | 20,936 |
| Gain on sale of product line | — | — | — | 7,000 | 20,257 |
| (Loss) income from operations | (8,622) | (2,665) | (1,679) | 8,867 | 22,368 |
| Other Income (Expense): | | | | | |
| Currency transaction (loss) gain | (122) | 92 | 81 | 81 | (36) |
| Interest expense | — | (2) | (5) | (10) | (698) |
| Interest income | 861 | 543 | 558 | 691 | 176 |
| Loss on early extinguishment of debt | — | — | — | — | (402) |
| Total other income (expense), net | 739 | 633 | 634 | 762 | (960) |
| (Loss) income before provision for income taxes | (7,883) | (2,032) | (1,045) | 9,629 | 21,408 |
| Provision for income taxes | — | — | 105 | 3,424 | 2,630 |
| (Loss) income from continuing operations | (7,883) | (2,032) | (1,150) | 6,205 | 18,778 |
| Discontinued operations: | | | | | |
| Income (loss) from discontinued operations | 91 | 123 | — | (40) | 417 |
| Gain on sale of discontinued operations | — | — | — | 4,914 | — |
| Gain from discontinued operations | 91 | 123 | — | 4,874 | 417 |
| Net (loss) income | $ (7,792) | $ (1,909) | $ (1,150) | $11,079 | $19,195 |
| Basic net (loss) income per common share: | | | | | |
| Continuing operations | $ (0.64) | $ (0.17) | $ (0.10) | $ 0.54 | $ 1.71 |
| Discontinued operations | 0.01 | 0.01 | — | 0.42 | 0.04 |
| Net (loss) income | $ (0.63) | $ (0.16) | $ (0.10) | $ 0.96 | $ 1.75 |
| Diluted net (loss) income per common share: | | | | | |
| Continuing operations | $ (0.64) | $ (0.17) | $ (0.10) | $ 0.51 | $ 1.61 |
| Discontinued operations | 0.01 | 0.01 | — | 0.40 | 0.04 |
| Net (loss) income | $ (0.63) | $ (0.16) | $ (0.10) | $ 0.91 | $ 1.65 |
| Weighted average common shares outstanding: | | | | | |
| Basic | 12,332 | 12,031 | 11,808 | 11,542 | 11,013 |
| Diluted | 12,332 | 12,031 | 11,808 | 12,119 | 11,657 |

| AT DECEMBER 31, | 2005 | 2004 | 2003 | 2002 | 2001 |
|---|---|---|---|---|---|
| **BALANCE SHEET DATA:** | | | | | |
| (In thousands) | | | | | |
| Cash, cash equivalents, marketable securities and restricted cash | $31,506 | $35,380 | $36,725 | $36,244 | $ 7,837 |
| Working capital | 30,515 | 36,052 | 37,396 | 37,807 | 23,168 |
| Total assets | 40,490 | 43,364 | 44,122 | 45,093 | 38,434 |
| Stockholders' equity | 31,320 | 36,872 | 38,236 | 38,956 | 24,402 |

The following table presents our unaudited consolidated statements of operations data for each quarter in the two years ended December 31, 2005. The information for each of these quarters is unaudited, but has been prepared on the same basis as the audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. We believe that all necessary adjustments, consisting only of normal recurring adjustments, have been made to present fairly the unaudited quarterly results when read in conjunction with our audited consolidated financial statements and the notes thereto appearing elsewhere in this document. These operating results are not necessarily indicative of the results of operations that may be expected for any future period

| FOR THE THREE MONTHS ENDED | DEC. 31 2005 | SEP. 30 2005 | JUN. 30 2005 | MAR. 31 2005 | DEC. 31 2004 | SEP. 30 2004 | JUN. 30 2004 | MAR. 31 2004 |
|---|---|---|---|---|---|---|---|---|
| **STATEMENT OF OPERATIONS DATA:** | | | | | | | | |
| (In thousands, except per share data (unaudited)) | | | | | | | | |
| Revenues: | | | | | | | | |
| Product sales | $ 5,098 | $ 4,926 | $ 5,164 | $ 4,125 | $ 3,795 | $ 3,947 | $ 4,756 | $ 4,781 |
| Net royalty income | 1,155 | 1,115 | 1,188 | 1,145 | 1,224 | 1,078 | 1,018 | 861 |
| Total revenues | 6,253 | 6,041 | 6,352 | 5,270 | 5,019 | 5,025 | 5,774 | 5,642 |
| Costs and Expenses: | | | | | | | | |
| Cost of product sales | 1,421 | 1,391 | 1,479 | 1,179 | 1,086 | 1,031 | 1,268 | 1,129 |
| Research and development | 4,357 | 4,326 | 3,857 | 2,844 | 2,870 | 2,043 | 2,067 | 2,025 |
| General and administrative | 1,576 | 1,122 | 1,161 | 1,485 | 1,367 | 1,183 | 1,218 | 1,296 |
| Selling and marketing | 1,812 | 1,483 | 1,629 | 1,416 | 1,213 | 1,318 | 1,467 | 1,544 |
| Total costs and expenses | 9,166 | 8,322 | 8,126 | 6,924 | 6,536 | 5,575 | 6,020 | 5,994 |
| Loss from operations | (2,913) | (2,281) | (1,774) | (1,654) | (1,517) | (550) | (246) | (352) |
| Total other income, net | 248 | 221 | 155 | 115 | 251 | 140 | 117 | 125 |
| Loss from continuing operations | (2,665) | (2,060) | (1,619) | (1,539) | (1,266) | (410) | (129) | (227) |
| Income from discontinued operations | — | — | 91 | — | 123 | — | — | — |
| Net loss | $ (2,665) | $ (2,060) | $(1,528) | $(1,539) | $ (1,143) | $ (410) | $ (129) | $ (227) |
| Basic and diluted net (loss) income per common share: | | | | | | | | |
| Continuing operations | $ (0.21) | $ (0.17) | $ (0.13) | $ (0.13) | $ (0.10) | $ (0.03) | $ (0.01) | $ (0.02) |
| Discontinued operations | — | — | 0.01 | — | 0.01 | — | — | — |
| Net loss | $ (0.21) | $ (0.17) | $ (0.12) | $ (0.13) | $ (0.09) | $ (0.03) | $ (0.01) | $ (0.02) |
| Weighted average common shares outstanding: | | | | | | | | |
| Basic and Diluted | 12,503 | 12,373 | 12,293 | 12,155 | 12,117 | 12,071 | 12,019 | 11,918 |

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

The following discussion of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains forward-looking statements based on our current expectations, assumptions, estimates and projections about us and our industry. These forward-looking statements are usually accompanied by words such as "believes," "anticipates," "plans," "expects" and similar expressions. Forward-looking statements involve risks and uncertainties, and our actual results may differ materially from the results anticipated in these forward-looking statements as a result of certain factors, as more fully described in Item 1A "Risk Factors".

## OVERVIEW

We are an advanced medical technology company that designs, develops, manufactures and markets proprietary implant technologies that allow interventional cardiologists to treat cardiac sources of migraine headaches, stroke and other potential brain attacks through minimally invasive, catheter-based procedures. We are investigating the potential connection between a common cardiac defect, PFO, and brain attacks such as migraine headaches, stroke and transient ischemic attacks ("TIA"). A PFO can allow venous blood, unfiltered and unmanaged by the lungs, to enter the arterial circulation of the brain, possibly triggering a cerebral event or brain attack. In 2001, our then new senior management team began divesting certain non-strategic assets in order to focus on this emerging PFO market opportunity utilizing our proprietary implant technologies. These divestitures included the November 2001 sale of our vena cava filter product line to Bard and the July 2002 sale of our neurosciences business unit to Integra. Net cash proceeds from these sales transactions of approximately $33.8 million, the related net royalty income from Bard that commenced in 2003 and the on-going business operations have provided us with the financial and operational flexibility to aggressively pursue this emerging market opportunity with our CardioSEAL® and STARFlex® implants, clinical research studies and development of next generation catheter-based implant technologies. More than 20,000 PFOs have been closed globally using our CardioSEAL® and STARFlex® implant technologies. We are currently conducting five PFO-closure related clinical research trials, focusing on PFO/migraine, PFO/stroke and our new proprietary BioSTAR™ implant technology.

## PFO/MIGRAINE

The prevalence of migraines in the United States is estimated to be approximately 10% of the general population or roughly 30 million individuals. We estimate that 20% of all migraine sufferers, or 6 million individuals, have the classic form of migraine, sometimes referred to as migraine with aura. It has also been reported that 50% of these patients do not satisfactorily respond to current approved forms of medication. Furthermore, data as reported at the most recent Transcatheter Cardiovascular Therapeutic symposium (TCT) meeting in October 2005 indicated that 60% of the patient subset in our MIST trial had a right to left shunt. That is twice what would be expected in the general population.

In 2005, we completed enrollment in our MIST study in the United Kingdom. Total costs for MIST are estimated to be in the range of $4.0 to $4.5 million, of which approximately $3.9 million was incurred through 2005. Study enrollment was completed in July 2005 and results are scheduled to be presented at the American College of Cardiology meeting on March 13, 2006.

In January 2006, we commenced enrollment in MIST II, a PFO/migraine IDE study approved by the FDA. We currently expect completion of enrollment in early 2007, with one-year follow-up evaluations. We currently project the costs of this clinical study to be in the range of $16 to $20 million through 2008.

In October 2005, we received approval from the regulatory authorities in the United Kingdom to begin enrollment in MIST III. In MIST III, control patients from the original MIST study, those who did not receive the STARFlex® implant, have the option to receive an implant after they have been unblinded as part of the MIST study. These patients will follow the identical protocol as in MIST after which they will be followed for an additional 18 months. In addition, migraine patients with a PFO who did receive a STARFlex® implant in MIST will be followed for an additional 18 months. We currently estimate the cost of MIST III to be approximately $1.2 million through 2007.

## PFO/STROKE

Stroke is the third leading cause of death in the United States and the leading cause of disability in adults. Each year, approximately 750,000 Americans suffer a new or recurrent stroke and 500,000 Americans experience a TIA. In 2003, we launched the CLOSURE I clinical trial to compare our STARFlex® cardiac septal repair implant with current medical therapy in stroke prevention. CLOSURE I is a 1,600 patient, prospective, randomized, multi-center trial, for which we received complete IDE approval from the FDA in June 2003. Although approximately 75 CLOSURE I clinical sites have enrolled patients, enrollment to date has progressed much slower than anticipated. We now believe that study changes, acceptable to the FDA, the investigators and us, are necessary in order to successfully complete this study. Until these changes are approved, it is difficult to estimate the completion date. It is currently anticipated that when completed, study data from CLOSURE I will be used to support a PFO PMA application. We currently

expect that total costs for CLOSURE I will be approximately $24 million through completion of the trial and submission to the FDA. Of this total, approximately $9.4 million was incurred through 2005, and we currently project 2006 costs to be approximately $4.1 million, largely dependent upon the rate of patient enrollment.

## BIOSTAR™ AND BIOTREK™

In November 2005, we completed enrollment in our BEST study (BioSTAR™ Evaluation STudy), which commenced in July 2005 following regulatory approval in the United Kingdom. This study is evaluating our new bioabsorbable, biological closure technology designed to promote a more natural, rapid and complete sealing of heart defects such as PFO. Approximately 60 patients were enrolled in the BEST study and will be followed for six months. The study was designed to gain commercial approval for BioSTAR™ through the CE Mark process. Approval is currently expected by the end of 2006.

In January 2006, we announced that we received a Phase I grant from the National Institutes of Health's (NIH) Small Business Technology Transfer Program to initiate a research program to evaluate our advanced septal repair implant called BioTREK™, a bioabsorbable, biological closure technology. We believe that the biomaterials in the BioSTAR™ and BioTREK™ implants, whether used alone or in combination, further complement our current CardioSEAL® and STARFlex® closure technology, providing us with an exceptionally promising and well-protected technology pipeline.

## 2005 REVENUES

Our 2005 revenues were predominantly derived from sales of our CardioSEAL® and STARFlex® products in the U.S. and Europe and net royalties earned from Bard. CardioSEAL® and STARFlex® product sales increased by approximately 13% from 2004 to 2005 in contrast to the approximate 20% decrease experienced from 2003 to 2004. We believe that a combination of increased market awareness of PFO closure and targeted marketing efforts has resulted in the addition of new customers, predominantly in the United States. We believe that the impact on 2004 U.S. sales of stricter end-user adherence to HDE guidelines, specifically related to off-label procedures, has stabilized. We currently expect an approximate 30-35% increase in CardioSEAL® and STARFlex® product sales from 2005 to 2006. Net royalties, which principally apply to Bard's worldwide sales of SNF and RNF products, were reported net of royalties payable to the estate of the original inventor. Net royalty income from Bard increased approximately 13% from 2004 to 2005, primarily as a result of increased sales of the RNF product, for which Bard received FDA regulatory approval for commercial sales and use as of December 31, 2002. We currently expect net royalty income earned from Bard to remain consistent with 2005 levels. We currently do not anticipate any other material sources of revenues in 2006.

We ended 2005 with approximately $31.5 million in cash, cash equivalents and marketable securities, providing us with what we believe is the financial strength and flexibility to complete our clinical research initiatives and to continue to invest in additional research and development programs, regulatory activities and commercial sales efforts, including planned headcount and territory expansion in Europe.

## CRITICAL ACCOUNTING POLICIES

We have prepared our consolidated financial statements in accordance with accounting principles generally accepted in the United States. In preparing our consolidated financial statements, we make estimates, assumptions and judgments that can have a significant impact on our results of operations and the valuation of certain assets and liabilities on our balance sheet. These estimates, assumptions and judgments about future events and their effects on our results of operations cannot be made with certainty, and are made based on our experience and on other assumptions that are believed to be reasonable under the circumstances. These estimates may change as new events occur or as additional information is obtained. While there are a number of accounting policies, methods and estimates affecting our financial statements described in Note 2 of Notes to Consolidated Financial Statements, our most critical accounting policies, described below, include: (i) revenue recognition; (ii) accounts receivable reserves; (iii) inventories; and (iv) expenses associated with clinical trials. A critical accounting policy is one that is both material to the presentation of our financial statements and requires us to make subjective or complex judgments that could have a material effect on our financial condition and results of operations. Because the use of estimates is inherent in the financial reporting process, actual results could differ from those estimates. Historically, our assumptions, judgments and estimates relative to our critical accounting policies have not differed materially from actual results.

*Revenue Recognition*

We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104 ("SAB 104"), "Revenue Recognition in Financial Statements". SAB 104 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred and title has transferred to the customer; (3) the fee is fixed and determinable; and (4) collection is reasonably assured. We use judgment concerning the satisfaction of these criteria, particularly with respect to collectibility. Should changes in conditions cause us to determine that these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

We require receipt of official purchase orders for all customer orders for our products. Prior to fulfillment of a customer order, we review that customer's account history and outstanding balances to determine if we believe that collectibility of the order value is reasonably assured. We recognize product revenues upon shipment unless customer purchase orders specifically designate that title to the products transfers upon receipt. Products sold to distributors, which accounted for approximately 2% of our product sales in 2005, are not subject to a right of return for unsold product.

We recognize royalty income as it is earned in accordance with relevant contract provisions. Where applicable, we report royalty income in our financial statements net of corresponding royalty obligations to third parties.

