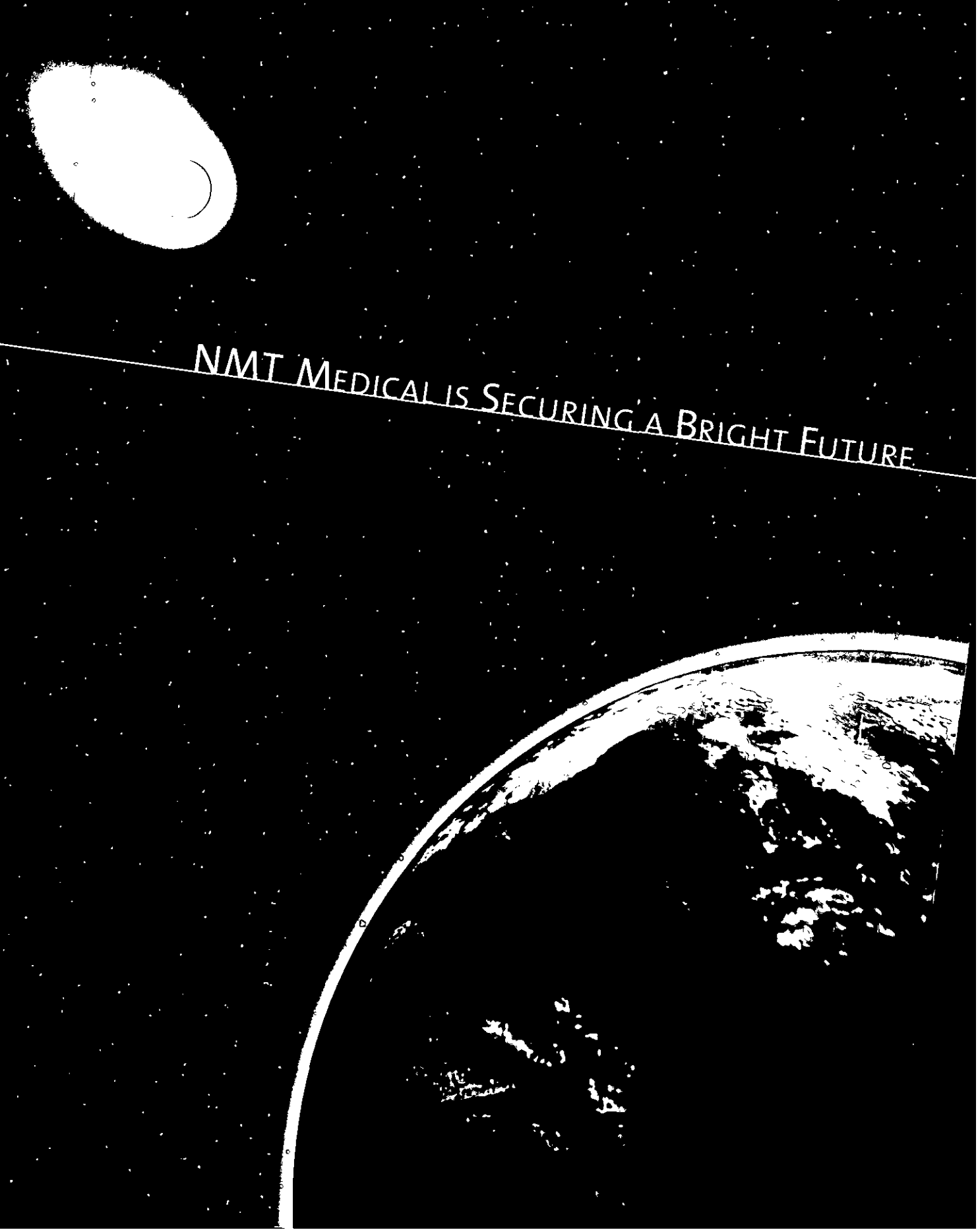
Annual Report 2006


# BRIGHT ON THE HORIZON

NMT Medical, Inc.



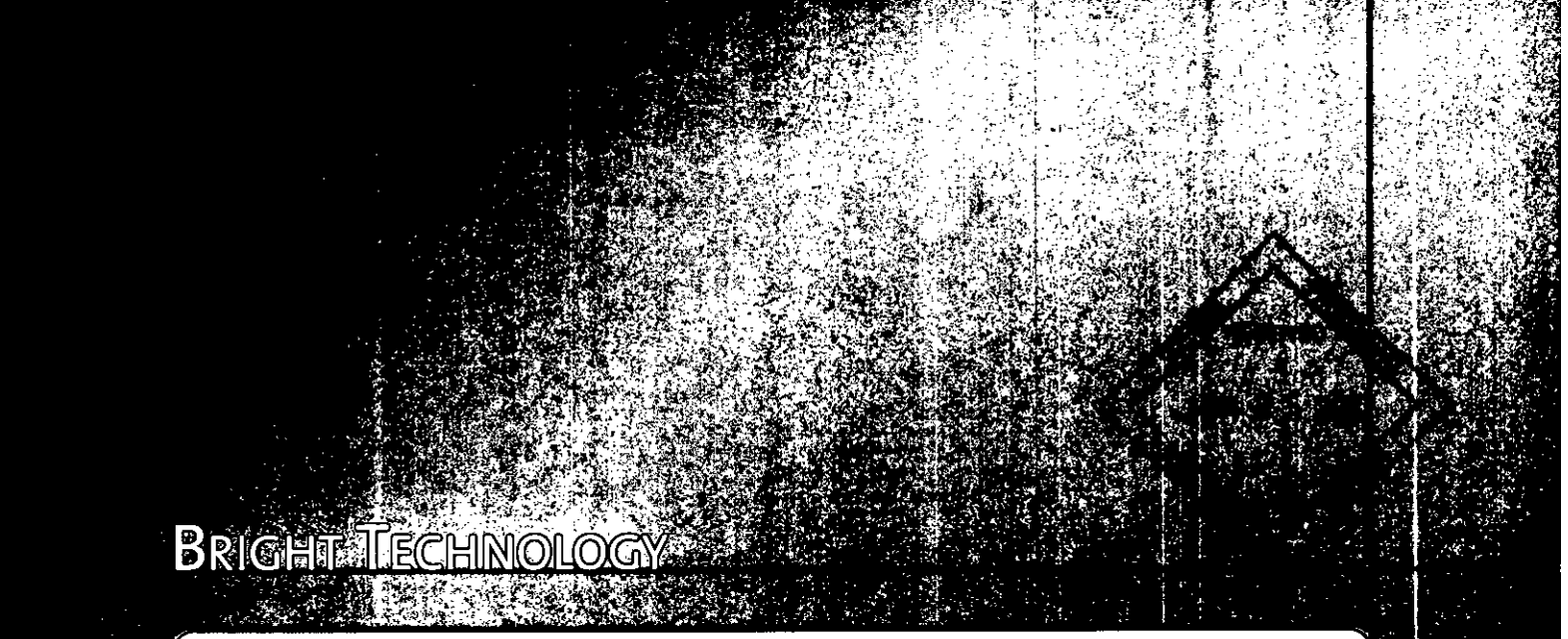
Bright on the horizon, there is hope for people suffering from strokes, migraines, and other attacks on the brain. For some, structural heart repair may be the key to a healthier life. NMT Medical is leading the emerging field of interventional repair of structural heart defects. With next generation technologies, ground-breaking clinical trials, and a close collaboration with the clinical community that inspires progressive treatment options, NMT Medical is securing a bright future for these patients.


NMT Medical is Securing a Bright Future

*"BioSTAR® is the first bioabsorbable septal implant. As demonstrated in a recent clinical trial, this leading edge technology demonstrated a more rapid and complete closure of atrial septal defects. Over time, the BioSTAR® scaffold will be replaced with the patient's native tissue."*

— Michael J. Mullen, MB, BS, MRCP, MD
Consultant Cardiologist, Royal Brompton Hospital, London, United Kingdom

The cardiac defect that may be a significant risk for strokes, transient ischemic attacks (TIAs) and migraine headaches is a right to left shunt of venous blood into the arterial circulation through a PFO, or patent foramen ovale. An incomplete closure in the septum between the left and right atria of the heart, a PFO can allow the venous blood, unfiltered and unmanaged by the lungs, to enter the arterial circulation of the brain, possibly triggering a cerebral event or brain attack.



# Bright Technology

With each generation of NMT Medical's cardiac septal repair technologies, the improvements aren't incremental. They are revolutionizing. BioSTAR®, the first bioabsorbable septal repair implant, and its in-development successor BioTREK™, are the most advanced technologies of their kind. BioSTAR® and BioTREK™ represent a convergence of pharmacology, biotechnology, and device engineering. It's a bright approach that yields industry-leading technology.

The clinical objectives for septal repair technologies are effectiveness, as measured by high closure rates, and safety, as measured by low complication rates. Many of the current septal repair concepts, both in commercial use and in clinical testing, have a number of limitations including low complete closure rates and late complications. In addition, the current technologies attempt to repair defects through fibrous encapsulation of the device or scar tissue formation, which may limit future access to the left atrium for treatment of acquired heart disease.

NMT Medical developed the BioSTAR® bioabsorbable septal repair implant to address the shortcomings. As evaluated in the BEST (BioSTAR® Evaluation STudy) clinical trial, the results of which were published in the October 2006 edition of *Circulation*, the official journal of the American Heart Association, BioSTAR® demonstrated closure rates at 30 days of 92%. This is a result that most of the currently competitive technologies can't achieve, even at six months post-treatment. At six months, BioSTAR® achieved a 96% closure rate. The published BioSTAR® study concluded, *"This study demonstrates the feasibility, safety, and effectiveness of BioSTAR® for the closure of ASD and PFO in humans with a high rate of early and complete shunt closure. BioSTAR® is a novel septal repair implant designed to provide biological closure of atrial-level defects using the patient's natural healing response. Because 90% to 95% of the implant is absorbed and replaced with healthy native tissue, future access to the left atrium may be achieved."*[1]

NMT's leadership in this field continues with the development of BioTREK™, a unique implant that is 100% bioabsorbable. Its base material is a biosynthetic polymer that seals the defect and then is absorbed as a noninflammatory natural metabolite.

BioTREK™ will represent an ideal approach to structural heart repair and is another example of NMT's commitment to pushing the boundaries of technology in the care of patients with structural heart disease.

*"By moving forward with CLOSURE I, the medical community will better understand the PFO/stroke risk and develop appropriate treatment strategies. The team at NMT Medical has shown leadership in supporting this landmark study to its completion."*

— Anthony J. Furlan, MD
Associate Director Cerebrovascular Center, Neurological Institute,
Cleveland Clinic, Cleveland, Ohio, and the Principal Investigator of CLOSURE I

# BRIGHT RESEARCH

In medicine, clinical trials are conducted for many reasons: to evaluate new technologies, devices and drugs, to evaluate the efficacy of a new intervention over accepted treatment, or to compare standard interventions. But all these reasons can be brought down to one word: answers. Answers to questions that can profoundly affect patients' lives. NMT Medical has taken on some difficult questions — Is there a PFO/migraine connection? What's the best treatment for recurrent stroke and TIA in young patients with a PFO and no other risk factors?

**STROKE & TIA TRIAL: CLOSURE I**

The best option for treating patients with PFO and previous stroke or transient ischemic attack (TIA) is a matter of debate among clinicians. Traditionally, warfarin has been the medical therapy of choice, although evidence to support its routine use is weak and the risk of bleeding with warfarin in this patient population has not been established.[2] The alternative to ongoing medical therapy may be PFO closure. NMT's CLOSURE I is the first approved prospective, multi-center, randomized controlled trial designed to bring a close to that debate. CLOSURE I will evaluate the safety and efficacy of the STARFlex® septal closure system versus best medical therapy in patients with a stroke and/or TIA due to presumed paradoxical embolism through a PFO. With enrollment of 800 patients almost complete, CLOSURE I is in line to be the first study to deliver a definitive evaluation of the safety and efficacy of medical therapy and closure. NMT Medical believes if PFO closure with STARFlex® is shown to be superior, then each year as many as 250,000 patients in the United States could potentially benefit.

*"NMT Medical sponsored and completed the first randomized, double-blind study to evaluate the connection between right to left shunts through a PFO and migraine headaches: MIST I. They have also taken the lead with two additional, important follow-on PFO/migraine studies now underway: MIST II and MIST III."*

— Andrew J. Dowson, MBBS, MRCGP, PhD
Director, Headache Service, Department of Neurology,
Kings College Hospital, London, United Kingdom,
and the Chief Investigator of MIST

# BRIGHT RESEARCH

**MIGRAINE TRIALS: MIST, MIST II AND MIST III**

There is a bright sign on the horizon for migraine sufferers. NMT Medical's clinical trial leadership is providing groundbreaking data demonstrating the positive treatment effect of PFO closure on migraine headaches.

The results of NMT's MIST (Migraine Intervention with STARFlex® Technology) study were presented at the American College of Cardiology's 55th Annual Scientific, late-breaking Clinical Trials Sessions on March 13, 2006. MIST, which was conducted in the United Kingdom, was the first prospective, randomized, double-blind study to evaluate the effect of PFO closure on migraine headaches. While preliminary analysis of MIST data did not satisfy the challenging primary endpoint, MIST investigators reported seeing a significant treatment effect and promising trend to support PFO closure with STARFlex® as a treatment option for certain types of migraine.

Encouraged by this initial success, NMT has moved ahead with MIST II, an FDA-approved pivotal study. The FDA approval included a primary endpoint of reduction of migraine headaches and the use of NMT's new bioabsorbable implant, BioSTAR®. MIST II's modified design will evaluate the safety and effectiveness of NMT's proprietary catheter-based implant technology for the treatment of migraine headaches in patients with a PFO.

In the UK, MIST III, a follow-on study to MIST, is ongoing. Patients who received the STARFlex® implant agreed to an additional 18 month follow-up, and those from the sham control group may choose to receive the implant and will be followed for two years. More than 90% of qualified patients who did not receive an implant in the original MIST study have received, or are scheduled to receive, an implant in the near future. This trend demonstrates that the migraine patient population is not satisfied with the current therapeutic options and makes the importance of these clinical trials even more apparent.

*"Even as BioSTAR® is being introduced to the market, NMT Medical has moved yet another bioabsorbable septal repair technology, BioTREK™, through the development process. Now in preclinical evaluation, BioTREK™ is a proprietary biosynthetic polymer designed to repair septal defects, absorb and be replaced with the patient's own cells."*

— Aaron V. Kaplan, MD
Associate Professor of Medicine (Cardiology) Dartmouth Medical School
and Director of Research, Cardiac Catheterization Laboratories,
Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire

# BRIGHT COLLABORATION

NMT Medical has a strong history of developing interdisciplinary partnerships to create and execute groundbreaking clinical studies and the development of superior treatment technologies. As an example, BioSTAR®, the first bioabsorbable septal repair technology, was developed by NMT Medical in Boston in close collaboration with a nearby biotechnology company. Preclinical evaluation was conducted over a two year period at a research facility in Germany. The first in man trial was completed at six leading cardiology centers in the United Kingdom and was recently approved by the FDA to be included in the MIST II PFO/migraine study at 25 leading centers in the United States.

The CLOSURE I clinical trial involves over 150 neurologists and interventional cardiologists working together for the first time in a landmark study at over 80 centers in the United States and Canada. Supporting CLOSURE I are numerous interactive teams of clinical support personnel and biostatisticians.

As a leader in the field of structural heart repair, NMT is continuing to leverage its legacy of forging strong partnerships. New clinical specialists such as pulmonologists are involved with the company in exploring additional indications for its technologies. Leading technology companies — biotechnology, pharmaceutical and device — are collaborating with NMT on advanced development projects. **It's a bright future.**

# BRIGHT FUTURE

**TO OUR PATIENTS, CLINICAL PARTNERS, EMPLOYEES AND INVESTORS:**

The past year was a landmark period for NMT Medical, as we accomplished several important clinical, regulatory and technology milestones. During 2006, we completed the BEST clinical trial which involved our new BioSTAR® bioabsorbable septal repair technology. The exciting and positive data from BEST (BioSTAR® Evaluation STudy) received expedited review and was published in the October 2006 edition of *Circulation*, the official journal of the American Heart Association. We currently anticipate commercial approval to launch BioSTAR® in Europe and Canada very soon. As previously reported, BioSTAR® has also been conditionally approved by the U.S. Food and Drug Administration (FDA) for inclusion in MIST II, our PFO/migraine trial underway in the United States.

Also during the year, we made important progress in our ongoing CLOSURE I clinical trial which is evaluating the effectiveness of our STARFlex® septal implant technology compared to medical therapy in stroke and TIA (transient ischemic attack) patients. With study enrollment now at over 650 patients and the recent FDA approval of our revised statistical plan, we now expect to complete enrollment in CLOSURE I by year end 2007. We believe NMT Medical will be the first to complete a randomized, controlled trial for this indication.

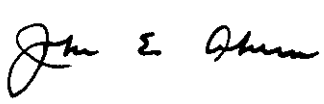
Additional progress was made with NMT Medical's three PFO/migraine studies. We expect the full results of MIST (Migraine Intervention with STARFlex® Technology) to be published in the near future. MIST III, a follow-on study to MIST, is ongoing in the United Kingdom. MIST II, the pivotal U.S. PFO/migraine study, was redesigned, with approval from the FDA, based on the outcome data from the predicate MIST trial. In addition, the FDA has allowed NMT to include its latest closure technology, BioSTAR®, in MIST II.

On the technology front, we completed additional pre-clinical research on another bioabsorbable implant, BioTREK™. Like BioSTAR®, BioTREK™ is designed to elicit a natural, biological repair response. BioTREK™ is a unique device that is 100% absorbed as a noninflammatory natural metabolite. The base material in BioTREK™ is a biosynthetic polymer derived in a proprietary process that isolates the material from bacteria modified by recombinant DNA technology. The FDA recently approved the polymer for use in absorbable sutures.

We are very excited about the progress we made during the year with both the BioSTAR® and BioTREK™ research programs. We believe that these advanced technologies will provide NMT with continued technology leadership and a sustainable competitive advantage, which are essential to gaining and maintaining significant market share within this growing opportunity. Our intellectual property portfolio also expanded during the year. NMT now has ownership or exclusive license to 64 U.S. patent applications and corresponding foreign patents as well as ownership to over 73 pending U.S. patent applications and corresponding foreign patents.

