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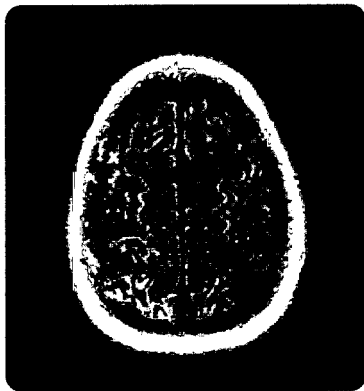
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NMT Medical, Inc. ANNUAL REPORT 2003
Getting to the Heart of Brain Attacks

Clinicians are seeing a connection.

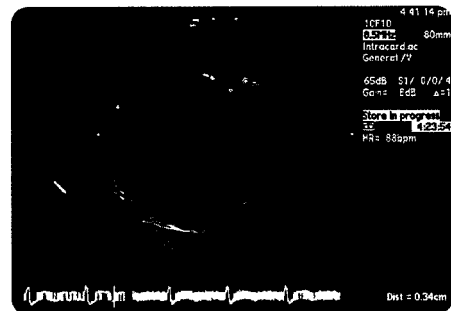
"Paradoxical embolism through a patent foramen ovale may be responsible for stroke more often than is usually suspected."

Lechat P, Mas JL, Lascault G, Loron P, Theard M, Klimczak M, Drobinski G, Thomas D, Grosgeat Y. Prevalence of patent foramen ovale in patients with stroke. *New England Journal of Medicine* 1988; 318(18):1148-52.



Stroke

PFO

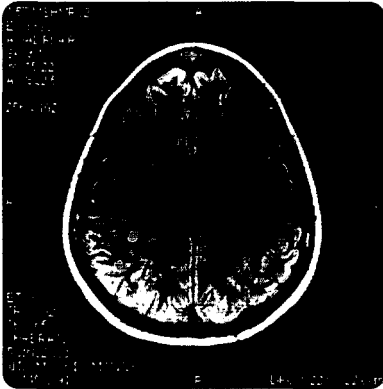


"...indications are bound to widen, especially if controlled trials and large series confirm that PFO closure reduces the life-long risk of recurrent stroke and perhaps other ailments."

Meier B, Lock J. Contemporary Management of Patent Foramen Ovale. *Circulation* 2003;107:5-9.

"The prospect that...PFO closure...may reduce migraine attacks or even cure some patients...is encouraging for all those suffering from this disabling condition."

Windecker S. Closing a common heart defect improves migraine. European Society of Cardiology Congress 2003, Vienna, Austria.



Migraine

Closure



"The ideal septal occluder scaffold should promote the healthiest and most complete healing response possible while eventually facilitating the full resorption of the material, leaving "native" tissue behind."

Jux C, Wohlsein P, Bruegmann M, Zutz M, Franzbach B, Bertram H. A new biological matrix for septal occlusion. *Journal of Interventional Cardiology* 2003;16(2):149-152.

Strokes. Transient ischemic attacks. Migraines. Evidence is mounting that these attacks on the brain may be linked to a common heart defect called patent foramen ovale (PFO).

NMT Medical is getting to the heart of this connection. With CLOSURE I, a landmark PFO-stroke clinical trial. Studies that could bring new hope to migraine sufferers. And the most advanced device for PFO closure – the 5th generation BioSTAR.™

NMT Medical leads the field in clinical research, technology, and experience. Our mission is the prevention of millions of debilitating cerebral events through minimally-invasive, catheter-based PFO closure. We are asking the right questions, conducting groundbreaking research, and producing the most technologically advanced device to get to the heart of brain attacks.

What brings neurologists and interventional

Partners: Individuals with a common interest working together to achieve more than can be accomplished alone.

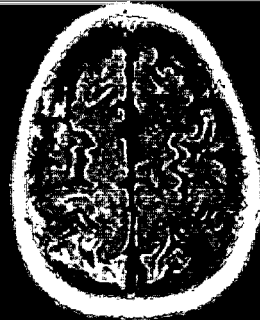
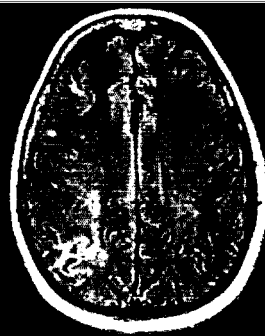
Partnership is a good description of the relationship that is developing between stroke neurologists and interventional cardiologists. These two usually disparate specialties are collaborating to diagnose and treat PFO-stroke patients.