*Accounts Receivable Reserves*

We provide allowances for doubtful accounts based on estimates of losses related to customer receivable balances. In establishing these allowances, we make assumptions with respect to the future collectibility of our receivable balances. Our assumptions are based on an individual assessment of a customer's credit quality, primarily its payment history, as well as subjective factors and trends, including the aging of receivable balances, the positive or negative effects of the current and projected industry outlook and the economy in general. Once we consider all of these factors, we determine the probability of customer default, the appropriateness of our current reserve balance and the need to record a charge or credit to operating expense to increase or decrease our reserve level. The amount of the reserve level for our customer accounts receivable fluctuates depending upon all of these factors. If our assumptions are incorrect, or if the financial condition of certain of our customers were to deteriorate, we may need to make additional allowances.

We also maintain a provision for estimated sales returns and allowances on product sales. We base these estimates on historical sales returns, analysis of credit memo data and other known factors. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowances would be made in the period in which such a determination is made and revenues in that period could be adversely affected.

*Inventories*

In accordance with SFAS No. 151, "Inventory Costs", an amendment of Accounting Research Bulletin (ARB) No. 43, Chapter 4, abnormal amounts of idle facility expenses should be recognized as current-period charges. In addition, SFAS No. 151 requires that allocation of fixed production overheads to the costs of production be based on the normal capacity of the production facilities. Management judgment will be required in the determination of a range of normal capacity levels, which will directly affect the allocation of fixed manufacturing overhead costs between inventory costs and period expense. Based upon increased inventory levels in 2004, primarily the result of lower than expected CLOSURE I enrollment and the effects of stricter adherence to HDE guidelines regarding off-label usage, we scaled back our 2005 implant device production below normalized capacity levels. The resulting excess idle capacity costs charged directly to cost of product sales as period costs during 2005 totaled approximately $800,000. Inventory levels at the end of 2005 decreased by approximately 32% compared to 2004. Based upon projected increases in 2006 demand, both for commercial sales and clinical trial enrollments, we currently anticipate increased 2006 production levels approximating normal capacity levels.

In addition, as a manufacturer of medical devices, we may be exposed to a number of economic and industry factors that could result in portions of our inventory becoming either obsolete or in excess of anticipated usage. In such an event, we would need to take a charge against earnings upon making such a determination. These factors include, but are not limited to, technological changes in our markets, our ability to meet changing customer requirements, competitive pressures in products and prices, reliability and replacement of and the availability of key components from our suppliers.

Our policy is to establish inventory reserves when we believe that our inventory may be in excess of anticipated demand or is obsolete based upon our assumptions about future demand for our products and market conditions. We regularly evaluate our ability to realize the value of our inventory based on a combination of factors, including usage rates, forecasted sales or usage, product end of life dates, estimated current and future market values and new product introductions. The assumptions we use in determining our estimates of future product demand may prove to be incorrect; in which case any provision required for excess or obsolete inventory would have to be adjusted. If we determine that our inventory is overvalued, we would be required to recognize such costs as cost of goods sold at the time of that determination and such recognition could have a significant impact on our reported operating results. When recorded, our reserves are intended to reduce the carrying value of our inventory to its net realizable value.

*Expenses Associated With Clinical Trials*

We have invested significant resources in several clinical trials designed to investigate the potential connection between a PFO and brain attacks such as migraine headaches, strokes and TIAs. MIST II, an IDE study approved by the FDA in the fourth quarter of 2005 and for which patient enrollment has been initiated in January 2006, is our second PFO/migraine trial. Prior to that, we completed enrollment in July 2005 for MIST in the United Kingdom. In October 2005, we announced approval of MIST III. Our CLOSURE I trial, commenced in 2003, is an FDA-approved IDE study in the U.S. to evaluate the safety and efficacy of the STARFlex® closure technology to prevent a recurrent embolic stroke and/or TIA in patients with a PFO. In November 2005, we

completed enrollment in the BEST study. Total expenses for all of our clinical trials were approximately $7.5 million, $4.6 million and $2.5 million for the years ended December 31, 2005, 2004 and 2003, respectively.

Our judgment is required in determining methodologies used to recognize various costs related to our clinical trials. We generally enter into contracts with vendors who render services over an extended period of time. Typically, we enter into three types of vendor contracts (i) time-based, (ii) patient-based, or (iii) a combination thereof. Under a time-based contract, using critical factors contained within the contract, usually the stated duration of the contract and the timing of services provided, we record the contractual expense for each service provided under the contract ratably over the period during which we estimate the service will be performed. Under a patient-based contract, we first determine an appropriate per patient cost using critical factors contained within the contract, which include the estimated number of patients and the total dollar value of the contract. We then record the expense based upon the total number of patients enrolled and/or monitored during the period. On a quarterly basis, we review both the timetable of services to be rendered and the timing of services actually rendered. Based upon this review, revisions may be made to the forecasted timetable or to the extent of services performed, or both, in order to reflect our most current estimate of the contract. Adjustments are recorded in the period in which the revisions are estimable. These adjustments could have a material effect on our results of operations. Additional STARFlex® and BioSTAR™ products manufactured to accommodate the expected requirements of our clinical trials are included in inventory because they are saleable units with alternative use outside of the trials. These units will be expensed as a cost of the trials as they are implanted. Substantially all expenses related to our clinical trials are included in research and development in our consolidated statements of operations.

## COMPARISON OF YEARS ENDED DECEMBER 31, 2005, 2004 AND 2003

The following two tables present consolidated statements of operations information as a reference for management's discussion which follows. The first table presents dollar and percentage changes for each listed line item for 2005 compared with 2004 and for 2004 compared with 2003. The second table presents consolidated statements of operations information for each of the three years in the period ended December 31, 2005 as a percentage of total revenues (except for cost of product sales, which is stated as a percentage of product sales).

| | YEARS ENDED DECEMBER 31, | | | INCREASE (DECREASE) | | % CHANGE | |
|---|---|---|---|---|---|---|---|
| | 2005 | 2004 | 2003 | 2004 to 2005 | 2003 to 2004 | 2004 to 2005 | 2003 to 2004 |
| (In thousands of dollars, except percentages) | | | | | | | |
| Revenues: | | | | | | | |
| Product sales | $19,313 | $17,279 | $21,574 | $ 2,034 | $(4,295) | 11.8% | (19.9)% |
| Net royalty income | 4,603 | 4,181 | 1,387 | 422 | 2,794 | 10.1% | 201.5% |
| Total revenues | 23,916 | 21,460 | 22,961 | 2,456 | (1,501) | 11.4% | (6.5)% |
| Costs and expenses: | | | | | | | |
| Cost of product sales | 5,470 | 4,514 | 5,303 | 956 | (789) | 21.2% | (14.9)% |
| Research and development | 15,384 | 9,004 | 6,961 | 6,380 | 2,043 | 70.9% | 29.3% |
| General and administrative | 5,344 | 5,065 | 5,546 | 279 | (481) | 5.5% | (8.7)% |
| Selling and marketing | 6,340 | 5,542 | 5,614 | 798 | (72) | 14.4% | (1.3)% |
| Settlement of litigation | — | — | 1,216 | — | (1,216) | — | (100.0)% |
| Total costs and expenses | 32,538 | 24,125 | 24,640 | 8,413 | (515) | 34.9% | (2.1)% |
| Loss from operations | (8,622) | (2,665) | (1,679) | (5,957) | (986) | 223.6% | 58.7% |
| Other Income: | | | | | | | |
| Currency transaction (loss) gain | (122) | 92 | 81 | (214) | 11 | (232.6)% | 13.6% |
| Interest income, net | 861 | 541 | 553 | 320 | (12) | 59.1% | (2.2)% |
| Total other income, net | 739 | 633 | 634 | 106 | (1) | 16.7% | (0.2)% |
| Loss before provision for income taxes | (7,883) | (2,032) | (1,045) | (5,851) | (987) | 288.0% | 94.4% |
| Provision for income taxes | — | — | 105 | — | (105) | — | (100.0)% |
| Loss from continuing operations | (7,883) | (2,032) | (1,150) | (5,851) | (882) | 288.0% | 76.7% |
| Income from discontinued operations | 91 | 123 | — | (32) | 123 | (26.0)% | — |
| Net loss | $ (7,792) | $ (1,909) | $ (1,150) | $(5,883) | $ (759) | 308.2% | 66.0% |

| YEARS ENDED DECEMBER 31, | 2005 | 2004 | 2003 |
|---|---|---|---|
| Revenues: | | | |
| Product sales | 80.8% | 80.5% | 94.0% |
| Net royalty income | 19.2% | 19.5% | 6.0% |
| Total revenues | 100.0% | 100.0% | 100.0% |
| Costs and expenses: | | | |
| Cost of product sales | 28.3% | 26.1% | 24.6% |
| Research and development | 64.3% | 42.0% | 30.3% |
| General and administrative | 22.3% | 23.6% | 24.2% |
| Selling and marketing | 26.5% | 25.8% | 24.5% |
| Settlement of litigation | — | — | 5.3% |
| Total costs and expenses | 136.1% | 112.4% | 107.3% |
| Loss from operations | (36.1)% | (12.4)% | (7.3)% |
| Other Income (Expense): | | | |
| Currency transaction (loss) gain | (0.5)% | 0.4% | 0.4% |
| Interest income, net | 3.6% | 2.5% | 2.4% |
| Total other income, net | 3.1% | 2.9% | 2.8% |
| Loss before provision for income taxes | (33.0)% | (9.5)% | (4.6)% |
| Provision for income taxes | — | — | 0.5% |
| Loss from continuing operations | (33.0)% | (9.5)% | (5.0)% |
| Income from discontinued operations | 0.4% | 0.6% | — |
| Net loss | (32.6)% | (8.9)% | (5.0)% |

## RESULTS OF OPERATIONS
## YEAR ENDED DECEMBER 31, 2005 COMPARED WITH YEAR ENDED DECEMBER 31, 2004

**Revenues.** Revenues for the years ended December 31, 2005 and 2004 were as follows:

| | YEARS ENDED DECEMBER 31, | | INCREASE | % CHANGE |
|---|---|---|---|---|
| | 2005 | 2004 | 2004 to 2005 | 2004 to 2005 |
| (In thousands of dollars, except percentages) | | | | |
| Product sales: | | | | |
| CardioSEAL® and STARFlex®: | | | | |
| North America | $16,095 | $13,564 | $ 2,531 | 18.7% |
| Europe | 3,218 | 3,556 | (338) | (9.5)% |
| | 19,313 | 17,120 | 2,193 | 12.8% |
| Other | — | 159 | (159) | (100.0)% |
| Total product sales | 19,313 | 17,279 | 2,034 | 11.8% |
| Net royalty income: | | | | |
| Bard | 4,451 | 3,942 | 509 | 12.9% |
| BSC | 152 | 239 | (87) | (36.4)% |
| Total net royalty income | 4,603 | 4,181 | 422 | 10.1% |
| Total revenues | $23,916 | $21,460 | $ 2,456 | 11.4% |

The increase in CardioSEAL® and STARFlex® implant sales for 2005 compared to 2004 was a result of increased product demand in the United States and Canada. We believe that a combination of increased market awareness of PFO closure and targeted marketing efforts has resulted in the addition of new customers.

The decrease in European sales was primarily attributable to increased clinical programs throughout Europe. However, we believe that the combination of our MIST study and headcount investments in the UK and other planned investments in Europe have increased awareness of PFO closure in that market. Incremental strengthening of the U.S. dollar in 2005 also had a slight unfavorable effect on 2005 European product sales. European sales represented approximately 16.7% and 20.8% of total CardioSEAL® and STARFlex® product sales in 2005 and 2004, respectively. Pending the MIST study data results expected in March 2006 and the potential awarding of the CE Mark for BioSTAR™ later in 2006, we currently believe that our European product sales will increase compared to current year levels.

Management currently anticipates between 30 – 35% growth in CardioSEAL® and STARFlex® product sales in 2006 compared to 2005, with European sales projected to approximate 35 – 40% of the total. We believe that, given the regulatory environment in the U.S., sales in North America will remain flat. However, it is uncertain if, and to what extent, 2006 enrollment in MIST II and an anticipated increase in CLOSURE I patient enrollment will affect the level of U.S. sales. If our HDE approval for PFO were to be deactivated by the FDA, that loss would potentially cause a material reduction in U.S. sales, resulting in significant operating losses based upon our current operational structure. We currently expect that planned European headcount growth and territory expansion during 2006 will result in approximately 200 – 250% growth in European product sales. If the MIST study data results, currently expected in March 2006, are favorable, we believe such a demonstration of clinical relevance of PFO closure in certain migraine patients in Europe could result in further demand for our PFO closure technologies in 2006. Additionally, relative weakening or strengthening of the U.S. dollar will have a favorable or unfavorable impact, respectively, on European product sales.

The increase in net royalty income for 2005 was directly attributable to Bard's sales of its RNF product, for which it received FDA regulatory approval for commercial sale and use as of December 31, 2002. The net royalty income from Bard was recorded net of approximately $1.6 million of royalties payable to the estate of the original inventor of SNF and RNF products. Although we currently anticipate that net royalties earned from Bard to remain consistent in 2006 compared with 2005 levels, that result is largely dependent upon continued market acceptance and penetration of its RNF product. As expected, net royalty income from BSC related to the 1994 exclusive license of our stent technology decreased further from 2004 to 2005. BSC is not prohibited from selling competing stents and has established a broad based stent program. We currently anticipate that future royalties earned from BSC will remain flat or decline compared to 2005 levels.

**Cost of Product Sales.** The increase in cost of product sales, as a percentage of total product sales, was primarily due to 2005 production volumes below normalized plant capacity levels. As a result, in accordance with the provisions of SFAS No. 151, "Inventory Costs", a portion of our 2005 fixed manufacturing overhead costs were not absorbed as part of inventory unit costs, but instead were charged to cost of product sales in the period incurred. Included in cost of product sales were royalty expenses of approximately $1.9 million and $1.7 million for the years ended December 31, 2005 and 2004, respectively. With 2006 production levels projected to increase to normalized plant capacity levels, we do not currently anticipate that a portion of our 2006 fixed manufacturing overhead will be charged as a period expense. Additionally, an anticipated higher proportion of European sales in 2006 compared to 2005 are expected to result in a lower weighted average selling price for our products. As a result of these contrasting trends, we currently expect 2006 cost of product sales, as a percentage of product sales, to increase slightly compared to 2005.

**Research and Development.** The increase in research and development expense was primarily related to (i) approximately $2.0 million of increased costs related to our MIST UK study; (ii) increased legal fees of approximately $1.6 million associated with patent infringement claims and ongoing patent research; (iii) approximately $1.0 million of technology license and product development costs related to future generation implant technologies; (iv) approximately $900,000 of costs related to our BEST clinical study; (v) increased headcount and related personnel costs of approximately $250,000; and (vi) approximately $300,000 of initial costs of MIST II, our U.S. PFO/migraine study for which enrollment has been initiated in January 2006. The combined costs of our clinical studies totaled approximately $7.5 million in 2005 compared to approximately $4.6 million in 2004.

We currently expect 2006 research and development expense to increase to approximately $30 million compared to approximately $15.4 million in 2005, an approximate 96% increase, primarily attributable to (i) an approximate $11 million increase in clinical trial costs, most notably the expected substantial completion of the enrollment phase of our new MIST II study; (ii) an approximate $3 million increase in technology license and product development costs related to future generation implant technologies; (iii) prosecution of existing patent infringement claims and ongoing patent research; and (iv) increases in personnel related costs. For additional information on clinical trials cost, refer to "Liquidity and Capital Resources; Contractual Obligations" below.