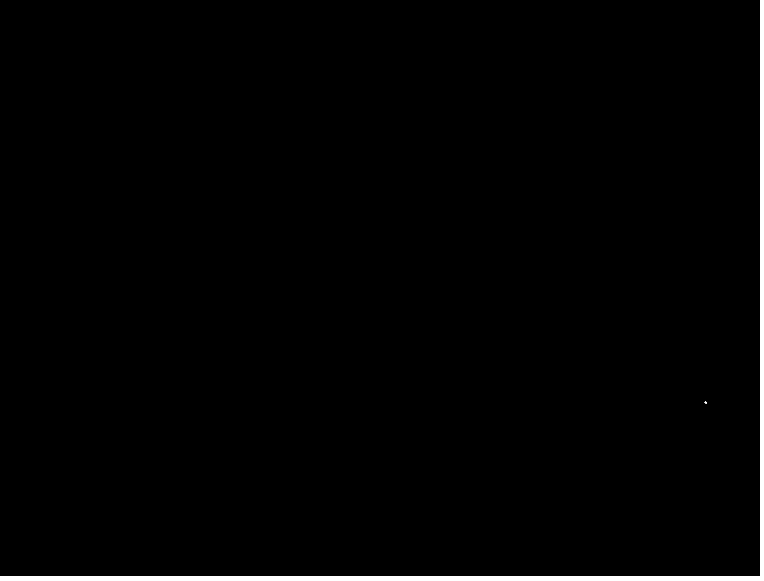
Financially, we also had a very successful year. We reported a 17% increase in total revenues and our strong balance sheet continues to give us the financial flexibility needed to expand our business. In late 2006 we announced the filing of a shelf registration statement for up to $65 million, which provides the opportunity to further accelerate our current and new technology initiatives, new clinical trials, and to further support product commercialization.

On all fronts, thanks to our clinical and technology partners and employees, NMT had a very good 2006. We all look forward to a bright future.



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

**Richard E. Davis**
Executive Vice President and
Chief Financial Officer



## *Financials*

# 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, 2006

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<br>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.

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the 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, 2006 was $124,843,108 based on the last reported sale price of registrant's Common Stock on the NASDAQ Global Market on that date, which was $10.01 per share.

As of March 6, 2007, there were 12,923,399 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 2007 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 certain kinds of cardiac structural heart disease through minimally invasive, catheter-based procedures. We are investigating the potential connection between a common cardiac defect that allows a right to left shunt or flow of blood through a defect like a patent foramen ovale, or a PFO, and brain attacks such as migraine headaches, embolic stroke, and transient ischemic attacks, or TIA. 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 utero, the PFO is an opening in the atrial wall that allows the mother's oxygenated blood to support the fetus. At birth, or usually by age one, the PFO completely closes, preventing venous blood and arterial blood from mixing. We believe that up to 25% of the population has a PFO that does not fully seal and most will never even know that they have this defect. Globally, more than 23,000 PFOs have been closed using our proprietary, 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 meetings of stockholders, initial reports of ownership and reports of changes in ownership of our common stock required to be filed pursuant to Section 16(a) of the 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 STARFlex® in Europe. We also re-sell third party products for use with the CardioSEAL® and STARFlex® implant devices, specifically vascular sizing balloons and sheaths. Since the second half of 2002, following completion of the transitional manufacturing agreement related to the sale of our former vena cava filter product line to C.R. Bard, Inc., or Bard, our cardiac septal repair implants have accounted for substantially all of our product sales. The aggregate of these product sales accounted for 78.6%, 80.8% and 80.5% of our total revenues for the years ended December 31, 2006, 2005 and 2004, respectively.

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

In the United States, we received 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 for 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. We recently 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. Over time, the BioSTAR® material is replaced by the body's own native tissue. During 2005, we completed our BEST (BioSTAR® Evaluation STudy) trial, and we anticipate receiving a CE Mark within the next few months.

**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 have filed for and currently anticipate receiving a CE Mark for our new BioSTAR® bioabsorbable, biological closure structural heart repair implant within the next few months.

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

## CLINICAL TRIALS

### 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. 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 14,000 members in the United Kingdom. Total costs of this trial, including third party contracts and agreements with clinical sites and other service providers, are currently estimated to be in the range of $4.7 to $4.9 million. Of this total, approximately $750,000 was incurred during 2006, and approximately $3.8 million was incurred through 2005. We currently estimate 2007 costs to be up to approximately $300,000.

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. Based upon our current direct sales force, our planned additional investments in that strategy and potential demand for our proprietary technology, we believe that we could gain a portion of this large market opportunity.

*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 is 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 is 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. The study incorporates our newest, most technologically advanced delivery system. More than 20 U.S. research centers are participating in MIST II, and enrollment began in January 2006. Patient follow-up will be over a one year period. We currently anticipate that when completed, study data from MIST II will be used to support a PFO PMA application. We currently estimate the costs of this clinical study to be in the range of $18 to $20 million through 2008. Of this total, approximately $1.7 million was incurred during 2006 and approximately $300,000 was incurred during 2005. We currently estimate 2007 costs to be approximately $14.6 million.

*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 completed during the fourth quarter of 2005. The goal of our BEST study is to secure European commercial approval for BioSTAR® through the CE Mark process which we anticipate receiving within the next few months. 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 recent 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. We currently estimate total costs of this study, including third party contracts and agreements with clinical sites and other service providers, to be in the range of $1.4 to $1.6 million. Of this total, approximately $370,000 was incurred in 2006 and approximately $900,000 was incurred in 2005. We currently estimate 2007 costs to be approximately $300,000.

*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, 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. We currently estimate the cost of MIST III to be approximately $1.7 million through 2007. Of this total, approximately $750,000 was incurred in 2006.

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

**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 each year because of their PFO, traditional therapeutic options have been lifetime medication or heart surgery. We believe that PFO closure using our proprietary implant technologies is an alternative treatment for a certain subset of patients and is another potentially large market opportunity for us.

In 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. Our CLOSURE I trial is expected to enroll approximately 1,600 patients at approximately 100 leading stroke and interventional cardiology centers in the United States, with half receiving a STARFlex® implant and the other half receiving drug therapy. Patient enrollment, which currently totals more than 600 patients, has progressed much slower than anticipated. We are continuing to work with our consultants, regulatory bodies and investigators to develop a course of action that will enable us to complete the CLOSURE I enrollment. We now believe that study changes, acceptable to the FDA, the investigators and us, are necessary in order to successfully complete this study. Until these changes are approved, it is difficult to estimate the completion date. On March 2, 2007 the FDA held a public and private advisory panel meeting in order to discuss and subsequently make recommendations regarding the clinical trial design for PFO closure devices intended to reduce recurrent stroke. While the official recommendation has not yet been published, the FDA and advisory panel concurred that only randomized, controlled trials would provide the data necessary to be considered for pre-market approval. We provided the FDA and advisory panel our plan to complete the CLOSURE I study. Included in the plan is a protocol specified interim analysis of the study data. We are blinded to that data, but are able to ask if a revised statistical plan, under consideration by us and our investigators and advisors, is appropriately powered. If the revised plan is appropriate and approved by the FDA, we will be able to provide more accurate guidance on the time needed to complete enrollment. We expect to have this guidance within the next 90 days.

In April 2002, we filed a PMA application with the FDA for the use of our STARFlex® implant device for PFO closure in certain high risk patient populations, including the population currently served by the HDE PFO approval, using a subset of the data we used to obtain our VSD PMA in December 2001. At a September 2002 meeting of the Circulatory Systems Devices Panel of the FDA, the panel did not recommend approval of this PMA. Working closely with the FDA and experts from the neurology and interventional cardiology communities, we submitted to the FDA the clinical trial design for our PFO IDE. The trial is a prospective, multi-center, randomized, controlled clinical trial designed to evaluate the safety and efficacy of our STARFlex® septal closure system versus medical therapy in patients who have had a stroke and/or a TIA due to a presumed paradoxical embolism through a PFO. Patients will be evaluated periodically over a two-year period, during which time, safety and efficacy data, including recurrent event rates (i.e., stroke and/or TIA), will be collected for all patients. We have committed significant financial and personnel resources to the execution of our CLOSURE I clinical trial. Including contracts with third party providers, agreements with participating clinical sites, internal clinical department costs and manufacturing costs of the STARFlex® devices to be implanted, total costs are currently estimated to be approximately $24 million through completion of the trial and submission to the FDA. Of this total, approximately $4.5 million, $3.2 million and $3.7 million were incurred during 2006, 2005 and 2004, respectively. We currently project 2007 costs to approximate $4.0 to $4.5 million, largely dependent upon the rate of patient enrollment.

In August 2006, we announced that the FDA approved our CARS IDE. This study will supplement 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 Humanitarian Device Exemption, or 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, combined with our ongoing CLOSURE I trial, allows us to maintain two sources for PFO closure in the United States.

In addition, we are evaluating recent 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.

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

## OUR STRATEGY

Our primary strategic objectives for 2007 include:

- receiving a CE Mark for BioSTAR®;
- launching BioSTAR® in Europe;
- completing the study enrollment/consent for MIST II;
- making significant progress with the FDA relating to CLOSURE I redesign; and
- gaining additional acceptable clinical data from MIST that demonstrates positive clinical efficacy of PFO closure in certain migraine patients.

If the results of our MIST, MIST II, and MIST III studies confirm a PFO/migraine connection and there is clinical and patient acceptance of our technology, we currently believe that PFO closure for migraine would represent a substantial and more immediate revenue growth opportunity for us as compared to PFO closure for stroke. With a strong balance sheet, including approximately $41.4 million of cash, cash equivalents, and marketable securities at December 31, 2006, and anticipated revenue growth from outside the United States, we currently believe that we have the available financial resources to complete these regulatory and clinical activities and to continue our focus on technological improvements to our products and intellectual property positions.

## ROYALTY INCOME

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

*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.

Net royalty income accounted for 21.4%, 19.2% and 19.5% of our total revenues for the years ended December 31, 2006, 2005 and 2004, respectively.

## RESEARCH AND DEVELOPMENT

Our research and development organization included 34 persons as of December 31, 2006, with departmental groups dedicated to product development, regulatory and clinical affairs, and quality assurance. Total company-sponsored research and development expenses were approximately $15.5 million, $12.7 million and $8.0 million for the years ended December 31, 2006, 2005, and 2004, respectively. We do not have any customer-sponsored research and development activities. Of these totals, approximately $8.2 million, $7.5 million and $4.6 million for the years ended December 31, 2006, 2005 and 2004, respectively, were clinical trials costs.

### Product Development

During 2005, we completed enrollment in our BEST clinical trial and we currently anticipate receiving a CE Mark in the next few months. We are continuing to develop our advanced biological closure technology called BioTREK™. BioTREK™ represents our second biological closure technology and follows our BioSTAR® implant technology. BioTREK™ incorporates a unique biosynthetic material that uses the body's own regenerative capability to restore function naturally. We believe that BioTREK™ will provide a more natural, biological closure of structures within the heart, such as the PFO. Under a Phase I grant recently received from the National Institutes of Health, or NIH, specifically a Small Business Technology Transfer Program grant from the National Heart, Lung and Blood Institute, we have initiated preclinical evaluation of BioTREK™.

Additionally, the research and development group continues to invest in strengthening our intellectual property assets in all aspects of 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® and STARFlex® directly in key European markets and through select distributors in other parts of Europe. As of December 31, 2006, worldwide sales and marketing personnel consisted of 27 persons, of which 14 are in various locations in the United States and 13 were based in Europe. Our European employees are based in Germany, France, the United Kingdom, Benelux and Scandinavia. During 2007, we plan to continue to expand our presence to include Ireland, Spain and other European countries.

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 migraine and stroke, we have focused added resources on enhancing the referral process and helping neurologists and interventional cardiologists form the partnerships needed to diagnose and treat PFO. These are often the most challenging aspects of introducing a new technology and promoting a new therapeutic concept. We have sponsored joint meetings in both Europe and the United States that brought together the interventional cardiology and stroke neurology communities on the subject of prevention and treatment of cardiac sources of migraine headache and stroke.

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

## CUSTOMERS

Our customers are generally hospitals, clinics and other healthcare centers. 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, 2006, we had approximately 350 active customers worldwide to which we sell our CardioSEAL® and STARFlex® products directly.

No customer accounted for greater than 10% of product sales in any of the three years in the period ended December 31, 2006.

## MANUFACTURING

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

## COMPETITION

Four companies, AGA Medical Corp., 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, radiofrequency welding, suturing, abrasion, adhesives and other approaches.

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

We have initiated patent infringement claims against Cardia. See Item 3 (Legal Proceedings).

## PATENTS AND PROPRIETARY TECHNOLOGY

We seek to protect our technology through the use of patents, trademarks and trade secrets. We are the owner or licensee of 64 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 70 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 2010 to 2023. 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 relating to our stents expire in 2012, the patents for our distal protection system expire from 2019 to 2023, the patent for our nitinol septal repair device expires in 2016, and the patent for our superelastic hinge joint, a novel concept with applicability to both implants and delivery systems, expires in 2017.

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 2010 to 2021, 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 nine trademarks, five of which are registered with the United States Patent and Trademark Office (see the following table).

| Trademark | Jurisdiction | Status | Renewal Date |
|---|---|---|---|
| STARFlex® | United States | Registered | Aug 2012 |
| STARFlex® | Canada | Registered | Sep 2020 |
| STARFlex® | European Community | Registered | Feb 2011 |
| STARFlex® | Japan | Registered | Jun 2014 |
| NMT Medical® | United States | Registered | Apr 2011 |
| NMT Medical® | Canada | Registered | Jan 2018 |
| CardioSEAL® | United States | Registered | Jan 2008 |
| Rapid Transport® | European Community | Registered | Aug 2013 |
| BioSTAR® | United States | Registered | Jun 2016 |
| BioSTAR® | European Community | Registered | Apr 2014 |
| BioSTAR® | Japan | Registered | Oct 2015 |
| Gator® | European Community | Registered | Apr 2014 |
| Elegant Solutions® | United States | Registered | Aug 2009 |
| At The Heart of Brain Attacks® | European Community | Registered | Sep 2015 |
| BioTREK® | Japan | Registered | Feb 2016 |
| BioSTAR™ | Canada | Pending | — |
| Gator™ | United States | Allowed | — |
| Gator™ | Canada | Pending | — |
| Gator™ | Japan | Pending | — |
| At The Heart of Brain Attacks™ | United States | Published | — |
| At The Heart of Brain Attacks™ | Canada | Pending | — |
| BioTREK™ | United States | Pending | — |
| BioTREK™ | Canada | Pending | — |
| BioTREK™ | European Community | Pending | — |

## LICENSED TECHNOLOGY; ROYALTY OBLIGATIONS

*Cardiac Septal Repair Implants*

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

*Vena Cava Filters*

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

*Stents*

We pay a royalty equal to 2.5% of net royalties received from BSC to a former employee of ours and joint inventor of our stent technology. These payments are reported in our consolidated financial statements as a reduction of royalty income.

## 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 devices are classified automatically by statute into Class III without any FDA rulemaking process, and may be marketed with a 510(k) until the FDA issues a final classification regulation requiring the submission of a PMA. The FDA is directed by statute to either down-classify pre-amendment Class III devices to Class I or II, or to publish a classification regulation retaining the device in Class III. In reclassifying these devices, the FDA considers data, including adverse safety and effectiveness information, submitted by manufacturers of pre-amendment Class III devices for which no final regulation has been issued. If the FDA calls for a PMA for a pre-amendment Class III device, a PMA must be submitted for the device even if it has already received 510(k) clearance. If the FDA down-classifies a pre-amendment Class III device to Class I or Class II, a PMA application is not required. Post-amendment Class III devices that are substantially equivalent to pre-amendment Class III devices, and for which a regulation calling for an approved PMA has not been published, can be marketed with a 510(k). A PMA application must be supported by extensive data, including preclinical and clinical trial data, to prove the safety and effectiveness of the device. The FDA charges a fee for PMA reviews unless an exemption or waiver applies. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) codified the FDA's modular review approach, whereby applicants are allowed to submit discrete sections of the PMA for review after completion. Under the FDC Act, the FDA must review PMAs within 180 days.

If human clinical trials of a device are required, and if the device presents a "significant risk", the manufacturer of the device is required to file an IDE application with the FDA prior to commencing clinical trials. The IDE application must be supported by data, typically the results of animal and, possibly, mechanical testing. If the IDE application is approved by the FDA, human clinical trials may begin at a specific number of investigational sites with a maximum number of patients, as approved by the FDA. Sponsors of clinical trials may charge for an investigational device provided that such costs do not exceed the amount necessary to recover the costs of manufacture, research, development and handling of the investigational device. The clinical trials must be conducted under the auspices of an independent IRB established pursuant to FDA regulations. If one or more IRBs determine that a clinical trial involves a "nonsignificant risk" device, the investigation is considered to have an approved IDE if certain conditions are met, including, for example, IRB approval of the investigation and compliance with informed consent requirements. The sponsor of a study involving a nonsignificant risk device does not need to obtain FDA approval of an IDE application before beginning the study.

After approval or clearance of a device, numerous regulatory requirements apply. These include establishment registration and device listing as well as requirements relating to labeling and corrections and removals reporting. The FDA also requires that all device manufacturers comply with the Quality System Regulation, 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 MIST II and CLOSURE I trials are being conducted under FDA approved IDEs with Category B HCFA status, meaning usage under the trial is eligible for Medicare coverage.

## FINANCIAL INFORMATION ABOUT GEOGRAPHIC AREAS

Please see Notes 2(l) and 13 of Notes to Consolidated Financial Statements for certain of our financial information concerning geographic areas.

## PRODUCT LIABILITY AND INSURANCE

Our business involves the risk of product liability claims. We maintain product liability insurance with coverage limits of $10 million per occurrence on a claims made basis and an umbrella policy of $5 million.

## EMPLOYEES

As of December 31, 2006, we had 115 full-time employees. We believe that we maintain good relations with our employees.

## 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.*

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

We derive a substantial portion of our ongoing revenues from sales of our CardioSEAL® and STARFlex® products. 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 either of these products would directly and adversely impact our business. These events or circumstances may include reduced demand for our products, lack of regulatory approvals, product liability claims and/or increased competition.

We were contacted by the FDA to review our existing HDE, which was approved more than six years ago. Since the HDE was approved, clinical conditions have significantly changed and the subset of patients who once qualified for consideration for PFO closure has increased beyond 4,000, the limit normally allowed under the HDE indication. Effective October 31, 2006, as a result and in connection with the CARS study, we voluntarily withdrew the HDE granted by the FDA on February 1, 2000 for our CardioSEAL® Septal Repair System for closure of PFO. At this time, we are unable to predict whether our action and the actions of the FDA will have a material positive or negative impact on our product revenue. The withdrawal does not reflect a device safety issue. CardioSEAL® will continue to be commercially available in the United States under the PMA indication for VSD.

### REVENUE GENERATED BY CARS IDE MAY BE LIMITED.

In August 2006, we received 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 both CARS and CLOSURE I 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 receive 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.

