NMT Medical, Inc.

2008 ANNUAL REPORT

The medical community eagerly awaits the answer to whether PFO closure or medical therapy alone provides the best risk benefit for reducing recurrent stroke or TIA. A positive outcome for CLOSURE I would be a transforming event for cardiologists, neurologists, patients, and NMT Medical.

To our investors, patients, clinical partners, and employees:

NMT Medical achieved several important milestones in 2008, further positioning the Company as a leader in the treatment of structural heart disease. Our goal is to effectively market our advanced medical technologies to take advantage of several emerging and potentially large opportunities.

In pursuit of NMT Medical's mission, we are currently investigating the potential relationship between a common heart defect – patent foramen ovale (PFO) – and brain attacks such as embolic stroke and transient ischemic attacks (TIAs). We made critical progress in 2008 toward determining the extent of these connections. NMT Medical's most significant accomplishment during the year was completing enrollment in CLOSURE I, our pivotal trial of PFO closure with the Company's STARFlex® septal repair implant as a treatment for stroke and TIA.

We plan to review CLOSURE I data in the fourth quarter of 2010 and expect to submit a Pre-Market Approval (PMA) application to the U.S. Food and Drug Administration (FDA) for the stroke/TIA indication shortly thereafter. We believe the results of this trial are increasingly significant as the medical community eagerly awaits the answer to whether PFO closure or medical therapy alone provides the best risk benefit for reducing recurrent stroke or TIA. A positive outcome for CLOSURE I would be a transforming event for cardiologists, neurologists, patients, and NMT Medical. Although an independent statistical committee determined that it was "highly likely" that sufficient primary outcome events (strokes and TIAs) would have occurred to allow analysis in October 2009, we chose to follow the more conservative two-year timetable recommended by the trial's Executive Committee. Maintaining the original two-year timetable for analysis may offer the best statistical power to observe a significant difference in treatment alternatives.

In April 2009 we announced that we had received PMA approval from the FDA for the commercial sale of the STARFlex® cardiac septal repair implant in the U.S. for patients with ventricular septal defects (VSD). STARFlex® accommodates easier implantation as well as the treatment of larger defects due to its unique self-centering mechanism, providing patients with a more advanced closure technology than its predecessor, CardioSEAL®.

In 2008 our international marketing efforts focused on BioSTAR®, the world's only bioabsorbable cardiac septal repair technology available for use in humans. In its first full year of sales, we significantly expanded our presence in European and Canadian markets. We also made progress toward entering new markets, chief among them Latin America.

As we continue to gain market share through BioSTAR® sales, our research and development team is focusing on future generations of biological cardiac septal repair technologies. Novel platforms such as BioTREK™ are in preclinical testing and showing great promise. We also continue to study the potential connection between PFOs and migraines through a sub-study in CLOSURE I and through MIST III, our 18-month, open-label study in the United Kingdom. We expect longer-term follow-up data from that study in the second quarter of 2009.

As the owner or licensee of 137 issued U.S. patents, with 70 more pending, as well as numerous foreign equivalents, we believe that NMT Medical's patent franchise is strong. We expect to further reinforce our intellectual property position going forward.

We are confident that our current cash position will allow us to complete CLOSURE I and bring STARFlex® to the U.S. market for the stroke and TIA indication, contingent upon FDA approval. We generated revenues of $17.9 million in 2008, ending the year with $17.6 million in cash, cash equivalents and marketable securities.

During 2008, we took steps to operate with a leaner, more efficient cost structure. These actions, which included head-count reductions across the organization, reprioritization of internal programs and restructuring of several departments, are expected to result in annualized cost savings of greater than $1 million beginning in 2009. With CLOSURE I enrollment complete, and with these cost reductions in place, we expect our cash burn rate to decrease significantly in 2009.

In February 2009, John Ahern announced his retirement as President and CEO and resigned as a director of the Company, leading to our appointments as President & CEO and to the additional position of Chief Operating Officer. John played an integral role in helping NMT establish its leadership position in the marketplace. We extend our sincere thanks to John for his contributions and dedication to NMT during his eight years of service.

Looking ahead, we are focused on achieving these primary goals in 2009:

- Increasing our market share and expanding our international presence with sales of BioSTAR®;
- Effectively managing our cash position; and
- Achieving additional regulatory approval for our technologies.

Long-term, we remain committed to NMT Medical's mission and to securing our position as technology leaders in the cardiac septal repair space. We look forward to reporting our progress in 2009. On behalf of our entire team, we thank you for your continued support.

Frank Martin
President and Chief Executive Officer

Richard E. Davis
Chief Operating Officer

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2008

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:

Title of each class	Name of each exchange on which registered
Common Stock, $.001 par value per share Preferred Stock Purchase Rights	NASDAQ Global Market

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

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. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.
(Check one):

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

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

The aggregate market value of the registrant's voting shares of Common Stock held by non-affiliates of the Registrant on June 30, 2008 was $58,831,918 based on the last reported sale price of registrant's Common Stock on the NASDAQ Global Market on that date, which was $4.66 per share.

As of March 10, 2009, there were 13,082,391 shares of the registrant's Common Stock, $.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2009 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K.

PART I

ITEM 1. BUSINESS

OVERVIEW

We are an advanced medical technology company that designs, develops, manufactures and markets proprietary implant technologies that allow interventional cardiologists to treat structural heart disease through minimally invasive, catheter-based procedures. We are investigating the potential connection between a common heart defect that allows a right to left shunt or flow of blood through a defect like a patent foramen ovale, or PFO, and brain attacks such as embolic stroke, transient ischemic attacks, or TIA, and migraine headaches. A PFO is a common right to left shunt that 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 30,000 PFOs have been treated globally with our minimally invasive, catheter-based implant technology.

We are a Delaware corporation and were incorporated in 1986. Our principal executive office is 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, or the SEC. We also make available on our website our proxy statements for our annual meeting 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 Securities Exchange Act of 1934, as amended, or 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.

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, or 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 CardioSEAL®, STARFlex® and BioSTAR® in Europe and Canada. We also re-sell third party products for use with the CardioSEAL®, STARFlex® and BioSTAR® 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., or Bard, our cardiac septal repair implants have accounted for substantially all of our product sales. Product sales accounted for 99.9%, 74.2% and 78.6% of our total revenues for the years ended December 31, 2008, 2007 and 2006, respectively.

Cardiac septal repair implant devices are used for the repair of structural heart disease and intracardiac shunts that result in abnormal blood flow through the chambers of the heart. Common cardiac septal defects include PFO, ventricular septal defect, or VSD, and atrial septal defects, or ASD. PFO, the most common of these defects, has been implicated as (i) a possible risk factor of embolic stroke and/or TIA, for which other current treatments include lifelong anticoagulation therapy or open heart surgery; (ii) a possible risk factor in sleep apnea, high altitude pulmonary edema, or HAPE, Alzheimers, among others; and (iii) a possible factor in certain migraine headaches. 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 approximately 750,000 procedures annually for stroke and TIA and 4.5 million procedures for migraine headaches. 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 the U.S. Food and Drug Administration, or the FDA, approval to market our septal repair implant devices under Humanitarian Device Exemption, or 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 pre-market approval, or 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 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®. In October 2006, we voluntarily withdrew this HDE due to significant changes in the clinical environment and we received approval from the FDA to conduct a clinical study with our STARFlex® implant under an Investigational Device Exemption, or an IDE, called CARS (Closure After Recurrent Stroke). CMCC worked with us to generate the clinical data necessary for our HDE and PMA applications and approvals.

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 Conformité Europeene, or 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, or RTS, which allows the interventional cardiologist to more easily implant the STARFlex® device. In 2007 we introduced an enhanced version of the RTS in Europe, called RTP (Rapid Transport™ Plus).

BioSTAR® is our proprietary bioabsorbable PFO implant and the first biological closure technology. The collagen matrix biomaterial in BioSTAR® enhances cell growth, promoting more rapid and complete sealing of the PFO defect. Data has shown that 90% to 95% of the implant is absorbed over time and replaced with healthy native tissue. During 2005, we completed our BEST (BioSTAR® Evaluation STudy) trial, and we received the CE Mark in June 2007. We also received a medical device license from Health Canada for BioSTAR® in June 2007.

Regulatory Factors

In the United States, the FDA classifies septal repair implant devices as Class III medical devices, which require a PMA prior to being marketed. Under the FDA's 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. Our CardioSEAL® product in the United States was granted an HDE in 2000 by the FDA for treating PFO patients with recurrent paradoxical stroke who have failed conventional drug therapy such as Coumadin®. On October 31, 2006 we voluntarily withdrew our HDE. The withdrawal was due to significant changes in the clinical environment since the HDE was granted six years prior. In order to accommodate the patients who were eligible for the HDE, and to support our ongoing CLOSURE I trial, we received an expedited approval for CARS. Patients who meet the requirements under CARS will benefit from an implant upgrade to our STARFlex® technology. We also sell our CardioSEAL® product in the United States under a PMA for patients with a ventricular septal defect, or 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 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 were granted a CE Mark for our BioSTAR® bioabsorbable, biological closure structural heart repair implant in June 2007. We also received a medical device license from Health Canada in June 2007.

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 and these ancillary third party products, account for substantially all of our current product sales.

CLINICAL TRIALS

Stroke/TIA Opportunity/Other

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 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.

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 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. In June 2003, the FDA approved CLOSURE I, our IDE clinical trial comparing STARFlex® structural heart repair implant with medical therapy in preventing recurrent stroke and TIA. The trial is a prospective, multi-center, randomized, controlled clinical trial designed to evaluate the safety and effectiveness 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. Current protocol requires that patients will be evaluated periodically over a two-year period, during which time, safety and effectiveness data, including recurrent event rates (i.e., stroke and/or TIA), will be collected for all patients. On March 2, 2007, we participated in FDA advisory panel meetings to discuss the current status of the ongoing PFO/stroke trials being sponsored by us and other companies. At the close of the meeting, both the FDA and advisory panel concurred that only randomized, controlled trials would provide the necessary data to be considered for a PMA for devices intended for transcatheter PFO closure in the stroke and TIA indication. During a closed session, we provided the FDA and advisory panel with a revised study hypothesis and statistical plan to complete the CLOSURE I study as a randomized controlled trial. On April 23, 2007, we announced that we received conditional approval from the FDA for our revised study hypothesis and statistical plan in the CLOSURE I PFO/stroke and TIA trial in the U.S. Subsequent to this meeting, a review of the revised plan and a look at the interim data was performed by the Data Safety Monitoring Board. Based on these analyses, the conditional probability of a statistically significant benefit requires an enrollment of 900 patients. Patient enrollment was completed in October 2008. We are currently working with the CLOSURE I Executive Committee, independent statistical experts and the FDA to determine an appropriate time interval to perform the study data analysis. The decision related to the data analysis timing will be determined by an evaluation of the number of recurrent events and the timing of these events and will be performed by a panel of independent statistical experts on blinded data. If the number and timing of events indicate that it is statistically appropriate to do so, data analysis will be interpreted in the fourth quarter of 2009. The Company would then expect to submit a PMA for the stroke and TIA indication to the FDA early in 2010, one year earlier than the current plan. We currently expect a decision from the FDA by the end of the first quarter of 2009 on the appropriate time interval for analyzing the patient follow-up data.

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 $30 million through completion of the trial and submission to the FDA. Of this total, approximately $22.6 million was incurred through 2008 with approximately $5.3 million incurred during 2008. We currently project 2009 costs to approximate $4.6 million.

In August 2006, we announced that the FDA approved our CARS IDE. This study will compliment our ongoing CLOSURE I clinical trial to evaluate the connection between PFO and stroke. We will provide eligible patients of both CARS and CLOSURE I with our newer STARFlex® implant technology. However, while patients in the CLOSURE I trial receive the implant at no cost, those covered under the CARS IDE can be charged for the device. Patients previously covered by our PFO HDE only had access to our original CardioSEAL® device. In addition, the FDA informed us that they had commenced a formal HDE review process for all existing PFO closure devices. Because of the many clinical advances since its approval over six years ago, the FDA asked us to consider voluntary withdrawal of our HDE, which we did in October 2006. We expressed concern to the FDA that we did not want to put patients who were currently covered under the HDE at risk of losing access to PFO closure. The FDA endorsed our support for those patients and as a result, quickly approved the CARS IDE. The CARS IDE will provide continued PFO closure access to certain patients who previously were eligible for treatment under the HDE. Approval of the CARS IDE allows us to maintain a source for PFO closure in the United States.

In addition, we are evaluating literature that shows a potential correlation between structural heart disease and other recurring events such as decompression illness, sleep apnea (oxygen desaturation), high altitude pulmonary edema (HAPE) and Alzheimer's. This correlation builds on the concept that a right to left shunt may not be natural or appropriate, and in certain patients it may present an additional risk to the aforementioned recurring events, which risk we believe may be managed with our technology.

BEST

In June 2005, we received approval in the United Kingdom for our BEST study, a multi-center study designed to evaluate our new BioSTAR® structural heart repair 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 began in July 2005 and was completed during the fourth quarter of 2005. The goal of our BEST study was to secure European and Canadian commercial approval for BioSTAR® through the CE Mark process in Europe and by obtaining a medical device license from Health Canada. The CE Mark and medical device license approval were received in June 2007. In May of 2006, we reported data from the six-month follow-up period of 57 patients at the late breaking clinical trials session at the EuroPCR, the largest international cardiology meeting in Europe. At 30 days post implant with BioSTAR®, complete closure rate was achieved in 88.5% of the study subjects. At six months, the complete closure rate increased to 96.4%. No major safety issues were observed. At the 2006 Transcatheter Cardiovascular Therapeutics 18th Annual Scientific Symposium, 30 day post implant complete closure rate was updated to 92% of the study patients. The average procedure time to close the septal defect with BioSTAR® was approximately 40 minutes. Total costs of this study, including third party contracts and agreements with clinical sites and other service providers, were approximately $1.4 million.

Migraine Opportunity

MIST

Several recent research studies have suggested that patients who have a significant right to left shunt 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 migraines 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. The trial was designed to test the hypothesis that PFO closure will lead to complete migraine resolution. A secondary hypothesis was that PFO closure reduced the intensity and duration of migraine symptoms. The primary endpoint was not achieved. 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. Preliminary results of MIST, which we released on March 13, 2006, found that over 60% of those screened had a right to left shunt. A shunt is a heart defect, which allows blood to cross from the right to left chambers of the heart, bypassing the lungs. Of those patients, almost 40% had a moderate or large PFO, six times greater than the general population. MIST results indicated for the first time in a randomized controlled study that closing a PFO provides a significant treatment effect in some patients. The study showed that approximately 42% of the patients treated with our STARFlex® technology had a reduction in migraine headache days of at least 50% compared to approximately 23% in the sham 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, or MAA, a migraine headache advocacy group representing more than 12,000 members in the United Kingdom. Total costs of this trial, including third party contracts and agreements with clinical sites and other service providers, were approximately $4.9 million. We believe that the MIST trial demonstrated that eliminating a right to left shunt with STARFlex® helps to remove a risk factor contributing to certain migraine attacks. We also believe that this may represent a potential breakthrough treatment for patients currently not responding to other therapies.