**General and Administrative.** The increase in general and administrative expense was primarily attributable to (i) increased professional fees, primarily related to corporate governance requirements of the Sarbanes-Oxley Act of 2002 ("SOX"), of approximately $200,000; (ii) increased stock-based compensation of approximately $160,000 related to our 2001 stock option re-pricing; (iii) and a one-time 401(k) employer match of $120,000, partially offset by; (iv) reduced corporate legal fees of approximately $220,000 and (v) reduced insurance costs of approximately $120,000. General and administrative expense is currently expected to increase by approximately 30% in 2006 compared to 2005, principally related to estimated, non-cash stock-based compensation expense of approximately $1.2 million pursuant to the new accounting rules, effective January 1, 2006, prescribed by SFAS 123(R), "Share-Based Payment" (See "Recent Accounting Pronouncements") and, to a lesser degree, increased personnel and related

costs. We currently expect general and administrative expense as a percentage of total revenues to be approximately 24% in 2006 compared to 22.3% in 2005.

**Selling and Marketing.** The increase in selling and marketing expense was the result of (i) an approximate $600,000 increase in sales incentive compensation; (ii) an approximate $250,000 increase in personnel and related costs; (iii) an approximate $175,000 increase in travel and entertainment expense; and (iv) an approximate $100,000 increase in physician training and market research consulting services, partially offset by the elimination of approximately $200,000 of 2004 costs related to our marketing program events. We currently expect total selling and marketing expense to increase by approximately 18% in 2006 compared to 2005, primarily related to planned headcount and market expansion in Europe and increased marketing programs.

**Interest Income.** The increase in interest income was primarily attributable to higher weighted average interest rates earned due to (i) the increased percentage of marketable securities versus cash equivalents in 2005 compared to 2004 and (ii) the general trend of increasing short-term interest rates. Average interest-bearing assets decreased by approximately $4.9 million, or 18.9%, during 2005 compared to 2004. We currently expect interest income to decrease by approximately 40% in 2006 compared to 2005, primarily related to the estimated use of $15 to $17 million of cash, cash equivalents and marketable securities to fund 2006 operations.

**Income Tax Provision.** Due to our reported net losses, we had no income tax provision in 2005 and 2004. We currently expect to incur operating losses in 2006 and, accordingly, we expect a minimal tax provision for the year ending December 31, 2006.

**Income from Discontinued Operations.** During the year ended December 31, 2005, we recorded approximately $91,000 of income from discontinued operations in connection with the final settlement of a tax claim related to our former neurosciences business unit. During the year ended December 31, 2004, we recorded approximately $123,000 of income from discontinued operations, primarily related to the partial recovery of a prior year judgment against us in connection with the termination of a former European employee of the neurosciences business unit. (See Note 3 of Notes to Consolidated Financial Statements).

## YEAR ENDED DECEMBER 31, 2004 COMPARED WITH YEAR ENDED DECEMBER 31, 2003

**Revenues.** Revenues for the years ended December 31, 2004 and 2003 were as follows:

| | YEARS ENDED DECEMBER 31, | | INCREASE | % CHANGE |
|---|---|---|---|---|
| | 2004 | 2003 | 2003 to 2004 | 2003 to 2004 |
| (In thousands of dollars, except percentages) | | | | |
| Product sales: | | | | |
| CardioSEAL® and STARFlex®: | | | | |
| North America | $13,564 | $17,853 | $(4,289) | (24.0)% |
| Europe | 3,556 | 3,564 | (8) | (0.2)% |
| | 17,120 | 21,417 | (4,297) | (20.1)% |
| Other | 159 | 157 | 2 | 1.3% |
| Total product sales | 17,279 | 21,574 | (4,295) | (19.9)% |
| Net royalty income: | | | | |
| Bard | 3,942 | 1,028 | 2,914 | 283.5% |
| BSC | 239 | 359 | (120) | (33.4)% |
| Total net royalty income | 4,181 | 1,387 | 2,794 | 201.4% |
| Total revenues | $21,460 | $22,961 | $(1,501) | (6.5)% |

CardioSEAL® and STARFlex® implant sales decreased approximately $4.3 million, or 20.1%, from 2003 to 2004. This was entirely attributable to our product sales in North America. We believe that this decrease was influenced primarily by stricter end-user adherence to patient selection criteria prescribed by the FDA's HDE guidelines, specifically related to off-label procedures and, to a lesser degree, by patient enrollment in our CLOSURE I clinical trial.

European sales were relatively flat from 2003 to 2004. We believe this resulted partially from the impact of MIST, which was started in the second half of 2004. Partially impacting sales was the weakening of the U.S. dollar which favorably impacted 2004 product sales by approximately $300,000. European sales represented approximately 20.8% and 16.6% of total CardioSEAL® and STARFlex® product sales in 2004 and 2003, respectively.

The substantial increase in net royalty income for 2004 was directly attributable to Bard's sales of its RNF product, for which it received FDA regulatory approval for commercial sale and use as of December 31, 2002. The net royalty income from Bard was recorded net of approximately $1.4 million of royalties payable to the original inventor of SNF and RNF products. As expected, net royalty income from BSC related to the 1994 exclusive license of our stent technology decreased from 2003 to 2004. BSC is not prohibited from selling competing stents and has established a broad based stent program.

**Cost of Product Sales.** The 1.5% increase in cost of sales, as a percentage of product sales in 2004, compared to 2003, was primarily due to: (i) the impact of fixed manufacturing overhead on lower than budgeted product volumes; and (ii) the effect of a higher proportion of European sales, which have a lower average selling price and a higher unit product cost compared to the U.S. This increase was partially offset by a higher European average selling price in 2004 compared to 2003, which was due to a combination of the weakening of the U.S. dollar and a higher proportion of direct versus distributor sales. Included in cost of product sales were royalty expenses of approximately $1.7 million and $2.1 million for the years ended December 31, 2004 and 2003, respectively.

**Research and Development.** The approximate $2.0 million increase in research and development expense in 2004 compared to 2003 was predominantly related to the launch of our MIST study and the full year impact of our CLOSURE I clinical trial which commenced in June 2003. Additionally, increased legal costs of approximately $340,000 associated with patent research and infringement claims were offset by reductions in personnel related costs of approximately $80,000. Clinical and regulatory costs for MIST totaled approximately $900,000. CLOSURE I costs included in research and development expense increased $940,000 to approximately $3.5 million in 2004 compared to approximately $2.5 million in 2003. We continued to invest heavily to protect and expand our intellectual property positions, having filed in excess of 30 utility and provisional patent applications in each of 2004 and 2003.

**General and Administrative.** The decrease in general and administrative expense in 2004 compared to 2003 was primarily attributable to: (i) reduced corporate legal fees of approximately $300,000; and (ii) lower stock-based compensation of approximately $90,000 associated with our 2001 stock option re-pricing.

**Selling and Marketing.** The modest decrease in selling and marketing expense in 2004 compared to 2003 was primarily attributable to: (i) reduced sales-based commissions of approximately $140,000 and (ii) reduced travel expense of approximately $110,000, partially offset by costs of approximately $210,000 associated with our collaboration with the National Stroke Association to promote market awareness of the potential relationship between PFO and recurrent stroke. The weakening of the U.S. dollar during 2004 had the effect of increasing expenses incurred in Europe by approximately $150,000.

**Settlement of Litigation.** During the year ended December 31, 2003, we incurred a charge of approximately $1.2 million in connection with the settlement of an arbitration proceeding with Bio-Tech Engineering, Inc. ("BTE"). The charge consisted of a $950,000 settlement payment to BTE plus legal costs (See Note 6 of Notes to Consolidated Financial Statements).

**Interest Income.** The modest decrease in interest income in 2004 compared to 2003 was primarily attributable to an approximate net $500,000 reduction in interest-bearing assets during 2004, partially offset by minimally higher weighted average interest rates earned due to the change in investment mix between marketable securities and cash equivalents. Approximately $24.9 million, or 75%, of the interest-bearing assets at December 31, 2005 were invested in marketable securities, consisting of corporate bonds and U.S. Government agency debt instruments, with scheduled maturities ranging from January 2005 through November 2006.

**Income Tax Provision.** Due to our reported net losses, we had no income tax provision in 2004 compared to an income tax provision of $105,000, or 10.0% of loss before income taxes, in 2003. The 2003 tax provision was primarily attributable to the $3.0 million of taxable income recognized upon receipt of the final Bard milestone payment in January 2003, which was recognized for financial statement purposes in 2002, partially offset by approximately $1.0 million of remaining tax loss carryforwards for which tax benefit had not been previously provided, and operating losses incurred in 2003.

**Income from Discontinued Operations.** During the year ended December 31, 2004, we recorded approximately $123,000 of income from discontinued operations, primarily related to the partial recovery of a prior year judgment against us in connection with the termination of a former European employee of the neurosciences business unit. (See Note 3 of Notes to Consolidated Financial Statements).

## LIQUIDITY AND CAPITAL RESOURCES

| FOR THE YEARS ENDED DECEMBER 31, | 2005 | 2004 | 2003 |
|---|---|---|---|
| (In thousands) | | | |
| Cash, cash equivalents, marketable securities and restricted cash | $31,506 | $35,380 | $36,725 |
| Net cash (used in) provided by operating activities | (5,108) | (984) | 454 |
| Net cash provided by (used in) investing activities | 4,277 | (19,001) | 7,930 |
| Net cash provided by financing activities | 1,883 | 598 | 406 |

**Net Cash (Used In) Provided by Operating Activities**

Net cash used in operating activities for the year ended December 31, 2005 totaled approximately $5.1 million and was comprised of (a) a net loss from operating activities of approximately $7.8 million, partially offset by (b) net changes in components of working capital of approximately $1.7 million and (c) various non-cash charges to operations of approximately $1.0 million.

The non-cash charges of approximately $1.0 million in 2005 consisted of: (a) depreciation of property and equipment; (b) amortization of bond premium related to our investments in corporate bonds and U.S. Government agency securities; and (c) stock-based compensation, principally related to our stock option re-pricing in 2001. Stock-based compensation related to the option 2001 re-pricing was completed in April 2005, at which time all of the associated options were fully vested (see Note 9 of Notes to Consolidated Financial Statements).

The primary elements of the approximate $1.7 million net change in working capital items in 2005 consisted of the following:

(a) Net trade accounts receivable increased during 2005 by approximately $1.1 million, or 60.2%, primarily due to an increase of approximately $1.3 million, or 34.5%, in product sales for the fourth quarter of 2005 compared to the fourth quarter of 2004. European sales accounted for approximately 13.0% of product sales during the fourth quarter of 2005 compared to approximately 26.4% for the fourth quarter of 2004. We currently expect trade accounts receivable to increase significantly in 2006 as a result of higher product sales, predominantly in Europe.

(b) Our inventories decreased by approximately $800,000 during 2005, primarily as a result of planned reductions in production levels and higher than anticipated increases in product sales. Based upon currently anticipated increases in 2006 product sales, we currently expect that inventory balances will increase significantly during 2006.

(c) Prepaid expenses and other current assets increased during 2005 by approximately $800,000. This increase was primarily attributable to approximately $900,000 of advance payments to third party contractors for the MIST II clinical trial, partially offset by an approximate $130,000 decrease in accrued interest receivable related to our investments in marketable securities.

(d) Current liabilities increased by approximately $2.7 million during 2005, primarily attributable to (i) an approximate $1.2 million increase in MIST, BEST and CLOSURE I cost accruals; (ii) an approximate $1.0 million increase in accounts payable balances, principally related to increased legal fees in connection with ongoing patent infringement claims and increased accounting fees in connection with SOX; (iii) an approximate $580,000 increase in payroll related costs, consisting of higher sales based commissions, bonuses and a one-time 401(k) employer match; and (iv) an approximate $130,000 increase in accrued royalties, primarily related to an approximate 35% increase in CardioSEAL® and STARFlex® product sales in the fourth quarter of 2005 compared to the fourth quarter of 2004. These increases were partially offset by a reduction in discontinued operations liabilities of approximately $400,000, attributable to the settlement of a French tax claim related to our former neurosciences business unit. We currently expect current liabilities to increase by 50-60% in 2006, primarily related to the MIST II and CLOSURE I clinical trials.

Net cash used in operating activities for 2004 represented a decrease of approximately $1.4 million compared to net cash provided by operating activities in 2003. This decrease was largely attributable to the receipt in 2003 of the final $3.0 million contingent cash consideration from Bard in connection with the sale of the vena cava filter product line and an approximate $800,000 increase in loss from operating activities, partially offset by a net increase in other working capital items of approximately $2.1 million.

**Net Cash Provided By (Used In) Investing Activities**

Net cash provided by investing activities of approximately $4.3 million in 2005 consisted primarily of (i) approximately $20.2 million of proceeds from maturities of marketable securities and (ii) an approximate $1.1 million release of restricted cash balances in connection with the settlement of the French tax claim, partially offset by approximately $16.7 million of purchases of marketable securities. This compared to net cash used in investing activities of approximately $19.0 million in 2004, which consisted primarily of approximately $27.1 million of purchases of marketable securities, net of (i) approximately $9.6 million of proceeds from maturities of marketable securities and (ii) restricted cash of approximately $1.1 million to collateralize a bank guarantee issued in October 2004 in favor of the French tax authorities. Purchases of property and equipment for use in our manufacturing, research and development and general and administrative operations totaled approximately $329,000 and $361,000 for the years ended December 31, 2005 and 2004.

**Net Cash Provided By Financing Activities**

Net cash provided by financing activities increased by approximately $1.3 million from 2004 to 2005, predominantly due to an increase in proceeds from the exercise of common stock options. Net cash provided by financing activities increased by approximately $192,000 from 2003 to 2004. This was primarily attributable to an approximate $164,000 increase in proceeds from the exercise of common stock options and the issuance of common stock under our employee stock purchase plan ("ESPP") and an approximate $28,000 reduction in payments of capital lease obligations, which were repaid in full during 2003. At December 31, 2005, we had no outstanding debt financing.

Primarily as a result of the ongoing costs of MIST II and CLOSURE I, we expect to incur operating losses at least through 2007. The total cost of our MIST II study is currently estimated to be approximately $16 to $20 million through projected completion of the study in early 2008. Of this amount, approximately $300,000 was incurred in 2005 and we currently expect to incur approximately $14 million in 2006. The total cost of our CLOSURE I clinical trial is currently estimated to be approximately $24 million through completion of the trial and submission to the FDA. Of this amount, approximately $9.4 million was incurred through 2005 and we currently expect to incur approximately $4.1 million in 2006, largely dependent upon the rate of patient enrollment.

Capital expenditures are currently projected to total approximately $1.3 million in 2006, primarily for manufacturing and research and development equipment.

We currently believe that aggregate cash, cash equivalents and marketable securities balances of approximately $31.5 million at December 31, 2005 will be sufficient to meet our working capital, financing and capital expenditure requirements through at least 2009. Based upon the anticipated growth in product sales in Europe and the anticipated rate of enrollment in our MIST II and CLOSURE I clinical trials, we expect that the aggregate of cash, cash equivalents and marketable securities will approximate $13 to $15 million at the end of 2006.