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

In September 2005, we received conditional approval from the FDA of an IDE to initiate enrollment in our pivotal PFO/migraine clinical study, named MIST II. In August 2006, utilizing analyzed data from MIST, the FDA granted conditional approval for modifications to the trial that we requested. These changes included adjustment to the primary endpoint for the study from resolution to reduction of migraine headache and upgrading the implant to the new BioSTAR®. Patient enrollment/consent, which commenced in January 2006, is currently estimated to be completed in 2007, with patient follow-up over a one-year period. We currently project the costs of this clinical study to be in the range of $18.0 to $20.0 million through 2008. We cannot be certain that this study will demonstrate an effective and sufficient treatment effect between PFO closure and migraine headaches utilizing our proprietary technology. We cannot be certain that our preliminary cost estimates for MIST II will not need to be adjusted upwards significantly. Furthermore, we cannot be certain that we will ultimately obtain a PMA from the FDA based upon the final results of this study or whether further studies might be required by the FDA before consideration of a PMA. In addition, if patient

enrollment were to progress as rapidly as we experienced for our MIST UK study, we cannot be certain of the effect, if any, on the level of commercial sales of our CardioSEAL® products in the United States during the enrollment period.

## 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 UNCERTAINTIES WITH RESPECT TO THE EXECUTION, COST AND ULTIMATE OUTCOME OF BEST.

In June 2005, we received approval to initiate our BEST clinical study in the United Kingdom. We currently estimate total costs of this study, including third-party contracts and agreements with clinical sites and other service providers, to be approximately $1.4 to $1.6 million. Furthermore, we cannot be certain that we will secure European commercial approval for our BioSTAR® technology through the CE Mark process.

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

Upon receipt of final FDA approval, we commenced our CLOSURE I study in June 2003. Through the period December 31, 2006, the rate of patient enrollment has been disappointing. At the present time, we are working with our consultants, regulatory bodies and investigators to develop a course of action designed to enable us to complete the CLOSURE I enrollment. We now believe that study changes, acceptable to the FDA, the investigators and us, are necessary in order to successfully complete this study. Until these changes are approved and implemented, it is difficult to estimate the completion date. It is currently anticipated that when completed, study data from CLOSURE I will be used to support a PFO PMA application. We currently estimate the total costs of CLOSURE I to be approximately $24.0 million through completion of the clinical trial and submission to the FDA. We have no direct experience conducting a clinical trial of this magnitude. We cannot be certain that patient enrollment will be completed at all. We cannot be certain that the projected costs of CLOSURE I will not need to be adjusted upwards, primarily related to the extended enrollment period. Furthermore, we cannot be certain that we will obtain a PMA from the FDA based upon the final results of the trial. If CLOSURE I does not result in a PMA, we may face uncertainties and/or limitations as to the continued growth of revenues of our CardioSEAL® and STARFlex® products, which may impact our profitability.

## WE 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.

## 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.

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

In the future, considering our anticipated significant spending on clinical trials, we may require additional funds for our research and product development programs, regulatory processes, preclinical and clinical testing, sales, marketing and manufacturing infrastructure and programs and potential licenses and acquisitions. On October 19, 2006, we announced that we filed a shelf registration statement on Form S-3 with the SEC. If the shelf registration statement is effective, it will permit us to offer and sell up to $65 million of equity or debt securities. Any additional equity financing may be dilutive to our stockholders, and additional debt financing, if available, may involve restrictive covenants. Our capital requirements will depend on numerous factors, including the level of sales of our products, the progress of our research and development programs, the progress of clinical testing, the time and cost involved in obtaining regulatory approvals, the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, competing technological and market developments, developments and changes in our existing research, licensing and other relationships and the terms of any collaborative, licensing and other similar arrangements that we may establish. We do not currently have any existing line of credit arrangements, and we may not be able to obtain any such credit facilities on acceptable terms, if at all.

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

In November 2004, we received approval to initiate our MIST clinical study in the United Kingdom. This study was designed to evaluate the effectiveness of structural heart repair (transcatheter closure of a PFO) in the treatment and prevention of migraine headaches. Patient enrollment was completed in early July 2005, with follow-up evaluations over a six-month period. 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 also indicated that approximately 42% of the patients treated with our STARFlex® technology had a reduction in migraine headache days of at least 50%. We currently estimate the total costs of MIST, including third-party contracts, agreements with clinical sites and other service providers, to be approximately $4.7 to $4.9 million. While the results of MIST represented proof of concept and a statistically significant treatment effect, we cannot be certain of the market acceptance of PFO closure as a treatment for certain migraine patients in Europe. Patients enrolled in MIST have an opportunity to consent to be treated and/or monitored as part of a follow-up study (MIST III).

## 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. Our future sales growth and financial results depend almost exclusively upon the growth of sales of this product line. CardioSEAL®, BioSTAR®, and STARFlex® product sales may not grow as quickly as we expect for various reasons, including, but not limited to, delays in receiving further FDA approvals for additional indications and product enhancements, difficulties in recruiting additional experienced sales and marketing personnel and increased competition. This focus has placed significant demands on our senior management team and other resources. Our future success will depend on our ability to manage and implement our focused business strategy effectively, including:

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

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

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

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

Furthermore, we cannot be certain that others have not or will not develop similar products, duplicate any of our products or design around any patents issued, or that may be issued, in the future to us or to our licensors. Whether or not patents are issued to us or to our licensors, others may hold or receive patents which contain claims having a scope that covers products developed by us. We could incur substantial costs in defending any patent infringement suits or in asserting any patent rights, including those granted by third parties. In addition, we may be required to obtain licenses to patents or proprietary rights from third parties. There can be no assurance that such licenses will be available on acceptable terms, if at all.

Our issued U.S. patents, and corresponding foreign patents, expire at various dates ranging from 2010 to 2023. When each of our patents expires, competitors may develop and sell products based on the same or similar technologies as those covered by the expired patent. We have invested in significant new patent applications, and we cannot be certain that any of these applications will result in an issued patent to enhance our intellectual property rights.

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

For the year ended December 31, 2006, net royalty income increased approximately 31% over the comparable period ended December 31, 2005. Net royalty revenue for the year ended December 31, 2006 included $500,000 related to the AGA settlement and the issuance of a sublicense to AGA. Excluding the amount related to the AGA settlement, net royalty revenue increased approximately 20%. Net royalty income accounted for 21.4%, 19.2% and 19.5% of our total revenues for the years ended December 31, 2006, 2005 and 2004, respectively. This increase has been directly attributable to higher sales by Bard of its RNF product, for which Bard received FDA approval for commercial sales and use as of December 31, 2002. We cannot be certain that the recent trend of Bard's RNF sales can be sustained or even maintained at its current level. Furthermore, these sales levels could fluctuate on a quarter-to-quarter basis. We incur virtually no operating expenses related to our net royalty income and, therefore, future increases or decreases, if any, in the level of Bard's RNF sales could have a material effect on net income (loss) in future periods. In addition, commencing in the fourth quarter of 2007, the royalty rate earned on Bard's RNF sales will decrease substantially from its current rate and may result in a net royalty expense.

## 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, financial condition and results of operations.

The FDA and other regulatory authorities require that our products be manufactured according to rigorous standards including, but not limited to, Good Manufacturing Practices and International Standards Organization, 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.

## 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. Since 2001, we have increased our combined U.S. and European sales and marketing organization headcount from 9 to 27. Because we had marketed our initial products, such as stents and vena cava filters, through third parties, we have limited experience marketing our products directly. We are uncertain that we can successfully expand geographically in Europe or other potential markets for our products. In order to market directly the CardioSEAL® and STARFlex® septal implants and any related products, we will have to continue to develop a marketing and sales organization with technical expertise and distribution capabilities.

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

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

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

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

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

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

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

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

### OUR EXPANDING EUROPEAN OPERATIONS EXPOSE US TO RISK INHERENT IN FOREIGN OPERATIONS.

As we increase our presence in Europe following the anticipated receipt of a CE Mark for our BioSTAR® technology, the impact of foreign currency fluctuations on our revenue and expenses could have an adverse impact on our worldwide 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 currently lease approximately 35,000 square feet of manufacturing, laboratory and administrative space at this facility, under leases that expire in September 2010, with one 5-year renewal option thereafter. The renewal option is subject to acceptance by the landlord.

## ITEM 3. LEGAL PROCEEDINGS

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

In September 2004, we and CMCC filed a civil complaint in the U.S. District Court for the District of Minnesota for infringement of a patent owned by CMCC and licensed exclusively to us. The complaint alleges that Cardia, of Burnsville, Minnesota is making, selling and/or offering to sell a medical device in the United States that infringes CMCC's U.S. patent relating to a device and method for repairing septal defects. We sought an injunction from the court to prevent further infringement by Cardia, as well as monetary damages. On August 30, 2006, the Court entered an order holding that Cardia's device does not infringe the patent-in-suit. The order has no effect on the validity and enforceability of the patent-in-suit and has no impact on our ability to sell our products. We have appealed the ruling to the U.S. Court of Appeals for the Federal Circuit where we seek to have the decision overturned.

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

On November 2, 2005, we filed an amended complaint adding the inventor of the '420 patent as a plaintiff. On November 3, 2005, AGA answered our amended complaint, denying liability and counterclaiming that the '420 patent is invalid, unenforceable, and not infringed. On November 17, 2005, we answered AGA's counterclaims by denying them.

On 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 has been 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. On April 12, 2006, we received the entire cash payment from the settlement totaling $30.0 million. The cash payment was shared equally, after our legal fees and expenses, with Dr. Marks.

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

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

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

# PART II

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

Our common stock is quoted on the NASDAQ Global Market under the symbol "NMTI". There were approximately 100 stockholders of record of our common stock on March 6, 2007, representing approximately 15,000 shareholder accounts. The following table lists the high and low closing sales prices for our common stock for the periods indicated.

| PERIOD | HIGH | LOW |
|---|---|---|
| 2005 | | |
| First quarter | $ 8.22 | $ 4.19 |
| Second quarter | 10.22 | 6.85 |
| Third quarter | 12.20 | 7.30 |
| Fourth quarter | 21.79 | 9.83 |
| 2006 | | |
| First quarter | $25.76 | $13.29 |
| Second quarter | 15.62 | 9.22 |
| Third quarter | 16.35 | 9.93 |
| Fourth quarter | 16.15 | 13.53 |

We did not declare or pay any cash dividends on shares of our common stock during the years ended December 31, 2006 and 2005 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 relating to the compensation plans under which our equity securities are authorized for issuance is set forth under "Equity Compensation Plan Information" in our definitive proxy statement for our 2007 Annual Meeting of Stockholders.*

## ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data for each of the five years in the period ended December 31, 2006 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.

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

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

| | 2006 | 2005 | 2004 | 2003 | 2002 |
|---|---|---|---|---|---|
| **STATEMENT OF OPERATIONS DATA:** (In thousands, except per share data) | | | | | |
| Revenues: | | | | | |
| Product sales | $22,135 | $19,313 | $17,279 | $21,574 | $24,546 |
| Net royalty income | 6,016 | 4,603 | 4,181 | 1,387 | 413 |
| Total revenues | 28,151 | 23,916 | 21,460 | 22,961 | 24,959 |
| Costs and expenses: | | | | | |
| Cost of product sales | 5,938 | 5,470 | 4,514 | 5,303 | 6,606 |
| Research and development | 15,455 | 12,746 | 8,045 | 6,340 | 4,990 |
| General and administrative | 8,681 | 7,982 | 6,024 | 6,167 | 6,050 |
| Selling and marketing | 8,704 | 6,340 | 5,542 | 5,614 | 5,446 |
| Settlement of litigation | — | — | — | 1,216 | — |
| Total costs and expenses | 38,778 | 32,538 | 24,125 | 24,640 | 23,092 |
| Gain on sale of product line | — | — | — | — | 7,000 |
| Net gain from settlement of litigation | 15,184 | — | — | — | — |
| Income (loss) from operations | 4,557 | (8,622) | (2,665) | (1,679) | 8,867 |
| Other income (expense): | | | | | |
| Currency transaction gain (loss) | 15 | (122) | 92 | 81 | 81 |
| Interest expense | — | — | (2) | (5) | (10) |
| Interest income | 1,816 | 861 | 543 | 558 | 691 |
| Total other income, net | 1,831 | 739 | 633 | 634 | 762 |
| Income (loss) before provision for income taxes | 6,388 | (7,883) | (2,032) | (1,045) | 9,629 |
| Provision for income taxes | 502 | — | — | 105 | 3,424 |
| Income (loss) from continuing operations | 5,886 | (7,883) | (2,032) | (1,150) | 6,205 |
| Discontinued operations: | | | | | |
| Income (loss) from discontinued operations | — | 91 | 123 | — | (40) |
| Gain on sale of discontinued operations | — | — | — | — | 4,914 |
| Gain from discontinued operations | — | 91 | 123 | — | 4,874 |
| Net income (loss) | $ 5,886 | $ (7,792) | $ (1,909) | $ (1,150) | $11,079 |
| Basic net income (loss) per common share: | | | | | |
| Continuing operations | $ 0.46 | $(0.64) | $ (0.17) | $ (0.10) | $ 0.54 |
| Discontinued operations | — | 0.01 | 0.01 | — | 0.42 |
| Net income (loss) | $ 0.46 | $(0.63) | $ (0.16) | $ (0.10) | $ 0.96 |
| Diluted net income (loss) per common share: | | | | | |
| Continuing operations | $ 0.43 | $ (0.64) | $ (0.17) | $ (0.10) | $ 0.51 |
| Discontinued operations | — | 0.01 | 0.01 | — | 0.40 |
| Net income (loss) | $ 0.43 | $ (0.63) | $ (0.16) | $ (0.10) | $ 0.91 |
| Weighted average common shares outstanding: | | | | | |
| Basic | 12,746 | 12,332 | 12,031 | 11,808 | 11,542 |
| Diluted | 13,597 | 12,332 | 12,031 | 11,808 | 12,119 |

| AT DECEMBER 31, | 2006 | 2005 | 2004 | 2003 | 2002 |
|---|---|---|---|---|---|
| **BALANCE SHEET DATA:** | | | | | |
| (In thousands) | | | | | |
| Cash, cash equivalents, marketable securities and restricted cash | $41,450 | $31,506 | $35,380 | $36,725 | $36,244 |
| Working capital | 38,860 | 30,515 | 36,052 | 37,396 | 37,807 |
| Total assets | 51,183 | 40,490 | 43,364 | 44,122 | 45,093 |
| Stockholders' equity | 39,899 | 31,320 | 36,872 | 38,236 | 38,956 |

The following table presents our unaudited consolidated statements of operations data for each quarter in the two years ended December 31, 2006. The information for each of these quarters is unaudited, but has been prepared on the same basis as the audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. We believe that all necessary adjustments, consisting only of normal recurring adjustments, have been made to present fairly the unaudited quarterly results when read in conjunction with our audited consolidated financial statements and the notes thereto appearing elsewhere in this document. These operating results are not necessarily indicative of the results of operations that may be expected for any future period.

| FOR THE THREE MONTHS ENDED | DEC. 31 2006 | SEP. 30 2006 | JUN. 30 2006 | MAR. 31 2006 | DEC. 31 2005 | SEP. 30 2005 | JUN. 30 2005 | MAR. 31 2005 |
|---|---|---|---|---|---|---|---|---|
| **STATEMENT OF OPERATIONS DATA:** | | | | | | | | |
| (In thousands, except per share data (unaudited)) | | | | | | | | |
| Revenues: | | | | | | | | |
| Product sales | $ 5,838 | $ 5,314 | $ 5,284 | $ 5,700 | $ 5,098 | $ 4,926 | $ 5,164 | $ 4,125 |
| Net royalty income | 1,370 | 1,597 | 1,817 | 1,232 | 1,155 | 1,115 | 1,188 | 1,145 |
| Total revenues | 7,208 | 6,911 | 7,101 | 6,932 | 6,253 | 6,041 | 6,352 | 5,270 |
| Costs and Expenses: | | | | | | | | |
| Cost of product sales | 1,602 | 1,454 | 1,407 | 1,475 | 1,421 | 1,391 | 1,479 | 1,179 |
| Research and development | 4,405 | 3,484 | 3,736 | 3,830 | 3,400 | 3,451 | 3,386 | 2,509 |
| General and administrative | 2,569 | 1,873 | 2,014 | 2,224 | 2,533 | 1,997 | 1,632 | 1,820 |
| Selling and marketing | 2,418 | 1,920 | 2,293 | 2,074 | 1,812 | 1,483 | 1,629 | 1,416 |
| Total costs and expenses | 10,994 | 8,731 | 9,450 | 9,603 | 9,166 | 8,322 | 8,126 | 6,924 |
| Net gain from settlement of litigation | — | — | (25) | 15,209 | — | — | — | — |
| (Loss) income from operations | (3,786) | (1,820) | (2,374) | 12,538 | (2,913) | (2,281) | (1,774) | (1,654) |
| Total other income, net | 559 | 491 | 495 | 285 | 248 | 221 | 155 | 115 |
| (Loss) income from continuing operations before income taxes | (3,227) | (1,329) | (1,879) | 12,823 | (2,665) | (2,060) | (1,619) | (1,539) |
| Provision for income taxes | 452 | 50 | — | — | — | — | — | — |
| (Loss) income from continuing operations | (3,679) | (1,379) | (1,879) | 12,823 | (2,665) | (2,060) | (1,619) | (1,539) |
| Income from discontinued operations | — | — | — | — | — | — | 91 | — |
| Net (loss) income | $(3,679) | $(1,379) | $(1,879) | $12,823 | $(2,665) | $(2,060) | $(1,528) | $(1,539) |
| Basic earnings per common share: | | | | | | | | |
| Continuing operations | $ (0.29) | $ (0.11) | $ (0.15) | $ 1.02 | $ (0.21) | $ (0.17) | $ (0.13) | $ (0.13) |
| Discontinued operations | — | — | — | — | — | — | 0.01 | — |
| Net (loss) income | $ (0.29) | $ (0.11) | $ (0.15) | $ 1.02 | $ (0.21) | $ (0.17) | $ (0.12) | $ (0.13) |
| Diluted earnings per common share: | | | | | | | | |
| Continuing operations | $ (0.29) | $ (0.11) | $ (0.15) | $ 0.93 | $ (0.21) | $ (0.17) | $ (0.13) | $ (0.13) |
| Discontinued operations | — | — | — | — | — | — | 0.01 | — |
| Net (loss) income | $ (0.29) | $ (0.11) | $ (0.15) | $ 0.93 | $ (0.21) | $ (0.17) | $ (0.12) | $ (0.13) |
| Weighted average common shares outstanding: | | | | | | | | |
| Basic | 12,858 | 12,777 | 12,718 | 12,626 | 12,503 | 12,373 | 12,293 | 12,155 |
| Diluted | 12,858 | 12,777 | 12,718 | 13,747 | 12,503 | 12,373 | 12,293 | 12,155 |

## 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 certain kinds of cardiac structural heart disease through minimally invasive, catheter-based procedures. We are investigating the potential connection between a common cardiac 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 migraine headaches, embolic stroke, and transient ischemic attacks, or TIA. 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 utero, the PFO is an opening in the arterial wall that allows the mother's oxygenated blood to support the fetus. At birth, or usually by age one, the PFO completely closes, preventing venous blood and arterial blood from mixing. We believe that up to 25% of the population has a PFO that does not fully seal and most will never even know that they have this defect.