MIST II

In September 2005, we received conditional approval from the FDA for an IDE to initiate enrollment in a PFO/migraine clinical study, named MIST II. MIST II was initially designed to be a prospective, randomized, multi-center, controlled study in the United States. In August 2006, utilizing data from our MIST and BEST (BioSTAR® Evaluation STudy) trials, we received conditional approval from the FDA for modifications we requested to the IDE. These changes included adjustment to the primary endpoint for the study from resolution to reduction of migraine headaches and an upgrade to the implant used in the study from STARFlex® to our new bioabsorbable BioSTAR®. MIST II was a double-blinded trial designed to randomize approximately 600 migraine patients with a PFO to either structural heart repair with our BioSTAR® technology or a control arm.

In January 2008, we announced that we were closing down this clinical study. We determined that it was in the best interest of our shareholders to better allocate these resources toward our ongoing stroke initiatives. We continue to believe in the relationship between PFO and migraine, but it became clear that an acceptable enrollment dynamic was not possible and completing this study would require more time and financial resources than we were willing to commit at this time.

MIST III (Long-term follow up of MIST patients)

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, i.e., those who did not receive the STARFlex® implant, have the option to receive an implant and participate in MIST III after they have been unblinded as part of the MIST study. These patients follow the 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 and opt to participate in MIST III will be followed for an additional 18 months. This study is designed to test whether or not the benefit demonstrated in MIST continues over time. We currently estimate the cost of MIST III to be approximately $1.2 million. Substantially all of these costs have been incurred through 2008, and only minimal spending is expected in 2009. 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 slightly less than 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. We expect long term follow up data to be available in the second quarter of 2009.

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

OUR STRATEGY

Our primary strategic objectives for 2009 include

- determine optimal timeframe in which to perform the data analysis of the patient follow up for the CLOSURE I trial;
- expand BioSTAR® sales and market leadership in Europe, Canada and Latin America; and
- enhance technological leadership with our biological closure technologies.

NET ROYALTY INCOME

Net royalty income accounted for 25.8% and 21.4% of our total revenues for the years ended December 31, 2007 and 2006, respectively. Beginning in 2008, the royalty rate we receive from Bard decreased substantially from the royalty rate we earned prior

to 2008, while the royalty rate we pay to the estate of the original inventor of these products remains the same. For the year ended December 31, 2008, this results in a net royalty expense reflected in general and administrative expenses of approximately $1.1 million. The net royalty income for the year ended December 31, 2008 was earned from Boston Scientific Corporation.

Vena Cava Filters

In November 2001, we sold our former vena cava filter product line, including the Recovery™ Filter, or RNF, and Simon Nitinol Filter, or SNF, products, to C.R. Bard, Inc. or 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, we 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 was substantially higher than the royalty rate applicable to SNF products. Beginning in 2008, the royalty rate we receive from Bard has decreased substantially from its former rate, while the royalty rate we pay to the estate of the original inventor of these products has remained the same. This has resulted in a net royalty expense of $1.1 million in 2008, that has been reflected in general and administrative expenses.

Stents

In November 1994, we licensed to Boston Scientific Corporation, or 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.

RESEARCH AND DEVELOPMENT

Our research and development organization included 24 persons as of December 31, 2008, with departmental groups dedicated to product development, regulatory and clinical affairs, and quality assurance. Total company-sponsored research and development expenses were approximately $13.2 million, $15.4 million and $15.5 million for the years ended December 31, 2008, 2007 and 2006 respectively. Of these totals, approximately $5.4 million, $6.0 million and $8.2 million for the years ended December 31, 2008, 2007 and 2006, respectively, were clinical trials costs. We currently expect 2009 research and development expenses to decrease to approximately $11.5 million compared to approximately $13.2 million in 2008. This anticipated decrease is primarily related to decreases in our clinical trial spending.

Product Development

During 2005, we completed enrollment in our BEST clinical trial and were granted a CE Mark for our biological closure implant BioSTAR® in June 2007. We also received a medical device license from Health Canada for BioSTAR® in June 2007. We are evaluating and developing our regulatory strategy for approval of BioSTAR® in the United States. We are continuing to develop our next 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. We continue preclinical evaluation of BioTREK™.

Additionally, the research and development group continues to invest in strengthening our intellectual property assets in all aspects of structural heart repair.

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®, STARFlex® and BioSTAR® directly in key European markets and through select distributors in other parts of Europe. As of December 31, 2008, worldwide sales and marketing personnel consisted of 17 persons, of which 9 are in various locations in the United States and 8 in various locations throughout Europe. Our European employees are based in Germany, France, the United Kingdom, Benelux and Scandinavia. During 2009, we plan to continue to expand our presence to include Spain, other European countries and Latin America.

Traditionally, the neurologist and the interventional cardiologist have not collaborated on patient diagnosis or treatment. We believe that the PFO/brain attack connection has changed that relationship. To further facilitate what we believe to be an emerging solution to these brain attacks associated with both stroke and migraine, 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®, STARFlex® and BioSTAR® 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. It is not necessary for our U.S. customers to obtain Institutional Review Board, or IRB, approval to purchase CardioSEAL® products for VSD closure, as we have received a PMA for this indication. At December 31, 2008, we had approximately 400 active customers worldwide to which we sell our CardioSEAL®, STARFlex® and BioSTAR® products directly.

No customer accounted for greater than 10% of product sales in any of the three years in the period ended December 31, 2008.

MANUFACTURING

We manufacture the CardioSEAL®, STARFlex® and BioSTAR® 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., or AGA, W. L. Gore & Associates, Inc., or Gore, Cardia, Inc., or 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 and Gore also sell 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 that utilize radiofrequency welding, suturing, abrasion, adhesives and other approaches.

We believe that the CardioSEAL®, STARFlex®, and BioSTAR® 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 and the Rapid Transport® Plus delivery system provide for simplicity by reducing the number of steps for implantation. We further believe that our new biological closure device BioSTAR® provides and BioTREK™ will provide, an even more biological response by promoting quicker healing and device endothelialization, improving both PFO closure rate and patient safety.

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 137 issued United States (U.S.) patents, and corresponding foreign patents, relating to our structural heart repair implant technologies and other related cardiovascular implant technologies. In addition, we have more than 72 pending U.S. patent applications in the field of structural heart repair, including implants, delivery systems and accessory products, most of which have corresponding foreign counterparts.

The issued U.S. patents expire at various dates ranging from 2009 to 2026. The patents related to our anastomosis devices, which are minimally invasive means of attaching vascular grafts, expire in 2016, 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 from 2019 to 2022, the patent for our nitinol septal repair device expires in 2016, the patent for our superelastic hinge joint, a novel concept with applicability to both implants and delivery systems, expires in 2017, the patents for our new generation PFO closure device expire from 2023 to 2025, and the patents for our flexible delivery system expire from 2024 to 2026.

In addition, we are the exclusive licensee within specific fields of use to several technologies. We are the exclusive licensee under certain patents, expiring from 2012 to 2015, relating to the CardioSEAL®, STARFlex®, and BioSTAR® cardiac septal repair implants, delivery systems and methods for repairing cardiac and vascular defects. We are the exclusive licensee to a patent used in nitinol septal repair devices which expires in 2011. We are also the exclusive licensee under certain patents, expiring from 2014 to 2019, related to the intestinal collagen layer utilized in our BioSTAR® device and under certain patents, expiring from 2009 to 2023, related to the novel bioabsorbable polymer utilized in our BioTREK™ device.

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 eight trademarks, four of which are registered with the United States Patent and Trademark Office (see the following table).

Trademark	Jurisdiction	Status	Renewal Date
At The Heart of Brain Attacks	Canada	Pending	—
At The Heart of Brain Attacks	European Community	Registered	Sep 2015
At The Heart of Brain Attacks	United States	Allowed	—
BioSTAR	Canada	Allowed	—
BioSTAR	European Community	Registered	Apr 2014
BioSTAR	Japan	Registered	Oct 2015
BioSTAR	United States	Registered	Jun 2016
BioTREK	Canada	Pending	—
BioTREK	European Community	Pending	—
BioTREK	Japan	Registered	Feb 2016
BioTREK	United States	Pending	—
CardioSEAL	United States	Registered	Jan 2018
Gator	Canada	Pending	—
Gator	European Community	Registered	Apr 2014
Gator	Japan	Registered	Sep 2017
Gator	United States	Allowed	—
NMT Medical	Canada	Registered	Jan 2018
NMT Medical	United States	Registered	Apr 2011
Rapid Transport	European Community	Registered	Aug 2013
STARFlex	Canada	Registered	Sep 2020
STARFlex	European Community	Registered	Feb 2011
STARFlex	Japan	Registered	Jun 2014
STARFlex	United States	Registered	Aug 2012

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®, STARFlex® and BioSTAR® septal repair implant devices. Royalties continue until the end of the term of the patents, which range from 2014 to 2016. We also have two royalty-free, worldwide sublicenses under the U.S. patents entitled "System for the Percutaneous Transluminal Front-End Loading Delivery of a Prosthetic Occluder" (U.S. Patent No. 5,626,599) and "System for the Percutaneous Transluminal Front-End Loading Delivery and Retrieval of a Prosthetic Occluder" (U.S. Patent No. 5,649,950) and their 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 royalty income that we earn from Bard. Beginning in 2008, the royalty rate we receive from Bard has decreased substantially from its former rate, while the royalty rate we pay to the estate of the original inventor of these products has remained the same. This has resulted in a net royalty expense that has been reflected in general and administrative expenses.

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, or 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, or 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 class III devices may be marketed with a 510(k) until the FDA issues a final regulation requiring the submission of a PMA. 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.

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 and receive agency approval 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 a manufacturer believes the device study will qualify as a Non-Significant Risk, or NSR, study, then the manufacturer can seek from IRBs agreement of the NSR status and approval of the study at the IRB's respective institutions. If the IRBs determine that a clinical trial involves a NSR study and approves the study, then 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 NSR study does not need to obtain FDA approval of an IDE application before beginning the study. However, if any one of the IRBs approached by the sponsor determines that the study is not NSR, then the manufacturer must inform all the other IRBs approached and the FDA, and submit an IDE application to the FDA.

After approval or clearance to market 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, or 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, or 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, or 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. 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, or DRG, that covers such treatment as established by the Federal Health Care Financing Administration, or 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 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, or 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 CLOSURE I trial is 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 20 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. 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. We maintain product liability insurance

EMPLOYEES

As of December 31, 2008, we had 79 full-time employees. We believe that we maintain good relations with our employees.

ENVIRONMENTAL MATTERS

Applicable federal, state and local environmental laws have not had and are not expected to have a material effect on our business. To date, we have not made any material capital expenditures and do not anticipate making any such expenditures during the next two fiscal years relating to environmental control facilities.

ITEM 1A. RISK FACTORS

Statements contained or incorporated by reference in this Annual Report on Form 10-K that are not based on historical fact are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding results of operations, selling and marketing expenses, general and administrative expenses, research and development expenses, the sufficiency of our cash for future operations, and the success of our cardiovascular business and clinical trials. Forward-looking statements may be identified by the use of forward looking terminology such as "may," "could," "will," "expect," "estimate," "anticipate," "continue," or similar terms, variations of such terms or the negative of those terms.

We cannot assure investors that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Such factors that could cause or contribute to such differences include those factors discussed below. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer.

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

Upon receipt of final FDA approval, we commenced our CLOSURE I study in June 2003. On April 23, 2007, we announced that we received conditional approval from the FDA for our revised study hypothesis and statistical plan in the CLOSURE I PFO stroke and TIA trial in the U.S. Based on an analysis, the conditional probability of a statistically significant benefit at the end of the data reviewed will require an enrollment of 900 patients. In October 2008, we announced that we completed patient enrollment in this clinical trial. We currently anticipate that when completed, study data from CLOSURE I will be used to support a PFO PMA application. We are now working with independent statistical experts and the FDA to determine the optimal timeframe in which to perform the analysis of patient follow up data. We currently estimate the total costs of CLOSURE I to be approximately $30 million through completion of the clinical trial and submission to the FDA. We have limited direct experience conducting a clinical trial of this magnitude. We cannot be certain that the projected costs of CLOSURE I will not need to be adjusted upwards. 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 growth of revenues of our CardioSEAL® and STAR Flex® products, which will negatively impact our profitability.

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

Given the current tightening of financing markets and the general economic environment, we believe it prudent to evaluate financing alternatives that will provide increased liquidity to the company if needed. In the future 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. On October 19, 2006, we announced that we filed a shelf registration statement on Form S-3 with the SEC. The shelf registration statement will permit us to offer and sell up to $65 million of equity or debt securities. However, given the current market conditions, we may not be able to raise sufficient market capital using this registration statement or otherwise. Any additional equity financing or other transaction involving securities exercisable or convertible into our equitable securities 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. Based on current projections and plans, we believe there is sufficient cash to fund operations through at least 2009. We do not have any line of credit arrangements, and we may not be able to obtain any such credit facilities on acceptable terms, if at all, but we are in discussions with a financial institution regarding a possible credit facility.

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®, STARFlex® and BioSTAR® products. As demand for, and costs associated with, these products fluctuates, including the potential impact of our revenue and 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 any 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.

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 healthcare 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.

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 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.

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

Our structural heart repair implant devices are marketed primarily through our direct sales force. Our combined U.S. and European sales and marketing organization headcount is 17. Because we had previously 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 further expand geographically in Europe, Latin America or other potential markets for our products. In order to market directly the CardioSEAL®, STARFlex® and BioSTAR® septal implants and any related products, we will have to continue to develop a marketing and sales organization with technical expertise and distribution capabilities. Expanding in these markets could also impose foreign currency risks on sales not denominated in US dollars, increase our costs to remain in compliance with foreign laws, and heighten risk of non-performance by the other parties to agreements to which the company is a party.

REVENUE GENERATED BY CARS IDE MAY BE LIMITED.

In August 2006, we announced FDA approval for a new PFO/stroke IDE, called CARS. The CARS IDE will supplement our ongoing CLOSURE I clinical trial to evaluate the connection between PFO and stroke. We will provide eligible patients of CARS with our newer STARFlex® implant technology. Patients previously covered by the HDE only had access to our original CardioSEAL® device. The CARS IDE will provide continued PFO closure access to certain patients who previously were eligible for treatment under the HDE. However, while patients in the CLOSURE I trial received the implant at no cost, those covered under the CARS IDE can be charged for the device. We anticipate a shift of some recurrent stroke patients with PFOs to the CARS IDE from the original HDE because patients will have access to the newer STARFlex® technology. At this time it is difficult to determine the impact on product revenue in the U.S. as a result of the transition from paid-for HDE devices to the paid-for devices under CARS. We believe the CARS IDE is a significant competitive achievement for us and is necessary to accommodate the growing demand for more advanced PFO/stroke treatments.

OUR MANUFACTURING OPERATIONS AND RELATED PRODUCT SALES MAY BE ADVERSELY AFFECTED BY A REDUCTION OR INTERRUPTION IN SUPPLY AND AN INABILITY TO OR DELAYS IN DEVELOPING ALTERNATIVE SOURCES OF SUPPLY.