We may require additional funds for our research and product development programs, regulatory processes, preclinical and clinical testing, sales and marketing infrastructure and programs and potential licenses and acquisitions. Any additional equity financing will be dilutive to stockholders, and additional debt financing, if available, may involve restrictive covenants. Our capital requirements will depend on numerous factors, including the level of sales of our products, the progress of our research and development programs, the progress of clinical testing, the time and cost involved in obtaining regulatory approvals, the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, competing technological and market developments, developments and changes in our existing research, licensing and other relationships and the terms of any collaborative, licensing and other similar arrangements that we may establish. We do not currently have any existing line of credit arrangements.

## CONTRACTUAL OBLIGATIONS

### Clinical Trials

At December 31, 2005 we have five significant clinical trials at various stages of completion. In connection with these trials, we have entered into various contractual obligations with third party service providers and the participating clinical sites. Under certain agreements, we have the right to terminate, in which case the remaining obligations would be limited to costs incurred as of that date. Including the internal costs of our clinical department and the manufacturing costs of products used, the following table provides, by trial, our current estimate of total costs to be incurred, actual cumulative costs through fiscal 2005, our current estimates of 2006 costs and the remaining costs estimated to be incurred subsequent to 2006. The estimated total costs, as well as the timing and amounts of estimated future costs, are dependent upon a variety of factors, including the timing of patient enrollment and patient monitoring and, in the case of new clinical trials, the finalization of various third party contracts. Of the total costs incurred through 2005, approximately $2.9 million was included in accrued expenses at December 31, 2005.

| (In millions of dollars) | Inception of Enrollment | Current Projected Total Costs Of Clinical Trial | Costs Incurred Through 2005 | Projected Costs To Be Incurred In 2006 | Projected Costs To Be Incurred After 2006 | Projected Completion/ Regulatory Filing |
|---|---|---|---|---|---|---|
| MIST II | 2006 | $16.0 - 20.0 | $ 0.3 | $ 14.0 | $ 1.7 - 5.7 | 2008 |
| MIST III | 2006 | 1.2 | — | 1.0 | 0.2 | 2007 |
| MIST | 2005 | 4.0 - 4.5 | 3.9 | 0.1 - 0.6 | — | 2006 |
| BEST | 2005 | 1.2 - 1.5 | 0.9 | 0.3 - 0.6 | — | 2006 |
| CLOSURE I | 2003 | 24.0 | 9.4 | 4.0 | 10.6 | 2009 |
| Totals | | $46.4 - 51.2 | $14.5 | $19.4 - 20.2 | $12.5 - 16.5 | |

### Royalty and License Agreements

We are party to various royalty agreements under which we are obligated to pay royalties: (i) to CMCC on commercial sales of our CardioSEAL® and STARFlex® product sales; (ii) to the estate of the original inventor of certain vena cava filter products on sales of those products by Bard; and (iii) to Lloyd Marks on sales of CardioSEAL® and STARFlex® products to the extent that the technology licensed to us is incorporated into these products, subject to a minimum annual royalty. Royalty expenses in 2005 totaled approximately $3.6 million and are expected to increase in the future.

We have also entered into a license and development agreement pursuant to which, under certain circumstances, we are obligated to make a one-time payment of $600,000 relating to certain product commercialization milestones, and potentially may be required to make royalty payments based on future sales.

### Operating Leases

Substantially all of our existing operating leases relate to our Boston, Massachusetts manufacturing, research and development and administrative offices. The facility leases, which expire in September 2010, include one five-year renewal option, subject to acceptance by the landlord upon exercise by us.

The following table summarizes our estimated minimum future operating lease contractual commitments at December 31, 2005:

| | | AMOUNTS DUE IN | | | |
|---|---|---|---|---|---|
| | Total | Less Than One Year | 1-3 Years | 4-5 Years | After 5 Years |
| Operating Leases | $4,610,000 | $ 920,000 | $2,941,000 | $ 749,000 | $ — |

## OFF-BALANCE SHEET FINANCING

During the year ended December 31, 2005, we have not engaged in material off-balance sheet activities, including the use of structured finance or specific purpose entities.

## RECENT ACCOUNTING PRONOUNCEMENTS

In December 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), "Share-Based Payment", which is a revision of FASB Statement No. 123, "Accounting for Stock- Based Compensation". Statement 123(R) supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees", and amends FASB Statement No. 95, "Statement of Cash Flows". Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in our income statement based on their fair values. Following January 1, 2006, pro forma disclosure is no longer an alternative.

Statement 123(R) must be adopted no later than January 1, 2006. We are evaluating the effect of Statement 123(R) and expect that its adoption will have a significant impact on our results of operations and earnings per share.

Statement 123(R) permits public companies to adopt its requirements using one of two methods:

- A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of Statement 123(R) that remain unvested on the effective date.
- A "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under Statement 123 for purposes of pro forma disclosures based upon either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

We currently expect to use the modified prospective method beginning with our interim report on Form 10-Q for the period ending March 31, 2006.

As permitted by Statement 123, we currently account for share-based payments to employees using Opinion 25's intrinsic value method and, as such, generally recognize no compensation cost for employee stock options. Accordingly, the adoption of Statement 123(R)'s fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. Had we adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net loss and net loss per share in Notes 2(k) and 9(a) to our consolidated financial statements. The impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend, in part, on levels of share-based payments granted in the future. However, our current best estimate for 2006 stock-based compensation expense is approximately $1.5 million. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption.

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

As of December 31, 2005 and 2004, we did not participate in any derivative financial instruments or other financial and commodity instruments for which fair value disclosure would be required under SFAS No. 107, "Disclosures About Fair Value of Financial Instruments". Our investments are primarily short-term money market accounts that are carried on our books at cost, which

approximates fair market value, and U.S. Government agency and corporate debt instruments that are carried on our books at amortized cost, increased or decreased by unrealized gains or losses, net of tax, respectively, which amounts are recorded as a component of stockholders' equity in our consolidated financial statements. Accordingly, we have no quantitative information concerning the market risk of participating in such investments.

We are subject to market risk in the form of interest rate risk and foreign currency risk. Interest rate risk is immaterial to the Company. We denominate certain product sales and operating expenses in non-U.S. currencies (See Note 2(l) of Notes to Consolidated Financial Statements). Accordingly, we face exposure to adverse movements in foreign currency exchange rates. These exposures may change over time and could have a material adverse impact on our financial condition.

We translate the accounts of our foreign subsidiaries in accordance with SFAS No. 52, "Foreign Currency Translation". The functional currency of our foreign subsidiaries is the U.S. dollar and, accordingly, translation gains and losses are reflected in the consolidated statements of operations. Revenue and expense accounts are translated using the weighted average exchange rate in effect during the period.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

All financial statements required to be filed under this Item 8, other than selected quarterly financial data, are filed as Appendix A hereto, are listed under Item 15(a) and are incorporated herein by this reference.

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

None.

## ITEM 9A. CONTROLS AND PROCEDURES

**Disclosure Controls and Procedures**

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2005. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2005, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Management's Annual Report on Internal Control Over Financial Reporting**

We are responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, 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, and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our 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. 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 and procedures may deteriorate.

We have assessed the effectiveness of our internal control over financial reporting as of December 31, 2005. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*.

Based on our assessment, we believe that, as of December 31, 2005, our internal control over financial reporting was effective at a reasonable assurance level based on these criteria.

Ernst & Young LLP, our independent registered public accounting firm, has issued an audit report, included below, on our assessment of our internal control over financial reporting.

**Changes in Internal Control Over Financial Reporting**

No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The Board of Directors and Stockholders of NMT Medical, Inc.:

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting that NMT Medical, Inc. 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 (the COSO criteria). NMT Medical, Inc.'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 an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit 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. Our audit included 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 considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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.

In our opinion, management's assessment that NMT Medical, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion NMT Medical, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2005 and 2004, and the related consolidated statements of income, cash flows and shareholders' equity for each of the three years in the period ended December 31, 2005 of NMT Medical, Inc. and our report dated March 9, 2006 expressed an unqualified opinion thereon.

Ernst & Young LLP

Boston, Massachusetts
March 9, 2006

## ITEM 9B. OTHER INFORMATION

None.

# PART III

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

**Directors and Executive Officers**

The information with respect to our directors and executive officers required under this item is incorporated by reference to the information set forth under the section entitled "Election of Directors" in our proxy statement for our 2006 Annual Meeting of Stockholders to be held on June 15, 2006. Information relating to certain filings of Forms 3, 4 and 5 is contained in our 2006 proxy statement under the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" and is incorporated herein by reference.

The information required under this item pursuant to Item 401(h) and 401(i) of Regulation S-K relating to an Audit Committee financial expert and identification of the Audit Committee of our Board of Directors is contained in our 2006 proxy statement under the caption "Corporate Governance" and is incorporated herein by reference.

We have adopted a written code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Our code of business conduct and ethics is posted on our website. We intend to disclose any amendments to, or waivers from, our code of business conduct and ethics on our website which is located at www.nmtmedical.com.

## ITEM 11. EXECUTIVE COMPENSATION

The information required under this item is incorporated by reference to the sections entitled "Executive Compensation," "Director Compensation" and "Compensation Committee Interlocks and Insider Participation" in our 2006 proxy statement.

The sections entitled "Report of the Joint Compensation and Options Committee" and "Stock Performance Graph" in our 2006 proxy statement are not incorporated herein by reference.

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

The information required under this item is incorporated by reference to the section entitled "Stock Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our 2006 proxy statement.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required under this item is incorporated by reference to the section entitled "Certain Transactions" in our 2006 proxy statement.

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required under this item is incorporated by reference to the section entitled "Independent Registered Public Accounting Firm" in our 2006 proxy statement.

# PART IV

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Financial Statements. The following documents are filed as Appendix A hereto and are included as part of this Annual Report on Form 10-K:

Financial Statements of NMT Medical, Inc. and Subsidiaries

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2005 and 2004

Consolidated Statements of Operations for the years ended December 31, 2005, 2004 and 2003

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2005, 2004 and 2003

Consolidated Statements of Cash Flows for the years ended December 31, 2005, 2004 and 2003

Notes to Consolidated Financial Statements

(b) Exhibits. The exhibits filed as part of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding such exhibits, and are incorporated herein by this reference. We have identified with asterisks in the Exhibit Index each management contract and compensation plan filed as an exhibit to this Annual Report on Form 10-K in response to Item 15(b) of Form 10-K.

(c) Financial Statement Schedules. We are not filing any financial statement schedules as part of this Annual Report on Form 10-K because such schedules are either not applicable or the required information is included in the financial statements or notes thereto.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**NMT MEDICAL, INC.**

By: /s/ JOHN E. AHERN

John E. Ahern
President and Chief Executive Officer

Dated: March 9, 2006

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

| SIGNATURE | TITLE | DATE |
|---|---|---|
| /s/ JOHN E. AHERN<br>John E. Ahern | President, Chief Executive Officer and Chairman of the Board (Principal Executive Officer) | March 9, 2006 |
| /s/ RICHARD E. DAVIS<br>Richard E. Davis | Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) | March 9, 2006 |
| /s/ CHERYL L. CLARKSON<br>Cheryl L. Clarkson | Director | March 9, 2006 |
| /s/ DANIEL F. HANLEY<br>Daniel F. Hanley, M.D. | Director | March 9, 2006 |
| /s/ JAMES E. LOCK<br>James E. Lock, M.D. | Director | March 9, 2006 |
| /s/ FRANCIS J. MARTIN<br>Francis J. Martin | Director | March 9, 2006 |
| /s/ HARRY A. SCHULT<br>Harry A. Schult | Director | March 9, 2006 |

# APPENDIX

## NMT MEDICAL, INC. AND SUBSIDIARIES
## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of NMT Medical, Inc.:

We have audited the accompanying consolidated balance sheets of NMT Medical, Inc. (a Delaware corporation) and subsidiaries as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of NMT Medical, Inc. and subsidiaries as of December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of NMT Medical, Inc.'s 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 and our report dated March 9, 2006 expressed an unqualified opinion thereon.

Ernst & Young LLP

Boston, Massachusetts
March 9, 2006

# NMT MEDICAL, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

| AT DECEMBER 31, | 2005 | 2004 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $10,390,139 | $ 9,338,208 |
| Marketable securities | 21,116,346 | 24,919,460 |
| Restricted cash | — | 1,122,200 |
| Accounts receivable, net of reserves of $369,984 in 2005 and $378,150 in 2004 | 2,846,684 | 1,776,605 |
| Inventories | 1,726,300 | 2,523,062 |
| Prepaid expenses and other current assets | 3,605,540 | 2,864,600 |
| Total current assets | 39,685,009 | 42,544,135 |
| Property and equipment, at cost: | | |
| Laboratory and computer equipment | 3,479,819 | 3,200,532 |
| Leasehold improvements | 1,136,859 | 1,136,859 |
| Office furniture and equipment | 984,148 | 934,160 |
| | 5,600,826 | 5,271,551 |
| Less accumulated depreciation and amortization | 4,796,057 | 4,481,190 |
| | 804,769 | 790,361 |
| Other assets | — | 29,263 |
| **Total Assets** | $40,489,778 | $43,363,759 |
| **Liabilities and Stockholders' Equity** | | |
| Current Liabilities: | | |
| Accounts payable | $ 2,654,399 | $ 1,682,272 |
| Accrued expenses | 6,515,809 | 4,309,586 |
| Discontinued operations liabilities | — | 500,000 |
| Total current liabilities | 9,170,208 | 6,491,858 |
| Commitments and Contingencies (Notes 7 and 14) | | |
| Stockholders' equity: | | |
| Preferred stock, $.001 par value | | |
| Authorized—3,000,000 shares | | |
| Issued and outstanding—none | — | — |
| Common stock, $.001 par value | | |
| Authorized—30,000,000 shares | | |
| Issued—12,635,832 shares in 2005 and 12,176,183 shares in 2004 | 12,636 | 12,176 |
| Additional paid-in capital | 48,232,778 | 46,093,075 |
| Less treasury stock—40,000 shares at cost | (119,600) | (119,600) |
| Accumulated other comprehensive loss | (52,834) | (152,596) |
| Accumulated deficit | (16,753,410) | (8,961,154) |
| Total stockholders' equity | 31,319,570 | 36,871,901 |
| **Total Liabilities and Stockholders' Equity** | $40,489,778 | $43,363,759 |

*See accompanying notes.*

## NMT MEDICAL, INC. AND SUBSIDIARIES

# CONSOLIDATED STATEMENTS OF OPERATIONS

| FOR THE YEARS ENDED DECEMBER 31, | 2005 | 2004 | 2003 |
|---|---|---|---|
| Revenues: | | | |
| Product sales | $19,313,103 | $17,278,760 | $21,573,769 |
| Net royalty income | 4,603,058 | 4,181,264 | 1,387,590 |
| Total revenues | 23,916,161 | 21,460,024 | 22,961,359 |
| Costs and Expenses: | | | |
| Cost of product sales | 5,469,722 | 4,513,764 | 5,302,700 |
| Research and development | 15,383,768 | 9,004,421 | 6,961,391 |
| General and administrative | 5,344,623 | 5,064,493 | 5,545,302 |
| Selling and marketing | 6,340,085 | 5,542,083 | 5,614,397 |
| Settlement of litigation | — | — | 1,216,357 |
| Total costs and expenses | 32,538,198 | 24,124,761 | 24,640,147 |
| Loss from operations | (8,622,037) | (2,664,737) | (1,678,788) |
| Other Income: | | | |
| Currency transaction (loss) gain | (122,387) | 92,047 | 81,399 |
| Interest income, net | 861,481 | 540,614 | 552,636 |
| Total other income, net | 739,094 | 632,661 | 634,035 |
| Loss before provision for income taxes | (7,882,943) | (2,032,076) | (1,044,753) |
| Provision for income taxes | — | — | 105,000 |
| Loss from continuing operations | (7,882,943) | (2,032,076) | (1,149,753) |
| Income from discontinued operations | 90,687 | 122,639 | — |
| Net loss | $ (7,792,256) | $ (1,909,437) | $ (1,149,753) |
| Basic and diluted net (loss) income per common share: | | | |
| Continuing operations | $ (0.64) | $ (0.17) | $ (0.10) |
| Discontinued operations | 0.01 | 0.01 | — |
| Net loss | $ (0.63) | $ (0.16) | $ (0.10) |
| Weighted average common shares outstanding: | | | |
| Basic and diluted | 12,332,001 | 12,031,434 | 11,808,071 |