In 2001, our then new senior management team began divesting certain non-strategic assets in order to focus on this emerging PFO market opportunity utilizing our proprietary implant technologies. These divestitures included the November 2001 sale of our vena cava filter product line to Bard and the July 2002 sale of our neurosciences business unit to Integra. Net cash proceeds from these sales transactions of approximately $33.8 million, the related net royalty income from Bard that commenced in 2003 and the on-going business operations have provided us with the financial and operational flexibility to aggressively pursue this emerging market opportunity with our CardioSEAL® and STARFlex® implants, clinical research studies and development of next generation catheter-based implant technologies. More than 23,000 PFOs have been closed globally using our CardioSEAL® and STARFlex® implant technologies. We are currently conducting five PFO-closure related clinical research trials, focusing on PFO/migraine, PFO/stroke and our new proprietary BioSTAR® implant technology.

#### PFO/Migraine

The prevalence of migraines in the United States is estimated to be approximately 10% of the general population or roughly 28 million individuals. We estimate that 20% of all migraine sufferers, or 6 million individuals, have the classic form of migraine, sometimes referred to as migraine with aura. It has also been reported that 50% of these patients do not satisfactorily respond to current approved forms of medication. Furthermore, data as reported at the 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 twice what would be expected in the general population.

In 2005, we completed enrollment in our MIST study in the United Kingdom. Total costs for MIST are estimated to be in the range of $4.7 to $4.9 million, of which approximately $4.6 million was incurred through 2006. Study enrollment was completed in July 2005 and results were presented at the American College of Cardiology meeting on March 13, 2006.

In September 2005, we received conditional approval from the U.S. Food and Drug Administration, or FDA, of an Investigational Device Exemption, or IDE, to initiate enrollment in our pivotal PFO/migraine clinical study, named MIST II. MIST II is a prospective, randomized, multi-center, controlled study. In August 2006, utilizing data from our MIST and BioSTAR® Evaluation STudy , or BEST, 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®. The double-blinded trial is designed to randomize approximately 600 migraine patients with a PFO to either structural heart repair with our BioSTAR® technology or a control arm. The study will also incorporate our newest, most technologically advanced delivery system. More than 20 U.S. research centers have committed to participate in MIST II, and enrollment began in January 2006. Patient follow-up will be over a one year period. We currently anticipate that when completed, study data from MIST II will be used to support a PFO pre-market approval, or PMA, application.

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 $1.7 million through 2007, of which approximately $750,000 was incurred in 2006.

**PFO/Stroke**

Stroke is the third leading cause of death in the United States and the leading cause of disability in adults. Each year, approximately 750,000 Americans suffer a new or recurrent stroke and 500,000 Americans experience a TIA. In 2003, we launched the CLOSURE I clinical trial to compare our STARFlex® cardiac septal repair implant with current medical therapy in stroke prevention. CLOSURE I is a 1,600 patient, prospective, randomized, multi-center trial, for which we received complete IDE approval from the FDA in June 2003. Although more than 80 CLOSURE I clinical sites have enrolled patients, enrollment to date has progressed much slower than anticipated. We now believe that study changes, acceptable to the FDA, the investigators and us, are necessary in order to successfully complete this study. Until these changes are approved, it is difficult to estimate the completion date. On March 2, 2007 the FDA held a public and private advisory panel meeting in order to discuss and subsequently make recommendations regarding the clinical trial design for PFO closure devices intended to reduce recurrent stroke. While the official recommendation has not yet been published, the FDA and advisory panel concurred that only randomized, controlled trials would provide the data necessary to be considered for pre-market approval. We provided the FDA and advisory panel our plan to complete the CLOSURE I study. Included in the plan is a protocol specified interim analysis of the study data. We are blinded to that data, but are able to ask if a revised statistical plan, under consideration by us and our investigators and advisors, is appropriately powered. If the revised plan is appropriate and approved by the FDA, we will be able to provide more accurate guidance on the time needed to complete enrollment. We expect to have this guidance within the next 90 days. We currently expect that total costs for CLOSURE I will be approximately $24 million through completion of the trial and submission to the FDA. Of this total, approximately $13.8 million was incurred through 2006, and we currently project 2007 costs to be approximately $4.0 to $4.5 million, largely dependent upon the rate of patient enrollment.

**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 recent 2006 Transcatheter Cardiovascular Therapeutics 18th Annual Scientific Symposium. The study was designed to gain commercial approval for BioSTAR® through the CE Mark process. Approval is currently expected within the next few months.

In January 2006, we announced that we received a Phase I grant from the National Institute 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.

**2006 Revenues**

Our 2006 revenues were predominantly derived from sales of our CardioSEAL® and STARFlex® products in the U.S. and Europe and net royalties earned from Bard. CardioSEAL® and STARFlex® product sales increased by approximately 15% from 2005 to 2006 and by 12% from 2004 to 2005. We believe that a combination of increased market awareness of PFO closure and targeted marketing efforts has resulted in the addition of new customers, predominantly in the United States. We currently expect an approximate 12 to 15% increase in worldwide CardioSEAL® and STARFlex® product sales from 2006 to 2007. This is highly dependent upon the timing of the anticipated CE Mark approval in Europe. Net royalties, which principally apply to Bard's worldwide sales of SNF and RNF products, were reported net of royalty payments to the estate of the original inventor. Net royalty income from Bard increased approximately 21% from 2005 to 2006 and 13% from 2004 to 2005, primarily as a result of increased sales of the RNF product, for which Bard received FDA regulatory approval for commercial sales and use as of December 31, 2002. We currently expect net royalty income earned from Bard through the third quarter of 2007 to remain consistent with 2006 levels. We currently do not anticipate any other material sources of revenues in 2007.

We ended 2006 with approximately $41.4 million in cash, cash equivalents and marketable securities, providing us with what we believe is the financial strength and flexibility to complete our clinical research initiatives and to continue to invest in additional research and development programs, regulatory activities and commercial sales efforts, including planned headcount and territory expansion in Europe.

## CRITICAL ACCOUNTING POLICIES

We have prepared our consolidated financial statements in accordance with accounting principles generally accepted in the United States. In preparing our consolidated financial statements, we make estimates, assumptions and judgments that can have a significant impact on our results of operations and the valuation of certain assets and liabilities on our balance sheet. These estimates, assumptions and judgments about future events and their effects on our results of operations cannot be made with

certainty, and are made based on our experience and on other assumptions that are believed to be reasonable under the circumstances. These estimates may change as new events occur or as additional information is obtained. While there are a number of accounting policies, methods and estimates affecting our financial statements described in Note 2 of Notes to Consolidated Financial Statements, our most critical accounting policies, described below, include: (i) revenue recognition; (ii) accounts receivable reserves; (iii) inventories; (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 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 1% of our product sales in 2006, are not subject to a right of return for unsold product.

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

*Accounts Receivable Reserves*

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

We also maintain a provision for estimated sales returns and allowances on product sales. We base these estimates on 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.

*Inventories*

In accordance with SFAS No. 151, "Inventory Costs," an amendment of Accounting Research Bulletin, or ARB, No. 43, Chapter 4, abnormal amounts of idle facility expenses should be recognized as current-period charges. In addition, SFAS No. 151 requires that allocation of fixed production overheads to the costs of production be based on the normal capacity of the production facilities. Management judgment will be required in the determination of a range of normal capacity levels, which will directly affect the allocation of fixed manufacturing overhead costs between inventory costs and period expense. Based upon increased inventory levels in 2004, primarily the result of lower than expected CLOSURE I enrollment and the effects of stricter adherence to HDE guidelines regarding off-label usage, we scaled back our 2005 implant device production below normalized capacity levels. The resulting excess idle capacity costs charged directly to cost of product sales as period costs during 2005 totaled approximately $800,000. Inventory levels at the end of 2006 increased approximately 11% as we prepared sufficient inventory to commence sales of BioSTAR® upon receipt of the anticipated CE Mark and for use in MIST II. Inventory levels at the end of 2005 decreased by approximately 32% compared to 2004. In 2006, production levels approximated normal capacity levels and no idle capacity costs were charged to cost of product sales.

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 migraine headaches, strokes and TIAs. MIST II, an IDE study approved by the FDA in the fourth quarter of 2005 and for which patient enrollment was initiated in January 2006, is our second PFO/migraine trial. Prior to that, we completed enrollment in July 2005 for MIST in the United Kingdom. In October 2005, we announced approval of MIST III. Our CLOSURE I trial, commenced in 2003, is an FDA-approved IDE study in the U.S. to evaluate the safety and efficacy of the STARFlex® closure technology to prevent a recurrent embolic stroke and/or TIA in patients with a PFO. In November 2005, we completed enrollment in the BEST study. Total expenses for all of our clinical trials were approximately $8.2 million, $7.5 million and $4.6 million for the years ended December 31, 2006, 2005 and 2004, 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 Statement of Financial Accounting Standards 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.

Prior to January 1, 2006, we used the intrinsic value method to account for share-based employee compensation under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and therefore did not recognize compensation expense in association with options granted at or above the market price of our common stock at the date of grant.

## COMPARISON OF YEARS ENDED DECEMBER 31, 2006, 2005 AND 2004

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 2006 compared with 2005 and for 2005 compared with 2004. The second table presents consolidated statements of operations information for each of the three years in the period ended December 31, 2006 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 | |
|---|---|---|---|---|---|---|---|
| | 2006 | 2005 | 2004 | 2005 to 2006 | 2004 to 2005 | 2005 to 2006 | 2004 to 2005 |
| (In thousands of dollars, except percentages) | | | | | | | |
| Revenues: | | | | | | | |
| Product sales | $22,135 | $19,313 | $17,279 | $ 2,822 | $ 2,034 | 14.6% | 11.8% |
| Net royalty income | 6,016 | 4,603 | 4,181 | 1,413 | $422 | 30.7% | 10.1% |
| Total revenues | 28,151 | 23,916 | 21,460 | 4,235 | 2,456 | 17.7% | 11.4% |
| Costs and expenses: | | | | | | | |
| Cost of product sales | 5,938 | 5,470 | 4,514 | 468 | 956 | 8.6% | 21.2% |
| Research and development | 15,455 | 12,746 | 8,045 | 2,709 | 4,701 | 21.3% | 58.4% |
| General and administrative | 8,681 | 7,982 | 6,024 | 699 | 1,958 | 8.8% | 32.5% |
| Selling and marketing | 8,704 | 6,340 | 5,542 | 2,364 | 798 | 37.3% | 14.4% |
| Total costs and expenses | 38,778 | 32,538 | 24,125 | 6,240 | 8,413 | 19.2% | 34.9% |
| Net gain from settlement of litigation | 15,184 | — | — | 15,184 | — | — | — |
| Income (loss) from operations | 4,557 | (8,622) | (2,665) | 13,179 | (5,957) | — | — |
| Other Income: | | | | | | | |
| Currency transaction (loss) gain | 15 | (122) | 92 | 137 | (214) | — | — |
| Interest income, net | 1,816 | 861 | 541 | 955 | 320 | 110.9% | 59.1% |
| Total other income, net | 1,831 | 739 | 633 | 1,092 | 106 | 147.8% | 16.7% |
| Income (loss) before provision for income taxes | 6,388 | (7,883) | (2,032) | 14,271 | (5,851) | — | — |
| Provision for income taxes | 502 | — | — | 502 | — | — | — |
| Income (loss) from continuing operations | 5,886 | (7,883) | (2,032) | 13,769 | (5,851) | — | — |
| Income from discontinued operations | — | 91 | 123 | (91) | (32) | (100.0)% | — |
| Net income (loss) | $ 5,886 | $ (7,792) | $ (1,909) | $13,678 | $(5,883) | — | — |

| YEARS ENDED DECEMBER 31, | 2006 | 2005 | 2004 |
|---|---|---|---|
| Revenues: | | | |
| Product sales | 78.6% | 80.8 % | 80.5 % |
| Net royalty income | 21.4% | 19.2 % | 19.5 % |
| Total revenues | 100.0% | 100.0 % | 100.0 % |
| Costs and expenses: | | | |
| Cost of product sales | 26.8% | 28.3 % | 26.1 % |
| Research and development | 54.9% | 53.3 % | 37.5 % |
| General and administrative | 30.8% | 33.4 % | 28.1 % |
| Selling and marketing | 30.9% | 26.5 % | 25.8 % |
| Total costs and expenses | 137.7% | 136.1 % | 112.4 % |
| Net gain from settlement of litigation | 53.9% | — | — |
| Income (loss) from operations | 16.2% | (36.1)% | (12.4)% |
| Other income (expense): | | | |
| Currency transaction gain (loss) | — | (0.5)% | 0.4 % |
| Interest income, net | 6.5% | 3.6 % | 2.5 % |
| Total other income, net | 6.5% | 3.1 % | 2.9 % |
| Income (loss) before provision for income taxes | 22.7% | (33.0)% | (9.5)% |
| Provision for income taxes | 1.8% | — | — |
| Income (loss) from continuing operations | 20.9% | (33.0)% | (9.5)% |
| Income from discontinued operations | — | 0.4 % | 0.6 % |
| Net income (loss) | 20.9% | (32.6)% | (8.9)% |

## RESULTS OF OPERATIONS
## YEAR ENDED DECEMBER 31, 2006 COMPARED WITH YEAR ENDED DECEMBER 31, 2005

**Revenues.** Revenues for the years ended December 31, 2006 and 2005 were as follows:

| | YEARS ENDED DECEMBER 31, | | INCREASE (DECREASE) | % CHANGE |
|---|---|---|---|---|
| | 2006 | 2005 | 2005 to 2006 | 2005 to 2006 |
| (In thousands of dollars, except percentages) | | | | |
| Product sales: | | | | |
| CardioSEAL® and STARFlex®: | | | | |
| North America | $19,298 | $16,095 | $3,203 | 19.9 % |
| Europe | 2,837 | 3,218 | (381) | (11.8)% |
| Total product sales | 22,135 | 19,313 | 2,822 | 14.6 % |
| Net royalty income: | | | | |
| Bard | 5,406 | 4,451 | 955 | 21.5 % |
| AGA | 500 | — | 500 | — |
| BSC | 110 | 152 | (42) | (27.6)% |
| Total net royalty income | 6,016 | 4,603 | 1,413 | 30.7 % |
| Total revenues | $28,151 | $23,916 | $4,235 | 17.7 % |

The increase in CardioSEAL® and STARFlex® implant sales for 2006 compared to 2005 was primarily the result of increased product demand in the United States and Canada. We believe that a combination of increased market awareness of PFO closure and targeted marketing efforts has resulted in the addition of new customers.

The decrease in European sales was primarily attributable to increased clinical programs throughout Europe. Given the current relatively small market for structural heart repair procedures, competitive trials may have impacted the total volume of procedures for which product was purchased. However, we believe that the combination of our MIST study results, the anticipated CE Mark

approval of our BioSTAR® technology, headcount investments in the UK, and other planned investments in Europe have increased awareness of the positive treatment effect on severe migraine sufferers with a PFO using our STARFlex® technology and will result in increased sales in Europe as a percentage of total sales. Incremental strengthening of the U.S. dollar in 2006 also had a slight unfavorable effect on 2006 European product sales. European sales represented approximately 12.8% and 16.7% of total CardioSEAL® and STARFlex® product sales in 2006 and 2005, respectively.

Management currently anticipates approximately 12 to 15% growth in CardioSEAL® and STARFlex® product sales in 2007 compared to 2006. Pending potential awarding of the CE Mark for BioSTAR® within the next few months, we currently believe that our European product sales will approximate 35% of the total. We believe that, given the regulatory environment in the U.S., sales in North America will remain flat. However, it is uncertain if, and to what extent, 2007 enrollment/consent in MIST II and an anticipated increase in CLOSURE I patient enrollment will affect the level of U.S. sales. At this time, we are unable to predict whether our actions and the actions of the FDA regarding the Humanitarian Device Exception, or HDE, will have a material positive or negative impact on product revenue. To-date, there does not appear to have been any significant impact on U.S. product sales as a result of this action. We currently expect that planned European headcount growth and territory expansion during 2007 will result in significant growth in European product sales. However, 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 have increased awareness of the positive treatment effect on severe migraine sufferers with a PFO using our STARFlex® technology along with (ii) the anticipated awarding of the CE Mark for BioSTAR® in the near future, our European product sales will increase as a percentage of total sales. Additionally, relative weakening or strengthening of the U.S. dollar will have a favorable or unfavorable impact, respectively, on European product sales.

The increase in net royalty income for 2006 was directly attributable to Bard's sales of its RNF product. The royalty income from Bard was recorded net of approximately $2.0 million of royalties payable to the estate of the original inventor of SNF and RNF products. Although we currently anticipate that net royalties earned from Bard will remain consistent through the third quarter of 2007 compared with 2006 levels, that result is largely dependent upon continued market acceptance and penetration of its RNF product. As expected, net royalty income from BSC related to the 1994 exclusive license of our stent technology decreased further from 2005 to 2006. BSC is not prohibited from selling competing stents and has established a broad based stent program. We currently anticipate that future royalties earned from BSC will remain flat or decline compared to 2006 levels. Commencing in the fourth quarter of 2007, the royalty rate earned on Bard's RNF sales will decrease substantially from its current rate. Depending upon the sales mix of vena cava filters by Bard, the net royalty revenue to NMT may be minimal and could become a net royalty expense.

**Cost of Product Sales.** For the year ended December 31, 2006, cost of product sales, as a percentage of total product sales, was approximately 26.8% compared with 28.3% for the year ended December 31, 2005. This decrease in percentage of product sales was primarily due to the increase in production levels to our normalized plant capacity levels. In 2005, we incurred unabsorbed manufacturing overhead costs due to production volumes below our normalized levels. As a result, in accordance with the provisions of SFAS No. 151, "Inventory Costs," a portion of our 2005 fixed manufacturing overhead costs were not absorbed as part of inventory unit costs, but instead were charged to cost of product sales in the period incurred. With 2006 production levels at normalized plant capacity levels, we did not charge any of our 2006 fixed manufacturing overhead as a period expense. Included in cost of product sales were royalty expenses of approximately $2.2 million and $1.9 million for the years ended December 31, 2006 and 2005, respectively. In 2007, we anticipate a higher proportion of European sales compared to 2006 to result in a lower weighted average selling price for our products. As a result, we currently expect 2007 cost of product sales to increase, as a percentage of sales, compared to 2006.