We procure certain components from a sole supplier in connection with the manufacture of some of our products. While we work closely with our suppliers to try to ensure continuity of supply while maintaining high quality and reliability, we cannot guarantee that those efforts will continue to be successful. In addition, due to the stringent regulations and requirements of governmental regulatory bodies, both in the U.S. and abroad, regarding the manufacture of our products, we may not be able to move quickly enough to establish alternative sources for these components. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, would adversely affect our ability to manufacture our products in a timely and cost effective manner and, accordingly, could potentially negatively impact our related product sales.

CURRENT LEVELS OF MARKET VOLATILITY ARE UNPRECEDENTED.

The capital markets have been experiencing extreme volatility and disruption for more than 12 months. In some cases, the markets have exerted downward pressure on stock prices for certain issuers, including, but not limited to, the Company. We believe the price of our common stock has been and may continue to be negatively effected in a manner unrelated to our business. The markets have also exerted downward pressure on the value of the marketable securities carried on our balance sheet, including corporate debentures and corporate bonds, resulting in further downward pressure on our stock price.

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 materially affect our business:

- delays in receipt of, or failure to receive, regulatory approvals or clearances;
- the loss of previous approvals or clearances, including our voluntary withdrawal of our PFO HDE;
- the ability to enroll patients and charge for implants in the CARS IDE;
- limitations on the intended use of a device imposed as a condition of regulatory approvals or clearances, and
- 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 materially affect our business.

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 developing, manufacturing, marketing and selling of our cardiac septal repair implant devices used for structural heart repair. Our future sales growth and financial results depend almost exclusively upon the growth of sales of this product line. CardioSEAL®, STARFlex® and BioSTAR® 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:

- achieving successful stroke-related clinical trials;
- developing next generation product lines;

- improving our sales and marketing 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 expire at various dates ranging from 2009 to 2026. 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 RELY ON A SMALL GROUP OF SENIOR EXECUTIVES, AND INTENSE INDUSTRY COMPETITION FOR QUALIFIED EMPLOYEES COULD AFFECT OUR ABILITY TO ATTRACT AND RETAIN NECESSARY, QUALIFIED PERSONNEL.

We rely on a small group of senior executives and in the medical device field, there is intense competition for qualified personnel, such that 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 ARE EXPOSED TO UNCERTAIN ROYALTY EXPENSE IN EXCESS OF ROYALTY REVENUE.

The royalty rate we receive from Bard decreased substantially from the royalty rate we earned prior to 2008, while the royalty rate we pay to the estate of the original inventor of these products will remain the same. Accordingly, we cannot assure you of the actual royalty expense we will incur in 2009.

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®, STARFlex® and BioSTAR® structural heart repair implants, 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.

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, or 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.

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.

OUR EXPANDING NON-US OPERATIONS EXPOSE US TO RISK INHERENT IN FOREIGN OPERATIONS.

As we increase our presence in Europe, Canada and Latin America following the receipt of a CE Mark (Europe) and medical device license approval (Canada) for our BioSTAR® technology, the impact of foreign currency fluctuations on our revenue and expenses could have an adverse impact on our profitability.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive offices are located at 27 Wormwood Street, Boston, Massachusetts 02210-1625. We lease approximately 35,000 square feet of manufacturing, laboratory and administrative space at this facility, under leases that expire in September 2012.

ITEM 3. LEGAL PROCEEDINGS

In September 2004, we and the Children's Medical Center Corporation, or CMCC, filed a civil complaint in the U.S. District Court for the District of Minnesota, or the District Court, for infringement of a patent owned by CMCC and licensed exclusively to us. The complaint alleges that Cardia, Inc., or 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 District Court to prevent further infringement by Cardia, as well as monetary damages. On August 30, 2006, the District Court entered an order holding that Cardia's device does not infringe the patent-in-suit. The order had no effect on the validity and enforceability of the patent-in-suit and had no impact on our ability to sell our products. We appealed the ruling to the U.S. Court of Appeals for the Federal Circuit and on June 6, 2007 the Federal Circuit ruled that the District Court incorrectly interpreted one of the patent's claims and incorrectly found no triable issue of fact concerning other claims. The Federal Circuit remanded the case to the District Court for further proceedings consistent with its opinion and instructed that on remand the district court may reconsider the question of summary judgment for us and CMCC based on the Federal Circuit's claim construction. On November 8, 2007, the District Court granted summary judgment in our and CMCC's favor, ruling that Cardia's device infringes the patent-in-suit and striking all of Cardia's invalidity defenses. On March 19, 2008, we and CMCC agreed with Cardia to settle this litigation. As part of the settlement, a judgment was entered against Cardia and in favor of us and CMCC, with Cardia agreeing to pay $2.25 million. The settlement will be shared equally between us and CMCC after deduction of our legal fees and expenses. The first and second payments of $500,000 each were received on September 30, 2008 and December 15, 2008, and were recorded as a reduction to general and administrative expenses, to offset legal fees incurred in connection with this legal proceeding. The remaining $1.25 million in payments are due to be paid in 2009.

In December 2007, we commenced proceedings for defamation against Dr. Peter Wilmshurst in the English High Court. Dr. Wilmshurst has filed a defense to the claim arguing, inter alia, that the words alleged to be defamatory are true. A case conference is scheduled to take place late in the first quarter of 2009. If the matter proceeds to trial, this is likely to take place in 2010. Dr. Wilmshurst is reportedly seeking alternative sources of funding, including applying for state aid. If the case continues, we will be required to pay money into court by way of security for costs. The amount of security depends on whether Dr. Wilmshurst has the funds to pay for further legal representation. Our potential liability is to pay Dr. Wilmshursts' costs, if we either lose, or withdraw from, the proceedings.

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, 2008.

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 Global Market under the symbol "NMTI". There were approximately 100 stockholders of record of our common stock on March 5, 2009, representing approximately 6,000 shareholder accounts. The following table lists the high and low closing sales prices for our common stock for the periods indicated.

PERIOD	HIGH	LOW
2007		
First quarter	$14.91	$12.20
Second quarter	16.00	11.02
Third quarter	12.00	7.37
Fourth quarter	7.64	4.86
2008		
First quarter	$ 6.96	$ 3.79
Second quarter	5.89	3.71
Third quarter	4.55	3.12
Fourth quarter	3.15	0.55

We did not declare or pay any cash dividends on shares of our common stock during the years ended December 31, 2008 and 2007 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.

Information regarding our equity compensation plans and the securities authorized for issuance thereunder is set forth in Item 12 below.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data for each of the five years in the period ended December 31, 2008 were derived from our audited consolidated financial statements. The selected consolidated financial data set forth below should be read in conjunction with, and is qualified in its entirety by our audited consolidated financial statements and related notes thereto found at Item 8, "Financial Statements and Supplementary Data" and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" which are included elsewhere in this Annual Report on Form 10-K.

	2008	2007	2006	2005	2004
STATEMENT OF OPERATIONS DATA:					
(In thousands, except per share data)					
Revenues:					
Product sales	$ 17,857	$ 19,855	$ 22,135	$ 19,313	$ 17,279
Net royalty income	18	6,900	6,016	4,603	4,181
Total revenues	17,875	26,755	28,151	23,916	21,460
Costs and expenses:					
Cost of product sales	5,969	5,409	5,938	5,470	4,514
Research and development	13,194	15,407	15,455	12,746	8,045
General and administrative	8,579	7,988	8,681	7,982	6,024
Selling and marketing	8,784	9,093	8,704	6,340	5,542
Total costs and expenses	36,526	37,897	38,778	32,538	24,125
Net gain from settlement of litigation	-	-	15,184	-	-
(Loss) income from operations	(18,651)	(11,142)	4,557	(8,622)	(2,665)
Other income (expense):					
Currency transaction (loss) gain	(123)	88	15	(122)	92
Interest expense	-	-	-	-	(2)
Interest income	767	1,830	1,816	861	543
Total other income, net	644	1,918	1,831	739	633
(Loss) income before income taxes	(18,007)	(9,224)	6,388	(7,883)	(2,032)
Income tax expense (benefit)	69	(122)	502	-	-
(Loss) income from continuing operations	(18,076)	(9,102)	5,886	(7,883)	(2,032)
Gain from discontinued operations	-	-	-	91	123
Net (loss) income	$ (18,076)	$ (9,102)	$ 5,886	$ (7,792)	$ (1,909)
Basic net (loss) income per common share:					
Continuing operations	$ (1.39)	$ (0.70)	$ 0.46	$ (0.64)	$ (0.17)
Discontinued operations	-	-	-	0.01	0.01
Net (loss) income	$ (1.39)	$ (0.70)	$ 0.46	$ (0.63)	$ (0.16)
Diluted net (loss) income per common share:					
Continuing operations	$ (1.39)	$ (0.70)	$ 0.43	$ (0.64)	$ (0.17)
Discontinued operations	-	-	-	0.01	0.01
Net (loss) income	$ (1.39)	$ (0.70)	$ 0.43	$ (0.63)	$ (0.16)
Weighted average common shares outstanding:					
Basic	13,020	12,926	12,746	12,332	12,031
Diluted	13,020	12,926	13,597	12,332	12,031

AT DECEMBER 31,	2008	2007	2006	2005	2004
BALANCE SHEET DATA:					
(In thousands)					
Cash, cash equivalents, marketable securities and restricted cash	$ 17,574	$ 30,974	$ 41,450	$ 31,506	$ 35,380
Working capital	13,978	30,822	38,860	30,515	36,052
Total assets	24,246	40,603	51,183	40,490	43,364
Long-term liabilities	507	352	-	-	-
Stockholders' equity	14,399	31,573	39,899	31,320	36,872

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. Our management's discussion and analysis of our financial condition and results of operations include the identification of certain trends and other statements that may predict or anticipate future business or financial results that are subject to important factors that could cause our actual results to differ materially from those indicated. See 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 structural heart disease through minimally invasive, catheter-based procedures. We are investigating the potential connection between a common heart defect that allows a right to left shunt or flow of blood through a defect like a patent foramen ovale, or PFO, and brain attacks such as embolic stroke, transient ischemic attacks, or TIA and migraine headaches. A common right to left shunt 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 2001, we 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®, STARFlex® and BioSTAR® implants, clinical research studies and development of next generation catheter-based implant technologies. More than 30,000 PFOs have been closed globally using our CardioSEAL®, STARFlex® and BioSTAR® implant technologies.

2008 Revenues

Our 2008 revenues were predominantly derived from sales of our CardioSEAL®, STARFlex® and BioSTAR® products in the U.S. and Europe. CardioSEAL®, STARFlex® and BioSTAR® product sales decreased by approximately 10% from 2007 to 2008. Sales in North America decreased by approximately 17% in 2008 compared to 2007, primarily due to decreased sales in the United States. We believe that sales in the United States continue to be impacted by delays in third party payors in approving reimbursement for the procedure as a result of the voluntary withdrawal of the Humanitarian Device Exemption, or HDE, for our CardioSEAL® septal repair system. In addition, we believe that given enrollment in CLOSURE I is complete, certain referring physicians may be waiting for the data prior to increasing their referral patterns thereby resulting in a short-term reduction in referrals. We believe that a combination of increased market awareness of PFO closure and our proprietary closure technology and targeted marketing efforts has resulted in the addition of new customers, predominantly in Europe. In 2009 we currently expect total product revenues to be approximately $18 million. Beginning in 2008, the royalty rate we receive from Bard has decreased substantially from its former rate, while the royalty rate we pay to the estate of the original inventor of these products has remained the same. This has resulted in a net royalty expense that has been reflected in general and administrative expenses.

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 October 2008, we announced that we completed patient enrollment in our pivotal CLOSURE I clinical trial. In 2003, we launched the CLOSURE I clinical trial to compare our STARFlex® cardiac septal repair implant with current medical therapy in stroke prevention. On March 2, 2007, we participated in a public and private FDA advisory panel meeting to discuss the current status of the ongoing PFO/stroke trials being sponsored by us and other companies. At the close of the meeting, both the FDA and advisory panel concurred that only randomized, controlled trials would provide the necessary data to be considered for premarket approval, or PMA, for devices intended for transcatheter PFO closure in the stroke and TIA indication. During a private session, we provided the FDA and advisory panel with a revised study hypothesis and statistical plan to complete the CLOSURE I study as a randomized controlled trial. On April 23, 2007, we announced that we received conditional approval from the FDA for our revised study hypothesis and statistical plan in the CLOSURE I PFO/stroke and TIA trial in the U.S. Subsequent to this meeting, a review of the revised plan and a look at the interim data was performed by the Data Safety Monitoring Board. Based on these analyses, the conditional probability of a statistically significant benefit will require an enrollment of 900 patients. In October 2008, we announced that we completed patient enrollment in this clinical trial.

We currently expect that total costs for CLOSURE I will be approximately $30 million through completion of the trial and submission to the FDA. Of this total, approximately $22.6 million was incurred through 2008, and we currently project 2009 costs to be approximately $4.6 million.

PFO/Migraine

The prevalence of migraines in the United States is estimated to be slightly less than 10% of the general population or roughly 28 million individuals. We estimate that 20% of all migraine sufferers, or approximately 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 Transcatheter Cardiovascular Therapeutic symposium, or TCT, meeting in October 2005 indicated that 60% of the patient subset in our MIST trial had a right to left shunt. That is more than 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 were $4.9 million. Study enrollment was completed in July 2005 and results were presented at the American College of Cardiology meeting on March 13, 2006. Results of the MIST study were published online on March 3, 2008 in the peer-reviewed journal, *Circulation*.

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, with substantially all of the spending having been incurred through 2008. We expect minimal spending in 2009.

BioSTAR® and BioTREK™

In November 2005, we completed enrollment in our BEST study, which commenced in July 2005 following regulatory approval in the United Kingdom. This study evaluated 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 were followed for six months. Data was published in the October 2006 edition of *Circulation* and was presented at the 2006 Transcatheter Cardiovascular Therapeutics 18th Annual Scientific Symposium. The study was designed to gain commercial approval for BioSTAR® through the CE Mark process which was granted in June 2007.

In January 2006, we announced that we received a Phase I grant from the National Institutes of Health's, or 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.

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; (iv) expenses associated with clinical trials, and (v) share-based compensation. 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 Securities and Exchange Commission (SEC), Staff Accounting Bulletin No. 104, or 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 purchase orders from our customers 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 4% of our product sales in 2008, 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. The amount of the allowance at both December 31, 2008 and 2007 was $60,000.

We also maintain a provision for estimated sales returns and allowances on product sales. We base these estimates on our assessment of historical sales returns, analysis of credit memo data and other known factors. If the historical data we use to estimate accounts receivable or sales returns 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. The amount of the allowance at December 31, 2008 and 2007 was $75,000 and $101,341, respectively.