Patent foramen ovale (PFO) is a small opening in a wall of the heart that is detectable in about 25% of the population. This wall separates the blood returning to the heart and lungs from the blood being pumped out to the rest of the body. Most people with PFO live without any adverse effects. However, for some, the PFO may enable tiny clots, normally filtered out of the blood by the lungs, to pass through the wall into arterial circulation. If the blood clot travels to the brain, stroke may result.

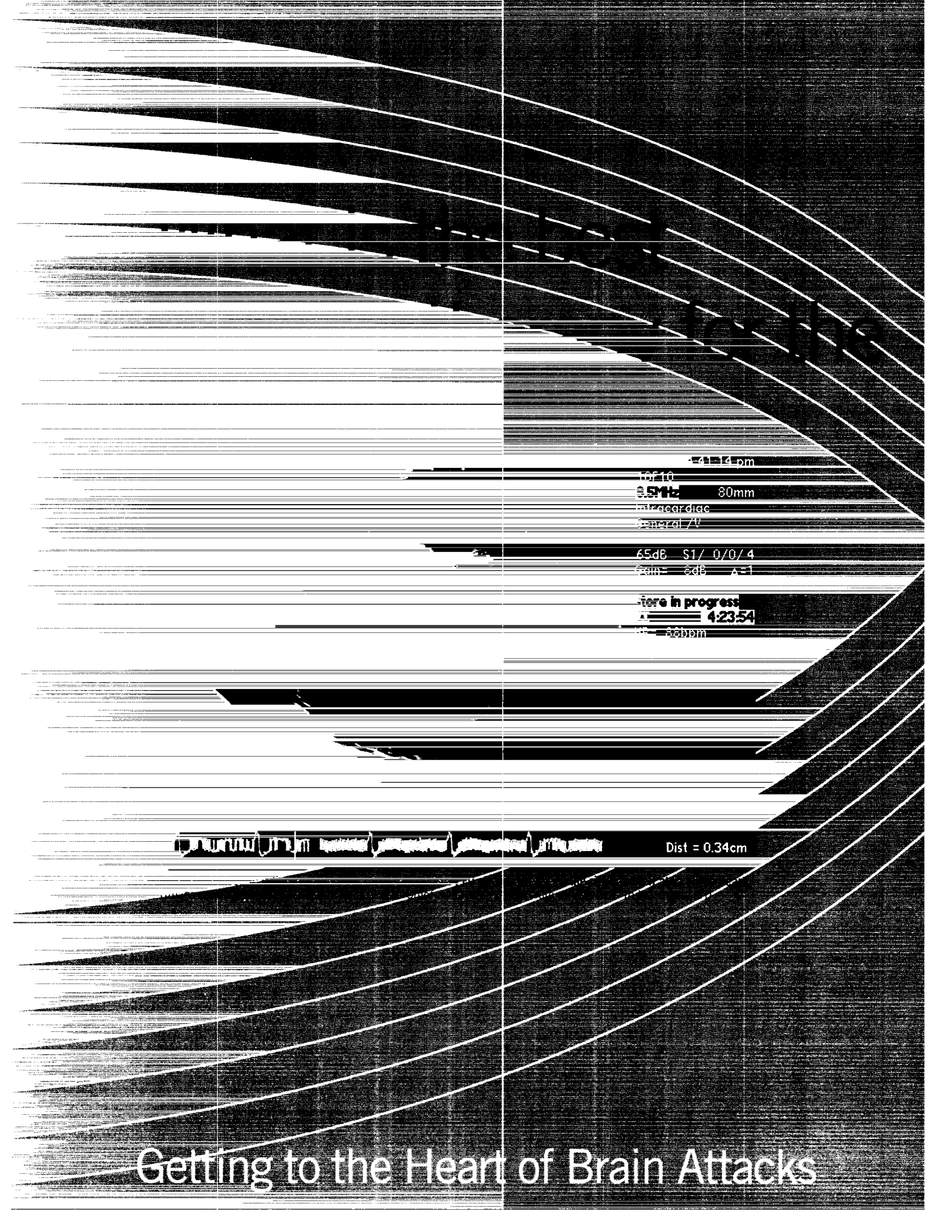
Increased awareness of the PFO-stroke connection is bringing more stroke neurologists and interventional cardiologists together to form a treatment team. NMT Medical is at the forefront of facilitating communication between these specialties. In May 2003, the Company sponsored an historic joint meeting of EURO-PCR, the largest interventional cardiology meeting in Europe, and EUROSTROKE, a major annual European conference attended by stroke neurologists. The two meetings were linked together via satellite, with a third link to the Erasmus University Hospital in Rotterdam, The Netherlands.