**Research and Development.** The increase in research and development expense was primarily related to (i) approximately $1.5 million of increased costs related to MIST II, for which enrollment began in January 2006; (ii) approximately $1.3 million of increased costs related to CLOSURE I; (iii) approximately $1.1 million of increased technology license and product development costs related to future generation implant technologies; (iv) increased headcount and related personnel costs of approximately $831,000, of which $188,000 resulted from non-cash share-based compensation expense pursuant to the new accounting rules, effective January 1, 2006, prescribed by SFAS No. 123R and (v) approximately $750,000 related to MIST III. These increased research and development expenses were partially offset by (i) decreased costs of our MIST study, which decreased by approximately $2.2 million for the year ended December 31, 2006 compared with the same period of 2005; and (ii) decreased costs of our BEST study of approximately $525,000. We currently expect 2007 research and development expenses to increase to approximately $28 million compared to approximately $15 million in 2006. This anticipated increase is primarily attributed to an increase in our clinical trial costs, most notably the expected completion of the enrollment/consent phase of our MIST II study.

**General and Administrative.** General and administrative expenses increased approximately $700,000 for the year ended December 31, 2006 compared to the year ended December 31, 2005. Contributing to the increase were increased personnel and recruitment costs of approximately $350,000. In addition, general and administrative expenses for the year ended December 31, 2006 included $519,000 of non-cash share-based compensation expense pursuant to SFAS No. 123(R). For the year ended December 31, 2005, general and administrative expenses included share-based compensation of approximately $257,000 related to our 2001 stock option re-pricing. General and administrative expense is currently expected to increase by approximately 10% in 2007 compared to 2006. This increase is primarily due to anticipated increases in legal fees related to intellectual property prosecution, increased expenses related to Sarbanes-Oxley 404 requirements, and additional SFAS 123R share-based compensation expense.

**Selling and Marketing.** Selling and marketing costs increased approximately $2.4 million for the year ended December 31, 2006 compared to the year ended December 31, 2005. The increase in selling and marketing expense was primarily the result of an increase in sales incentive compensation and personnel and related costs, primarily in Europe, as well as incremental participation in scientific symposia. We currently expect worldwide selling and marketing expense in 2007 to be relatively flat when compared to 2006. This is primarily due to the reallocation of resources to support the anticipated growth in Europe, offset by the investments not required due to the voluntary withdrawal of the HDE in the U.S.

**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 has been shared equally, after deduction of our legal fees and expenses, with the inventor of the patent, Dr. Lloyd Marks.

**Interest Income.** The increase in interest income of approximately $955,000 for the year ended December 31, 2006 compared to the year ended December 31, 2005 was attributable to higher cash balances during 2006 as a result of our receiving approximately $15 million from the settlement of the AGA litigation in April 2006 as well as higher weighted average interest rates earned due to (i) the increased percentage of marketable securities versus cash and cash equivalents in 2006 compared to 2005; and (ii) the general trend of increasing short-term interest rates. We currently expect interest income to decrease by approximately 30% in 2007 compared to 2006, primarily related to the use of $21 to $24 million of cash, cash equivalents, and marketable securities to fund 2007 operations.

**Income Tax Provision.** We recorded a tax provision for the year ended December 31, 2006 of $502,000 compared to no tax provision for the year ended December 31, 2005. The provision for the year ended December 31, 2006 was as a result of the $15.2 million gain from the settlement of litigation with AGA and less than forecasted clinical trial expenses. We currently expect to incur operating losses in 2007 and, accordingly, expect to carryback such losses to offset a portion of the current year tax provision.

## YEAR ENDED DECEMBER 31, 2005 COMPARED WITH YEAR ENDED DECEMBER 31, 2004

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

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

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

The decrease in European sales was primarily attributable to increased clinical programs throughout Europe. However, we believe that the combination of our MIST study and headcount investments in the UK and other planned investments in Europe have increased awareness of PFO closure in that market. Incremental strengthening of the U.S. dollar in 2005 also had a slight unfavorable effect on 2005 European product sales. European sales represented approximately 16.7% and 20.8% of total CardioSEAL® and STARFlex® product sales in 2005 and 2004, respectively.

The increase in net royalty income for 2005 was directly attributable to Bard's sales of its RNF product. The net royalty income from Bard was recorded net of approximately $1.6 million of royalties payable to the estate of the original inventor of SNF and RNF products. As expected, net royalty income from BSC related to the 1994 exclusive license of our stent technology decreased further from 2004 to 2005. BSC is not prohibited from selling competing stents and has established a broad based stent program.

**Cost of Product Sales.** The increase in cost of product sales, as a percentage of total product sales, was primarily due to 2005 production volumes below normalized plant capacity levels. As a result, in accordance with the provisions of SFAS No. 151, "Inventory Costs", a portion of our 2005 fixed manufacturing overhead costs were not absorbed as part of inventory unit costs, but instead were charged to cost of product sales in the period incurred. Included in cost of product sales were royalty expenses of approximately $1.9 million and $1.7 million for the years ended December 31, 2005 and 2004, respectively.

**Research and Development.** The increase in research and development expense was primarily related to (i) approximately $2.0 million of increased costs related to our MIST UK study; (ii) approximately $1.0 million of technology license and product development costs related to future generation implant technologies; (iii) approximately $900,000 of costs related to our BEST clinical study; (iv) increased headcount and related personnel costs of approximately $250,000; and (v) approximately $300,000 of initial costs of MIST II. The combined costs of our clinical studies totaled approximately $7.5 million in 2005 compared to approximately $4.6 million in 2004.

**General and Administrative.** The increase in general and administrative expense was primarily attributable to (i) increased professional fees, primarily related to corporate governance requirements of the Sarbanes-Oxley Act of 2002, or SOX, of approximately $200,000; (ii) increased share-based compensation of approximately $160,000 related to our 2001 stock option re-pricing; (iii) and a 401(k) employer match of $120,000, partially offset by; (iv) reduced corporate legal fees of approximately $220,000 and (v) reduced insurance costs of approximately $120,000.

**Selling and Marketing.** The increase in selling and marketing expense was the result of (i) an approximate $600,000 increase in sales incentive compensation; (ii) an approximate $250,000 increase in personnel and related costs; (iii) an approximate $175,000 increase in travel and entertainment expense; and (iv) an approximate $100,000 increase in physician training and market research consulting services, partially offset by the elimination of approximately $200,000 of 2004 costs related to our marketing program events.

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

**Income Tax Provision.** Due to our reported net losses, we had no income tax provision in 2005 and 2004.

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

## LIQUIDITY AND CAPITAL RESOURCES

| FOR THE YEARS ENDED DECEMBER 31, | 2006 | 2005 | 2004 |
|---|---|---|---|
| (In thousands) | | | |
| Cash, cash equivalents, marketable securities and restricted cash | $41,450 | $31,506 | $35,380 |
| Net cash provided by (used in) operating activities | 8,174 | (5,108) | (984) |
| Net cash (used in) provided by investing activities | (12,046) | 4,277 | (19,001) |
| Net cash provided by financing activities | 1,768 | 1,883 | 598 |

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

Net cash provided by operating activities for the year ended December 31, 2006 totaled approximately $8.2 million and consisted of a net income of approximately $5.9 million. Net income included $15.2 million for the gain on settlement of the AGA litigation. Net income also included non-cash charges of approximately $690,000. Working capital requirements also decreased by approximately $1.6 million.

The non-cash charges of approximately $690,000 during the year ended December 31, 2006 consisted of (i) share-based compensation, principally related to the new accounting rules, effective January 1, 2006, prescribed by SFAS 123R; (ii) depreciation of property and equipment, and (iii) amortization of bond discount.

The primary elements of the $1.6 million net decrease in working capital requirements during the year ended December 31, 2006 consisted of the following:

a) Current liabilities increased by approximately $2.1 million. Included in accrued expenses is a $1 million accrual for costs relating to the transition of our clinical research organization involved with our CLOSURE I trial.

b) Prepaid expenses and other current assets increased by approximately $450,000. The increase consisted of (i) a $200,000 increase in our royalties due from Bard; and (ii) an increase of $170,000 in accrued interest receivable on interest-bearing investments.

c) In anticipation of receiving a CE Mark and having BioSTAR® commercially available by early 2007, our inventories increased approximately $200,000 during the year ended December 31, 2006.

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

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

Net cash used in investing activities of approximately $12.0 million during the year ended December 31, 2006 consisted primarily of approximately $49.3 million of purchases of marketable securities, offset by approximately $37.9 million of proceeds from maturities of marketable securities. Purchases of property and equipment for use in our manufacturing, research and development, and general and administrative activities totaled approximately $566,000 during the year ended December 31, 2006. This compared to approximately $4.3 million provided by operations in 2005, which consisted primarily of approximately $20.2 million of proceeds from maturities of marketable securities and an approximate $1.1 million release of restricted cash balances in connection with the settlement of the French tax claim, partially offset by $16.7 million of purchases of marketable securities.

**Net Cash Provided By Financing Activities**

Net cash provided by financing activities was approximately $1.8 million for the year ended December 31, 2006 and $1.9 million for the year ended December 31, 2005. For both periods, this was primarily attributable to proceeds from the exercise of common stock options and the issuance of shares of common stock pursuant to our employee stock purchase plan. For the year ended December 31, 2006, financing activities also reflected excess tax benefits from share-based compensation of $583,000.

Primarily as a result of the anticipated ongoing costs of MIST II, MIST III and CLOSURE I, we currently expect to incur operating losses at least through 2008. The total cost of our MIST II study is currently estimated to be approximately $18.0 to $20.0 million through 2008. Of this amount, approximately $2.0 million was incurred through 2006 and we currently expect to incur approximately $14.6 million in 2007. The total cost of our MIST III study is currently estimated to be $1.7 million through 2007. Of this amount, approximately $750,000 was incurred through 2006 and we currently expect to incur approximately $1.0 million in 2007. The total cost of our CLOSURE I clinical trial is currently estimated to be approximately $24.0 million through completion of the trial and submission to the FDA. Of this amount, approximately $13.9 million was incurred through 2006 and we currently expect to incur approximately $4.0 to $4.5 million in 2007, largely dependent upon the rate of enrollment.

Capital expenditures are projected to total approximately $1.0 million during 2007, primarily for manufacturing and research and development equipment.

We currently believe that aggregate cash, cash equivalents, and marketable securities balances of approximately $41.4 million at December 31, 2006 will be sufficient to meet our working capital, financing and capital expenditure requirements through at least 2008.

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 announced that we filed a shelf registration statement on Form S-3 with the SEC and it will permit us to offer and sell up to $65 million of equity or debt securities. Any additional equity financing will be dilutive to stockholders, and additional debt financing, if available, may involve restrictive covenants. Our capital requirements will depend on numerous factors, including the level of sales of our products, the progress of our research and development programs, the progress of clinical testing, the time and cost involved

in obtaining regulatory approvals, the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, competing technological and market developments, developments and changes in our existing research, licensing and other relationships and the terms of any collaborative, licensing and other similar arrangements that we may establish. We do not currently have any existing line of credit arrangements.

## CONTRACTUAL OBLIGATIONS

### Clinical Trials

At December 31, 2006, we had five significant clinical trials at various stages of completion. In connection with these trials, we have entered into various contractual obligations with third party service providers and the participating clinical sites. Under certain agreements, we have the right to terminate, in which case the remaining obligations would be limited to costs incurred as of that date. Including the internal costs of our clinical department and the manufacturing costs of products used, the following table provides, by trial, our current estimate of total costs to be incurred, actual cumulative costs through fiscal 2006, our current estimates of 2007 costs and the remaining costs estimated to be incurred subsequent to 2007. 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 2006, approximately $4.1 million was included in accrued expenses at December 31, 2006.

| (In millions of dollars) | Inception of Enrollment | Current Projected Total Costs Of Clinical Trial | Costs Incurred Through 2006 | Projected Costs To Be Incurred In 2007 | Projected Costs To Be Incurred After 2007 | Projected Completion/ Regulatory Filing |
|---|---|---|---|---|---|---|
| MIST II | 2006 | $18.0 - 20.0 | $ 2.0 | $ 14.6 | $1.4 - 3.4 | 2008 |
| MIST III | 2006 | 1.7 | 0.7 | 1.0 | — | 2007 |
| MIST | 2005 | 4.7 - 4.9 | 4.6 | 0.3 | — | Completed |
| BEST | 2005 | 1.4 - 1.6 | 1.3 | 0.3 | — | Completed |
| CLOSURE I | 2003 | 24.0 | 13.8 | 4.0 - 4.5 | 5.7 - 6.2 | To be determined |
| Totals | | $49.6 - 52.2 | $22.4 | $20.2 - 20.7 | $7.1 - 9.6 | |

### Royalty and License Agreements

We are party to various royalty agreements under which we are obligated to pay royalties: (i) to CMCC on commercial sales of our CardioSEAL® and STARFlex® product sales; (ii) to the estate of the original inventor of certain vena cava filter products on sales of those products by Bard; and (iii) to Dr. Lloyd Marks on sales of CardioSEAL® and STARFlex® products to the extent that the technology licensed to us is incorporated into these products, subject to a minimum annual royalty. Royalty expenses in 2006 totaled approximately $4.4 million.

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

### Operating Leases

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

The following table summarizes our estimated minimum future operating lease contractual commitments at December 31, 2006:

| | PAYMENTS DUE BY PERIOD | | | | |
|---|---|---|---|---|---|
| | Total | Less Than One Year | 1-3 Years | 3-5 Years | After 5 Years |
| Operating Leases | $3,079,208 | $ 813,000 | $1,655,208 | $ 611,000 | $ — |

### OFF-BALANCE SHEET FINANCING

During the year ended December 31, 2006, we have not engaged in material off-balance sheet activities, including the use of structured finance or specific purpose entities.

### RECENT ACCOUNTING PRONOUNCEMENTS

In July 2006, the Financial Accounting Standards Board, or the FASB, issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109," or FIN 48, which clarifies the accounting and disclosure for uncertainty in tax positions, as defined. FIN 48 seeks to reduce the diversity in practice associated with certain aspects of the recognition and measurement related to accounting for income taxes. This interpretation is effective for fiscal years beginning after December 15, 2006. We are currently evaluating the impact that the adoption of FIN 48 will have, if any, on our consolidated financial statements and notes thereto.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, "Fair Value Measurements," or SFAS 157. SFAS 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. SFAS 157 applies whenever other standards require assets or liabilities to be measured at fair value and does not expand the use of fair value in any new circumstances. SFAS 157 establishes a hierarchy that prioritizes the information used in developing fair value estimates. The hierarchy gives the highest priority to quoted prices in active markets and the lowest priority to unobservable data, such as the reporting entity's own data. SFAS 157 requires fair value measurements to be disclosed by level within the fair value hierarchy. SFAS 157 is effective for fiscal years beginning after November 15, 2007. We have not yet determined the impact, if any, that SFAS 157 will have on our financial statements.

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

As of December 31, 2006 and 2005, we did not participate in any derivative financial instruments or other financial and commodity instruments for which fair value disclosure would be required under SFAS No. 107, "Disclosures About Fair Value of Financial Instruments." Our investments are primarily short-term money market accounts that are carried on our books at cost, which approximates fair market value, and U.S. Government agency and corporate debt instruments that are carried on our books at amortized cost, increased or decreased by unrealized gains or losses, net of tax, respectively, which amounts are recorded as a component of stockholders' equity in our consolidated financial statements. Accordingly, we have no quantitative information concerning the market risk of participating in such investments.

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

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

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

## ITEM 9A. CONTROLS AND PROCEDURES

### Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2006. 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, 2006, 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, 2006. 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, 2006, our internal control over financial reporting was effective at a reasonable assurance level based on these criteria.

Ernst & Young LLP, our independent registered public accounting firm, has issued an audit report dated March 9, 2007, included below, on our assessment of our internal control over financial reporting.

### Changes in Internal Control Over Financial Reporting

No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

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

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting that NMT Medical, Inc. maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). NMT Medical, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, management's assessment that NMT Medical, Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion NMT Medical, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2006 of NMT Medical, Inc. and our report dated March 9, 2007 expressed an unqualified opinion thereon.

Ernst & Young LLP

Boston, Massachusetts
March 9, 2007

## ITEM 9B. OTHER INFORMATION

None.

# 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 2007 Annual Meeting of Stockholders to be held on June 20, 2007. Information relating to certain filings of Forms 3, 4 and 5 is contained in our 2007 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 2007 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 2007 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 2007 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 2007 proxy statement.

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required under this item is incorporated by reference to the section entitled *"Independent Registered Public Accounting Firm"* in our 2007 proxy statement.

# PART IV

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

Financial Statements of NMT Medical, Inc. and Subsidiaries:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2006 and 2005

Consolidated Statements of Operations for the years ended December 31, 2006, 2005 and 2004

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2006, 2005 and 2004

Consolidated Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004

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.**

By: /s/ JOHN E. AHERN

John E. Ahern
President and Chief Executive Officer

Dated: March 12, 2007

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

| SIGNATURE | TITLE | DATE |
|---|---|---|
| /s/ JOHN E. AHERN<br>John E. Ahern | President, Chief Executive Officer and Chairman of the Board (Principal Executive Officer) | March 12, 2007 |
| /s/ RICHARD E. DAVIS<br>Richard E. Davis | Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) | March 12, 2007 |
| /s/ CHERYL L. CLARKSON<br>Cheryl L. Clarkson | Director | March 12, 2007 |
| /s/ DANIEL F. HANLEY<br>Daniel F. Hanley, M.D. | Director | March 12, 2007 |
| /s/ JAMES E. LOCK<br>James E. Lock, M.D. | Director | March 12, 2007 |
| /s/ FRANCIS J. MARTIN<br>Francis J. Martin | Director | March 12, 2007 |
| /s/ HARRY A. SCHULT<br>Harry A. Schult | Director | March 12, 2007 |

## APPENDIX A

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

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of NMT Medical, Inc. (a Delaware corporation) as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period 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 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 consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of NMT Medical, Inc. as of December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of NMT Medical, Inc.'s internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 9, 2007 expressed an unqualified opinion thereon.