*See accompanying notes.*

# NMT MEDICAL, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

| | COMMON STOCK | | | TREASURY STOCK | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Number of Shares | $0.001 Par Value | Additional Paid-In Capital | Number of Shares | Cost | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity | Comprehensive (Loss) |
| Balance, December 31, 2002 | 11,712,877 | $11,713 | $44,728,424 | — | $ — | $ (5,901,964) | $118,000 | $38,956,173 | $ — |
| Common stock issued under the employee stock purchase plan | 52,669 | 53 | 154,611 | — | — | — | — | 154,664 | — |
| Exercise of common stock options and warrants | 149,241 | 149 | 279,396 | — | — | — | — | 279,545 | — |
| Stock-based compensation | — | — | 192,115 | — | — | — | — | 192,115 | — |
| Tax benefit from exercise of stock options | — | — | 41,000 | — | — | — | — | 41,000 | — |
| Purchase of treasury stock | — | — | — | (40,000) | (119,600) | — | — | (119,600) | — |
| Unrealized loss on marketable securities | — | — | — | — | — | — | (118,000) | (118,000) | (118,000) |
| Net loss | — | — | — | — | — | (1,149,753) | — | (1,149,753) | (1,149,753) |
| Net comprehensive loss | | | | | | | | | $(1,267,753) |
| Balance, December 31, 2003 | 11,914,787 | 11,915 | 45,395,546 | (40,000) | (119,600) | (7,051,717) | — | 38,236,144 | $ — |
| Common stock issued under the employee stock purchase plan | 58,134 | 58 | 206,627 | — | — | — | — | 206,685 | — |
| Exercise of common stock options | 203,262 | 203 | 391,576 | — | — | — | — | 391,779 | — |
| Stock-based compensation | — | — | 99,326 | — | — | — | — | 99,326 | — |
| Unrealized loss on marketable securities | — | — | — | — | — | — | (152,596) | (152,596) | (152,596) |
| Net loss | — | — | — | — | — | (1,909,437) | — | (1,909,437) | (1,909,437) |
| Net comprehensive loss | | | | | | | | | $(2,062,033) |
| Balance, December 31, 2004 | 12,176,183 | 12,176 | 46,093,075 | (40,000) | (119,600) | (8,961,154) | (152,596) | 36,871,901 | $ — |
| Common stock issued under the employee stock purchase plan | 49,332 | 49 | 222,037 | — | — | — | — | 222,086 | — |
| Exercise of common stock options and warrants | 410,317 | 411 | 1,660,478 | — | — | — | — | 1,660,889 | — |
| Stock-based compensation | — | — | 257,188 | — | — | — | — | 257,188 | — |
| Unrealized gain on marketable securities | — | — | — | — | — | — | 99,762 | 99,762 | 99,762 |
| Net loss | — | — | — | — | — | (7,792,256) | — | (7,792,256) | (7,792,256) |
| Net comprehensive loss | | | | | | | | | $(7,692,494) |
| Balance, December 31, 2005 | 12,635,832 | $12,636 | $48,232,778 | (40,000) | $(119,600) | $(16,753,410) | $ (52,834) | $31,319,570 | |

*See accompanying notes.*

## NMT MEDICAL, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

| FOR THE YEARS ENDED DECEMBER 31, | 2005 | 2004 | 2003 |
|---|---|---|---|
| Cash flows from operating activities: | | | |
| Net loss | $(7,792,256) | $(1,909,437) | $(1,149,753) |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities- | | | |
| Depreciation and amortization | 762,728 | 827,810 | 570,469 |
| Increase in accounts receivable reserves | — | — | 392,000 |
| Stock-based compensation | 257,188 | 99,326 | 192,115 |
| Tax benefit from exercise of stock options | — | — | 41,000 |
| Deferred income taxes | — | — | (282,000) |
| Change in assets and liabilities- | | | |
| Accounts receivable | (1,070,079) | 770,241 | (481,524) |
| Receivable from sale of product line | — | — | 3,000,000 |
| Inventories | 796,762 | (591,121) | (752,992) |
| Prepaid expenses and other current assets | (800,986) | (976,069) | (852,668) |
| Accounts payable | 972,127 | 406,491 | (957,662) |
| Accrued expenses | 2,181,223 | 389,061 | 1,145,883 |
| Discontinued operations liabilities | (414,954) | — | (410,505) |
| Net cash (used in) provided by operating activities | (5,108,247) | (983,698) | 454,363 |
| Cash flows from investing activities: | | | |
| Purchases of property and equipment | (329,275) | (361,420) | (149,871) |
| Purchases of marketable securities | (16,685,722) | (27,117,705) | — |
| Maturities of marketable securities | 20,170,000 | 9,600,000 | 8,000,000 |
| Restricted cash | 1,122,200 | (1,122,200) | — |
| Decrease in other assets | — | — | 80,000 |
| Net cash provided by (used in) investing activities | 4,277,203 | (19,001,325) | 7,930,129 |
| Cash flows from financing activities: | | | |
| Proceeds from exercise of common stock options and warrants | 1,660,889 | 391,779 | 279,545 |
| Proceeds from issuance of common stock under the employee stock purchase plan | 222,086 | 206,685 | 154,664 |
| Payments of capital lease obligations | — | — | (27,865) |
| Net cash provided by financing activities | 1,882,975 | 598,464 | 406,344 |
| Net increase (decrease) in cash and cash equivalents | 1,051,931 | (19,386,559) | 8,790,836 |
| Cash and cash equivalents, beginning of period | 9,338,208 | 28,724,767 | 19,933,931 |
| Cash and cash equivalents, end of period | $10,390,139 | $ 9,338,208 | $28,724,767 |

*See accompanying notes.*

## (1) OPERATIONS

We are an advanced medical technology company that designs, develops, manufactures and markets proprietary implant technologies that allow interventional cardiologists to treat cardiac sources of migraine headaches, stroke and other potential brain attacks through minimally invasive, catheter-based procedures. We are investigating the potential connection between a common cardiac defect called a patent foramen ovale (PFO) and brain attacks such as migraine headaches, stroke, and transient ischemic attacks (TIAs). A PFO can allow venous blood, unfiltered and unmanaged by the lungs, to directly enter the arterial circulation of the brain, possibly triggering a cerebral event or brain attack. More than 20,000 PFOs have been closed globally with our minimally invasive, catheter-based implant technology.

## (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and our wholly-owned subsidiaries. Intercompany transactions and balances have been eliminated in consolidation.

(b) Management Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the reported amounts of revenues and expenses during the reporting periods and the disclosure of contingent assets and liabilities at the date of the financial statements. Actual results could differ from those estimates.

(c) Cash, Cash Equivalents, Marketable Securities and Restricted Cash

We consider all investments with maturities of 90 days or less from the date of purchase to be cash equivalents and all investments with original maturity dates greater than 90 days to be marketable securities.

Cash and cash equivalents, which are carried at cost and approximate market, consist of cash, money market accounts and commercial paper investments.

In accordance with SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities", we have classified our marketable securities as available-for-sale. Available-for-sale securities represent those securities that do not meet the definition of held-to-maturity and are not actively traded. In accordance with SFAS No. 115, these securities are reported at fair market value, with unrealized gains and losses, net of tax, included as a separate component of stockholders' equity.

The estimated fair value of marketable securities is determined based on broker quotes or quoted market prices or rates for the same or similar instruments. The estimated fair value and cost of our marketable securities are as follows:

| | 2005 | | 2004 | |
|---|---|---|---|---|
| AT DECEMBER 31, | FAIR VALUE | AMORTIZED COST | FAIR VALUE | AMORTIZED COST |
| Corporate bonds | $11,021,806 | $11,059,535 | $15,773,019 | $15,913,407 |
| Government agency securities | 6,189,495 | 6,203,540 | 8,172,445 | 8,184,604 |
| Commercial Paper | 2,980,130 | 2,981,139 | 973,996 | 974,045 |
| Certificates of Deposit | 924,915 | 924,966 | — | — |
| | $21,116,346 | $21,169,180 | $24,919,460 | $25,072,056 |

Maturities of marketable securities classified as available-for-sale by contractual maturity are shown below:

| AT DECEMBER 31, | 2005 | 2004 |
|---|---|---|
| Due within one year | $21,116,346 | $17,330,950 |
| Due in 1-2 years | — | 7,588,510 |
| | $21,116,346 | $24,919,460 |

At December 31, 2005 there were $52,932 of gross unrealized losses and $98 of gross unrealized gains on marketable securities. The aggregate fair value of marketable securities with unrealized losses at December 31, 2005 was approximately $20.1 million. Approximately $5.5 million of these securities were in a continuous, unrealized loss position for more than twelve months. The aggregate unrealized losses were approximately $18,000. The Company believes that the impairment of those investments are not other-than-temporary at this time. These corporate debt securities are all highly rated investments which have been subject to routine market changes that have not been significant to date. There were net unrealized losses on marketable securities of $152,596 at December 31, 2004. There were no realized gains or losses on marketable securities in each of the three years in the period ended December 31, 2005.

Accrued interest of approximately $225,000 and $357,000 were included in prepaid expenses and other current assets in the accompanying consolidated balance sheets at December 31, 2005 and 2004, respectively.

On September 16, 2005, a bank guarantee was released in connection with our settlement of a French tax claim (see Note 3). As a result, approximately $1.1 million of cash that was used to collateralize the bank guarantee was no longer restricted at December 31, 2005.

(d) Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market and consist of the following:

| AT DECEMBER 31, | 2005 | 2004 |
|---|---|---|
| Raw materials and work-in-process | $ 619,496 | $1,165,310 |
| Finished Goods | 1,106,804 | 1,357,752 |
| | $1,726,300 | $2,523,062 |

Finished goods comprise materials, labor and manufacturing overhead.

(e) Financial Instruments

SFAS No. 107, "Disclosures About Fair Value of Financial Instruments", requires disclosure of an estimate of the fair value of certain financial instruments. Our financial instruments consist of cash and cash equivalents, marketable securities and accounts receivable. The estimated fair value of these financial instruments approximates their carrying value at December 31, 2005 and 2004, respectively. The estimated fair values have been determined through information obtained from market sources and management estimates. We do not have any derivative or any other financial instruments as defined by SFAS No. 133, "Accounting for Derivative and Hedging Instruments".

(f) Concentration of Credit Risk and Significant Customers

SFAS No. 105, "Disclosure of Information About Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentrations of Credit Risk", as amended by SFAS No. 133, requires disclosure of any significant off-balance-sheet and credit risk concentrations. Financial instruments that subject us to potential credit risk consist primarily of trade accounts receivable with customers in the health care industry. We perform ongoing credit evaluations of our customers' financial condition, but do not require collateral. We continuously monitor collections from customers and maintain a provision for estimated credit losses based upon historical experience and any specific customer collection issues that we have identified. Historically, we have not experienced significant losses related to our accounts receivable. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

No customer accounted for greater than 10% of product sales in any of the three years ended December 31, 2005.

At December 31, 2005, approximately 16% of gross accounts receivable represented accounts denominated in foreign currencies that were translated at year-end exchange rates. For the years ended December 31, 2005, 2004 and 2003, product sales to customers outside North America accounted for approximately 16.7%, 20.6% and 16.5% of total product sales, respectively.

(g) Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment. In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", we periodically review long-lived assets for impairments whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Based on management's assessment, no impairment of long-lived assets existed as of December 31, 2005 or 2004.

(h) Depreciation and Amortization

We provide for depreciation and amortization of our property and equipment by charges to operations using the straight-line method, which allocates the cost of property, plant and equipment over the following estimated useful lives:

| Asset Classification | Estimated Useful Life |
|---|---|
| Leasehold improvements | Shorter of Economic Useful Life or Life of Lease |
| Laboratory and computer equipment | 3-7 Years |
| Office furniture and equipment | 5-10 Years |

Depreciation and amortization expense was $315,000, $353,000 and $349,000 for the years ended December 31, 2005, 2004 and 2003, respectively. Maintenance and repairs are charged to expense when incurred. Additions and improvements are capitalized.

(i) Revenue Recognition

In accordance with Staff Accounting Bulletin ("SAB") No. 104, we record product sales upon transfer of title to the customer, provided that there is persuasive evidence of an arrangement, there are no significant post-delivery obligations and the sales price is fixed or determinable and collection of the sales price is probable. Products sold to our distributors are not subject to a right of return for unsold product. Royalty income is recognized as earned, net of related royalty obligations to third parties.

(j) Net Income (Loss) per Common Share

Basic and diluted net income (loss) per share is presented in conformity with SFAS No. 128, "Earnings per Share", for all periods presented. In accordance with SFAS No. 128, basic net income (loss) per share was determined by dividing net income (loss) by the weighted average common shares outstanding during the period. Diluted net income (loss) per share was determined by dividing net income (loss) by the weighted average common shares outstanding, including potential common shares from the exercise of stock options and warrants using the treasury stock method, if dilutive. We incurred a net loss for each of the three years in the period ended December 31, 2005 and, accordingly, all of our outstanding options and warrants were not dilutive. Options and warrants to purchase a total of 1,739,509, 1,899,630 and 2,028,836 common shares have therefore been excluded from the computation of diluted weighted average shares outstanding for the years ended December 31, 2005, 2004 and 2003, respectively.

(k) Stock-Based Compensation

We account for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees", and related interpretations. Under APB No. 25, no compensation expense is recognized when the option price is equal to the market price of the underlying stock on the date of grant. Under an alternative method of accounting, SFAS No. 123, "Accounting for Stock-Based Compensation", options are valued at the grant date using an option pricing model, and compensation expense is recognized ratably over the vesting period (see Note 2(n)).

The fair value of options and employee stock purchase plan shares granted have been estimated at the date of grant using the Black-Scholes option pricing model prescribed by SFAS No. 123 based upon the following assumptions:

| | 2005 | 2004 | 2003 |
|---|---|---|---|
| Risk-free interest rates | 3.86%-4.48% | 3.31%-4.35% | 2.84%-3.79% |
| Expected dividend yield | — | — | — |
| Weighted average expected lives | 5 years | 7 years | 7 years |
| Expected volatility | 68.2%-69.4% | 69.6%-72.7% | 67.5%-75.5% |
| Weighted average grant-date fair value of options granted during the period | $6.85 | $2.58 | $2.59 |

The following table illustrates the pro forma effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

| | 2005 | 2004 | 2003 |
|---|---|---|---|
| Net loss as reported | $ (7,792,256) | $(1,909,437) | $(1,149,753) |
| Add: Employee stock-based compensation included in net loss as reported | 257,188 | 99,326 | 192,115 |
| Less: Total employee stock-based compensation expense determined under fair value based method for all awards | (2,731,788) | (1,256,070) | (1,332,167) |
| Pro forma net loss | $(10,266,856) | $(3,066,181) | $(2,289,805) |
| Basic and diluted net loss per common share: | | | |
| As reported | $ (0.63) | $ (0.16) | $ (0.10) |
| Pro forma | $ (0.83) | $ (0.25) | $ (0.19) |

Our stock option grants generally vest over several years and we intend to grant varying levels of stock options in future periods. In 2005, we granted certain fully vested stock options (see Note 9(a)). Therefore, the effects indicated above of applying SFAS No. 123 are not necessarily representative of the effects on similar illustrated disclosures in future years.