Inventories

In accordance with Financial Accounting Standards Board (FASB) Statement No. 151, "Inventory Costs, an amendment of ARB, No. 43, Chapter 4", or SFAS 151, abnormal amounts of idle facility expenses should be recognized as current-period charges. In addition, SFAS 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. Inventory levels at the end of 2008 decreased approximately 3% compared to the end of 2007. We also experienced an increase in cost of product sales as a percentage of product sales in 2008, which was partially the result of the impact of fixed manufacturing overhead on lower than budgeted production volumes.

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 product sales 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, strokes, TIAs and migraine headaches. 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 October 2008, we announced that we completed patient enrollment in this trial. In November 2005, we completed enrollment in the BEST study. Total expenses for all of our clinical trials were approximately $5.4 million, $6.0 million and $8.2 million for the years ended December 31, 2008, 2007 and 2006, 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.

Share-Based Compensation

We adopted the provisions of FASB No. 123R, "Share-Based Payment," or SFAS 123R, beginning January 1, 2006, using a modified prospective transition method. SFAS 123R requires us to measure the cost of employee services in exchange for an award of equity instruments based on the grant-date fair value of the award and to recognize cost over the requisite service period. Under the modified prospective transition method, financial statements for periods prior to the date of adoption are not adjusted for the change in accounting. However, compensation expense is recognized for (i) all share-based payments granted after the effective date under SFAS 123R, and (ii) all awards granted under SFAS 123R to employees prior to the effective date that remain unvested on the effective date. We recognize compensation expense on fixed awards with pro rata vesting on a straight-line basis over the vesting period. We use the Black-Scholes option-pricing model to estimate fair value of share-based awards. The fair value of our share-based awards are dependent on the assumptions we use for expected life (in years), the expected stock price volatility, the expected dividend yield and the risk free interest rate.

COMPARISON OF YEARS ENDED DECEMBER 31, 2008, 2007 AND 2006

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 2008 compared with 2007 and for 2007 compared with 2006. The second table presents consolidated statements of operations information for each of the three years in the period ended December 31, 2008 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	
	2008	2007	2006	2007 to 2008	2006 to 2007	2007 to 2008	2006 to 2007
(In thousands of dollars, except percentages)							
Revenues:							
Product sales	$ 17,857	$19,855	$22,135	$(1,998)	$ (2,280)	(10.1)%	(10.3)%
Net royalty income	18	6,900	6,016	(6,882)	884	(99.7)%	14.7 %
Total revenues	17,875	26,755	28,151	(8,880)	(1,396)	(33.2)%	(5.0)%
Costs and expenses:							
Cost of product sales	5,969	5,409	5,938	560	(529)	10.4 %	(8.9)%
Research and development	13,194	15,407	15,455	(2,213)	(48)	(14.4)%	(0.3)%
General and administrative	8,579	7,988	8,681	591	(693)	7.4 %	(8.0)%
Selling and marketing	8,784	9,093	8,704	(309)	389	(3.4)%	4.5 %
Total costs and expenses	36,526	37,897	38,778	(1,371)	(881)	(3.6)%	(2.3)%
Net gain from settlement of litigation	-	-	15,184	-	(15,184)	-	-
(Loss) income from operations	(18,651)	(11,142)	4,557	(7,509)	(15,699)	67.4%	(344.5)%
Other income (expense):							
Currency transaction (loss) gain	(123)	88	15	(211)	73	(239.8)%	486.7 %
Interest income	767	1,830	1,816	(1,063)	14	(58.1)%	0.8 %
Total other income, net	644	1,918	1,831	(1,274)	87	(66.4)%	4.8 %
(Loss) income before income taxes	(18,007)	(9,224)	6,388	(8,783)	(15,612)	95.2 %	-
Income tax expense (benefit)	69	(122)	502	191	(624)	(156.6)%	-
Net (loss) income	$(18,076)	$(9,102)	$ 5,886	$(8,974)	$(14,988)	98.6 %	-

YEARS ENDED DECEMBER 31,	2008	2007	2006
Revenues:			
Product sales	99.9%	74.2%	78.6%
Net royalty income	0.1%	25.8%	21.4%
Total revenues	100.0%	100.0%	100.0%
Costs and expenses:			
Cost of product sales	33.4%	27.2%	26.8%
Research and development	73.8%	57.6%	54.9%
General and administrative	48.0%	29.9%	30.8%
Selling and marketing	49.1%	34.0%	30.9%
Total costs and expenses	204.3%	141.6%	137.7%
Net gain from settlement of litigation	-	-	53.9%
(Loss) income from operations	(104.3)%	(41.6)%	16.2%
Other income (expense):			
Currency transaction (loss) gain	(0.7)%	0.3%	-
Interest income	4.3%	6.8%	6.5%
Total other income, net	3.6%	7.2%	6.5%
(Loss) income before income taxes	(100.7)%	(34.5)%	22.7%
Income tax (benefit) provision	0.4%	(0.5)%	1.8%
Net (loss) income	(101.1)%	(34.0)%	20.9%

RESULTS OF OPERATIONS
YEAR ENDED DECEMBER 31, 2008 COMPARED WITH YEAR ENDED DECEMBER 31, 2007

Revenues. Revenues for the years ended December 31, 2008 and 2007 were as follows:

	YEARS ENDED DECEMBER 31,		INCREASE (DECREASE)	% CHANGE
	2008	2007	2007 to 2008	2007 to 2008
(In thousands of dollars, except percentages)				
Product sales:				
CardioSEAL®, STARFlex® and BioSTAR®:				
North America	$11,716	$14,185	$(2,469)	(17.4)%
Europe	6,141	5,670	471	8.3%
Total product sales	17,857	19,855	(1,998)	(10.1)%
Net royalty income:				
Bard	-	6,849	(6,849)	(100.0)%
BSC	18	51	(33)	(64.7)%
Total net royalty income	18	6,900	(6,882)	(99.7)%
Total revenues	$17,875	$26,755	$(8,880)	(33.2)%

The decrease in CardioSEAL® and STARFlex® implant sales for 2008 compared to 2007 was primarily the result of decreased product demand in North America, primarily in the United States. We believe that sales in the United States continue to be impacted by delays by third party payors in approving reimbursement for the procedures as a result of the voluntary withdrawal of the HDE of our CardioSEAL® septal repair system. In addition, we believe that given enrollment in CLOSURE I is complete, certain referring physicians are waiting for the data prior to increasing their referral patterns thereby resulting in a short-term reduction in referrals.

The increase in European sales was primarily related to the launch of BioSTAR®, our bioabsorbable structural heart repair implant technology and our Rapid Transport™ delivery system following the awarding of the CE Mark for BioSTAR® in June 2007. The increase was also attributable to increased sales and marketing programs, as well as greater acceptance of our technology by the clinical community throughout Europe. We believe that as a result of the combination of (i) our MIST study results and headcount investments in the UK and other planned investments in Europe having increased awareness of the positive treatment effect on severe migraine sufferers with a PFO using our technology along with (ii) the impact of the June 2007 awarding of the CE Mark for BioSTAR®, our European product sales will continue to increase as a percentage of total sales. Despite the growth in European sales, we did not achieve our targeted level of revenue in Europe due to several factors including the extremely competitive environment in Europe resulting from several ongoing PFO treatment clinical trials vying for the same patient subset and limited cath-lab time available due to the increasing number of percutaneous valve repair procedures, and the growing severity of the deteriorating economy during the second half of 2008. European sales represented approximately 34.4% and 28.6% of total product sales in 2008 and 2007, respectively.

We currently believe that in 2009 our European product sales will approach 35% of total product sales. We currently believe that, given the current regulatory approvals of our products in the U.S., sales in North America will only increase modestly. We currently expect that planned European growth and territory expansion during 2009 will result in an approximate 30% growth in European product sales. We also expect to expand into the Latin America market in 2009. Additionally, relative weakening or strengthening of the U.S. dollar will have a favorable or unfavorable impact, respectively, on sales not denominated in US dollars.

Beginning in 2008, the royalty rate we receive from Bard for sales by Bard of its RNF product decreased substantially from the rate we received prior to 2008, while the royalty rate we pay to the estate of the original inventor of the product remains the same. For the year ended December 31, 2008, this resulted in a net royalty expense reflected in general and administrative expenses of approximately $1.1 million.

Cost of Product Sales. For the year ended December 31, 2008, cost of product sales, as a percentage of total product sales, was approximately 33.4% compared with 27.2% for the year ended December 31, 2007. The increase in cost of product sales as a percentage of product sales was primarily the result of the impact of fixed manufacturing overhead on lower than budgeted production volumes as well as increased sales in Europe, where the selling price of our product is lower than the selling price of our products in North America and product costs of BioSTAR® are greater than products sold in the United States. Contributing to the increased costs of BioSTAR® are additional costs to distribute BioSTAR® and additional royalties. Included in cost of product sales were royalty expenses of approximately $2.2 million and $2.1 million for the years ended December 31, 2008 and 2007, respectively. In 2009, we anticipate a higher proportion of European sales compared to 2008. As a result, we currently expect 2009 cost of product sales to increase slightly to approximately 33.5% to 34.0%, as a percentage of product sales.

Research and Development. Research and development expense decreased approximately $2.2 million, or 14.4%, for the year ended December 31, 2008 compared with the year ended December 31, 2007. The decrease in research and development expenses was primarily due to expense reductions as a result of closing down our MIST II clinical study, as well as the timing of expenditures related to our development programs. For the year ended December 31, 2007, research and development expenses included $600,000 for a one-time non-refundable payment made to a supplier of our collagen matrix material. These expense reductions for the year ended December 31, 2008, were offset by an increase in spending for our CLOSURE I trial compared to the year ended December 31, 2007. For 2009, research and development expense is expected to decrease to $11.5 million from $13.2 million due primarily to the completion of our clinical trial enrollment work.

General and Administrative. General and administrative expense increased $600,000, or 7.4%, for the year ended December 31, 2008 compared with the year ended December 31, 2007. Included in general and administrative expense for the year ended December 31, 2008 is $1.1 million of net royalty expense related to our agreement with Bard. Legal expenses for the year ended December 31, 2008 were approximately $575,000 greater than legal expenses incurred for the year ended December 31, 2007, primarily due to litigation costs. Included as a reduction to general and administrative expense for the year ended December 31, 2008 are the first two payments of $500,000 each received pursuant to a settlement agreement with Cardia, Inc. For 2009, general and administrative expenses are currently expected to decrease slightly from $8.6 million in 2008 to approximately $8.3 million in 2009.

Selling and Marketing. Selling and marketing expense decreased $300,000, or 3.4%, for the year ended December 31, 2008 compared to the year ended December 31, 2007. This slight decrease was primarily the result of decreased travel costs as well as lower sales commission expenses. We currently expect worldwide selling and marketing expense in 2009 to decrease approximately $1.5 million compared to 2008, the result of a restructured and refocused sales structure which includes increased use of distribution channels.

Interest Income. Interest income decreased approximately $1.1 million for the year ended December 31, 2008 compared to the year ended December 31, 2007. We currently expect interest income to approximate $200,000 in 2009. This decrease compared to 2008 is primarily related to the anticipated use of approximately $10 million of cash, cash equivalents, and marketable securities to fund 2009 operations.

Income Tax Provision. We provide for taxes on income from continuing operations based upon our anticipated effective income tax rate. We incurred a loss from continuing operations in 2008 and therefore have not made a provision for taxes on continuing operations for the year ended December 31, 2008. For the year ended December 31, 2008, we recorded income tax expense of approximately $69,000 for the establishment of a liability for uncertain tax positions. For the year ended December 31, 2007, we recorded a benefit from income taxes of $122,000 as a result of the tax benefit for a portion of the taxes paid in 2006 that is refundable by carryback partially offset by the establishment of a liability for uncertain tax positions. We currently expect to incur operating losses in 2009.

RESULTS OF OPERATIONS
YEAR ENDED DECEMBER 31, 2007 COMPARED WITH YEAR ENDED DECEMBER 31, 2006

Revenues. Revenues for the years ended December 31, 2007 and 2006 were as follows:

	YEARS ENDED DECEMBER 31,		INCREASE (DECREASE)	% CHANGE
	2007	2006	2006 to 2007	2006 to 2007
(In thousands of dollars, except percentages)				
Product sales:				
CardioSEAL®, STARFlex® and BioSTAR®:				
North America	$14,185	$19,298	$(5,113)	(26.5)%
Europe	5,670	2,837	2,833	99.9%
Total product sales	19,855	22,135	(2,280)	(10.3)%
Net royalty income:				
Bard	6,849	5,406	1,443	26.7%
AGA	-	500	(500)	-
BSC	51	110	(59)	(53.6)%
Total net royalty income	6,900	6,016	884	14.7%
Total revenues	$26,755	$28,151	$(1,396)	(5.0)%

The decrease in CardioSEAL® and STARFlex® implant sales for 2007 compared to 2006 was primarily the result of decreased product demand in North America, primarily in the United States. We believe that sales in the United States continued to be impacted by delays by third party payors in approving reimbursement for the procedures as a result of the voluntary withdrawal of the HDE of our CardioSEAL® septal repair system.

The increase in European sales was primarily related to the launch of BioSTAR®, our bioabsorbable structural heart repair implant technology and our Rapid Transport™ delivery system following the awarding of the CE Mark for BioSTAR® in June 2007. The increase was also attributable to increased sales and marketing programs, as well as greater acceptance of our technology by the clinical community throughout Europe. European sales represented approximately 28.6% and 12.8% of total product sales in 2007 and 2006, respectively.

The increase in net royalty income for 2007 was directly attributable to Bard's sales of its RNF product. The royalty income from Bard was recorded net of approximately $2.6 million of royalties payable to the estate of 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 further from 2006 to 2007. BSC is not prohibited from selling competing stents and has established a broad based stent program. Through 2007, the Bard royalty rate applicable to RNF product sales was substantially higher than the royalty rate applicable to SNF products.

Cost of Product Sales. For the year ended December 31, 2007, cost of product sales, as a percentage of total product sales, was approximately 27.2% compared with 26.8% for the year ended December 31, 2006. This increase was primarily due to the increased sales in Europe, where the selling price of our product is lower than the selling price of our products in North America and products costs of BioSTAR® are greater than products sold in the United States. Included in cost of product sales were royalty expenses of approximately $2.1 million and $2.2 million for the years ended December 31, 2007 and 2006, respectively.

Research and Development. Research and development costs were relatively flat for the year ended December 31, 2007 compared to the year ended December 31, 2006. Clinical trial costs in 2007 decreased by $2.2 million with the completion of the MIST, MIST III and BEST trials. This decrease was offset by a one-time payment of $600,000 to a supplier of our collagen matrix material, increased new product development investments of approximately $400,000 and increased salary and related expenses of approximately $250,000.

General and Administrative. General and administrative expenses decreased approximately $700,000 for the year ended December 31, 2007 compared to the year ended December 31, 2006. Contributing to this decrease in general and administrative expenses were lower bonus expense of approximately $360,000 and lower share-based compensation expense pursuant to SFAS 123R of approximately $130,000. General and administrative expenses for 2006 also included approximately $150,000 for a 401(k) employer match.

Selling and Marketing. Selling and marketing costs increased approximately $400,000 for the year ended December 31, 2007 compared to the year ended December 31, 2006. The increase in selling and marketing expense was primarily the result of an increase in expenses related to the launch of BioSTAR® partially offset by savings spread across many expense categories.