Ernst & Young LLP

Boston, Massachusetts
March 9, 2007

## NMT MEDICAL, INC. AND SUBSIDIARIES

### CONSOLIDATED BALANCE SHEETS

| AT DECEMBER 31, | 2006 | 2005 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 8,285,561 | $ 10,390,139 |
| Marketable securities | 33,163,998 | 21,116,346 |
| Accounts receivable, net of allowances of $282,468 in 2006 and $369,984 in 2005 | 2,729,188 | 2,846,684 |
| Inventories | 1,909,236 | 1,726,300 |
| Prepaid expenses and other current assets | 4,055,627 | 3,605,540 |
| Total current assets | 50,143,610 | 39,685,009 |
| Property and equipment, at cost: | | |
| Laboratory and computer equipment | 3,830,430 | 3,479,819 |
| Leasehold improvements | 1,307,563 | 1,136,859 |
| Office furniture and equipment | 1,028,397 | 984,148 |
| | 6,166,390 | 5,600,826 |
| Less accumulated depreciation and amortization | 5,127,063 | 4,796,057 |
| | 1,039,327 | 804,769 |
| **Total Assets** | **$51,182,937** | **$40,489,778** |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,284,347 | $ 2,654,399 |
| Accrued expenses | 8,999,151 | 6,515,809 |
| Total current liabilities | 11,283,498 | 9,170,208 |
| Commitments and contingencies (Notes 7 and 15) | | |
| Stockholders' equity: | | |
| Preferred stock, $.001 par value | | |
| Authorized-3,000,000 shares | | |
| Issued and outstanding-none | — | — |
| Common stock, $.001 par value | | |
| Authorized-30,000,000 shares | | |
| Issued-12,901,310 shares in 2006 and 12,635,832 shares in 2005 | 12,901 | 12,636 |
| Additional paid-in capital | 50,870,411 | 48,232,778 |
| Less treasury stock-40,000 shares at cost | (119,600) | (119,600) |
| Accumulated deficit | (10,867,401) | (16,753,410) |
| Accumulated other comprehensive income (loss) | 3,128 | (52,834) |
| Total stockholders' equity | 39,899,439 | 31,319,570 |
| **Total Liabilities and Stockholders' Equity** | **$51,182,937** | **$40,489,778** |

*See accompanying notes.*

## NMT MEDICAL, INC. AND SUBSIDIARIES

# CONSOLIDATED STATEMENTS OF OPERATIONS

| FOR THE YEARS ENDED DECEMBER 31, | 2006 | 2005 | 2004 |
|---|---|---|---|
| Revenues: | | | |
| Product sales | $22,135,286 | $19,313,103 | $17,278,760 |
| Net royalty income | 6,016,044 | 4,603,058 | 4,181,264 |
| Total revenues | 28,151,330 | 23,916,161 | 21,460,024 |
| Costs and expenses: | | | |
| Cost of product sales | 5,938,575 | 5,469,722 | 4,513,764 |
| Research and development | 15,454,948 | 12,745,721 | 8,044,946 |
| General and administrative | 8,680,671 | 7,982,670 | 6,023,968 |
| Selling and marketing | 8,703,728 | 6,340,085 | 5,542,083 |
| Total costs and expenses | 38,777,922 | 32,538,198 | 24,124,761 |
| Net gain from settlement of litigation | 15,183,894 | — | — |
| Income (loss) from operations | 4,557,302 | (8,622,037) | (2,664,737) |
| Other income (expense): | | | |
| Currency transaction gain (loss) | 14,468 | (122,387) | 92,047 |
| Interest income, net | 1,816,239 | 861,481 | 540,614 |
| Total other income, net | 1,830,707 | 739,094 | 632,661 |
| Income (loss) before provision for income taxes | 6,388,009 | (7,882,943) | (2,032,076) |
| Provision for income taxes | 502,000 | — | — |
| Income (loss) from continuing operations | 5,886,009 | (7,882,943) | (2,032,076) |
| Income from discontinued operations | — | 90,687 | 122,639 |
| Net income (loss) | $ 5,886,009 | $ (7,792,256) | $ (1,909,437) |
| Basic net income (loss) per common share: | | | |
| Continuing operations | $ 0.46 | $ (0.64) | $ (0.17) |
| Discontinued operations | — | 0.01 | 0.01 |
| Net income (loss) | $ 0.46 | $ (0.63) | $ (0.16) |
| Diluted net income (loss) per common share: | | | |
| Continuing operations | $ 0.43 | $ (0.64) | $ (0.17) |
| Discontinued operations | — | 0.01 | 0.01 |
| Net income (loss) | $ 0.43 | $ (0.63) | $ (0.16) |
| Weighted average common shares outstanding: | | | |
| Basic | 12,745,601 | 12,332,001 | 12,031,434 |
| Diluted | 13,597,080 | 12,332,001 | 12,031,434 |

*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, December 31, 2003 | 11,914,787 | 11,915 | 45,395,546 | (40,000) | (119,600) | (7,051,717) | — | 38,236,144 | $ — |
| Common stock issued under the employee stock purchase plan | 58,134 | 58 | 206,627 | — | — | — | — | 206,685 | — |
| Exercise of common stock options | 203,262 | 203 | 391,576 | — | — | — | — | 391,779 | — |
| Share-based compensation | — | — | 99,326 | — | — | — | — | 99,326 | — |
| Unrealized loss on marketable securities | — | — | — | — | — | — | (152,596) | (152,596) | (152,596) |
| Net loss | — | — | — | — | — | (1,909,437) | — | (1,909,437) | (1,909,437) |
| Net comprehensive loss | | | | | | | | | $(2,062,033) |
| Balance, December 31, 2004 | 12,176,183 | 12,176 | 46,093,075 | (40,000) | (119,600) | (8,961,154) | (152,596) | 36,871,901 | $ — |
| Common stock issued under the employee stock purchase plan | 49,332 | 49 | 222,037 | — | — | — | — | 222,086 | — |
| Exercise of common stock options and warrants | 410,317 | 411 | 1,660,478 | — | — | — | — | 1,660,889 | — |
| Share-based compensation | — | — | 257,188 | — | — | — | — | 257,188 | — |
| Unrealized gain on marketable securities | — | — | — | — | — | — | 99,762 | 99,762 | 99,762 |
| Net loss | — | — | — | — | — | (7,792,256) | — | (7,792,256) | (7,792,256) |
| Net comprehensive loss | | | | | | | | | $(7,692,494) |
| Balance, December 31, 2005 | 12,635,832 | $12,636 | $48,232,778 | (40,000) | $(119,600) | $(16,753,410) | $ (52,834) | $31,319,570 | |
| 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 | |

*See accompanying notes.*

## NMT MEDICAL, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

| FOR THE YEARS ENDED DECEMBER 31, | 2006 | 2005 | 2004 |
|---|---|---|---|
| Cash flows from operating activities: | | | |
| Net income (loss) | $ 5,886,009 | $ (7,792,256) | $ (1,909,437) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities- | | | |
| Depreciation and amortization | 331,006 | 314,867 | 352,866 |
| Amortization of bond (discount) premium | (511,142) | 447,861 | 474,944 |
| Share-based compensation expense | 870,229 | 257,188 | 99,326 |
| Change in assets and liabilities- | | | |
| Accounts receivable | 117,496 | (1,070,079) | 770,241 |
| Inventories | (182,936) | 796,762 | (591,121) |
| Prepaid expenses and other current assets | (450,087) | (800,986) | (976,069) |
| Accounts payable | (370,052) | 972,127 | 406,491 |
| Accrued expenses | 2,483,342 | 2,181,223 | 389,061 |
| Discontinued operations liabilities | — | (414,954) | — |
| Net cash provided by (used in) operating activities | 8,173,865 | (5,108,247) | (983,698) |
| Cash flows from investing activities: | | | |
| Purchases of property and equipment | (565,564) | (329,275) | (361,420) |
| Purchases of marketable securities | (49,330,548) | (16,685,722) | (27,117,705) |
| Maturities of marketable securities | 37,850,000 | 20,170,000 | 9,600,000 |
| Restricted cash | — | 1,122,200 | (1,122,200) |
| Net cash (used in) provided by investing activities | (12,046,112) | 4,277,203 | (19,001,325) |
| Cash flows from financing activities: | | | |
| Proceeds from exercise of common stock options and warrants | 852,045 | 1,660,889 | 391,779 |
| Proceeds from issuance of common stock under the employee stock purchase plan | 332,624 | 222,086 | 206,685 |
| Excess tax benefits from share-based compensation | 583,000 | — | — |
| Net cash provided by financing activities | 1,767,669 | 1,882,975 | 598,464 |
| Net (decrease) increase in cash and cash equivalents | (2,104,578) | 1,051,931 | (19,386,559) |
| Cash and cash equivalents, beginning of period | 10,390,139 | 9,338,208 | 28,724,767 |
| Cash and cash equivalents, end of period | $ 8,285,561 | $10,390,139 | $ 9,338,208 |
| Supplemental cash flow information: | | | |
| Cash paid for income taxes | $ 50,000 | $ — | $ — |

*See accompanying notes.*

## (1) OPERATIONS

We are an advanced medical technology company that designs, develops, manufactures and markets proprietary implant technologies that allow interventional cardiologists to treat certain kinds of cardiac structural heart disease through minimally invasive, catheter-based procedures. We are investigating the potential connection between a common cardiac 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 migraine headaches, stroke, and transient ischemic attacks, or TIA. A PFO can allow venous blood, unfiltered and unmanaged by the lungs, to directly enter the arterial circulation of the brain, possibly triggering a cerebral event or brain attack. More than 23,000 PFOs have been closed globally with our minimally invasive, catheter-based implant technology.

## (2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

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

(b) Management Estimates

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

(c) Cash, Cash Equivalents, and Marketable Securities

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

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

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

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

| | 2006 | | 2005 | |
|---|---|---|---|---|
| AT DECEMBER 31, | FAIR VALUE | AMORTIZED COST | FAIR VALUE | AMORTIZED COST |
| Corporate bonds | $19,807,998 | $19,805,628 | $11,021,806 | $11,059,535 |
| Government agency securities | 4,760,775 | 4,759,736 | 6,189,495 | 6,203,540 |
| Commercial Paper | 5,394,654 | 5,394,889 | 2,980,130 | 2,981,139 |
| Certificates of Deposit | 3,200,571 | 3,200,617 | 924,915 | 924,966 |
| | $33,163,998 | $33,160,870 | $21,116,346 | $21,169,180 |

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

| AT DECEMBER 31, | 2006 | 2005 |
|---|---|---|
| Due within one year | $31,980,570 | $21,116,346 |
| Due in 1-2 years | 1,183,428 | — |
| | $33,163,998 | $21,116,346 |

At December 31, 2006 there were $11,054 of gross unrealized gains and $7,926 of gross unrealized losses on marketable securities. The aggregate fair value of marketable securities with unrealized gains at December 31, 2006 was approximately $17.2 million. We believe any impairment of those investments are not other-than-temporary at this time. These corporate debt securities are all highly rated investments which have been subject to routine market changes that have not been significant to date. There were net unrealized losses on marketable securities of $52,834 at December 31, 2005. There were no realized gains or losses on marketable securities in each of the three years in the period ended December 31, 2006.

Accrued interest of approximately $396,000 and $225,000 were included in prepaid expenses and other current assets in the accompanying consolidated balance sheets at December 31, 2006 and 2005, respectively.

(d) Inventories

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

| AT DECEMBER 31, | 2006 | 2005 |
|---|---|---|
| Raw materials | $ 773,704 | $ 515,979 |
| Work-in-process | 229,808 | 103,517 |
| Finished goods | 905,724 | 1,106,804 |
| | $1,909,236 | $1,726,300 |

Finished goods comprise materials, labor and manufacturing overhead.

(e) Financial Instruments

SFAS No. 107, "Disclosures About Fair Value of Financial Instruments," requires disclosure of an estimate of the fair value of certain financial instruments. Our financial instruments consist of cash and cash equivalents, marketable securities and accounts receivable. The estimated fair value of these financial instruments approximates their carrying value at December 31, 2006 and 2005, respectively. The estimated fair values have been determined through information obtained from market sources and management estimates. We do not have any derivative or any other financial instruments as defined by SFAS No. 133, "Accounting for Derivative and Hedging Instruments."

(f) Concentration of Credit Risk and Significant Customers

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 material off-balance sheet activities, including the use of structured finance or specific purpose entities.

No customer accounted for greater than 10% of product sales in any of the three years ended December 31, 2006.

At December 31, 2006, approximately 21.9% of gross accounts receivable represented accounts denominated in foreign currencies that were translated at year-end exchange rates. For the years ended December 31, 2006, 2005 and 2004, product sales to customers outside North America accounted for approximately 12.8%, 16.7% and 20.6% of total product sales, respectively.

(g) Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment. In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," we periodically review long-lived assets for impairments whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Based on management's assessment, no impairment of long-lived assets existed as of December 31, 2006 or 2005.

(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 $331,000, $315,000 and $353,000 for the years ended December 31, 2006, 2005 and 2004, respectively. Maintenance and repairs are charged to expense when incurred. Additions and improvements are capitalized.

(i) Revenue Recognition

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

(j) Net Income (Loss) per Common Share

Basic and diluted net income (loss) per share is presented in conformity with SFAS No. 128, "Earnings per Share," for all periods presented. In accordance with SFAS No. 128, basic net income (loss) per share was determined by dividing net income (loss) by the weighted average common shares outstanding during the period. Diluted net income 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. For the year ended December 31, 2006, 851,000 shares were included in the diluted earnings per share calculation. We incurred a net loss for the years ended December 31, 2005 and 2004, accordingly, none of our outstanding options and warrants was dilutive. Options to purchase a total of 241,750, 1,739,509 and 1,899,630 common shares have been excluded from the computation of diluted weighted average shares outstanding for the years ended December 31, 2006, 2005 and 2004, respectively.

(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 (APB Opinion No. 25). Under APB Opinion No. 25, for stock options granted at market price, no compensation cost was recognized, and a disclosure was made regarding the pro forma effect on net earnings assuming compensation cost had been recognized in accordance with Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123). On December 16, 2004, the Financial Accounting Standards Board issued SFAS No. 123 (Revised 2004) *Share Based Payment* (SFAS No. 123R), which requires companies to measure and recognize compensation expense for all share-based payments at fair value. SFAS No. 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 No. 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 No. 123R for all share-based payments granted or modified after the effective date, and based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date, 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 No. 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 No. 123R using the modified prospective method. Other than restricted stock, no share-based employee compensation cost has been reflected in net income prior to the adoption of SFAS No. 123R. Results for prior periods have not been restated.

(l) Foreign Currency

The accounts of our foreign subsidiaries are translated in accordance with SFAS No. 52, "Foreign Currency Translation." The functional currency of our foreign subsidiaries is the U.S. dollar and, accordingly, translation gains and losses are reflected in the consolidated statements of operations. Revenue and expense accounts are translated using the weighted average exchange rate in effect during the period. Foreign currency transaction gains or losses are reflected in the consolidated statements of operations. We had foreign currency transaction gains (losses) of approximately $14,000, $(122,000) and $92,000 for the years ended December 31, 2006, 2005 and 2004, respectively. Foreign currency transaction gains and losses result from differences in exchange rates between the functional currency and the currency in which a transaction is denominated and are included in the consolidated statement of operations in the period in which the exchange rate changes.

(m) Comprehensive Income

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

(n) Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes–an interpretation of FASB Statement No. 109*, or FIN 48, which clarifies the accounting and disclosure for uncertainty in tax positions, as defined. FIN 48 seeks to reduce the diversity in practice associated with certain aspects of the recognition and measurement related to accounting for income taxes. This interpretation is effective for fiscal years beginning after December 15, 2006. We are currently evaluating the impact that the adoption of FIN 48 will have, if any, on our consolidated financial statements and notes thereto. However, we do not expect the adoption of FIN 48 to have a material effect on our financial position or operating results.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, "Fair Value Measurements," or SFAS 157. SFAS 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the reporting entity transacts. SFAS 157 applies whenever other standards require assets or liabilities to be measured at fair value and does not expand the use of fair value in any new circumstances. SFAS 157 establishes a hierarchy that prioritizes the information used in developing fair value estimates. The hierarchy gives the highest priority to quoted prices in active markets and the lowest priority to unobservable data, such as the reporting entity's own data. SFAS 157 requires fair value measurements to be disclosed by level within the fair value hierarchy. SFAS 157 is effective for fiscal years beginning after November 15, 2007. We have not yet determined the effects that SFAS 157 will have on our financial statements.

(o) 401(k) Plan

We offer a savings plan to eligible employees that is intended to qualify under Section 401(k) of the Internal Revenue Code. Participating employees may defer up to 15% of their pre-tax compensation, as defined, subject to certain limitations. In December 2006, our Board of Directors approved a 401(k) employer match for the year ended December 31, 2006. In connection with this employer match, $149,000 was expensed in 2006 and distributed to 401(k) participant accounts in February 2007. The Board of Directors approved a similar employer match for the year ended December 31, 2005 in the amount of $120,000. We did not make any employer matching or other discretionary contributions to the 401(k) Plan for the year ended December 31, 2004.

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

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

| FOR THE YEARS ENDED DECEMBER 31, | 2006 | 2005 | 2004 |
|---|---|---|---|
| Supplemental disclosure of cash flow information: | | | |
| Cash paid during the year for - | | | |
| Interest | $ — | $ — | $ 1,570 |
| Income taxes | $50,000 | $ — | $365,215 |

(q) Expenses Associated with Clinical Trials

We have invested significant resources in several clinical trials designed to investigate the potential connection between a PFO and brain attacks such as migraine headaches, strokes and TIAs. MIST II (Migraine Intervention with STARFlex® Technology), approved by the FDA in the fourth quarter of 2005 and for which patient enrollment began in January 2006, is our second PFO/migraine trial. Prior to that, we completed enrollment in July 2005 for our first PFO/migraine study (MIST) in the United Kingdom. In October 2005, we announced approval of MIST III, a study designed to expand data and follow-up on MIST migraine patients. Our CLOSURE I trial, commenced in 2003, is an FDA-approved investigational device exemption, 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 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 $8.2 million, $7.5 million and $4.6 million for the years ended December 31, 2006, 2005 and 2004, respectively.

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

(r) Reclassifications

Certain amounts in the prior periods' consolidated financial statements have been reclassified to be consistent with the current years' presentation.