Approximately 1,400 members of the interventional cardiology and stroke neurology communities witnessed a live case demonstration of PFO closure with NMT Medical's STARFlex® device. It was an unprecedented gathering of physicians who will champion the prevention of cardiac sources of stroke. NMT Medical has made a commitment to supporting these specialties through education, research, and technology. By joining forces, we can accomplish more.

cardiologists together?



Getting to the Heart of Brain Attacks



4.14 cm
10F10
0.5MHz 80mm
intracardiac
Sector / V

65dB S1/ 0/0/4
Gain= 6dB A=1

Time in progress
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888mm



Dist = 0.34cm

Getting to the Heart of Brain Attacks

PFO patient with stroke?

Sometimes to move forward, you have to take a stand. That is why NMT Medical made the decision to launch the most extensive clinical trial ever conducted to determine the most appropriate treatment for PFO patients threatened by stroke or transient ischemic attack (TIA): PFO closure or anticoagulation drug regimens of warfarin and/or aspirin. It's an enormous program involving 1,600 patients, more than 100 major medical centers, and two-year follow-up. But it is designed to deliver a definitive answer to the question "Is PFO closure better than medical therapy in treating the PFO stroke or TIA patient?"

Designed by stroke specialists, CLOSURE I is the largest, prospective, multi-center, randomized controlled trial designed to evaluate the safety and efficacy of NMT Medical's STARFlex® septal closure system vs. best medical therapy in patients with a stroke and/or TIA due to presumed paradoxical embolism through a PFO. STARFlex® is commercially available in Europe, but is an investigational device in the US and only available to patients in the CLOSURE I study.

Leading the CLOSURE I trial as principal investigator is Anthony Furlan, MD, Director of the Stroke Program at The Cleveland Clinic. The lead interventional cardiologist investigator in the study is Mark Reisman, MD, Director of Cardiovascular Research at Swedish Medical Center in Seattle. The traditional treatment for prevention of recurrent stroke has been a lifelong regimen of blood thinners. However, this medical therapy imposes significant lifestyle limitations on patients and carries serious side effects. Since PFO may be the most common underlying cause of stroke for patients under 55, the importance of this objectively designed study is evident. Other members of the CLOSURE I executive committee who participated in the design of the study are:

Harold Adams, MD; Neurology, University of Iowa Medical Center, Iowa City, IA

Lawrence Brass, MD; Neurology, Yale New Haven Hospital University Medical Center, New Haven, CT

Howard Herrmann, MD; Cardiology, University of Pennsylvania, Philadelphia, PA

Steven Kittner, MD; Neurology, University of Maryland Medical Center, Baltimore, MD

Michael Landzberg, MD; Cardiology, Brigham & Women's Hospital, Boston, MA

Reginald Low, MD; Cardiology, University of California Davis Medical Center, Davis, CA

Albert Raizner, MD; Cardiology, Texas Medical Center, Baylor College of Medicine,

Methodist Hospital, Houston, TX

Carole Thomas, MD; Neurology, Drexel University, Hahnemann Hospital, Philadelphia, PA

Lawrence Wechsler, MD; Neurology, University of Pittsburgh Medical Center, Pittsburgh, PA

Is PFO closure an

There are few conditions more evocative of extreme pain than migraine. Medical therapy has shown mixed results in treating its debilitating symptoms. Considerable research is being conducted to unlock the mysteries of migraine. And one of the most remarkable findings has been a possible connection with PFO.