(l) Foreign Currency

The accounts of our foreign subsidiaries are translated in accordance with SFAS No. 52, "Foreign Currency Translation". The functional currency of our foreign subsidiaries is the U.S. dollar and, accordingly, translation gains and losses are reflected in the consolidated statements of operations. Revenue and expense accounts are translated using the weighted average exchange rate in effect during the period. Foreign currency transaction gains or losses are reflected in the consolidated statements of operations. We had foreign currency transaction (losses) gains of approximately $(122,000), $92,000 and $81,000 for the years ended December 31, 2005, 2004 and 2003, respectively. Foreign currency transaction gains and losses result from differences in exchange rates between the functional currency and the currency in which a transaction is denominated and are included in the consolidated statement of operations in the period in which the exchange rate changes.

(m) Comprehensive Income

We apply the provisions of SFAS No. 130, "Reporting Comprehensive Income", which establishes standards for reporting and displaying comprehensive income and its components in the consolidated financial statements. Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Accumulated other comprehensive loss consists entirely of unrealized gains and losses on marketable securities.

(n) Recent Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), "Share-Based Payment", which is a revision of FASB Statement No. 123, Accounting for Stock-Based Compensation. Statement 123(R) supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and amends FASB Statement No. 95, Statement of Cash Flows. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

Statement 123(R) must be adopted no later than January 1, 2006. We adopted Statement 123(R) on January 1, 2006.

Statement 123(R) permits public companies to adopt its requirements using one of two methods:

- A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of Statement 123(R) that remain unvested on the effective date.
- A "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under Statement 123 for purposes of pro forma disclosures based upon either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

We currently expect to use the modified prospective method beginning with our interim report on Form 10-Q for the period ended March 31, 2006.

As permitted by Statement 123, we currently account for share-based payments to employees using Opinion 25's intrinsic value method and, as such, generally recognize no compensation cost for employee stock options. Accordingly, the adoption of Statement 123(R)'s fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. Had we adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net income and earnings per share in Notes 2(k) and 9(a) to our consolidated financial statements. The impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, our current best estimate for 2006 stock based compensation expense is approximately $1.5 million. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. While we cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options), the amount of operating cash flows recognized in prior periods for such excess tax deductions was $41,000 in 2003.

(o) 401(k) Plan

We offer a savings plan to eligible employees that is intended to qualify under Section 401(k) of the Internal Revenue Code. Participating employees may defer up to 15% of their pre-tax compensation, as defined, subject to certain limitations. In December 2005, our Board of Directors approved a one-time 401(k) employer match for the year ended December 31, 2005. In connection with this employer match, $120,000 was expensed in 2005 and distributed to 401(k) participant accounts in February 2006. We did not make any employer matching or other discretionary contributions to the 401(k) Plan for the years ended December 31, 2004 and 2003.

(p) Supplemental Cash Flow Information and Noncash Investing and Financing Activities

The following table summarizes the supplemental disclosures of our financing and investing transactions for the periods indicated below:

| FOR THE YEARS ENDED DECEMBER 31, | 2005 | 2004 | 2003 |
|---|---|---|---|
| Supplemental disclosure of cash flow information: | | | |
| Cash paid during the year for - | | | |
| Interest | $ — | $ 1,570 | $ 5,361 |
| Income taxes | $ — | $365,215 | $111,880 |
| Supplemental disclosure of noncash financing and investing transactions: | | | |
| Receipt of treasury stock | $ — | $ — | $119,600 |

(q) Expenses Associated with Clinical Trials

We have invested significant resources in several clinical trials designed to investigate the potential connection between a PFO and brain attacks such as migraine headaches, strokes and TIAs. MIST II (Migraine Intervention with STARFlex® Technology), approved by the FDA in the fourth quarter of 2005 and for which patient enrollment has been initiated in January 2006, is our second PFO/migraine trial. Prior to that, we completed enrollment in July 2005 for our first PFO/migraine study (MIST) in the United Kingdom. In October 2005, we announced approval of MIST III, a study designed to expand data and follow-up on MIST migraine patients. Our CLOSURE I trial, commenced in 2003, is an FDA-approved investigational device exemption ("IDE") study in the U.S. to evaluate the safety and efficacy of our STARFlex® closure technology to prevent a recurrent embolic stroke and/or TIA in patients with a PFO. In November 2005, we completed enrollment in our BEST study (BioSTAR™ Evaluation STudy). The BioSTAR™ implant represents a new generation biological closure technology that we are developing and evaluating in order to promote a more natural, rapid and complete sealing of heart defects such as a PFO.

Total expenses for our clinical trials were approximately $7.5 million, $4.6 million and $2.5 million for the years ended December 31, 2005, 2004 and 2003, respectively.

Our judgment is required in determining methodologies used to recognize various costs related to our clinical trials. We generally enter into contracts with vendors who render services over an extended period of time. Typically, we enter into three types of vendor contracts (i) time-based, (ii) patient-based, or (iii) a combination thereof. Under a time-based contract, using critical factors contained within the contract, usually the stated duration of the contract and the timing of services provided, we record the

contractual expense for each service provided under the contract ratably over the period during which we estimate the service will be performed. Under a patient-based contract, we first determine an appropriate per patient cost using critical factors contained within the contract, which include the estimated number of patients and the total dollar value of the contract. We then record the expense based upon the total number of patients enrolled and/or monitored during the period. On a quarterly basis, we review both the timetable of services to be rendered and the timing of services actually rendered. Based upon this review, revisions may be made to the forecasted timetable or to the extent of services performed, or both, in order to reflect our most current estimate of the contract. Adjustments are recorded in the period in which the revisions are estimable. These adjustments could have a material effect on our results of operations. Additional STARFlex® and BioSTAR™ products manufactured to accommodate the expected requirements of our clinical trials are included in inventory because they are saleable units with alternative use outside of the trials. These units will be expensed as a cost of the trials as they are implanted. Substantially all expenses related to our clinical trials are included in research and development in our consolidated statements of operations.

(r) Reclassifications

Certain amounts in the accompanying consolidated statements of cash flows have been reclassified to conform to the current year presentation for discontinued operations.

## (3) DISCONTINUED OPERATIONS

On July 6, 2005, we settled a French tax claim related to our former neurosciences business unit, which was sold in 2002 to Integra LifeSciences Holding Corporation ("Integra"). Pursuant to an indemnification agreement, we paid $324,267 to Integra, which amount was net of a previous deposit payment of approximately $60,000. In connection with this settlement, we recorded income from discontinued operations of $90,687 for the year ended December 31, 2005.

In December 2004, we recorded approximately $123,000 of income from discontinued operations, primarily related to the partial recovery, on appeal, of a prior year judgment against us in connection with the termination of a European employee of our former neurosciences business unit.

## (4) INCOME TAXES

We provide for income taxes in accordance with the provisions of SFAS No. 109, "Accounting for Income Taxes". Accordingly, a deferred tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities, as measured by the tax rates expected to be in effect when these differences reverse.

The provision for income taxes in the accompanying consolidated statements of operations for the years ended December 31, 2005, 2004 and 2003 consisted of the following:

| FOR THE YEARS ENDED DECEMBER 31, | 2005 | 2004 | 2003 |
|---|---|---|---|
| Foreign—current | $ — | $ — | $(38,000) |
| Federal—current | (92,000) | (190,000) | 386,000 |
| State—current | — | — | 39,000 |
| | (92,000) | (190,000) | 387,000 |
| Foreign—deferred | — | — | — |
| Federal—deferred | 92,000 | 190,000 | (282,000) |
| State—deferred | — | — | — |
| | 92,000 | 190,000 | (282,000) |
| | $ — | $ — | $105,000 |

We have U.S. net tax operating loss carryforwards of approximately $8.4 million and tax credit carryforwards of approximately $1.1 million to reduce federal and state taxable income in future periods, if any. These carryforwards are subject to review and possible adjustment by the Internal Revenue Service and their utilization may be limited by aggregate changes in significant ownership of the Company over a three year period as prescribed by Section 382 of the Internal Revenue Code. These carryforwards expire on various dates through 2025. We also have approximately $2.3 million of foreign net operating loss carryforwards.

The tax effects of temporary differences that give rise to significant portions of the current deferred tax asset at December 31, 2005 and 2004 are as follows:

| | 2005 | 2004 |
|---|---|---|
| Net operating losses | $3,284,000 | $ — |
| Tax credit carryforwards | 1,052,000 | 772,000 |
| Timing differences, including reserves, accruals and write-offs | 1,154,000 | 886,000 |
| | 5,490,000 | 1,658,000 |
| Less—Valuation allowance | (5,490,000) | (1,566,000) |
| Net deferred tax asset | $ — | $ 92,000 |

We have provided a valuation allowance for our gross deferred tax asset due to the uncertainty regarding the ability to realize the entire asset.

A reconciliation of the federal statutory tax rate to our effective tax rate is as follows:

| FOR THE YEARS ENDED DECEMBER 31, | 2005 | 2004 | 2003 |
|---|---|---|---|
| Statutory federal income tax rate (benefit) | (34.0)% | (34.0)% | (34.0)% |
| State income taxes, net of federal income tax benefit | — | — | 2.5 |
| Change in valuation allowance/utilization of net operating loss and tax credit carryforwards | 35.5 | 31.7 | 38.7 |
| Other | (1.5) | 2.3 | 2.8 |
| | — % | — % | 10.0% |

### (5) NET ROYALTY INCOME

In connection with the November 2001 sale of our vena cava filter product line to C.R. Bard, Inc. ("Bard"), we entered into a royalty agreement pursuant to which Bard commenced payment of royalties in 2003. As part of that agreement, we continue to pay related royalty obligations to the original inventor of these products. On November 22, 1994, we granted to an unrelated third party an exclusive, worldwide license, including the right to sublicense to others, to develop, produce and market our stent technology. Royalty income has been reported in the accompanying consolidated statements of operations net of related royalty obligations to third parties. Net royalty income totaled approximately $4.6 million, $4.2 million and $1.4 million and during the years ended December 31, 2005, 2004 and 2003, respectively.

### (6) SETTLEMENT OF LITIGATION

On June 1, 2002, we received a Demand for Arbitration in the amount of $10 million, plus legal fees and interest, from Bio-Tech Engineering, Inc., Kevin Maughan and Ferenc Schmidt (collectively, "BTE"), claiming that we were in breach of contract. Following hearings, on September 22, 2003, the Company and BTE entered into a settlement agreement, pursuant to which we paid $950,000 to BTE and BTE agreed to a general release of any and all claims against the Company. Also as part of the settlement, the Company and BTE terminated their license and technology agreement, BTE transferred all associated patent rights to the Company and the parties agreed to have the case dismissed with prejudice. The Company and BTE each paid half of the arbitration fees. Included in the accompanying consolidated statement of operations for the year ended December 31, 2003 was a settlement of litigation charge of approximately $1.2 million, which consisted of the settlement amount plus legal fees.

### (7) COMMITMENTS

(a) Operating Leases

We have operating leases for (i) office and laboratory space aggregating approximately 35,000 square feet; and (ii) office equipment and motor vehicle leases expiring through 2009. The office leases require payment of a pro rata share of common area maintenance expenses and real estate taxes in excess of base year amounts. In November 2005, we entered into an amendment to our office lease agreement, which extended the term by four years through September 2010, and included certain incentives, including one month of free rent during 2006 and reimbursement for tenant improvements up to a maximum of $248,000. The effects of the variable rent disbursements have been expensed on a straight line basis over the life of the lease in accordance with FASB Statement No. 13 "Accounting for Leases". The office lease amendment also provides for one five year renewal option subject to approval by the landlord.

Future minimum rental payments due under operating lease agreements at December 31, 2005 are approximately as follows:

| YEARS ENDING DECEMBER 31, | |
|---|---|
| 2006 | $ 920,000 |
| 2007 | 956,000 |
| 2008 | 971,000 |
| 2009 | 1,014,000 |
| 2010 | 749,000 |
| | $4,610,000 |

Rent expense for the years ended December 31, 2005, 2004 and 2003 totaled approximately $981,000, $946,000 and $975,000, respectively.

(b) Royalties and Licensed Technology

We have entered into various agreements that require payment of royalties based on specified percentages of future sales, as defined. In addition, we have agreed to pay royalties to a former employee and a stockholder/founder based on sales or licenses of products where they were the sole or joint inventor.

Royalty expense under royalty agreements was approximately $3,610,000, $3,245,000 and $2,730,000 for the years ended December 31, 2005, 2004 and 2003, respectively. Approximately $1,565,000, $1,431,000 and $484,000 of these royalties were included as a reduction of related royalty income earned from third parties for the years ended December 31, 2005, 2004 and 2003, respectively.

We have also entered into a license and development agreement pursuant to which, under certain circumstances, we are obligated to make a one-time payment of $600,000 upon certain product commercialization milestones, and potentially may be required to make royalty payments based on future sales.

(c) Employment Agreements

We have employment agreements with our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") through December 2007 and 2006, respectively. In the event of termination without cause, as defined therein, these employment agreements provide up to one year's continued salary as then in effect, in addition to any earned incentive compensation, and, in the case of the CEO, continued health insurance coverage for eighteen months. Upon consummation of a change in control of the Company, as defined, these executives would be entitled to a cash payment equal to a percentage of the total deal consideration paid by an acquirer. This percentage would range from 1.0% to 4.2% for our CEO and from 0% to 0.875% for our CFO.

(d) Clinical Trials

*MIST*

In November 2004, we received approval in the United Kingdom for the MIST study, the first prospective, randomized, double-blinded study to evaluate the effectiveness of transcatheter closure of a PFO, using our proprietary STARFlex® septal repair technology, in the treatment and prevention of migraine headaches. MIST is a multi-center study involving approximately 16 centers, with an enrollment of 147 migraine patients with aura, who have a PFO and who were randomized to either PFO closure with the STARFlex® implant or a control arm. The study was designed by a scientific advisory board comprised of some of the top European and North American migraine specialists and interventional cardiologists. The MIST study's patient recruitment process was supported by the Migraine Action Association (MAA), a migraine headache advocacy group representing more than 14,000 members in the United Kingdom. Total costs of this trial, including third party contracts and agreements with clinical sites and other service providers, are currently estimated to be in the range of $4.0 to $4.5 million. Of this total, approximately $3.0 million and $900,000 were incurred during 2005 and 2004, respectively. We currently estimate 2006 costs to be approximately $300,000. It is currently anticipated that results from this study will be available on March 13, 2006.