## (3) DISCONTINUED OPERATIONS

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

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

## (4) INCOME TAXES

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

The provision for income taxes in the accompanying consolidated statements of operations for the years ended December 31, 2006, 2005 and 2004 consisted of the following:

| FOR THE YEARS ENDED DECEMBER 31, | 2006 | 2005 | 2004 |
|---|---|---|---|
| Foreign-current | $ — | $ — | $ — |
| Federal-current | 746,000 | (92,000) | (190,000) |
| State-current | — | — | — |
| | 746,000 | (92,000) | (190,000) |
| Foreign-deferred | — | — | — |
| Federal-deferred | (244,000) | 92,000 | 190,000 |
| State-deferred | — | — | — |
| | (244,000) | 92,000 | 190,000 |
| | $ 502,000 | $ — | $ — |

We have Federal and State tax credit carryforwards of approximately $1.6 million available to reduce federal and state taxable income in future periods, if any. These carryforwards are subject to review and possible adjustment by the Internal Revenue Service and their utilization may be limited by aggregate changes in significant ownership of us over a three year period as prescribed by Section 382 of the Internal Revenue Code. These carryforwards expire on various dates through 2026.

The tax effects of temporary differences that give rise to significant portions of the current deferred tax asset at December 31, 2006 and 2005 are as follows:

| | 2006 | 2005 |
|---|---|---|
| Net operating losses | $ — | $3,284,000 |
| Tax credit carryforwards | 1,632,000 | 1,052,000 |
| Timing differences, including reserves, accruals and write-offs | 1,128,000 | 1,154,000 |
| | 2,760,000 | 5,490,000 |
| Less—Valuation allowance | (2,516,000) | (5,490,000) |
| Net deferred tax asset | $ 244,000 | $ — |

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

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

| FOR THE YEARS ENDED DECEMBER 31, | 2006 | 2005 | 2004 |
|---|---|---|---|
| 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 | (31.4) | 35.5 | 31.7 |
| Other permanent items | 5.3 | (1.5) | 2.3 |
| | 7.9% | —% | —% |

### (5) NET ROYALTY INCOME

In connection with the November 2001 sale of our vena cava filter product line to C.R. Bard, Inc. ("Bard"), we entered into a royalty agreement pursuant to which Bard commenced payment of royalties in 2003. As part of that agreement, we continue to pay related royalty obligations to the 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 $6.0 million, $4.6 million and $4.2 million during the years ended December 31, 2006, 2005 and 2004, respectively.

### (6) SETTLEMENT OF LITIGATION

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

On 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 has been 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. On April 12, 2006, we received the entire cash payment from the settlement totaling $30.0 million. The cash payment was shared equally, after our legal fees and expenses, with Dr. Marks.

### (7) COMMITMENTS

(a) Operating Leases

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

Future minimum rental payments due under operating lease agreements at December 31, 2006 are approximately as follows:

| YEARS ENDING DECEMBER 31, | |
|---|---|
| 2007 | $ 813,442 |
| 2008 | 808,180 |
| 2009 | 847,028 |
| 2010 | 611,000 |
| 2011 | — |
| | $3,079,650 |

Rent expense for the years ended December 31, 2006, 2005 and 2004 totaled approximately $983,000, $981,000 and $946,000 respectively.

(b) Royalties and Licensed Technology

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

Royalty expense under royalty agreements was approximately $4,417,000, $3,610,000 and $3,245,000 for the years ended December 31, 2006, 2005 and 2004, respectively. Approximately $2,028,000, $1,565,000 and $1,431,000 of these royalties were included as a reduction of related royalty income earned from third parties for the years ended December 31, 2006, 2005 and 2004, respectively. The remaining amount of royalty expense is reflected within cost of product sales and research and development expenses.

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

(c) Employment Agreements

We have employment agreements with our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO") through December 2007 and 2008, respectively. In the event of termination without cause, as defined therein, these employment agreements provide up to one year's continued salary as then in effect, in addition to any earned incentive compensation, and, in the case of the CEO, continued health insurance coverage for eighteen months. Upon consummation of a change in control of the Company, as defined, these executives would be entitled to a cash payment equal to a percentage of the total deal consideration paid by an acquirer. This percentage would range from 1.0% to 4.2% for our CEO and from 0.25% to 1.0% for our CFO.

(d) Clinical Trials

*MIST*

In November 2004, we received approval in the United Kingdom for the MIST study, the first prospective, randomized, double-blinded study to evaluate the effectiveness of transcatheter closure of a PFO, using our proprietary STARFlex® septal repair technology, in the treatment and prevention of migraine headaches. MIST is a multi-center study involving approximately 16 centers, with an enrollment of 147 migraine patients with aura, who have a PFO and who were randomized to either PFO closure with the STARFlex® implant or a control arm. The study was designed by a scientific advisory board comprised of some of the top European and North American migraine specialists and interventional cardiologists. The MIST study's patient recruitment process was supported by the Migraine Action Association (MAA), a migraine headache advocacy group representing more than 14,000 members in the United Kingdom. Total costs of this trial, including third party contracts and agreements with clinical sites and other service providers, are currently estimated to be in the range of $4.7 to $4.9 million. Of this total, approximately $750,000 and $3.0 million were incurred during 2006 and 2005, respectively. We currently estimate 2007 costs to be approximately $300,000.

*MIST II*

In September 2005, we received conditional approval from the U.S. Food and Drug Administration, or FDA, of an IDE, to initiate enrollment in our pivotal PFO/migraine clinical study, named MIST II. MIST II is a prospective, randomized, multi-center, controlled study. The double-blinded trial is designed to randomize approximately 600 migraine patients with a PFO to either structural heart repair with our BioSTAR® technology or a control arm. The study will also incorporate our newest, most technologically advanced delivery system. More than twenty U.S. research centers have committed to participate in MIST II, and enrollment began in January 2006. Patient follow-up will be over a one year period. We currently project the costs of this clinical study to be in the range of $18 to $20 million through 2008. Of this total, approximately $1.7 million and $300,000 was incurred during 2006 and 2005, respectively, and we currently estimate 2007 costs to be approximately $14.6 million.

*MIST III*

In October 2005, we received approval from the regulatory authorities in the United Kingdom to begin enrollment in MIST III. In MIST III, control patients from the original MIST study, those who did not receive the STARFlex® implant, have the option to receive an implant after they have been unblinded as part of the MIST study. These patients will follow the identical protocol as in MIST after which they will be followed for an additional 18 months. In addition, migraine patients with a PFO who did receive a STARFlex® implant in MIST will be followed for an additional 18 months. We currently estimate the cost of MIST III to be approximately $1.7 million to be incurred through 2007, of which approximately $750,000 was incurred in 2006.

*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 is to secure European commercial approval for our novel BioSTAR® technology through the Conformité Europeene ("CE Mark") process, which we anticipate receiving within the next few months. We currently estimate total costs of this study, including third party contracts and agreements with clinical sites and other service providers, to be in the range of $1.4 to $1.6 million. Of this total, approximately $1.3 million was incurred through 2006 and we currently estimate 2007 costs to be approximately $300,000.

*CLOSURE I*

We have committed significant financial and personnel resources to the execution of our pivotal CLOSURE I clinical trial. Including contracts with third party providers, agreements with participating clinical sites, internal clinical department costs and manufacturing costs of the STARFlex® devices to be implanted, total costs are currently estimated to be approximately $24 million through completion of the trial and submission to the FDA. Of this total, approximately $4.5 million, $3.2 million and $3.7 million were incurred during 2006, 2005 and 2004, respectively. We currently project 2007 costs to approximate $4.0 to $4.5 million, largely dependent upon the rate of patient enrollment. Currently there are more than 600 patients enrolled and enrollment has progressed much slower than anticipated. We now believe that study changes, acceptable to the FDA, the investigators and us, are necessary in order to successfully complete this study. Until these changes are approved, it is difficult to estimate the completion date. On March 2, 2007 the FDA held a public and private advisory panel meeting in order to discuss and subsequently make recommendations regarding the clinical trial design for PFO closure devices intended to reduce recurrent stroke. While the official recommendation has not yet been published, the FDA and advisory panel concurred that only randomized, controlled trials would provide the data necessary to be considered for pre-market approval. We provided the FDA and advisory panel our plan to complete the CLOSURE I study. Included in the plan is a protocol specified interim analysis of the study data. We are blinded to that data, but are able to ask if a revised statistical plan, under consideration by us and our investigators and advisors, is appropriately powered. If the revised plan is appropriate and approved by the FDA, we will be able to provide more accurate guidance on the time needed to complete enrollment. We expect to have this guidance within the next 90 days.

(e) Guarantees and Indemnifications

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

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

## (8) STOCKHOLDERS' EQUITY

(a) Preferred Stock

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

(b) Rights Agreement

In June 1999, our Board of Directors adopted a stockholder rights plan ("Rights Plan"). The Rights Plan is intended to protect our stockholders from unfair or coercive takeover practices. In accordance with the Rights Plan, our Board of Directors declared a dividend distribution of one purchase right (a "Right") for each share of common stock outstanding to our stockholders of record on June 10, 1999. Each share of common stock newly issued after that date also carries with it one Right. Subject to the conditions contained in the Rights Plan, each Right entitles the registered holder to purchase from 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.

### (9) STOCK OPTIONS

Our 1996 Stock Option Plan (the "1996 Plan"), 1998 Stock Incentive Plan (the "1998 Plan") and 2001 Stock Incentive Plan (the "2001 Plan") (collectively, the "Plans") generally provide for the grant of incentive stock options, nonstatutory stock options and restricted stock awards, as appropriate, to our eligible employees, officers, directors, consultants and advisors. The 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, 2006 there were 1,320,983 options outstanding and 240,324 options available for grant under the 1998 and 2001 Plans. There can be no additional grants under the 1996 Plan as this plan has expired.

In November 2005, we granted to employees 175,800 fully vested options with an exercise price of $16.34, the fair market value on the date of grant. Of the $2,731,788 pro forma share-based compensation expense for 2005 disclosed in Note 10, approximately $1,385,000 relates to these options. Had we granted these options with longer time-based vesting, we would have incurred significant share-based compensation expense in future years in accordance with newly issued SFAS No. 123R.

Our 1996 Stock Option Plan for Non-Employee Directors (the "Directors Plan") provides for the automatic grant of non-statutory stock options to purchase shares of common stock to our directors who are not our employees and who do not otherwise receive compensation from us. Under the terms of the Directors Plan, as amended, each new non-employee director not otherwise compensated by us receives an initial grant of options to purchase 20,000 shares of common stock at an exercise price equal to the fair market value per share at the date of grant, subject to vesting in equal monthly installments over a three-year period. Subsequently, coincident with such director's re-election to the Board at our annual meeting of stockholders, there is an additional grant of options to purchase 5,000 shares of common stock that fully vests six months after the date of grant. In addition, following each annual meeting of stockholders, each eligible director who served as a member of a committee of the Board of Directors during the preceding fiscal year is granted an additional option to purchase (i) 2,000 shares of common stock if such director served as a chairperson of such committee or (ii) 1,000 shares of common stock if such director did not serve as chairperson of such committee. At December 31, 2006 there were 198,600 options outstanding under the Directors Plan. There can be no additional grants under this plan, as this plan has expired.

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

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

All unexercised options expire ten years from date of grant.

### (10) SHARE-BASED COMPENSATION

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 123 (revised 2004) "Share-Based Payment" ("SFAS No. 123R"). SFAS No. 123R replaces SFAS No. 123, "Accounting for Stock-Based Compensation," supersedes APB Opinion No. 25 "Accounting for Stock Issued to Employees" ("APB No. 25"), and amends SFAS No. 95, "Statement of Cash Flows." SFAS No. 123R requires entities to recognize compensation expense for all share-based payments to employees and directors, including grants of employee stock options, based on the grant-date fair value of those share-based payments (with limited exceptions), adjusted for expected forfeitures. In April 2005, the Securities and Exchange Commission ("SEC") issued a final ruling that extended the compliance date for SFAS No. 123R to the first interim or annual reporting period of the registrant's first fiscal year that begins on or after June 15, 2005. Effective January 1, 2006, we adopted SFAS No. 123R using the modified prospective application method. Prior to the adoption of SFAS No. 123R, we followed the intrinsic value method in accordance with APB No. 25 to account for employee stock options. Historically, all stock options have been granted with an exercise price equal to the fair market value of the common stock on the date of grant. Accordingly, no compensation expense was recognized from option grants to employees and directors prior to the adoption of SFAS No. 123R.

Under the modified prospective approach, SFAS No. 123R applies to new awards issued on or after January 1, 2006 as well as awards that were outstanding as of December 31, 2005, including those that are subsequently modified, repurchased or cancelled. Under the modified prospective approach, we utilize the straight-line attribution method for recognizing share-based compensation expense under SFAS No. 123R. We recorded $870,000 of compensation expense in the year ended December 31, 2006, for share-based payment awards made to our employees and directors consisting of stock options issued based on the estimated fair values. Of these amounts, for the year ended December 31, 2006, $519,000 was recorded as part of general and administrative expenses, $188,000 was included in research and development expenses, $134,000 was included in selling and marketing and $29,000 was included in cost of product sales.

At December 31, 2006, 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 No. 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 2005 and 2004, and in 2006, if not for the net gain from settlement of litigation we would have also recorded a net loss. Accordingly, we have not recorded any benefits from tax deductions in our SFAS No. 123R calculation for the year ended December 31, 2006. Under prior accounting rules, the benefits of tax deductions in excess of recognized compensation cost would have been included in net operating cash flows. Total cash flow remains unchanged from what would have been reported under prior accounting rules.

Results for the year ended December 31, 2005 have not been restated. Had compensation expense for employee stock options been determined based on fair value at the grant date consistent with SFAS No. 123R, with stock options expensed using the straight-line attribution method, our net income and earnings per share for the years ended December 31, 2005 and 2004 would have been reduced to the pro forma amounts indicated below:

| | 2006 | 2005 |
|---|---|---|
| Net loss as reported (Under APB No. 25) | $ (7,792,256) | $(1,909,437) |
| Add: Share-based employee compensation included in net loss as reported | 257,188 | 99,326 |
| Less: Total stock-based employee compensation expense determined under fair value based methods for all awards | (2,731,788) | (1,256,070) |
| Pro forma net loss | $(10,266,856) | $(3,066,181) |
| Basic and Diluted net loss per common share: | | |
| As reported | $ (0.63) | $ (0.16) |
| Pro forma | $ (0.83) | $ (0.25) |

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

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| Expected life (years) | 4 | 7 | 7 |
| Expected stock price volatility | 58% - 63% | 68% - 69% | 70% - 73% |
| Expected dividend yield | 0 | 0 | 0 |
| Risk-free interest rate | 4.27% - 5.23% | 3.86% - 4.48% | 3.31% - 4.35% |

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 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 No. 123R, we adjust the estimated forfeiture rate based upon actual experience. The expected life for the year ended December 31, 2006 was based upon the actual forfeiture rate for the preceding four years, which resulted in a life shorter than the vesting period. In accordance with the requirements of SFAS No. 123R, we used the expected life equal to the vesting period of four years. For the years ended December 31, 2005 and 2004, we used the midpoint of the vesting period to the grant expiration, which ranged from four years to ten years, to obtain the expected life of seven years.

The following table summarizes a reconciliation of all stock option activity for the year ended December 31, 2006:

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Options outstanding at January 1, 2006 | 1,739,509 | $ 6.14 | | |
| Granted | 137,075 | 14.89 | | |
| Exercised | (236,372) | 3.61 | | $ 2,667 |
| Cancelled | (120,329) | 10.91 | | |
| Options outstanding at December 31, 2006 | 1,519,883 | 6.94 | 6.58 | $10,715 |
| Options Exercisable at December 31, 2006 | 1,243,172 | $ 6.65 | 6.24 | $ 9,035 |

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.

Net cash proceeds from the exercise of stock options were $852,045 for the year ended December 31, 2006. We have not recorded any tax benefit from stock option exercises, since we have a minimal tax provision for the year ended December 31, 2006, and expect to have operating losses through 2008.

The following table summarizes information about stock options at December 31, 2006:

| | OUTSTANDING OPTIONS | | | EXERCISABLE OPTIONS | |
|---|---|---|---|---|---|
| | Shares | Weighted Average Remaining Life (in years) | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| $ 1.50 - 2.25 | 106,192 | 3.94 | $ 1.97 | 106,192 | $ 1.97 |
| $ 2.26 - 3.50 | 322,837 | 6.41 | 3.18 | 254,378 | 3.10 |
| $ 3.51 - 5.18 | 298,781 | 6.32 | 4.35 | 234,462 | 4.43 |
| $ 5.19 - 7.80 | 439,173 | 5.72 | 6.66 | 391,870 | 6.60 |
| $ 7.81 - 12.19 | 111,150 | 8.70 | 10.03 | 87,127 | 10.02 |
| $12.20 - 15.92 | 23,125 | 9.22 | 14.52 | 1,000 | 15.56 |
| $15.93 - 17.60 | 210,975 | 8.87 | 16.53 | 167,933 | 16.40 |
| $17.61 - 23.10 | 7,650 | 9.09 | 20.05 | 210 | 21.25 |
| $ 1.50 - 23.10 | 1,519,883 | 6.58 | $ 6.94 | 1,243,172 | $ 6.65 |

**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 29,806, 49,332 and 58,134 shares of common stock under the ESPP during the years ended December 31, 2006, 2005 and 2004, respectively. The average purchase prices for total ESPP shares acquired were $11.16, $4.50 and $3.56 for the years ended December 31, 2006, 2005 and 2004, respectively. At December 31, 2006, there were 141,247 shares available for issuance under the ESPP, as amended.

## (11) RELATED PARTY TRANSACTIONS

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

## (12) ACCRUED EXPENSES

Accrued expenses consisted of the following:

| AT DECEMBER 31, | 2006 | 2005 |
|---|---|---|
| Clinical trials | $ 4,135,710 | $ 2,861,782 |
| Payroll and payroll related | 1,264,429 | 1,253,173 |
| Royalties | 1,247,775 | 992,556 |
| Professional Fees | 648,431 | 572,442 |
| Other accrued expenses | 1,702,806 | 835,856 |
| | $ 8,999,151 | $ 6,515,809 |

## (13) FINANCIAL INFORMATION BY GEOGRAPHIC AREA

Revenues by destination country for the years ended December 31, 2006, 2005 and 2004 were as follows:

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| United States | $25,314,000 | $20,583,000 | $17,567,000 |
| Germany | 312,000 | 905,000 | 1,671,000 |
| United Kingdom | 1,258,000 | 822,000 | 452,000 |
| Other | 1,267,330 | 1,606,161 | 1,770,024 |
| | $28,151,330 | $23,916,161 | $21,460,024 |

Net book value of long-lived assets by country at December 31, 2006 and 2005 were as follows:

| | 2006 | 2005 |
|---|---|---|
| United States | $ 1,032,330 | $ 793,556 |
| Other | 6,997 | 11,213 |
| | $ 1,039,327 | $ 804,769 |

## (14) 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, | 2006 | 2005 | 2004 |
|---|---|---|---|
| Balance at beginning of period | $369,984 | $378,150 | $385,000 |
| Provision for bad debt and sales returns adjustments | — | — | — |
| Write-offs and returns | (87,516) | (8,166) | (6,850) |
| Balance at end of period | $282,468 | $369,984 | $378,150 |

## (15) LEGAL PROCEEDINGS

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

In September 2004, we and CMCC filed a civil complaint in the U.S. District Court for the District of Minnesota for infringement of a patent owned by CMCC and licensed exclusively to us. The complaint alleges that Cardia of Burnsville, Minnesota is making, selling and/or offering to sell a medical device in the United States that infringes CMCC's U.S. patent relating to a device and method for repairing septal defects. We sought an injunction from the court to prevent further infringement by Cardia, as well as monetary damages. On August 30, 2006 the court entered an order holding that Cardia's device does not infringe the patent-in-suit. The order has no effect on the validity and enforceability of the patent-in-suit and has no impact on our ability to sell our products. We have appealed the ruling to the U.S. Court of Appeals for the Federal Circuit where we seek to have the decision overturned.