Studies have indicated that up to half of the patients suffering from migraine with aura have a PFO. That is twice the PFO rate as in the general population. It has been theorized that blood clots passing from the PFO to the brain, too small to cause a stroke, could nonetheless trigger an attack. Alternatively, other biological substances usually cleared in the lungs could escape through the PFO, and travel to the brain via arterial circulation.

In an abstract delivered at the European Society of Cardiology Congress in late 2003, Dr. Stephan Windecker revealed the results of PFO closure in 215 migraine sufferers. One year after closure, four out of five reported a marked reduction of their migraine attacks. On average, every second migraine was abolished. A quarter of all patients with migraine before PFO closure had no further headache during the year after closure.

In another study reported in the *Journal of Interventional Cardiology* (2003;16(1):39-42), Dr. Eva Morandi and her colleagues found that migraine aura disappeared in 6 of 8 patients after PFO closure, 5 of 17 no longer had migraines, and 10 of 17 were substantially improved.

According to The National Headache Foundation, some 28 million people in the USA suffer from migraines. The magnitude of this problem and the intriguing results of recent clinical experience have prompted NMT Medical to take the lead on migraine-PFO research. We will launch a clinical trial outside the USA in 2004 designed to answer the questions surrounding this connection. We may well find that we have also launched a significant advancement in migraine treatment.

Can the next generation



PROSODY Researchers used microstimulation to elicit vocalizations in a mouse brain. (Image courtesy of Christian Ahissar, PhD, University of Cambridge; Gernot Gammag and Peter Winkler, DVM, Institute of Pathology, School of Medicine, Heinrich Heine University, Hannover, Germany)

Coming to the Heart of Brain Activity

BioSTAR™ deliver better healing?

NMT Medical has been at the forefront of septal occluder design. In just a decade, over 18,000 NMT Medical devices, representing several generations of products, have been implanted worldwide. CardioSEAL® and STARFlex® have been awarded the CE mark in Europe, and are commercially available in several countries. CardioSEAL® has been approved in the USA by the FDA under a Humanitarian Device Exemption for selected patients with PFO who have experienced a second stroke while on anticoagulant therapy. A PMA approval has been granted for CardioSEAL® for use in certain high-risk patients with ventricular septal defects (VSD).

Our most recent innovation is our 5th generation implant. Named BioSTAR™ it is the first percutaneous transcatheter closure device made almost entirely of resorbable material. Because excellent biocompatibility is the foundation for a successful implanted device, 90% of the inert material has been replaced by a highly purified (acellular) bioengineered type-1 collagen.



BioSTAR™ at 180 days in the atrial level defect in a sheep heart (Image courtesy of: Christian Jux, MD, University of Goettingen, Germany and Peter Wohlsein, DVM, Institute of Pathology, School of Veterinary Medicine Hannover, Hannover, Germany)

In a pre-clinical study reported in the *Journal of Interventional Cardiology*, a complete pathomorphological investigation including histology was carried out on BioSTAR™. After only two weeks, BioSTAR™ showed significant new tissue growth over the device. The overall results were excellent: faster healing, decreased thrombogenicity, and decreased immunological host response.

The positive outcomes of this and other pre-clinical studies have shown that BioSTAR™ could optimize outcomes in PFO closure while minimizing the potential for complications. Based on this encouraging data, NMT Medical is proceeding to human trials with BioSTAR™.



Dear Fellow Shareholders,

These are exciting times for NMT Medical. During 2003, the Company continued to build and maintain a leadership position in the emerging, early stage opportunity of treating cardiac sources of stroke and other brain attacks with our proprietary catheter-based technologies.

The Company was first to receive full IDE approval from the FDA for a stroke prevention clinical trial to evaluate the effectiveness of transcatheter closure of a common cardiac defect called a patent foramen ovale (PFO).