Net Gain from Settlement of Litigation. On March 24, 2006, we entered into a Settlement and Mutual General Release Agreement with AGA. AGA agreed to make a cash payment of $30.0 million and was granted a nonexclusive sublicense to the patent involved in the litigation. The cash payment was shared equally, after deduction of our legal fees and expenses, with the inventor of the patent, Dr. Lloyd Marks.

Interest Income. Interest income was relatively flat for the year ended December 31, 2007 compared to the year ended December 31, 2006.

Income Tax Provision. We have provided for taxes on income from continuing operations based on our anticipated effective income tax rate. For fiscal 2007 we recorded a benefit from income taxes of $121,879 as a result of the tax benefit for a portion of the taxes paid in 2006 that is refundable by carryback partially offset by the establishment of a liability for uncertain tax positions. The provision for the year ended December 31, 2006 of $502,000 was as a result of the $15.2 million gain from the settlement of litigation with AGA and less than forecasted clinical trial expenses.

LIQUIDITY AND CAPITAL RESOURCES

We currently believe that aggregate cash, cash equivalents, and marketable securities balances of approximately $17.6 million as of December 31, 2008 will be sufficient to complete our CLOSURE I trial and bring our STARFlex® implant to the commercial market in the United States, subject to FDA approval. Based upon current projections, we expect that the aggregate of cash, cash equivalents, and marketable securities will approximate $6 million to $8 million at the end of 2009. This projection assumes a use of cash for 2009 of approximately $10 million compared to $13.4 million in 2008. We believe our cash use for 2009 will decrease compared to 2008, with clinical trial spending decreasing approximately $1.0 million, given that the enrollment in our CLOSURE I trial has been completed. We have also implemented a series of cost reduction initiatives including reducing headcount throughout the organization, reprioritizing our internal programs and restructuring various departments that we believe will decrease expenses by greater then $1.0 million in 2009 compared to 2008. Based on current projections and plans, we believe there is sufficient cash to fund operations through at least 2009 and into fiscal 2010. However, these forecasts are forward-looking statements that involve risks and uncertainties and actual results could vary materially.

We have incurred operating losses of $18.7 million and $11.1 million over the past two years and have experienced decreasing sales over those time periods. Our cash used in operations significantly parallels the operating losses we have incurred and we have an accumulated deficit of $38.0 million as of December 31, 2008. In addition, we expect to incur significant additional research and development and other costs in both 2009 and 2010—including costs to complete our CLOSURE I trial and bring the STARFlex® implant to commercial market in the United States, pending U.S. FDA approval. Our costs, including research and development for our product candidates and sales, marketing and promotion expenses for any of our existing or future products to be marketed by us or our distributors currently exceed and will likely continue to exceed revenues during this period. However, given the current global economic climate, it is unlikely that equity sources of capital at acceptable value will be available in the short-term. We do not currently have any line of credit arrangements, but we are in discussions with a financial institution regarding a possible credit facility.

FOR THE YEARS ENDED DECEMBER 31,	2008	2007	2006
(In thousands)			
Cash, cash equivalents, marketable securities	$17,574	$30,974	$41,450
Net cash (used in) provided by operating activities	(13,566)	(11,148)	8,174
Net cash provided by (used in) investing activities	11,169	9,242	(12,046)
Net cash provided by financing activities	312	604	1,768

Net Cash (Used in) Provided by Operating Activities

Net cash used in operating activities for the year ended December 31, 2008 totaled approximately $13.6 million and consisted primarily of a net loss of approximately $18.1 million. Net loss in 2008 included non-cash charges of approximately $911,000. Working capital requirements also decreased by approximately $3.6 million.

The non-cash charges of approximately $911,000 during the year ended December 31, 2008 consisted of share-based compensation expense and depreciation of property and equipment, offset partially by accretion of bond discount on marketable debt securities.

The primary elements of the $3.6 million net decrease in working capital requirements during the year ended December 31, 2008 consisted of a decrease in prepaid expenses and other current assets of approximately $2.2 million, due primarily to the reduction in the royalty receivable due from Bard as a result of the decrease in the royalty rate we receive from Bard, a reduction in accounts receivable of $534,000, a $414,000 increase in accounts payable and a $402,000 increase in accrued expenses and long-term liabilities.

Net cash used in operating activities for the year ended December 31, 2007 totaled approximately $11.1 million and consisted of a net loss of approximately $9.1 million. Net loss in 2007 included non-cash charges of approximately $585,000. Working capital requirements also decreased by approximately $2.6 million.

Net Cash Provided By (Used in) Investing Activities

Net cash provided by investing activities of approximately $11.2 million during the year ended December 31, 2008 consisted primarily of approximately $27.5 million of proceeds from maturities of marketable securities, offset by approximately $16.2 million of purchases of marketable securities. Purchases of property and equipment for use in our manufacturing, research and development, and general and administrative activities totaled approximately $129,000 during the year ended December 31, 2008 compared to approximately $367,000 in 2007. This compared to approximately $9.2 million provided by operations in 2007, which consisted primarily of approximately $38.1 million of proceeds from maturities of marketable securities, offset by approximately $28.4 million of purchases of marketable securities.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was approximately $312,000 for the year ended December 31, 2008 and approximately $604,000 for the year ended December 31, 2007. For both periods, net cash from financing activities includes proceeds from the exercise of common stock options and the issuance of shares of common stock pursuant to our employee stock purchase plan.

Factors Affecting Sources of Liquidity

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. On October 19, 2006, we filed a shelf registration statement on Form S-3 with the SEC and that will permit us to offer and sell up to $65 million of equity or debt securities. However, given the current market conditions it is not clear how much market capital we would be able to raise using this registration statement or otherwise. 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 have any line of credit arrangements, and we may not be able to obtain any such credit facilities on acceptable terms, if at all, but we are in discussions with a financial institution regarding a possible credit facility.

CONTRACTUAL OBLIGATIONS

Clinical Trials

During 2008, we incurred costs for two 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 2008, our current estimates of 2009 costs and the remaining costs estimated to be incurred subsequent to 2009. 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 2008, approximately $2.1 million was included in accrued expenses at December 31, 2008.

(In millions of dollars)	Inception Of Enrollment	Current Projected Total Costs Of Clinical Trial	Costs Incurred Through 2008	Projected Costs To Be Incurred In 2009	Projected Costs To Be Incurred After 2009	Projected Trial Completion/ Regulatory Filing
CLOSURE I	2003	30.0	22.6	4.6	2.8	To be determined
BEST	2005	1.4	1.4	—	—	Completed
MIST	2005	4.9	4.9	—	—	Completed
MIST II	2007	—	3.9	—	—	Not applicable
MIST III	2006	1.2	1.1	0.1	—	2009
Totals		$37.5	$33.9	$4.7	$2.8	

Operating Leases and Minimum Royalty and License Agreements

Substantially all of our operating leases relate to our Boston, Massachusetts manufacturing, research and development and administrative offices. The facility leases expire in September 2012.

We are party to various royalty and license agreements under which we are obligated to pay royalties and license fees. Some of the commitments are contingent on sales volumes, while other agreements have minimum payment commitments.

The following table summarizes our estimated minimum future operating lease and license agreement contractual commitments at December 31, 2008:

		PAYMENTS DUE BY PERIOD			
	Total	Less Than One Year	1-3 Years	3-5 Years	After 5 Years
Operating leases	$3,503,516	$ 867,586	$1,750,614	$885,316	$-
Minimum license obligations	300,000	150,000	150,000	-	-
Total	$3,803,516	$1,017,586	$1,900,614	$885,316	$ -

OFF-BALANCE SHEET FINANCING

During the year ended December 31, 2008, we have not engaged in any off-balance sheet activities, including the use of structured finance or specific purpose entities.

RECENT ACCOUNTING PRONOUNCEMENTS

(a) Recently Adopted

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, "Fair Value Measurements," or SFAS 157. The Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements. This statement requires quantitative disclosures about fair value measurements for each major category of assets and liabilities measured at fair value on a recurring and non-recurring basis during a period. In February 2008, the FASB issued FASB Staff Positions, or FSP, 157-1 and 157-2. FSP 157-1 amends SFAS No. 157 to exclude SFAS No. 13, "Accounting for Leases," or SFAS No. 13, and its related interpretive accounting pronouncements that address leasing transactions, while FSP 157-2 delays the effective date of the application to January 1, 2009 for all nonfinancial assets and nonfinancial liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis (that is, at least annually). We adopted SFAS No. 157 as of January 1, 2008. The adoption had no impact on the condensed consolidated results of operations or financial position included herein, but requires that we provide additional required disclosures in the notes to our consolidated financial statements issued after the effective date.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB No. 115", or SFAS 159. The Statement permits companies to choose to measure many financial instruments and certain other items at fair value in order to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for fiscal years beginning after November 15, 2007. On January 1, 2008 we adopted SFAS 159 and have made no elections under SFAS 159.

(b) Future Adoption

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141 (revised 2007), "Business Combinations", or SFAS 141R, and Statement of Financial Accounting Standards No. 160, "Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51," or SFAS 160. SFAS 141R will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141R and SFAS 160 are effective for the Company beginning in the first quarter of fiscal 2009. Early adoption is not permitted. We are evaluating the impact, if any, SFAS 141R and SFAS 160 will have on our operating results and financial position, and believe the impact will not be material.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2008 and 2007, we did not participate in any derivative financial instruments or other financial and commodity instruments for which fair value disclosure would be required under FASB Statement No. 157, "Fair Value Measurement." Our investments are primarily corporate and U.S. government agency 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 have an unrealized loss on our portfolio of approximately $110,000 at December 31, 2008, which is associated with one investment. This investment has been in a significant unrealized loss position for less than 4 months as of December 31, 2008 and matures in May 2009. We have not considered this investment as other than temporarily impaired at December 31, 2008 based on the following: i) our evaluation of the issuer's financial position, ii) the duration of the impairment, and iii) our ability and intent to hold this investment until its maturity in May 2009. We will continue to monitor our investments for impairment.

We are subject to market risk in the form of foreign currency risk. We denominate certain product sales and operating expenses in non-U.S. currencies, resulting in 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, 2008. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under 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, 2008, 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, 2008. In making this assessment, we used the criteria set forth by the Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria).

Based on our assessment, we believe that, as of December 31, 2008, our internal control over financial reporting was effective at a reasonable assurance level based on these criteria.

Deloitte & Touche LLP, the independent registered public accounting firm that audited our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, has issued an attestation report on our internal control over financial reporting. That report appears below in this item 9A of this Annual Report on Form 10-K.

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, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of NMT Medical, Inc.

Boston, Massachusetts

We have audited the internal control over financial reporting of NMT Medical, Inc. and subsidiaries (the "Company") as of December 31, 2008, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

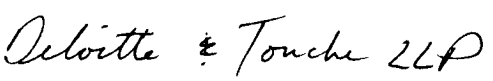
We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, 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 by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's 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. 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 the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the 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, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2008 of the Company and our report dated March 11, 2009 expressed an unqualified opinion on those financial statements.



DELOITTE & TOUCHE LLP

Boston, Massachusetts

March 11, 2009

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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 2009 Annual Meeting of Stockholders to be held on June 4, 2009. Information relating to certain filings of Forms 3, 4 and 5 is contained in our 2009 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 relating to an Audit Committee financial expert and identification of the Audit Committee of our Board of Directors is contained in our 2009 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 2009 proxy statement.

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 2009 proxy statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required under this item is incorporated by reference to the section entitled *"Certain Transactions"* in our 2009 proxy statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required under this item is incorporated by reference to the section entitled *"Independent Registered Public Accounting Firm"* in our 2009 proxy statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Consolidated 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:

Reports of Independent Registered Public Accounting Firms

Consolidated Balance Sheets at December 31, 2008 and 2007

Consolidated Statements of Operations for the years ended December 31, 2008, 2007 and 2006

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2008, 2007 and 2006

Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006

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 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.

/s/ FRANCIS J. MARTIN
Francis J. Martin
President, Chief Executive Officer

Dated: March 13, 2009

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/ FRANCIS J. MARTIN Francis J. Martin	President, Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2009
/s/ RICHARD E. DAVIS Richard E. Davis	Chief Operating Officer and Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2009
/s/ JAMES J. MAHONEY, JR. James J. Mahoney, Jr.	Chairman of the Board	March 13, 2009
/s/ CHERYL L. CLARKSON Cheryl L. Clarkson	Director	March 13, 2009
/s/ DANIEL F. HANLEY Daniel F. Hanley, M.D.	Director	March 13, 2009
/s/ JAMES E. LOCK James E. Lock, M.D.	Director	March 13, 2009
/s/ DAVID L. WEST David L. West, Ph.D., M.P.H.	Director	March 13, 2009

APPENDIX A

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of NMT Medical, Inc.

Boston, Massachusetts

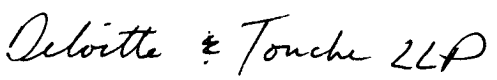
We have audited the accompanying consolidated balance sheets of NMT Medical, Inc. and subsidiaries (the "Company") as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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 financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of NMT Medical, Inc. and subsidiaries as of December 31, 2008 and 2007, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2007, the Company adopted Financial Accounting Standards Board Interpretation No. 48 *Accounting for Uncertainty in Income Taxes, an Interpretation of Financial Accounting Standards Board Statement No. 109*.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2008, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 11, 2009 expressed an unqualified opinion on the Company's internal control over financial reporting.



DELOITTE & TOUCHE LLP

Boston, Massachusetts

March 11, 2009

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated statements of operations, stockholders' equity, and cash flows of NMT Medical, Inc. (a Delaware corporation) for the year ended December 31, 2006. 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 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 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 results of its operations and its cash flows for the year ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 10 to the consolidated financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123R, "Share-Based Payments" using the modified-prospective transition method.

Ernst & Young LLP

Boston, Massachusetts

March 9, 2007

NMT MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

AT DECEMBER 31,	2008	2007
Assets		
Current assets:		
Cash and cash equivalents	$ 4,899,179	$ 6,984,383
Marketable securities	12,674,639	23,989,995
Accounts receivable, net of allowances of $135,000 in 2008 and $161,341 in 2007	2,511,934	3,046,308
Inventories	2,018,173	2,071,534
Prepaid expenses and other current assets	1,212,947	3,407,084
Total current assets	23,316,872	39,499,304
Property and equipment, at cost:		
Laboratory and computer equipment	1,974,468	3,393,215
Leasehold improvements	1,276,121	1,302,649
Office furniture and equipment	334,300	583,038
	3,584,889	5,278,902
Less accumulated depreciation and amortization	2,656,196	4,175,357
Total property and equipment, net	928,693	1,103,545
Total Assets	$ 24,245,565	$ 40,602,849
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,870,606	$ 2,456,316
Accrued expenses	6,468,167	6,221,427
Total current liabilities	9,338,773	8,677,743
Long-term liabilities	$ 507,426	$ 352,185
Commitments and contingencies (Notes 6 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—13,122,391 shares in 2008 and 13,012,142 shares in 2007	13,122	13,012
Additional paid-in capital	52,659,855	51,645,489
Treasury stock—40,000 shares at cost	(119,600)	(119,600)
Accumulated other comprehensive (loss) income	(108,407)	3,873
Accumulated deficit	(38,045,604)	(19,969,853)
Total stockholders' equity	14,399,366	31,572,921
Total Liabilities and Stockholders' Equity	$ 24,245,565	$ 40,602,849

See accompanying notes.