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

On 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 has been 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. On April 12, 2006, we received the entire cash payment from the settlement totaling $30.0 million. The cash payment was shared equally, after our legal fees and expenses, with Dr. Marks.

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

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

## EXHIBIT INDEX

| Exhibit No. | Description | Incorporated by Reference to: Form and SEC File No. | SEC Filing Date | Exhibit No. | Filed with this 10-K |
|---|---|---|---|---|---|
| | ***Acquisition Agreements*** | | | | |
| 2.1' | Asset Purchase Agreement, dated as of October 19, 2001, among the Registrant and C.R. Bard, Inc. | 8-K (000-21001) | 11-16-2001 | 2.1 | |
| 2.2 | Stock Purchase Agreement, dated as of July 31, 2002, between the Registrant and Integra LifeSciences Corporation | 8-K (000-21001) | 8-14-2002 | 2.1 | |
| 2.3 | Agreement and Plan of Merger by and among the Registrant, NMT Heart, Inc., InnerVentions, Inc. and Fletcher Spaght, Inc., dated as of January 25, 1996 | S-1 (333-06463) | 6-20-1996 | 10.3 | |
| | ***Certificate of Incorporation and By-Laws*** | | | | |
| 3.1 | Second Amended and Restated Certificate of Incorporation of the Registrant | 10-Q (000-21001) | 8-5-1998 | 3.1 | |
| 3.2 | Certificate of Amendment of Second Amended and Restated Certificate of Incorporation of the Registrant | 10-Q (000-21001) | 8-16-1999 | 3.1 | |
| 3.3 | Certificate of Designation, Series A Junior Participating Preferred Stock of the Registrant | 10-Q (000-21001) | 8-16-1999 | 3.2 | |
| 3.4 | Amended and Restated By-Laws of the Registrant | S-1 (333-06463) | 6-20-1996 | 3.2 | |
| | ***Instruments Defining the Rights of Security Holders*** | | | | |
| 4.1 | Form of Common Stock Certificate of the Registrant | S-1/A (333-06463) | 7-12-1996 | 4.1 | |
| 4.2 | Rights Agreement, dated as of June 7, 1999, between the Registrant and American Stock Transfer & Trust Company, as Rights Agent | 8-K (000-21001) | 6-8-1999 | 4.1 | |
| | ***Material Contracts-Equity Compensation Plans and Related Agreements*** | | | | |
| 10.1* | 1994 Stock Option Plan of the Registrant | S-1 (333-06463) | 6-20-1996 | 10.28 | |
| 10.2* | 1996 Stock Option Plan of the Registrant, as amended | 10-Q (000-21001) | 8-5-1998 | 10.1 | |
| 10.3* | 1996 Stock Option Plan for Non-Employee Directors, as amended, of the Registrant | 10-Q (000-21001) | 8-11-2003 | 10.3 | |
| 10.4* | 1998 Stock Incentive Plan of the Registrant | 10-Q (000-21001) | 8-5-1998 | 10.2 | |
| 10.5* | 2001 Stock Incentive Plan, as amended, of the Registrant | 10-Q (000-21001) | 8-10-2004 | 10.1 | |
| 10.6* | 2001 Employee Stock Purchase Plan, as amended, of the Registrant | 10-Q (000-21001) | 8-11-2003 | 10.2 | |
| 10.7* | Amendment, dated as of December 31, 2002, to Incentive Stock Option Agreement between the Registrant and John E. Ahern, dated as of September 21, 2000 | 10-K (000-21001) | 3-20-2003 | 10.37 | |
| 10.8* | Incentive Stock Option Agreement Granted Under 2001 Stock Incentive Plan between the Registrant and John E. Ahern, dated as of December 31, 2002 | 10-K (000-21001) | 3-20-2003 | 10.34 | |
| 10.9* | Incentive Stock Option Agreement Granted Under 2001 Stock Incentive Plan between the Registrant and Richard E. Davis, dated as of September 21, 2004 | 8-K (000-21001) | 9-27-2004 | 99.1 | |

## EXHIBIT INDEX

| Exhibit No. | Description | Incorporated by Reference to: Form and SEC File No. | SEC Filing Date | Exhibit No. | Filed with this 10-K |
|---|---|---|---|---|---|
| 10.10* | Form of Incentive Stock Option Agreement Granted Under 2001 Stock Incentive Plan, as amended | 10-Q (000-21001) | 11-10-2004 | 10.1 | |
| 10.11* | Form of Incentive Stock Option Agreement Granted Under 1998 Stock Incentive Plan | 10-Q (000-21001) | 11-10-2004 | 10.2 | |
| 10.12* | Form of Incentive Stock Option Letter Agreement Granted Under 1996 Stock Option Plan | 10-Q (000-21001) | 11-10-2004 | 10.3 | |
| 10.13* | Form of Nonstatutory Stock Option Letter Agreement Granted Under 1996 Stock Option Plan for Non-Employee Directors, as amended | 10-Q (000-21001) | 11-10-2004 | 10.4 | |
| | ***Material Contracts-Registration Rights Agreements*** | | | | |
| 10.14 | Registration Rights Agreement between the Registrant and Fletcher Spaght, Inc., dated as of February 14, 1996 | S-1 (333-06463) | 6-20-1996 | 10.6 | |
| 10.15 | Amendment No. 1, dated as of July 1, 1998, to Registration Rights Agreement between the Registrant and Fletcher Spaght, Inc., dated as of February 14, 1996 | 10-K (000-21001) | 4-15-1999 | 10.6.1 | |
| 10.16 | Form of Registration Rights Agreement between the Registrant and certain of its existing stockholders, dated as of February 14, 1996 | S-1 (333-06463) | 6-20-1996 | 10.26 | |
| 10.17 | Registration Rights Agreement, dated as of March 30, 1999, among the Registrant and the individuals listed on Schedule A thereto | 10-Q (000-21001) | 5-17-1999 | 10.3 | |
| | ***Material Contracts-Leases*** | | | | |
| 10.18 | Lease by and between the Registrant and the Trustees of Wormwood Realty, dated as of May 8, 1996 | S-1 (333-06463) | 6-20-1996 | 10.27 | |
| 10.19 | Amendment of Leases by and between the Registrant and Fort Point Place-VEF V, LLC, as successor to Trustees of Wormwood Realty Trust, dated as of November 9, 2005 | 8-K (000-21001) | 11-14-2005 | 10.1 | |
| | ***Material Contracts-License and Technology Related Agreements*** | | | | |
| 10.20' | License and Development Agreement by and between the Registrant and Boston Scientific Corporation, dated as of November 22, 1994 | S-1/A (333-06463) | 9-5-1996 | 10.9 | |
| 10.21' | Technology Purchase Agreement by and between the Registrant and Morris Simon, M.D., dated as of April 14, 1987 | S-1/A (333-06463) | 9-5-1996 | 10.11 | |
| 10.22 | Asset and Technology Donation and Transfer Agreement by and between C.R. Bard, Inc. and Children's Medical Center Corporation dated as of May 12, 1995 | S-1/A (333-06463) | 7-12-1996 | 10.12 | |
| 10.23 | Stock Transfer Agreement between Children's Medical Center Corporation and InnerVentions, Inc., dated as of June 19, 1995 | S-1/A (333-06463) | 7-12-1996 | 10.13 | |
| 10.24' | License Agreement by and between Children's Medical Center Corporation and InnerVentions, Inc., dated as of June 19, 1995 | S-1/A (333-06463) | 8-13-1996 | 10.14 | |
| 10.25 | Sublicense Agreement by and between Children's Medical Center Corporation and InnerVentions, Inc., dated as of June 19, 1995 | S-1/A (333-06463) | 7-12-1996 | 10.15 | |
| 10.26 | Assignment Agreement by and between the Registrant and The Beth Israel Hospital Association, dated as of June 30, 1994 | S-1/A (333-06463) | 7-12-1996 | 10.16 | |

## EXHIBIT INDEX

| Exhibit No. | Description | Incorporated by Reference to: Form and SEC File No. | SEC Filing Date | Exhibit No. | Filed with this 10-K |
|---|---|---|---|---|---|
| 10.27† | Agreement by and between the Registrant and Lloyd A. Marks, dated as of April 15, 1996 | S-1/A (333-06463) | 8-13-1996 | 10.17 | |
| 10.28 | License Agreement, dated as of October 2000, by and between the Registrant and Children's Medical Center Corporation | 10-K (000-21001) | 4-2-2001 | 10.66 | |
| 10.29† | Royalty Agreement, dated as of October 19, 2001, by and among the Registrant and C.R. Bard, Inc. | 8-K (000-21001) | 11-16-2001 | 10.1 | |
| | ***Material Contracts-Employment Agreements and Compensation Arrangements*** | | | | |
| 10.30#* | Amended and Restated Employment Agreement by and between the Registrant and John E. Ahern, dated as of December 31, 2002 | 10-K (000-21001) | 3-20-2003 | 10.36 | |
| 10.31#* | Second Amended and Restated Employment Agreement by and between the Registrant and John E. Ahern, dated as of December 13, 2005 | 8-K (000-21001) | 12-14-2005 | 10.1 | |
| 10.32#* | Amendment No. 1, dated as of April 28, 2003, to Employment Agreement by and between the Registrant and Richard E. Davis, dated as of February 14, 2001 | 10-K/A (000-21001) | 4-30-2003 | 10.39 | |
| 10.33#* | Amended and Restated Employment Agreement by and between the Registrant and Richard E. Davis, dated as of May 20, 2004 | 10-Q (000-21001) | 8-10-2004 | 10.2 | |
| 10.34* | Revised Summary of Compensation Arrangement Applicable to the Registrant's Non-Employee Directors | | | | * |
| 10.35* | Revised Summary of Compensation Arrangement Applicable to the Registrant's Named Executive Officers | | | | * |
| | ***Additional Exhibits*** | | | | |
| 14.1 | Code of Business Conduct and Ethics of the Registrant | 10-K (000-21001) | 3-24-2004 | 14.1 | |
| 21.1 | Subsidiaries of the Registrant | | | | * |
| 23.1 | Consent of Ernst & Young LLP | | | | * |
| 31.1 | Certification by Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | * |
| 31.2 | Certification by Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | * |
| 32.1 | Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | * |
| 32.2 | Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | * |

# Management contracts or compensatory plans or arrangements required to be filed as an exhibit hereto pursuant to Item 15(a) of Form 10-K.

† Confidential treatment requested as to certain portions, which portions have been separately filed with the Securities and Exchange Commission.

**EXHIBIT 10.34**

## REVISED SUMMARY OF COMPENSATION ARRANGEMENT APPLICABLE TO THE COMPANY'S NON-EMPLOYEE DIRECTORS

As of March 12, 2007, the following represents the compensation program for non-employee directors of NMT Medical, Inc. (the "Company") who are not otherwise compensated by the Company:

- an option to purchase 20,000 shares of the Company's Common Stock (the "Common Stock") upon initial election and an option to purchase 5,000 shares (7,000 shares for the Company's Lead Director) of Common Stock annually thereafter upon re-election at the Company's annual meeting of stockholders;
- 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 chairperson of such committee or (ii) 1,000 shares of Common Stock if such director did not serve as chairperson of such committee;
- $15,000 ($18,000 for the Company's Lead Director) per year for their services as directors;
- $2,000 ($2,500 for the Company's Lead Director) for each meeting of the Board of Directors that they attend in person;
- $1,000 ($1,250 for the Company's Lead Director) for each telephonic meeting of the Board of Directors that they participate in;
- $1,000 ($1,500 for each committee chairperson) for each board committee meeting that they attend in person;
- $500 ($750 for each committee chairperson) for each telephonic board committee meeting that they participate in; and
- expense reimbursement for attending Board of Directors and board committee meetings.

## EXHIBIT 10.35

### REVISED SUMMARY OF COMPENSATION ARRANGEMENT APPLICABLE TO THE COMPANY'S NAMED EXECUTIVE OFFICERS

As of March 12, 2007, the following represents the compensation of the executive officers of NMT Medical, Inc. (the "Company"):

| | 2007 Compensation | | |
|---|---|---|---|
| Executive Officer | Annual Salary | Bonus for Work Exercise Price | Shares Underlying Stock Options Granted in 2006 |
| John E. Ahern | | | |
| President and Chief Executive Officer | $400,000 | $ 0 | 50,000 |
| Richard E. Davis | | | |
| Executive Vice President and Chief Financial Officer | $300,000 | $135,000 (1) | 0 |

(1) Mr. Davis' bonus was paid in accordance with the terms of that certain Amended and Restated Employment Agreement that he entered into with the Company on May 20, 2004, which is filed as an exhibit to the Company's Quarterly Report on Form 10-Q as filed with the SEC on August 10, 2004.

## EXHIBIT 21.1

### LIST OF SUBSIDIARIES FOR NMT MEDICAL, INC.:

NMT Heart, Inc.

NMT Investments Corp.

Nitinol Medical Technologies FSC, Inc.

Nitinol Medical Technologies International B.V.

NMT Neurosciences Holdings (UK) Limited

NMT Medical SARL

NMT Medical GmbH

NMT Medical (UK) Limited

**EXHIBIT 23.1**

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Form S-3 Nos. 333-138073 and Form S-8 No. 333-31751, 333-67265, 333-62618, 333-107462, 333-118041 and 333-136406) of NMT Medical, Inc. and in the related Prospectus of our reports dated March 9, 2007, with respect to the consolidated financial statements of NMT Medical, Inc., NMT Medical, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of NMT Medical, Inc., included in the Annual Report (Form 10-K) for the year ended December 31, 2006.

Ernst & Young LLP

Boston, Massachusetts
March 9, 2007

## EXHIBIT 31.1

### CERTIFICATIONS

I, John E. Ahern, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 12, 2007

/s/ JOHN E. AHERN
John E. Ahern
President and Chief Executive Officer
(Principal Executive Officer)

## EXHIBIT 31.2

### CERTIFICATIONS

I, Richard E. Davis, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 12, 2007

/s/ RICHARD E. DAVIS
Richard E. Davis
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

## EXHIBIT 32.1

### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of NMT Medical, Inc. (the "Company") for the period ended December 31, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, John E. Ahern, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2007

/s/ JOHN E. AHERN
John E. Ahern
President and Chief Executive Officer
(Principal Executive Officer)

**EXHIBIT 32.2**

## CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of NMT Medical, Inc. (the "Company") for the period ended December 31, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Richard E. Davis, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2007

/s/ RICHARD E. DAVIS
Richard E. Davis
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

# CORPORATE DIRECTORY

## BOARD OF DIRECTORS

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

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

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

Francis J. Martin[1,2,3]
Chief Executive Officer
Corindus Inc.

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

## COMMITTEES OF THE BOARD

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

[2] Member of the Audit Committee

[3] Member of the Nominating and Corporate Governance Committee

## CORPORATE OFFICERS

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

Richard E. Davis
Executive Vice President and
Chief Financial Officer

## ORGANIZATION

Carol A. Devellian
Vice President of
Research and Development

Geoff Fournie
Vice President of Clinical
Development – Europe

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

Brad Ryno
Vice President of Worldwide Sales

Ron Seyffert
Director of Marketing

Fred Tobia
Vice President of Clinical
and Regulatory Affairs

## CORPORATE HEADQUARTERS

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

## FORM 10-K AVAILABILITY

A copy of the Annual Report on Form 10-K for the year ended December 31, 2006 may be obtained at no charge by writing to the Company.

## TRANSFER AGENT

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

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young LLP
Boston, Massachusetts

## COUNSEL

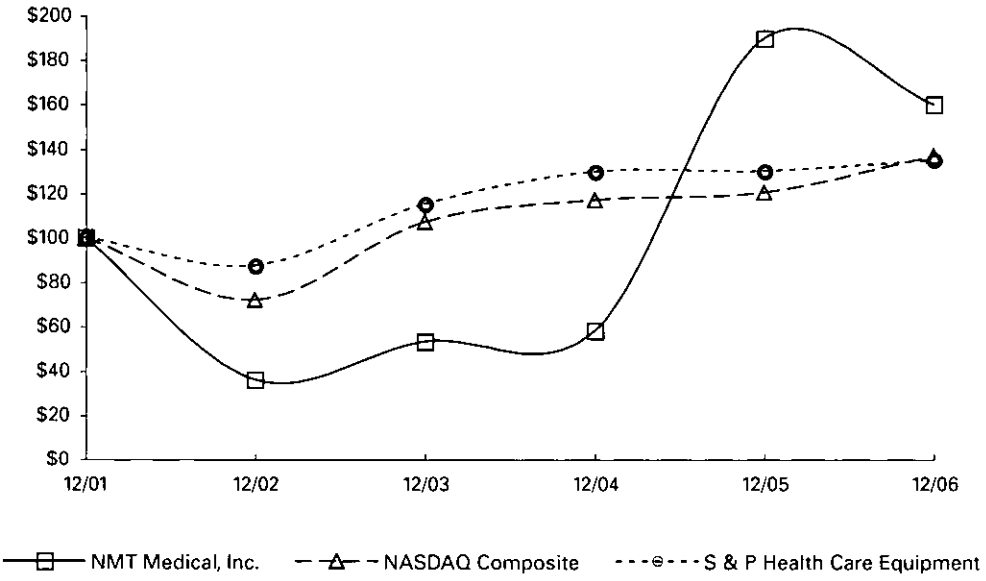
WilmerHale
60 State Street
Boston, Massachusetts 02109

## ANNUAL MEETING

The Annual Meeting of Stockholders will be held on Thursday, June 21, 2007 at 1:00 pm, at the Seaport Hotel, One Seaport Lane, Boston.

## COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among NMT Medical, Inc., The NASDAQ Composite Index
and The S & P Health Care Equipment Index




* $100 invested on 12/31/01 in stock or index-including reinvestment of dividends. Fiscal year ending December 31.

NMT Medical, Inc.

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

www.nmtmedical.com

END