*MIST II*

In September 2005, we received conditional approval from the U.S. Food and Drug Administration ("FDA") of an Investigational Device Exemption ("IDE") to initiate enrollment in our pivotal PFO/migraine clinical study, named MIST II. MIST II is a prospective, randomized, multi-center, controlled study. The double-blinded trial is designed to randomize approximately 600 migraine patients with a PFO to either PFO closure with our STARFlex® technology or a control arm. The study will incorporate our newest, most technologically advanced delivery system. More than twenty U.S. research centers have committed to participate in MIST II, and enrollment began in January 2006. Patient follow-up will be over a one year period. We currently project the costs of this clinical study to be in the range of $16 to $20 million through 2008. Of this total, approximately $300,000 was incurred during 2005 and we currently estimate 2006 costs to be approximately $14 million.

*MIST III*

In October 2005, we received approval from the regulatory authorities in the United Kingdom to begin enrollment in MIST III. In MIST III, control patients from the original MIST study, those who did not receive the STARFlex® implant, have the option to receive an implant after they have been unblinded as part of the MIST study. These patients will follow the identical protocol as in MIST after which they will be followed for an additional 18 months. In addition, migraine patients with a PFO who did receive a STARFlex® implant in MIST will be followed for an additional 18 months. We currently estimate the cost of MIST III to be approximately $1.2 million to be incurred through 2007.

*BEST*

In June 2005, we received approval in the United Kingdom for our BioSTAR™ Evaluation STudy (BEST), a multi-center study designed to evaluate our new BioSTAR™ PFO closure technology, the first in-human use of a bioabsorbable collagen matrix incorporated on our STARFlex® platform. BioSTAR™, our first biological closure technology, is designed to optimize the biological response by promoting quicker healing and device endothelialization. Patient enrollment was initiated in July 2005 and completed during the fourth quarter 2005. The goal of our BEST study is to secure European commercial approval for our novel BioSTAR™ technology through the Conformité Europeene ("CE Mark") process, which we anticipate receiving by the end of 2006. We currently estimate total costs of this study, including third party contracts and agreements with clinical sites and other service providers, to be in the range of $1.2 to $1.5 million. Of this total, approximately $900,000 was incurred in 2005 and we currently estimate 2006 costs to be approximately $400,000.

*CLOSURE I*

We have committed significant financial and personnel resources to the execution of our pivotal CLOSURE I clinical trial. Including contracts with third party providers, agreements with participating clinical sites, internal clinical department costs and manufacturing costs of the STARFlex® devices to be implanted, total costs are currently estimated to be approximately $24 million through completion of the trial and submission to the FDA. Of this total, approximately $3.2 million, $3.7 million and $2.5 million were incurred during 2005, 2004 and 2003, respectively. We currently project 2006 costs to approximate $4.1 million, largely dependent upon the rate of patient enrollment.

(e) Guarantees and Indemnifications

We recognize liabilities for guarantees in accordance with FASB Interpretation No. 45 ("FIN 45"), "Guarantor's Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others". FIN 45 requires that, upon issuance of a guarantee, the guarantor must recognize a liability for the fair value of the obligation it assumes under that guarantee.

In the ordinary course of our business, we agree to indemnification provisions in certain of our agreements with our customers, clinical sites, licensors and real estate lessors. With respect to our customer agreements and licenses, we generally indemnify the customer or licensor against losses, expenses and other damages that result from, among other things, product liability claims or infringement of a third party's intellectual property. With respect to our real estate leases, we indemnify our lessor for losses, expenses and other damages that result from, among other things, personal injury and property damage that occur at our facilities and for any breach by us of the terms of the lease. Based on our policies, practices and claims and payment history, we believe that the estimated fair value of these indemnification obligations is minimal.

## (8) STOCKHOLDERS' EQUITY

(a) Preferred Stock

Our Second Amended and Restated Certificate of Incorporation provides for, and the Board of Directors and stockholders authorized, 3,000,000 shares of $0.001 par value preferred stock. We have designated 50,000 shares as Series A Junior Participating Preferred Stock ("Series A") in connection with the Rights Agreement discussed below. No shares of Series A have been issued. However, upon issuance, the Series A will be entitled to vote, receive dividends, and have liquidation rights. The remaining authorized preferred stock is undesignated and our Board of Directors has the authority to issue such shares in one or more series and to fix the relative rights and preferences without vote or action by the stockholders.

(b) Rights Agreement

In June 1999, our Board of Directors adopted a stockholder rights plan ("Rights Plan"). The Rights Plan is intended to protect our stockholders from unfair or coercive takeover practices. In accordance with the Rights Plan, our Board of Directors declared a dividend distribution of one purchase right (a "Right") for each share of common stock outstanding to our stockholders of record on June 10, 1999. Each share of common stock newly issued after that date also carries with it one Right. Subject to the conditions contained in the Rights Plan, each Right entitles the registered holder to purchase from the Company one one-thousandth (1/1000th) of a share of Series A at an initial purchase price of $20, as adjusted from time to time for certain events. The Rights become exercisable (a "Triggering Event") ten (10) business days after the earlier of our announcement that a person or group has acquired beneficial ownership of 15% or more (25% or more in the case of Whitney Equity Partners, L.P. and its affiliates) (each, a "Triggering Holder") of our common stock or an announcement of a tender or exchange offer which would result in a person or group acquiring 15% or more of our common stock; in either case, our Board of Directors can extend this ten-day period. At such time, if we have not redeemed or exchanged the Rights, each holder of a Right (other than the Triggering Holder) will have the right to receive, upon payment of the then current purchase price of the Right, and in lieu of one one-thousandth (1/1000th) of a Series A share, the number of shares of our common stock that equals the result obtained by dividing the then current purchase price of the Right by 50% of the then current market price per share of our common stock. In the event that the number of shares of our common stock then currently authorized, but not outstanding or reserved for issuance for purposes other than the exercise of the Rights, are not sufficient to permit the exercise in full of the Rights, we will either (i) reduce the purchase price of the Right accordingly; or (ii) make other substitute provisions of equivalent value as specified in the Rights Plan. If, at any time following the Triggering Event, we are acquired in a merger or other business combination transaction in which we are not the surviving corporation or more than 50% of our assets or earning power is sold to a person or group, each holder of a Right shall thereafter have the right to receive, upon purchase of each Right, that number of shares of common stock of the acquiring company equal to the result obtained by dividing the then current exercise price of the Right by 50% of the then current market price per share of the acquirer's common stock.

The Rights expire on June 9, 2009. We may redeem the Rights for $.001 per Right at any time prior to the Rights becoming exercisable, or June 9, 2009.

## (9) STOCK OPTIONS AND WARRANTS

(a) Stock Options

Our 1996 Stock Option Plan (the "1996 Plan"), 1998 Stock Incentive Plan (the "1998 Plan") and 2001 Stock Incentive Plan (the "2001 Plan") (collectively, the "Plans") generally provide for the grant of incentive stock options, nonstatutory stock options and restricted stock awards, as appropriate, to our eligible employees, officers, directors, consultants and advisors. The Compensation Committee of the Board of Directors administers the Plans, subject to the terms and conditions of the respective Plans. Options granted generally vest in equal annual

installments over a four-year period from the date of grant. At December 31, 2005 there were 1,533,909 options outstanding and 282,582 options available for grant under the Plans.

In November 2005, we granted to employees 175,800 fully vested options with an exercise price of $16.34, the fair market value on the date of grant. Of the $2,731,788 pro forma stock-based compensation expense for 2005 disclosed in Note 2(k), approximately $1,385,000 relates to these options. Had we granted these options with longer time-based vesting, we would have incurred significant stock-based compensation expense in future years in accordance with newly issued SFAS No. 123R.

Our 1996 Stock Option Plan for Non-Employee Directors (the "Directors Plan") provides for the automatic grant of non-statutory stock options to purchase shares of common stock to our directors who are not our employees and who do not otherwise receive compensation from us. Under the terms of the Directors Plan, as amended, each new non-employee director not otherwise compensated by us receives an initial grant of options to purchase 20,000 shares of common stock at an exercise price equal to the fair market value per share at the date of grant, subject to vesting in equal monthly installments over a three-year period. Subsequently, coincident with such director's re-election to the Board at our annual meeting of stockholders, there is an additional grant of options to purchase 5,000 shares of common stock that fully vests six months after the date of grant. In addition, following each annual meeting of stockholders, each eligible director who served as a member of a committee of the Board of Directors during the preceding fiscal year is granted an additional option to purchase (i) 2,000 shares of common stock if such director served as a chairperson of such committee or (ii) 1,000 shares of common stock if such director did not serve as chairperson of such committee. At December 31, 2005 there were 180,600 options outstanding and 46,000 options available for grant under the Directors Plan.

On March 1, 2001, our Board of Directors authorized an offer for employees to exchange certain Plan options outstanding. Under this exchange offer, certain employees elected to have a total of 322,521 existing options cancelled in exchange for 131,558 new options. The new options were granted at $2.19 per share, which was the fair market value of the common stock as of the date of grant. These options are subject to variable accounting as defined in FASB Interpretation No. 44 ("FIN 44"), "Accounting for Certain Transactions Involving Stock Compensation". In addition, we granted 83,450 additional options to employees who participated in the option exchange program, which are subject to variable accounting under FIN 44. We have followed the provisions of FIN 44 and have revalued to market the re-priced options, through the date of exercise, cancellation or expiration, at each reporting date, over the four-year vesting period which ended in April 2005. Compensation expense, included in general and administrative expense, related to the re-priced options was approximately $257,000, $67,000 and $159,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

During fiscal 2002, in conjunction with an amendment to the employment agreement of our CEO, the terms of a previously granted option to him to acquire 150,000 shares of common stock was modified to allow for an extended exercise period upon certain termination scenarios. Based upon our stock price at the date of measurement, a total of approximately $140,000 of compensation expense was recognized over the vesting period of the option in accordance with FIN 44. Of that amount, approximately $33,000 was expensed for each of the years ended December 31, 2004 and 2003.

At December 31, 2005 there were 25,000 nonqualified options outstanding to purchase shares of common stock issued to a former officer/director, subject to certain milestone vesting and expiring in February 2008.

All unexercised options expire ten years from date of grant.

The following table summarizes a reconciliation of all stock option activity for each of the three years during the period ended December 31, 2005:

| FOR THE YEARS ENDED DECEMBER 31, | 2005 | | 2004 | | 2003 | |
|---|---|---|---|---|---|---|
| | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| Outstanding: | | | | | | |
| Beginning balance | 1,879,630 | $ 4.48 | 2,008,836 | $ 4.34 | 1,725,574 | $ 4.43 |
| Granted | 363,400 | 12.53 | 301,850 | 3.72 | 441,000 | 3.80 |
| Cancelled | (113,204) | 6.40 | (227,794) | 4.55 | (91,826) | 5.46 |
| Exercised | (390,317) | 4.00 | (203,262) | 1.93 | (65,912) | 1.54 |
| Ending balance | 1,739,509 | $ 6.14 | 1,879,630 | $ 4.48 | 2,008,836 | $ 4.34 |
| Exercisable | 1,227,064 | $ 6.29 | 1,089,137 | $ 4.25 | 866,478 | $ 3.89 |

For various price ranges, information for options outstanding and exercisable at December 31, 2004 was as follows:

| | OUTSTANDING OPTIONS | | | EXERCISABLE OPTIONS | |
|---|---|---|---|---|---|
| | Shares | Weighted Average Remaining Life (in years) | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| $ 1.25 – 1.56 | 30,156 | 5.10 | $ 1.44 | 30,156 | $ 1.44 |
| $ 1.76 – 2.25 | 150,810 | 4.97 | 2.07 | 150,810 | 2.07 |
| $ 2.63 – 3.50 | 403,800 | 7.11 | 3.13 | 252,162 | 2.98 |
| $ 3.63 – 5.18 | 362,079 | 7.33 | 4.33 | 232,467 | 4.46 |
| $ 5.65 – 7.80 | 481,264 | 6.77 | 6.67 | 333,992 | 6.58 |
| $ 8.04 – 11.78 | 126,850 | 7.28 | 9.99 | 51,677 | 9.67 |
| $12.76 – 15.67 | 3,900 | 9.87 | 15.41 | — | — |
| $16.34 – 21.25 | 180,650 | 9.80 | 16.37 | 175,800 | 16.34 |
| $ 1.25 – 21.25 | 1,739,509 | 7.14 | $ 6.14 | 1,227,064 | $ 6.29 |

(b) Warrants

The following table summarizes our warrant activity:

| | Shares | Weighted Average Exercise Price |
|---|---|---|
| Balance, December 31, 2002 | 103,329 | $2.69 |
| Exercised | (83,329) | 2.15 |
| Balance, December 31, 2003 and 2004 | 20,000 | 4.94 |
| Exercised | (20,000) | 4.94 |
| Balance, December 31, 2005 | — | $ — |

Pursuant to Emerging Issues Task Force (EITF) Issue 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock", we believe that equity classification is appropriate for all outstanding warrants.

(c) Employee Stock Purchase Plan

We offer an employee stock purchase plan ("ESPP") for all eligible employees. Under the ESPP, which qualifies as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code, shares of our common stock can be purchased at 85% of the lower of the fair market value of the stock on the first or last day of each six-month offering period. Employee purchases in any year are limited to the lesser of $25,000 worth of stock, determined by the fair market value of the common stock at the time the offering begins, or 12% of annual base pay.

A total of 275,000 common shares have been reserved for issuance under the ESPP, as amended. Employees purchased 49,332, 58,134 and 52,669 shares of common stock under the ESPP during the years ended December 31, 2005, 2004 and 2003, respectively.

The average purchase prices for total ESPP shares acquired were $4.50, $3.56 and $2.94 for the years ended December 31, 2005, 2004 and 2003, respectively. At December 31, 2005, there were 21,053 shares available for issuance under the ESPP, as amended.

## (10) RELATED PARTY TRANSACTIONS

Pursuant to the terms of an exclusive license agreement with Children's Medical Center Corporation ("CMCC"), we pay royalties on sales of our CardioSEAL® and STARFlex® products to CMCC. James E. Lock, M.D., a member of our Board of Directors and an affiliate of CMCC, receives from CMCC a portion of these royalties.

## (11) ACCRUED EXPENSES

Accrued expenses consisted of the following:

| AT DECEMBER 31, | 2005 | 2004 |
|---|---|---|
| Clinical trials | $2,861,782 | $1,708,976 |
| Payroll and payroll related | 1,253,173 | 675,858 |
| Royalties | 992,556 | 863,626 |
| Professional Fees | 572,442 | 565,278 |
| Other accrued expenses | 835,856 | 495,848 |
| | $6,515,809 | $4,309,586 |

## (12) FINANCIAL INFORMATION BY GEOGRAPHIC AREA

Revenues by destination country for the years ended December 31, 2005, 2004 and 2003 were as follows:

| | 2005 | 2004 | 2003 |
|---|---|---|---|
| United States | $20,583,000 | $17,567,000 | $19,137,000 |
| Germany | 905,000 | 1,671,000 | 1,658,000 |
| United Kingdom | 822,000 | 452,000 | 239,000 |
| Other | 1,606,161 | 1,770,024 | 1,927,359 |
| | $23,916,161 | $21,460,024 | $22,961,359 |

Net book value of long-lived assets by country at December 31, 2005 and 2004 were as follows:

| | 2005 | 2004 |
|---|---|---|
| United States | $793,556 | $773,949 |
| Other | 11,213 | 16,412 |
| | $804,769 | $790,361 |

## (13) VALUATION OF QUALIFYING ACCOUNTS

The following table sets forth the activity in our allowance for doubtful accounts and sales returns:

| FOR THE YEARS ENDED DECEMBER 31, | 2005 | 2004 | 2003 |
|---|---|---|---|
| Balance at beginning of period | $378,150 | $385,000 | $265,000 |
| Provision for bad debt and sales returns adjustments | — | — | 392,000 |
| Write-offs and returns | (8,166) | (6,850) | (272,000) |
| Balance at end of period | $369,984 | $378,150 | $385,000 |

### (14) LEGAL PROCEEDINGS

We are a party to the following legal proceedings that could have a material adverse impact on our results of operations or liquidity if there were an adverse outcome. Although we intend to pursue our rights in each of these matters vigorously, we cannot predict the ultimate outcomes.