NMT MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE YEARS ENDED DECEMBER 31,	2008	2007	2006
Revenues:			
Product sales	$ 17,856,449	$ 19,854,658	$ 22,135,286
Net royalty income	18,170	6,900,467	6,016,044
Total revenues	17,874,619	26,755,125	28,151,330
Costs and expenses:			
Cost of product sales	5,968,933	5,409,180	5,938,575
Research and development	13,194,376	15,407,153	15,454,948
General and administrative	8,578,640	7,987,917	8,680,671
Selling and marketing	8,783,784	9,093,349	8,703,728
Total costs and expenses	36,525,733	37,897,599	38,777,922
Net gain from settlement of litigation	-	-	15,183,894
(Loss) income from operations	(18,651,114)	(11,142,474)	4,557,302
Other income (expense):			
Currency transaction (loss) gain	(123,192)	87,952	14,468
Interest income	767,724	1,830,191	1,816,239
Total other income, net	644,532	1,918,143	1,830,707
(Loss) income before income taxes	(18,006,582)	(9,224,331)	6,388,009
Income tax expense (benefit)	69,169	(121,879)	502,000
Net (loss) income	$(18,075,751)	$ (9,102,452)	$ 5,886,009
Basic net (loss) earnings per common share:			
Net (loss) income	$ (1.39)	$ (0.70)	$ 0.46
Diluted net (loss) earnings per common share:			
Net (loss) income	$ (1.39)	$ (0.70)	$ 0.43
Weighted average common shares outstanding:			
Basic	13,019,653	12,926,020	12,745,601
Diluted	13,019,653	12,926,020	13,597,080

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 Income (Loss)
Balance, January 1, 2006	12,635,832	$12,636	$48,232,778	(40,000)	$(119,600)	$(16,753,410)	$ (52,834)	$31,319,570	
Common stock issued under the employee stock purchase plan	29,806	29	332,595	—	—	—	—	332,624	—
Exercise of common stock options	235,672	236	851,809	—	—	—	—	852,045	—
Share-based compensation	—	—	870,229	—	—	—	—	870,229	—
Unrealized gain on marketable securities	—	—	—	—	—	—	55,962	55,962	55,962
Tax benefit on stock option exercises	—	—	583,000	—	—	—	—	583,000	—
Net income	—	—	—	—	—	5,886,009	—	5,886,009	5,886,009
Net comprehensive income									$ 5,941,971
Balance, December 31, 2006	12,901,310	$12,901	$50,870,411	(40,000)	$(119,600)	$(10,867,401)	$ 3,128	$ 39,899,439	
Common stock issued under the employee stock purchase plan	35,808	36	307,314	—	—	—	—	307,350	—
Exercise of common stock options	75,024	75	296,958	—	—	—	—	297,033	—
Share-based compensation	—	—	716,846	—	—	—	—	716,846	—
Unrealized gain on marketable securities	—	—	—	—	—	—	745	745	745
Change in estimated tax benefit from stock option exercises	—	—	(546,040)	—	—	—	—	(546,040)	—
Net loss	—	—	—	—	—	(9,102,452)	—	(9,102,452)	(9,102,452)
Net comprehensive loss									$ (9,101,707)
Balance, December 31, 2007	13,012,142	$13,012	$51,645,489	(40,000)	$(119,600)	$(19,969,853)	$ 3,873	$ 31,572,921	
Common stock issued under the employee stock purchase plan	95,974	96	274,076	—	—	—	—	274,172	—
Exercise of common stock options	14,275	14	37,611	—	—	—	—	37,625	—
Share-based compensation	—	—	702,679	—	—	—	—	702,679	—
Unrealized loss on marketable securities	—	—	—	—	—	—	(112,280)	(112,280)	(112,280)
Net loss	—	—	—	—	—	(18,075,751)	—	(18,075,751)	(18,075,751)
Net comprehensive loss									$(18,188,031)
Balance, December 31, 2008	13,122,391	$13,122	$52,659,855	(40,000)	$(119,600)	$(38,045,604)	$(108,407)	$ 14,399,366	

See accompanying notes.

NMT MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31,	2008	2007	2006
Cash flows from operating activities:			
Net (loss) income	$(18,075,751)	$(9,102,452)	$ 5,886,009
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities–			
Depreciation and amortization	303,706	302,571	331,006
Accretion of bond discount	(95,247)	(434,244)	(511,142)
Share-based compensation expense	702,679	716,846	870,229
Change in estimated tax benefit from stock option exercises	-	(546,040)	-
Change in assets and liabilities-			
Accounts receivable	534,374	(317,120)	117,496
Inventories	53,361	(162,298)	(182,936)
Prepaid expenses and other current assets	2,194,137	648,543	(450,087)
Accounts payable	414,290	171,969	(370,052)
Accrued expenses and long-term liabilities	401,981	(2,425,539)	2,483,342
Net cash (used in) provided by operating activities	(13,566,470)	(11,147,764)	8,173,865
Cash flows from investing activities:			
Purchases of property and equipment	(128,854)	(366,789)	(565,564)
Purchases of marketable securities	(16,171,677)	(28,441,008)	(49,330,548)
Maturities of marketable securities	27,470,000	38,050,000	37,850,000
Net cash provided by (used in) investing activities	11,169,469	9,242,203	(12,046,112)
Cash flows from financing activities:			
Proceeds from exercise of common stock options	37,625	297,033	852,045
Proceeds from issuance of common stock under the employee stock purchase plan	274,172	307,350	332,624
Excess tax benefits from share-based compensation	-	-	583,000
Net cash provided by financing activities	311,797	604,383	1,767,669
Net (decrease) increase in cash and cash equivalents	(2,085,204)	(1,301,178)	(2,104,578)
Cash and cash equivalents, beginning of period	6,984,383	8,285,561	10,390,139
Cash and cash equivalents, end of period	$ 4,899,179	$ 6,984,383	$ 8,285,561
Supplemental cash flow information:			
Cash paid for income taxes	$ 15,805	$ 17,747	$ 50,000

See accompanying notes.

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) OPERATIONS

We are an advanced medical technology company that designs, develops, manufactures and markets proprietary implant technologies that allow interventional cardiologists to treat structural heart disease through minimally invasive, catheter-based procedures. We are investigating the potential connection between a common heart defect that allows a right to left shunt or flow of blood through a defect like a patent foramen ovale, or PFO, and brain attacks such as embolic stroke, transient ischemic attacks, or TIA, and migraine headaches. A PFO is a common right to left shunt that 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 30,000 PFOs have been treated 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 our company and our wholly-owned subsidiaries. Intercompany transactions and balances have been eliminated in consolidation.

We have incurred operating losses of $18.7 million and $11.1 million over the past two years and have experienced decreasing sales over those time periods. Our cash used in operations significantly parallels the operating losses we have incurred and we have an accumulated deficit of $38.0 million as of December 31, 2008. We have historically funded our operations primarily through public offerings, the sale of non-strategic business assets, and settlements resulting from the successful defense of our patents. In addition, we expect to incur significant additional research and development and other costs in both 2009 and 2010 - including costs to complete our CLOSURE I trial and bring the STARFlex® implant to commercial market in the United States, pending U.S. FDA approval. Our costs, including research and development for our product candidates and sales, marketing and promotion expenses for any of our existing or future products to be marketed by us or our distributors currently exceed and will likely continue to exceed revenues during this period. In addition, given the current global economic climate, it is unlikely that equity sources of capital at acceptable value will be available in the short-term.

At December 31, 2008, we had cash, cash equivalents and marketable securities of $17.6 million. We believe such amounts are sufficient for us to operate as we have internally forecast for 2009 and we have taken several actions over the last year to both reduce our expenditures and further enhance our ability to generate revenue. In particular, we have reevaluated both programs and resources allocated to those programs and reduced spending where appropriate. These reductions are anticipated to reduce our cash outflows by greater than $1.0 million in 2009. We have also repositioned our sales force in Europe and the rest of the world to increase our sales. We also believe that, while the completion of the CLOSURE I trial will continue to require working capital, expenditures will be approximately $1.0 million less in 2009 than 2008. Should such actions not be sufficient to ensure that the cash, cash equivalents and marketable securities we have on hand at December 31, 2008 is enough to support our operations, we have the ability to further slow our spend on research and development activities and, if necessary, take additional actions. We are in discussions with a financial institution regarding a possible credit facility. Based on current projections and plans, we believe there is sufficient cash to fund operations through at least 2009 and into fiscal 2010. Improvements in cash flows from operations, or obtaining additional financing, is expected or required to continue as a going concern thereafter.

Successful completion of our CLOSURE I clinical trial and bringing the STARFlex® implant to commercial market in the United States, pending FDA approval, and, ultimately, the attainment of profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure and if necessary, obtaining additional financing and/or reducing expenditures. There are no assurances, however, that we will be able to achieve an adequate level of sales to support our cost structure or obtain additional financing on favorable terms, or at all. Failure to raise capital if needed could materially adversely impact our business, financial condition, results of operations and cash flows and impact our ability to continue as a going concern.

(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, and Marketable Securities

We consider investments with maturities of 90 days or less from the date of purchase to be cash equivalents and 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 marketable securities at December 31, 2008, consisted of approximately $12.7 million of debt instruments with maturities ranging from January 2009 to September 2009. There are no investments in our portfolio that have been in an unrealized loss position for 12 months or longer. We hold one investment, with a fair value of

$669,000, a cost basis (including accrued interest) of $780,000 and an unrealized loss recorded in accumulated other comprehensive loss of $111,000 at December 31, 2008. This investment has been in a significant unrealized loss position for less than four months as of December 31, 2008 and matures in May 2009. We have not considered this investment as other than temporarily impaired at December 31, 2008 based on the following: i) our evaluation of the issuer's financial position, ii) the duration of the decline in fair value below our cost, and iii) our ability and intent to hold this investment until its maturity in May 2009. Accrued interest receivable of approximately $136,000 and $238,000 was included in prepaid expenses and other current assets in the accompanying consolidated balance sheets at December 31, 2008 and December 31, 2007, respectively.

On January 1, 2008 we adopted SFAS No. 157 *"Fair Value Measurements,"* or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, which are the following:

Level 1 – Quoted prices in active markets that are accessible at the market date for identical unrestricted assets or liabilities.

Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs for which all significant inputs are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

		FAIR VALUE MEASUREMENTS AT THE REPORTING DATE USING		
	DECEMBER 31, 2008	LEVEL 1	LEVEL 2	LEVEL 3
Corporate Debentures/Bonds	$ 7,729,687	$ —	$ 7,729,687	$ —
Commercial Paper	2,344,964	—	2,344,964	—
Certificates of Deposit	600,000	—	600,000	—
Treasury Bills	1,999,988	1,999,988	—	—
Total	$12,674,639	$1,999,988	$10,674,651	$ —

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

DECEMBER 31,	2008	2007
Due within one year	$12,674,639	$21,993,005
Due in 1-2 years	—	1,996,990
	$12,674,639	$23,989,995

(d) Inventories

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

AT DECEMBER 31,	2008	2007
Raw materials	$ 573,417	$ 750,389
Work-in-process	134,154	109,058
Finished goods	1,310,602	1,212,087
	$2,018,173	$2,071,534

Finished goods are comprised of materials, labor and manufacturing overhead.

The Company records abnormal amounts of idle facility expenses as current-period charges in accordance with FASB Statement No. 151, "Inventory Costs," or SFAS 151. The Company allocates fixed production overheads to the costs of production based on the normal capacity of the production facilities. Management judgment is required in the determination of a range of normal capacity levels, which directly affects the allocation of fixed manufacturing overhead costs between inventory costs and period expense. In 2006 and 2007, production levels approximated normal capacity levels and no idle capacity costs were charged to cost of product sales. In 2008, idle capacity costs charged directly to cost of product sales approximated $220,000.

The Company establishes inventory reserves when management believes that inventory on-hand may be in excess of anticipated demand or is obsolete based upon assumptions about future demand for its products and market conditions. When recorded, excess or obsolete inventory reserves are recorded as adjustments to the carrying value of inventory. As such, inventory is recorded at its net realizable value.

(e) 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, 2008 and 2007, respectively. The estimated fair values have been determined through information obtained from market sources and management estimates. We do not have any derivatives as defined by FASB Statement No. 133, "Accounting for Derivative and Hedging Instruments."

(f) Concentration of Credit Risk and Significant Customers

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. We have not engaged in off-balance sheet activities, including the use of structured finance or special purpose entities.

No customer accounted for greater than 10% of product sales in any of the three years ended December 31, 2008.

At December 31, 2008, 31.0% of gross accounts receivable represented accounts denominated in foreign currencies that were translated at year-end exchange rates. For the years ended December 31, 2008, 2007 and 2006, product sales to customers outside North America accounted for 34.4%, 28.6% and 12.8% of total product sales, respectively.

(g) Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment. 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, 2008 or 2007.

(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 $304,000, $303,000 and $331,000 for the years ended December 31, 2008, 2007 and 2006, respectively. Maintenance and repairs are charged to expense when incurred. Additions and improvements are capitalized.

(i) Revenue Recognition

In accordance with Securities and Exchange Commission (SEC) Staff Accounting Bulletin, or 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 reasonably assured. 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.

We also maintain a provision for estimated sales returns and allowances on product sales. The reserve is based on management's assessment of historical sales returns and other known factors.

(j) Net Income (Loss) per Common Share

Basic and diluted net income (loss) per share is presented in conformity with FASB Statement No. 128, "Earnings per Share," or SFAS 128, for all periods presented. In accordance with SFAS 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 per share was determined by dividing net income 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 reported net losses for the years ended December 31, 2008 and 2007, accordingly, none of our outstanding options and warrants were dilutive. For the year ended December 31, 2006 in

which we reported net income, 851,000 common stock equivalents were included in the diluted earnings per share calculation. Options to purchase a total of 1,662,463, 1,608,124 and 241,750 common shares have been excluded from the computation of diluted weighted average shares outstanding for the years ended December 31, 2008, 2007 and 2006, respectively, as they were anti-dilutive.

(k) Share-Based Compensation

Prior to January 1, 2006, we accounted for share-based employee compensation, including stock options, using the method prescribed in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related Interpretations, or APB Opinion No. 25. Under APB Opinion No. 25, for stock options granted at market price, no compensation cost was recognized. In 2004, the Financial Accounting Standards Board issued SFAS No. 123 (Revised 2004) *Share Based Payment*, or SFAS 123R, which requires companies to measure and recognize compensation expense for all share-based payments at fair value. SFAS 123R eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, and generally requires that such transactions be accounted for using prescribed fair-value-based methods. SFAS 123R permits public companies to adopt its requirements using one of two methods: (a) a "modified prospective" method in which compensation costs are recognized beginning with the effective date based on the requirements of SFAS 123R for all share-based payments granted or modified after the effective date, and based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date, or (b) a "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits companies to restate based on the amounts previously recognized under SFAS 123 for purposes of pro forma disclosures either for all periods presented, or prior interim periods of the year of adoption. Effective January 1, 2006, we adopted SFAS 123R using the modified prospective method. We utilize the straight-line attribution method for recognizing share-based compensation expense under SFAS 123R.

(l) Foreign Currency

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 a foreign currency loss of approximately $123,000 for the year ended December 31, 2008 and we had foreign currency transaction gains of approximately $88,000 and $14,000 for the years ended December 31, 2007 and 2006, 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

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) income consists entirely of unrealized gains and losses on marketable securities.

(n) Income Taxes

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. Effective January 1, 2007, we adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109", or FIN 48. In accordance with the provisions of FIN 48, we classified uncertain tax positions as non-current income tax liabilities unless expected to be paid within one year. We report penalties and tax-related interest expense as a component of the provision for income taxes and interest income from tax refunds as a component of other income in the consolidated statement of operations.

(o) Guarantees and Indemnifications

We recognize liabilities for guarantees in accordance with FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others", or FIN 45. 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.

(p) Recent Accounting Pronouncements

(a) Recently adopted

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, "Fair Value Measurements," or SFAS 157. The Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements. This statement requires quantitative disclosures about fair value measurements for each major category of assets and liabilities measured at fair value on a recurring and non-recurring basis during a period. In February 2008, the FASB issued FASB Staff Positions, or FSP, 157-1 and 157-2. FSP 157-1 amends SFAS No. 157 to exclude SFAS No. 13, "Accounting for Leases," or SFAS No. 13, and its related interpretive accounting pronouncements that address leasing transactions, while FSP 157-2 delays the effective date of the

application to January 1, 2009 for all nonfinancial assets and nonfinancial liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis (that is, at least annually). We adopted SFAS No. 157 as of January 1, 2008. The adoption had no impact on the condensed consolidated results of operations or financial position included herein, but requires that we provide additional required disclosures in the notes to our consolidated financial statements issued after the effective date.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB No. 115", or SFAS 159. The Statement permits companies to choose to measure many financial instruments and certain other items at fair value in order to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for fiscal years beginning after November 15, 2007. On January 1, 2008 we adopted SFAS 159 and have made no elections under SFAS 159.

(b) Future Adoption

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141 (revised 2007), "Business Combinations", or SFAS 141R, and Statement of Financial Accounting Standards No. 160, "Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51," or SFAS 160. SFAS 141R will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141R and SFAS 160 are effective for the Company beginning in the first quarter of fiscal 2009. Early adoption is not permitted. We are evaluating the impact, if any, SFAS 141R and SFAS 160 will have on our operating results and financial position, and believe the impact will not be material.

(q) 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. There was no employer match for the years ended December 31, 2008 and 2007. The Board of Directors approved a 401(k) employer match for the year ended December 31, 2006 in the amount of $149,000.

(r) Segment Reporting

We operate our business as one segment.

(s) 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. 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, or 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 October 2008, we announced that we completed the patient enrollment in this trial. 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 believe promotes a more natural, rapid and complete sealing of heart defects such as a PFO.

Total expenses for our clinical trials were approximately $5.4 million, $6.0 million and $8.2 million for the years ended December 31, 2008, 2007 and 2006, respectively. This included direct advertising costs of approximately $179,000, $200,000 and $52,000 for the years ended December 31, 2008, 2007 and 2006, 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. Units used in clinical trials 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.

(3) INCOME TAXES

The expense (benefit) for income taxes in the accompanying consolidated statements of operations for the years ended December 31, 2008, 2007 and 2006 consisted of the following:

FOR THE YEARS ENDED DECEMBER 31,	2008	2007	2006
Foreign-current	$ 68,063	$ 7,950	$ —
Federal-current	—	(382,612)	746,000
State-current	1,106	8,783	—
	69,169	(365,879)	746,000
Foreign-deferred	—	—	—
Federal-deferred	—	244,000	(244,000)
State-deferred	—	—	—
	—	244,000	(244,000)
	$ 69,169	$ (121,879)	$ 502,000

We have U.S. net tax operating loss carryforwards of approximately $18.9 million and tax credit carryforwards of approximately $4.0 million that are available to reduce federal and state tax liabilities in future periods, if any. These carryforwards expire on various dates through 2027. We also have U.S. net tax operating losses of approximately $4.4 million that relate to excess stock option benefits. If and when these net operating losses are realized, the benefit will credit additional paid-in capital.

The tax effects of temporary differences that give rise to significant portions of the current deferred tax asset at December 31, 2008 and 2007 are as follows:

	2008	2007
Net operating losses	$ 7,354,367	$ 1,743,830
Tax credit carryforwards	4,003,830	3,377,066
Timing differences, including reserves, accruals and write-offs	1,130,638	922,473
	12,488,835	6,043,369
Less—Valuation allowance	(12,488,835)	(6,043,369)
Net deferred tax asset	$ —	$ —

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

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

FOR THE YEARS ENDED DECEMBER 31,	2008	2007	2006
Statutory federal income tax rate (benefit)	(34.0)%	(34.0)%	34.0%
State income taxes, net of federal income tax benefit	—	—	—
Change in valuation allowance/utilization of net operating loss and tax credit carryforwards	35.4	31.2	(31.4)
Tax reserve	(0.3)	1.3	—
Other	(1.5)	0.1	5.3
	(0.4)%	(1.4)%	7.9%

On January 1, 2007 we adopted the provisions of FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109", or FIN 48. The adoption of FIN 48 did not result in any adjustment to the financial statements at January 1, 2007.

The following table summarizes the activity related to our unrecognized tax benefits:

FOR THE YEARS ENDED DECEMBER 31,	2008	2007
Balance at January 1	$157,929	$ —
(Decreases) increases related to settlements of prior year tax positions	(8,282)	105,883
Increases related to current year tax positions	50,365	52,046
Balance at December 31	$200,012	$157,929

Our unrecognized tax benefits at December 31, 2008 relate to various tax jurisdictions. If these unrecognized tax benefits of $200,012 at December 31, 2008 were recognized, they would decrease our annual effective tax rate. We also recorded a liability for potential interest in the amount of $25,694. It is our policy to record and classify interest and penalties as income tax expense. We do not expect our unrecognized tax benefits to change significantly over the next twelve months.

We file U. S., state and foreign income tax returns in jurisdictions with varying statutes of limitations. The 2006 through 2008 tax years remain subject to examination by federal authorities and the 2005 through 2008 tax years remain subject to examination by their respective tax authorities.

(4) NET ROYALTY INCOME

In connection with the November 2001 sale of our vena cava filter product line to C.R. Bard, Inc., or 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 estate of 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 $6.9 million and $6.0 million during the years ended December 31, 2007 and 2006, respectively. Beginning in 2008, the royalty rate we receive from Bard has decreased substantially from its former rate, while the royalty rate we pay to the estate of the original inventor of these products has remained the same. This has resulted in a net royalty expense of approximately $1.1 million for the year ended December 31, 2008, that has been reflected in general and administrative expenses.

(5) SETTLEMENT OF LITIGATION

In September 2004, we and the Children's Medical Center Corporation, or CMCC, filed a civil complaint in the U.S. District Court for the District of Minnesota, or the District Court, for infringement of a patent owned by CMCC and licensed exclusively to us. The complaint alleges that Cardia, Inc., or 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 District Court to prevent further infringement by Cardia, as well as monetary damages. On August 30, 2006, the District Court entered an order holding that Cardia's device does not infringe the patent-in-suit. The order had no effect on the validity and enforceability of the patent-in-suit and had no impact on our ability to sell our products. We appealed the ruling to the U.S. Court of Appeals for the Federal Circuit and on June 6, 2007 the Federal Circuit ruled that the District Court incorrectly interpreted one of the patent's claims and incorrectly found no triable issue of fact concerning other claims. The Federal Circuit remanded the case to the District Court for further proceedings consistent with its opinion and instructed that on remand the district court may reconsider the question of summary judgment for us and CMCC based on the Federal Circuit's claim construction. On November 8, 2007, the District Court granted summary judgment in our and CMCC's favor, ruling that Cardia's device infringes the patent-in-suit and striking all of Cardia's invalidity defenses. On March 19, 2008, we and CMCC agreed with Cardia to settle this litigation. As part of the settlement, a judgment was entered against Cardia and in favor of us and CMCC, with Cardia agreeing to pay $2.25 million. The settlement will be shared equally between us and CMCC after deduction of our legal fees and expenses. The first and second payments of $500,000 each were received on September 30, 2008 and December 15, 2008, and were recorded as a reduction to general and administrative expenses, to offset legal fees incurred in connection with this legal proceeding. The remaining $1.25 million in payments are due to be paid in 2009.

On March 24, 2006, we entered into a Settlement and Mutual General Release Agreement with AGA. AGA agreed to make a cash payment of $30.0 million and was granted a nonexclusive sublicense to the patent involved in the litigation. On April 12, 2006, we received the entire cash payment from the settlement totaling $30.0 million which was shared equally, after deduction of our legal fees and expenses, with the inventor of the patent, Dr. Lloyd Marks. All parties agreed to have the case dismissed with prejudice and also agreed to a general release of any and all claims.

(6) 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 2012. 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 September 2008, we entered into an amendment to our office lease agreement, which extended the term by two years through September 2012. The effects of the variable rent disbursements have been expensed on a straight line basis over the life of the lease.

Future minimum rental payments due under operating lease agreements at December 31, 2008 are approximately as follows:

YEARS ENDING DECEMBER 31,	
2009	$ 867,586
2010	830,981
2011	919,633
2012	885,316
2013	—
	$3,503,516

Rent expense for the years ended December 31, 2008, 2007 and 2006 totaled $912,000, $968,000 and $983,000, 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 $5,238,000, $5,107,000 and $4,417,000 for the years ended December 31, 2008, 2007 and 2006, respectively. Approximately $2,300,000 and $2,028,000 of these royalties were included as a reduction of related royalty income earned from third parties for the years ended December 31, 2007 and 2006, respectively. Approximately $2.8 million of these royalties were included in general and administrative expense for the year ended December 31, 2008. This royalty expense was reduced by $1.7 million of royalty income resulting in a net royalty expense of $1.1 million included in general and administrative expense. The remaining amount of royalty expense is reflected within cost of product sales and research and development expenses.

(c) Employment Agreements

We have an oral agreement with our interim President and Chief Executive Officer, or CEO, providing that, among other things, he receive an annual salary during his tenure as interim CEO, with a minimum salary to be paid in the event that he is replaced by a successor CEO less than six months after the beginning of his tenure in February 2009. The employment agreement with our Chief Operating Officer, or COO, is through December 2010. In the event of termination without cause of the COO's contract, as defined therein, that employment agreement provides up to one year's continued salary as then in effect, in addition to any earned incentive compensation. Upon consummation of a change in control of the Company, as defined, the COO 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 0.33% to 1.4%.

(d) Clinical Trials

We have commitments to third parties in excess of amounts accrued. While these commitments are not significant, we expect to spend significant amounts in our clinical trials.

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 $30 million through completion of the trial and submission to the FDA. Of this total, approximately $22.6 million was incurred through 2008, and approximately $5.3 million was incurred during 2008. We currently project 2009 costs to approximate $4.6 million. On March 2, 2007, we participated in a public and private FDA advisory panel meeting to discuss the current status of the ongoing PFO/stroke trials being sponsored by us and other companies. At the close of the meeting, both the FDA and advisory panel concurred that only randomized, controlled trials would provide the necessary data to be considered for premarket approval, or PMA, for devices intended for transcatheter PFO closure in the stroke and TIA indication. During a private session, we provided the FDA and advisory panel with a revised study hypothesis and statistical plan to complete the CLOSURE I study as a randomized controlled trial.

On April 23, 2007, we announced that we received conditional approval from the FDA for our revised study hypothesis and statistical plan in the CLOSURE I PFO/stroke and TIA trial in the U.S. Subsequent to this meeting, a review of the revised plan and a look at the interim data was performed by the Data Safety Monitoring Board. Based on these analyses, the conditional probability of a statistically significant benefit will require an enrollment of 900 patients. Patient enrollment was completed in October 2008. We are currently working with the CLOSURE I Executive Committee, independent statistical experts and the FDA to determine an appropriate time interval to perform the study data analysis. The decision related to the data analysis timing will be determined by an evaluation of the number of recurrent events and the timing of these events and will be performed by a panel of independent statistical experts on blinded data. If the number and timing of events indicate that it is statistically appropriate to do so, data analysis will be interpreted in the fourth quarter of 2009. The Company would then expect to submit a PMA for the stroke and TIA indication to the FDA in the first quarter of 2010, one year earlier than the current plan.

BEST

In June 2005, we received approval in the United Kingdom for our BioSTAR® Evaluation STudy, or 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 of 2005. The goal of our BEST study was to secure European commercial approval for our novel BioSTAR® technology through the Conformité Europeene, or CE Mark, process. The approval was received in June 2007. We also received a medical device license from Health Canada in June 2007. Total costs of this study, including third party contracts and agreements with clinical sites and other service providers, were $1.4 million.

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 12,000 members in the United Kingdom. Total costs of this trial, which was completed in 2006, including third party contracts and agreements with clinical sites and other service providers, were approximately $4.9 million.

MIST II

In September 2005, we received conditional approval from the FDA for an IDE to initiate enrollment in our pivotal PFO/migraine clinical study, named MIST II. MIST II was initially designed to be a prospective, randomized, multi-center, controlled study. In August 2006, utilizing data from our MIST and BEST (BioSTAR® Evaluation STudy) trials, we received conditional approval from the FDA for modifications we requested to the IDE. These changes included adjustment to the primary endpoint for the study from resolution to reduction of migraine headaches and an upgrade to the implant used in the study from STARFlex® to our new bioabsorbable BioSTAR®. MIST II was a double-blinded trial designed to randomize approximately 600 migraine patients with a PFO to either structural heart repair with our BioSTAR® technology or a control arm.

In January 2008, we announced that we were closing down this clinical study in order to focus our resources on the PFO/stroke opportunity. When we announced the decision, we ceased patient enrollment in MIST II, which was being conducted at 20 centers in the U.S. Due to strict enrollment requirements, MIST II had little likelihood of being completed in a reasonable timeframe. More than 1,400 patients had been screened for enrollment in the trial, but only two patients met the requirements to be randomized. Approximately $3.9 million was incurred for MIST II.

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. Of this total, approximately $1.1 million was incurred through 2008.

(e) Guarantees and Indemnifications

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.

(7) 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, or 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, or 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 us 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 (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. There are no Rights outstanding as of December 31, 2008.

(8) STOCK OPTIONS

Our 1996 Stock Option Plan, 1998 Stock Incentive Plan, 2001 Stock Incentive Plan and 2007 Stock Incentive Plan, or 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 Joint Compensation and Options Committee of our 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, 2008 there were 1,702,463 options outstanding and 502,907 options available for grant under the 2001 and 2007 Plans. There can be no additional grants under the 1996 and 1998 Plans as these plans have expired.