In September 2004, we and the Children's Medical Center Corporation ("CMCC") filed a civil complaint in the U.S. District Court for the District of Minnesota for infringement of a patent owned by CMCC and licensed exclusively to us. The complaint alleges that Cardia of Burnsville, Minnesota is making, selling and/or offering to sell a medical device in the United States that infringes CMCC's U.S. patent relating to a device and method for repairing septal defects. We sought an injunction from the court to prevent further infringement by Cardia, as well as monetary damages. The court has entered a pre-trial order stating that the case is to be ready for trial in the spring of 2006.

On March 22, 1999, we filed a patent infringement suit in the United States District Court for the District of Massachusetts (the "Court") against AGA Medical Corp. ("AGA") alleging that AGA was infringing United States Patent No. 5,108,420 (the "'420 patent"), relating to aperture occlusion devices, to which we have an exclusive license. We sought an injunction from the Court to prevent further infringement by AGA, as well as monetary damages. On April 12, 1999, AGA served its answer and counterclaims denying liability and alleging that we had engaged in false or misleading advertising and in unfair or deceptive business practices. AGA's counterclaims sought an injunction and an unspecified amount of damages. On May 3, 1999, we answered AGA's counterclaims denying liability. On April 25, 2001, the Court granted our motion to stay all proceedings in this matter pending reexamination of the '420 patent by the United States Patent and Trademark Office and, on December 2, 2003, the Court dismissed our claim and AGA's counterclaim without prejudice to our ability to refile suit after the conclusion of the reexamination proceedings. Although a Patent Office examiner initially rejected the claims of the '420 patent, on August 19, 2004, the Board of Patent Appeals and Interferences reversed the examiner's rejection of the claims of the '420 patent and returned the reexamination for action consistent with its decision. On January 26, 2005, the Patent Office mailed a Notice of Intent to Issue a Reexamination Certificate. This reexamination certificate was issued on June 7, 2005. On October 13, 2004, AGA initiated a declaratory action in the United States District Court for the District of Minnesota seeking a declaration that the '420 patent is invalid, unenforceable, and not infringed. On December 7, 2004, we revived our original Massachusetts action by filing a complaint alleging that AGA is infringing the '420 patent. On September 1, 2005, AGA's declaratory judgment action in the United States District Court for the District of Minnesota was transferred to the District of Massachusetts. On October 13, 2005, we answered AGA's complaint in its declaratory judgment action, denying AGA's claims. On November 2, 2005, we filed an amended complaint adding the inventor of the '420 patent as a plaintiff. On November 3, 2005, AGA answered our amended complaint, denying liability and counterclaiming that the '420 patent is invalid, unenforceable, and not infringed. On November 17, 2005, we answered AGA's counterclaims by denying them.

On July 6, 2005, we settled a French tax claim related to our former neurosciences business unit (see Note 3).

Other than as described above, we have no material pending legal proceedings.

## EXHIBIT INDEX

**Exhibit No.**

| | |
|---|---|
| 2.1(2) | Asset Purchase Agreement, dated as of October 19, 2001, between the Company and C. R. Bard, Inc. (9) |
| 2.2 | Stock Purchase Agreement, dated as of July 31, 2002, between the Company and Integra LifeSciences Corporation. (10) |
| 3.1 | Second Amended and Restated Certificate of Incorporation. (3) |
| 3.2 | Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation, as filed with the office of the Secretary of State of the State of Delaware on June 3, 1999. (6) |
| 3.3 | Amended and Restated By-laws. (1) |
| 4.1 | Form of Common Stock Certificate. (1) |
| 4.2 | Rights Agreement, dated as of June 7, 1999, between the Company and American Stock Transfer & Trust Company, as Rights Agent, which includes as Exhibit A, the form of Certificate of Designation, as Exhibit B the form of Rights Certificate, and as Exhibit C, the Summary of Rights to Purchase Preferred Stock. (5) |
| 10.1 | Agreement and Plan of Merger by and among the Company, NMT Heart, Inc., InnerVentions, Inc. and Fletcher Spaght, Inc., dated as of January 25, 1996. (1) |
| 10.2 | License and Development Agreement by and between the Company and Boston Scientific Corporation, dated as of November 22, 1994. (1) |
| 10.3(2) | Technology Purchase Agreement by and between the Company and Morris Simon, M.D., dated as of April 14, 1987. (1) |
| 10.4 | Asset and Technology Donation and Transfer Agreement by and between C.R. Bard, Inc. and Children's Medical Center Corporation dated as of May 12, 1995. (1) |
| 10.5 | Stock Transfer Agreement by and between Children's Medical Center Corporation and InnerVentions, Inc., dated as of June 19, 1995. (1) |
| 10.6(2) | License Agreement by and between Children's Medical Center Corporation and InnerVentions, Inc., dated June 19, 1995. (1) |
| 10.7 | Sublicense Agreement by and between Children's Medical Center Corporation and InnerVentions, Inc., dated June 19, 1995. (1) |
| 10.8 | Assignment Agreement by and between the Company and The Beth Israel Hospital Association, dated June 30, 1994. (1) |
| 10.9(2) | License Agreement by and between the Company and Lloyd A. Marks, dated as of April 15, 1996. (1) |
| 10.10 | Agreement of Lease by and between the Company and the Trustees of Wormwood Realty, dated as of May 8, 1996. (1) |
| 10.11 | Amendment of Leases by and between the Company and Fort Point Place—VEF V, LLC, as successor to Trustees of Wormwood Realty Trust, dated as of November 9, 2005. (18) |
| 10.12 | Company 1994 Stock Option Plan. (1)(**) |
| 10.13 | Company 1996 Stock Option Plan. (1)(**) |
| 10.14 | Amendment No. 1 to 1996 Stock Option Plan. (3)(**) |
| 10.15 | Company 1996 Stock Option Plan for Non-Employee Directors, as amended. (12)(**) |
| 10.16 | Company 1998 Stock Incentive Plan (3)(**) |
| 10.17 | Company 2001 Stock Incentive Plan, as amended (13)(**) |
| 10.18 | Company 2001 Employee Stock Purchase Plan, as amended (12)(**) |
| 10.19 | License Agreement, dated as of October 2000, by and between the Company and Children's Medical Center Corporation. (8) |
| 10.20(2) | Royalty Agreement, dated as of October 19, 2001, between the Company and C. R. Bard, Inc. (9) |
| 10.21 | Registration Rights Agreement by and between the Company and Fletcher Spaght, Inc., dated as of February 14, 1996. (1) |
| 10.22 | Amendment No. 1, dated July 1, 1998 to the Registration Rights Agreement by and between the Company and Fletcher Spaght, Inc., dated as of February 14, 1996. (7) |

# EXHIBIT INDEX

**Exhibit No.**

| | |
|---|---|
| 10.23 | Form of Registration Rights Agreement between the Company and certain of its existing stockholders, dated as of February 14, 1996. (1) |
| 10.24 | Registration Rights Agreement dated as of March 30, 1999 by and among the Company and the individuals listed on Schedule A thereto. (4) |
| 10.25 | Stock Option Agreement evidencing grant by the Company to John Ahern, dated as of September 21, 2000. (11)(**) |
| 10.26(2) | Amended and Restated Employment Agreement by and between the Company and John E. Ahern, dated as of December 31, 2002. (11)(**) |
| 10.27 | Amendment dated as of December 31, 2002 to Stock Option Agreement evidencing grant by the Company to John E. Ahern of September 21, 2000. (11)(**) |
| 10.28 | Stock Option Agreement evidencing grant by the Company to John E. Ahern, dated as of December 31, 2002. (11) (**) |
| 10.29 | Second Amended and Restated Employment Agreement by and between the Company and John E. Ahern, dated as of December 13, 2005. (19)(**) |
| 10.30(2) | Amendment No.1 dated as of April 28, 2003 to Employment Agreement by and between the Company and Richard E. Davis, dated as of February 14, 2000. (11)(**) |
| 10.31(2) | Amended and Restated Employment Agreement by and between the Company and Richard E. Davis, dated as of May 20, 2004. (13)(**) |
| 10.32 | Incentive Stock Option Agreement evidencing grant by the Company to Richard E. Davis, dated as of September 21, 2004. (14)(**) |
| 10.33 | Form of Incentive Stock Option Agreement Granted Under 2001 Stock Incentive Plan, as amended. (15)(**) |
| 10.34 | Form of Incentive Stock Option Agreement Granted Under 1998 Stock Incentive Plan. (15)(**) |
| 10.35 | Form of Incentive Stock Option Letter Agreement Under 1996 Stock Option Plan. (15)(**) |
| 10.36 | Form of Nonstatutory Stock Option Letter Agreement Under 1996 Stock Option Plan For Non-Employee Directors, as amended. (15)(**) |
| 10.37 | Amendment of the Company's director compensation program relating to the Board's Lead Director, dated as of March 15, 2005. (17)(**) |
| 10.38 | Summary of compensation arrangement applicable to the Company's Board of Directors. (20)(**) |
| 10.39 | Summary of compensation arrangement applicable to the Company's named executive officers. (20)(**) |
| 10.40 | Amendment of cash compensation arrangements applicable to the Company's non-employee directors, dated as of January 1, 2006. (21) |
| 10.41 | Revised summary of compensation arrangement applicable to the Company's non-employee directors, dated as of March 9, 2006. Filed herewith. (**) |
| 10.42 | Revised summary of compensation arrangement applicable to the Company's named executive officers, dated as of March 9, 2006. Filed herewith. (**) |
| 14.1 | Code of Business Conduct and Ethics of the Company. (16) |
| 21.1 | Subsidiaries of the Registrant. Filed herewith. |
| 23.1 | Consent of Ernst & Young LLP. Filed herewith. |
| 31.1 | Certification pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended. Filed herewith. |
| 31.2 | Certification pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended. Filed herewith. |
| 32.1 | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith. |
| 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. Filed herewith. |

## EXHIBIT INDEX

**Exhibit No.**

(1) Incorporated by reference to Exhibits to the Registrant's Registration Statement on Form S-1 (File No. 333-06463).

(2) Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Commission.

(3) Incorporated by reference to Exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998 (File No. 000-21001).

(4) Incorporated by reference to Exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999 (File No. 000-21001).

(5) Incorporated by reference to Exhibits to the Registrant's Current Report on Form 8-K, dated June 7, 1999 (File No. 000-21001).

(6) Incorporated by reference to Exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999 (File No. 000-21001).

(7) Incorporated by reference to Exhibits to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 (File No. 000-21001).

(8) Incorporated by reference to Exhibits to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File No. 000-21001).

(9) Incorporated by reference to Exhibits to the Registrant's Current Report on Form 8-K, dated November 5, 2001 (File No. 000-21001).

(10) Incorporated by reference to Exhibits to the Registrant's Current Report on Form 8-K, dated July 31, 2002 (File No. 000-21001).

(11) Incorporated by reference to Exhibits to the Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2002 (File No. 000-21001).

(12) Incorporated by reference to Exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003 (File No. 000-21001).

(13) Incorporated by reference to Exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004 (File No. 000-21001).

(14) Incorporated by reference to Exhibits to the Registrant's Current Report on Form 8-K, dated September 21, 2004 (File No. 000-21001).

(15) Incorporated by reference to Exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004 (File No. 000-21001).

(16) Incorporated by reference to Exhibits to the Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2003 (File No. 000-21001).

(17) Incorporated by reference to Exhibits to the Registrant's Current Report on Form 8-K, dated March 15, 2005 (File No. 000-21001).

(18) Incorporated by reference to Exhibits to the Registrant's Current Report on Form 8-K, dated November 14, 2005 (File No. 000-21001).

(19) Incorporated by reference to Exhibits to the Registrant's Current Report on Form 8-K, dated December 14, 2005 (File No. 000-21001).

(20) Incorporated by reference to Exhibits to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2004 (File No. 000-21001).

(21) Incorporated by reference to Exhibits to Registrant's Current Report on Form 8-K, dated January 6, 2006 (File No. 000-21001).

(**) Management contract or compensatory plan or arrangement required to be filed as an Exhibit to this Annual Report on Form 10-K.

## Corporate Directory

### BOARD OF DIRECTORS

John E. Ahern
Chairman of the Board,
President and Chief Executive
Officer of the Company

Cheryl L. Clarkson[1,2,3]
Chairman of the Board,
Chief Executive Officer
SkinHealth, Inc.

Daniel F. Hanley, MD[1]
Professor of Neurology, Neurosurgery
and Anesthesia/Critical Medicine,
Professor, School of Nursing,
the Jeffrey and Harriett Legum
Professor of Acute Care Neurology,
and Director of Brain Injury
Outcomes Program, Johns Hopkins
Medical Institutions

James E. Lock, MD
Chair, Department of Cardiology
and Physician-in-Chief,
Children's Hospital, Boston
Nadas Professor of Pediatrics,
Harvard Medical School

Francis J. Martin[1,2,3]
Executive Chairman
Capella, Inc.

Harry A. Schult[2,3]
Vice President
Enterprise Risk Management
TeleAtlas NV

### CORPORATE OFFICERS

John E. Ahern
Chairman of the Board,
President and Chief Executive
Officer of the Company

Richard E. Davis
Vice President and
Chief Financial Officer

### ORGANIZATION

Carol A. Devellian
Vice President of
Research and Development

Geoff Fournie
Vice President of Clinical
Development – Europe

Paul A. Garant
Vice President of Quality Assurance,
Manufacturing and Facilities

Brad Ryno
Vice President of Worldwide Sales

Ron Seyffert
Director of Marketing

Fred Tobia
Director of Clinical
and Regulatory Affairs

### CORPORATE HEADQUARTERS

27 Wormwood Street
Boston, Massachusetts 02210-1625
(617) 737-0930

### FORM 10-K AVAILABILITY

A copy of the Annual Report on
Form 10-K for the year ended December 31,
2005 may be obtained at no charge by
writing to the Company.

### TRANSFER AGENT

American Stock Transfer & Trust
59 Maiden Lane
Plaza Level
New York, NY 10038

### INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young LLP
Boston, Massachusetts

### COUNSEL

WilmerHale, LLP
60 State Street
Boston, Massachusetts 02109

### ANNUAL MEETING

The Annual Meeting of Stockholders
will be held on Thursday, June 15,
2006 at 1:00 p.m. at the Seaport Hotel,
One Seaport Lane, Boston.

### COMMITTEES OF THE BOARD

[1] Member of the Joint Compensation and Stock Options Committee

[2] Member of the Audit Committee

[3] Member of the Nominating and Corporate Governance Committee

NMT Medical, Inc.

27 Wormwood Street
Boston, MA 02210-1625
617 737-0930

**www.nmtmedical.com**