Our 1996 Stock Option Plan for Non-Employee Directors, or 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 8,000 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. Also, the Lead Director and Chairman of the Board are granted an additional option to purchase 2,000 and 5,000 shares, respectively. At December 31, 2008 there were 162,300 options outstanding under the Directors Plan. There can be no additional grants under this plan, as this plan has expired.

All unexercised options expire ten years from date of grant.

The following table summarizes reconciliation of all stock option activity for the year ended December 31, 2008:

	Number of Shares of Common Stock Issuable Upon Exercise of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at January 1, 2008	1,731,807	$ 7.40		
Granted	168,650	3.46		
Exercised	14,275	2.63		$20
Cancelled	183,719	8.32		
Options outstanding at December 31, 2008	1,702,463	6.96	5.63	$ 2
Options vested or expected to vest at December 31, 2008	1,637,111	6.94	5.5	$ 2
Options exercisable at December 31, 2008	1,375,703	6.86	4.9	$—

The aggregate intrinsic value represents the pretax value (the period's closing market price, less the exercise price, times the number of in-the-money options) that would have been received by all option holders had they exercised their options at the end of the period.

The aggregate intrinsic value of options exercised during the years ended December 31, 2008, 2007 and 2006 was $20,000, $688,000 and $2.7 million, respectively.

Net cash proceeds from the exercise of stock options were $37,625 and $297,033 for the years ended December 31, 2008 and 2007, respectively.

The following table summarizes information about stock options at December 31, 2008:

	OUTSTANDING OPTIONS			EXERCISABLE OPTIONS	
	Shares	Weighted Average Remaining Life (in years)	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
$0.88 – 2.25	111,927	4.83	$ 1.53	71,927	$ 1.89
$2.26 – 3.50	290,449	4.26	3.16	290,449	3.16
$3.51 – 5.18	377,406	5.87	4.34	303,489	4.41
$5.19 – 7.80	407,574	4.17	6.66	364,985	6.65
$7.81 – 12.19	302,161	8.04	9.57	164,630	10.02
$12.20 – 15.92	24,534	7.66	15.15	10,779	15.15
$15.93 – 17.60	181,312	6.81	16.56	165,670	16.52
$17.61 – 23.21	7,100	6.80	20.02	3,774	20.04
$0.88 – 23.21	1,702,463	5.63	$ 6.96	1,375,703	$ 7.07

Employee Stock Purchase Plan

We offer an employee stock purchase plan, or 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 425,000 common shares have been reserved for issuance under the ESPP, as amended. At our 2006 annual meeting, our stockholders approved an amendment to our ESPP, as amended, to increase the number of shares of our common stock authorized for issuance from 275,000 to 425,000 shares. Employees purchased 95,974, 35,808 and 29,806 shares of common stock under the ESPP during the years ended December 31, 2008, 2007 and 2006, respectively. The average purchase prices for total ESPP shares acquired were $2.86, $8.58 and $11.16 for the years ended December 31, 2008, 2007 and 2006, respectively. At December 31, 2008, there were 9,465 shares available for issuance under the ESPP, as amended.

(9) SHARE-BASED COMPENSATION

The expense for share-based payment awards made to our employees and directors consisting of stock options issued based on the estimated fair values of the share-based payments on date of grant was recorded on the following lines in the consolidated statements of operations:

FOR THE YEAR ENDED DECEMBER 31,	2008	2007
Cost of product sales	$ 35,830	$ 36,118
Research and development	156,833	165,415
General and administrative	420,329	387,123
Selling and marketing	89,687	128,190
	$ 702,679	$716,846

We use the Black-Scholes option-pricing model to estimate fair value of share-based awards with the following weighted average assumptions:

	2008	2007	2006
Expected life (years)	4	4	4
Expected stock price volatility	57% - 69%	55% - 58%	58% - 63%
Weighted average stock price volatility	60.38%	56.19%	61.34%
Expected dividend yield	0	0	0
Risk-free interest rate	2.32% - 3.57%	3.28% - 4.07%	4.27% - 5.23%

The risk-free interest rate is based on U.S. Treasury interest rates whose term is consistent with the expected life of the stock options. Expected volatility, weighted average volatility and expected life are based on our historical experience. Expected dividend yield was not considered in the option pricing formula since we do not pay dividends and have no current plans to do so in the future. As required by SFAS 123R, we adjust the estimated forfeiture rate based upon actual experience. The expected life for options granted during the years ended December 31, 2008, 2007 and 2006 was based upon the actual forfeiture rate for the preceding four years, which resulted in an expected life equal to the vesting period. The weighted average grant-date fair value of options granted during the years ended December 31, 2008, 2007 and 2006 was $1.68, $9.25 and $14.89, respectively.

At December 31, 2008, there was $1.0 million of unrecognized compensation cost related to share-based payments that is expected to be recognized over a weighted-average period of fewer than four years.

SFAS 123R 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 APB No. 25. This requirement reduces reported operating cash flows and increases reported financing cash flows in periods after adoption. We have recorded net losses in 2008 and 2007 and have not recorded any tax benefits or tax deductions in those years.

(10) RELATED PARTY TRANSACTIONS

Pursuant to the terms of an exclusive license agreement with Children's Medical Center Corporation, or CMCC, we pay royalties on sales of our CardioSEAL®, STARFlex® and BioSTAR® products to CMCC. These payments were approximately $1.8 million for the year ended December 31, 2008. James E. Lock, M.D., a member of our Board of Directors and affiliated with CMCC, receives from CMCC a portion of these royalties.

(11) PREPAID EXPENSES AND OTHER CURRENT ASSETS AND ACCRUED EXPENSES

Prepaid expenses and other current assets consisted of the following:

AT DECEMBER 31,	2008	2007
Royalty receivable	$ 486,849	$ 2,447,337
Other	726,098	959,747
	$ 1,212,947	$ 3,407,084

Accrued expenses consisted of the following:

AT DECEMBER 31,	2008	2007
Clinical trials	$ 2,076,749	$ 2,438,606
Payroll and payroll related	642,534	706,427
Royalties	1,566,763	1,368,037
Professional Fees	461,985	361,296
Other accrued expenses	1,720,136	1,347,061
	$ 6,468,167	$ 6,221,427

(12) FINANCIAL INFORMATION BY GEOGRAPHIC AREA

Revenues by geographic area for the years ended December 31, 2008, 2007 and 2006 were as follows:

	2008	2007	2006
North America	$11,733,591	$ 21,084,910	$ 25,314,000
Europe	6,141,028	5,670,215	2,837,330
	$17,874,619	$ 26,755,125	$ 28,151,330

Net book value of long-lived assets by geographic area at December 31, 2008 and 2007 were as follows:

	2008	2007
United States	$ 926,054	$ 1,099,527
Other	2,639	4,018
	$ 928,693	$ 1,103,545

(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,	2008	2007
Balance at beginning of period	$ 161,341	$ 282,468
Provision for bad debt and sales returns adjustments	—	—
Write-offs and returns	(26,341)	(121,127)
Balance at end of period	$ 135,000	$ 161,341

(14) LEGAL PROCEEDINGS

In September 2004, we and the Children's Medical Center Corporation, or CMCC, filed a civil complaint in the U.S. District Court for the District of Minnesota, or the District Court, for infringement of a patent owned by CMCC and licensed exclusively to us. The complaint alleges that Cardia, Inc., or 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 District Court to prevent further infringement by Cardia, as well as monetary damages. On August 30, 2006, the District Court entered an order holding that Cardia's device does not infringe the patent-in-suit. The order had no effect on the validity and enforceability of the patent-in-suit and had no impact on our ability to sell our products. We appealed the ruling to the U.S. Court of Appeals for the Federal Circuit and on June 6, 2007 the Federal Circuit ruled that the District Court incorrectly interpreted one of the patent's claims and incorrectly found no triable issue of fact concerning other claims. The Federal Circuit remanded the case to the District Court for further proceedings consistent with its opinion and instructed that on remand the district court may reconsider the question of summary judgment for us and CMCC based on the Federal Circuit's claim construction. On November 8, 2007, the District Court granted summary judgment in our and CMCC's favor, ruling that Cardia's device infringes the patent-in-suit and striking all of Cardia's invalidity defenses. On March 19, 2008, we and CMCC agreed with Cardia to settle this litigation. As part of the settlement, a judgment was entered against Cardia and in favor of us and CMCC, with Cardia agreeing to pay $2.25 million. The settlement will be shared equally between us and CMCC after deduction of our legal fees and expenses. The first and second payments of $500,000 each were received on September 30, 2008 and December 15, 2008, and were recorded as a reduction to general and administrative expenses, to offset legal fees incurred in connection with this legal proceeding. The remaining $1.25 million in payments are due to be paid in 2009.

In December 2007, we commenced proceedings for defamation against Dr. Peter Wilmshurst in the English High Court. Dr. Wilmshurst has filed a defense to the claim arguing, inter alia, that the words alleged to be defamatory are true. A case conference is scheduled to take place late in the first quarter of 2009. If the matter proceeds to trial, this is likely to take place in 2010. Dr. Wilmshurst is reportedly seeking alternative sources of funding, including applying for state aid. If the case continues, we will be required to pay money into court by way of security for costs. The amount of security depends on whether Dr. Wilmshurst has the funds to pay for further legal representation. Our potential liability is to pay Dr. Wilmshursts' costs, if we either lose, or withdraw from, the proceedings.

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

(15) SUMMARY OF QUARTERLY DATA (UNAUDITED)

A summary of quarterly data follows (in thousands, except per share amounts);

FOR THE THREE MONTHS ENDED	MAR 31, 2008	JUN 30, 2008	SEP 30, 2008	DEC 31, 2008
Total revenues	$ 4,820	$ 4,463	$ 4,154	$ 4,438
Total costs and expenses	9,057	10,275	8,506	8,687
Loss from operations	(4,237)	(5,812)	(4,353)	(4,249)
Net loss	(3,894)	(5,625)	(4,351)	(4,206)
Net loss per share:				
Basic and diluted	$ (0.30)	$ (0.43)	$ (0.33)	$ (0.32)

FOR THE THREE MONTHS ENDED	MAR 31, 2007	JUN 30, 2007	SEP 30, 2007	DEC 31, 2007
Total revenues	$ 6,834	$ 6,472	$ 6,408	$ 7,041
Total costs and expenses	7,804	9,641	10,196	10,256
Loss from operations	(970)	(3,169)	(3,788)	(3,215)
Net loss	(336)	(2,636)	(3,200)	(2,930)
Net loss per share:				
Basic and diluted	$ (0.03)	$ (0.20)	$ (0.25)	$ (0.23)

CORPORATE DIRECTORY

BOARD OF DIRECTORS

James J. Mahoney, Jr.[1,2]
Chairman of the Board
of the Company,
President, Mahoney Group

Frank Martin
President and Chief Executive
Officer of the Company

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

Daniel F. Hanley, MD[1,2,3]
Professor of Neurology, Neurosurgery
and Anesthesia/Critical Medicine,
Professor, School of Nursing, the
Jeffrey and Harriett Legum Chair 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

David L. West, Ph.D., M.P.H.[1,3]
Vice President,
Quintiles Consulting

CORPORATE OFFICERS

Frank Martin
President and Chief Executive
Officer of the Company

Richard E. Davis
Chief Operating Officer and
Chief Financial Officer

ORGANIZATION

Carol A. Devellian
Vice President of
Research and Development

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

Brad Ryno
Vice President of
North American Sales

Ron Seyffert
Vice President of International
Sales and Marketing

Fred Tobia
Vice President of Clinical
and Regulatory Affairs

CORPORATE HEADQUARTERS

27 Wormwood Street
Boston, Massachusetts

FORM 10-K AVAILABILITY

A copy of the Annual Report on Form 10-K for the year ended December 31, 2008 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

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

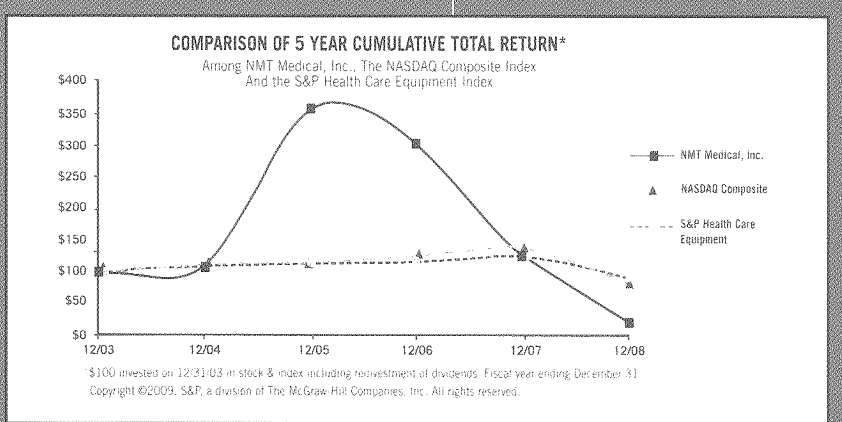
Deloitte & Touche LLP
Boston, Massachusetts

COUNSEL

Wilmer Hale
60 State Street
Boston, Massachusetts

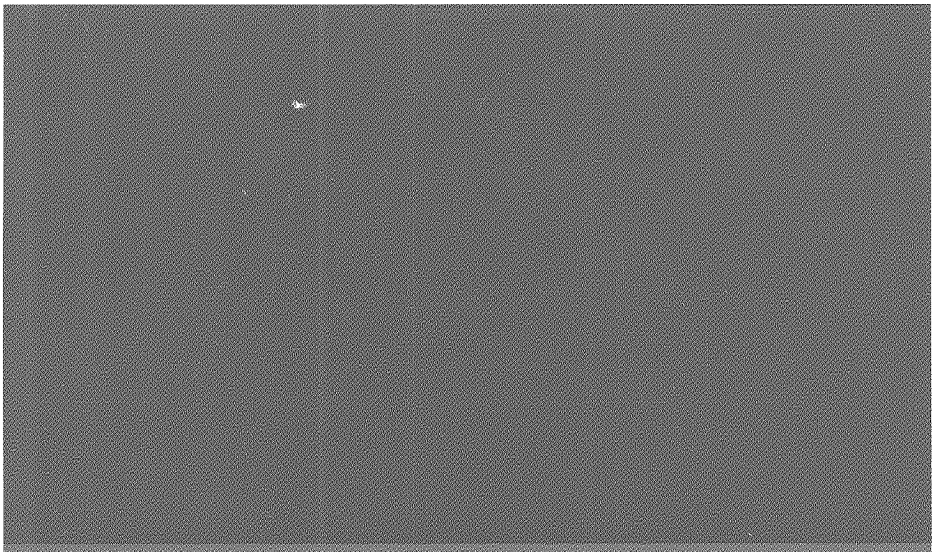
ANNUAL MEETING

The Annual Meeting of Stockholders will be held on June 4, 2009 at 1:00 pm, at the Corporate Headquarters, 27 Wormwood Street, Boston.



Committees of the Board

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



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