Under certain conditions, the PFO acts like a flap valve between the right and left atria of the heart. The PFO may allow embolic material in the venous circulation to pass, unfiltered by the lungs, to the arterial circulation where it can then travel to an artery in the brain and potentially cause a stroke or TIA (transient ischemic attack). Stroke is the third leading cause of death in the United States and is the leading cause of permanent disability in adults. In the United States, the PFO defect may be a contributing factor in over 100,000 patients per year that have suffered a stroke or TIA.

NMT's clinical study, named CLOSURE I, is a ground-breaking endeavor designed to evaluate its STARFlex® implant in preventing recurrent stroke and TIA in patients after their initial event. The study is expected to enroll 1,600 patients, with half receiving a STARFlex® implant and the other half receiving traditional medical therapy. Follow-up will measure recurrent events over a period of two years. We have assembled a group of leading stroke experts and interventional cardiologists to help design and execute CLOSURE I.

More than 100 leading research centers in North America have committed to participate exclusively in CLOSURE I. Principal investigator for the study is Anthony Furlan, MD, Director of the Stroke Program at The Cleveland Clinic. Lead interventional cardiologist investigator in the study is Mark Reisman, MD, Director of Cardiovascular Research at Swedish Medical Center in Seattle. Data management and analysis is being conducted by the Harvard Clinical Research Institute (HCRI) in Boston under the direction of Richard Kuntz, MD.

Even though the PFO stroke and TIA connection has not yet been established in a scientific study like CLOSURE I, other discovery is evolving. Recent medical research has suggested a possible connection between a PFO and another brain attack: migraine headaches. In one study, 50% of migraine patients evaluated had a PFO, more than twice what would be expected in a normal population. Also, observational studies have reported that patients who have had their PFO sealed for other reasons, such as stroke, have reported incidentally that their symptoms were reduced or eliminated. While no one knows what triggers a migraine attack, we believe that in some patients it may be related to materials in the venous blood shunting through a PFO.

The Company's intention is to be the first to evaluate the PFO/migraine connection in a multi-center, science-based clinical trial. We have brought together a group of leading medical experts in the migraine field and plan to initiate a study outside the United States later this year.

Discovery and innovation in PFO closure technology is another area that NMT Medical intends to maintain leadership. We are concluding pre-clinical studies of our next, and fifth, generation catheter-based implant called BioSTAR™. What is unique about BioSTAR™ is that it enables us to eliminate 90% of

the inert material contained in our current implants by replacing it with a resorbable, collagen matrix. As the matrix is absorbed, it is rapidly replaced with native cardiac tissue. We believe that BioSTAR™ will be a more biocompatible device than currently offered PFO implants and provide better patient outcomes. Our current intention is to begin human clinicals with BioSTAR™ later this year.

Developing early stage opportunities which address large unmet needs such as the ones NMT Medical is pursuing requires leadership and innovation beyond the clinical and technology areas. The Company has further demonstrated leadership by forging a synergistic cooperation between two clinical specialties, the interventional cardiologist who can use their transcatheter skills to close a PFO and the neurologist who provides care for patients with stroke, migraine, and other brain attacks. The partnership we are creating between the cardiologist and neurologist is centered around a common interest: conducting the appropriate clinical trials and providing the latest technology to patients who may not have other options. It's a partnership that's working.

Additionally, NMT Medical has developed cooperative relationships during 2003 with the American Stroke Association (ASA) and Inova Health System in "Operation Stroke" and earlier this year with the National Stroke Association. These outreach programs are designed to provide physicians, allied health professionals, care givers and patients with important information on stroke, treatment options, and ongoing clinical trials such as our CLOSURE I study.

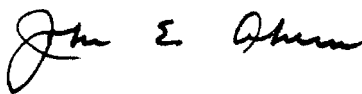
During 2003, we elected Daniel F. Hanley, MD to our board of directors. Dr. Hanley is Professor of Neurology, Neurosurgery and Anesthesia/Critical Medicine and Professor, School of Nursing, the Jeffrey and Harriett Legum Professor of Acute Care Neurology and Director of Brain Injury Outcome Program at Johns Hopkins Medical Institutions. His area of clinical expertise as a leading expert in brain injury will further complement the strength of our board moving forward.

Also in 2003, Brad Ryno joined the NMT Medical management team as Director of Commercial Development, North America. Brad is responsible for all field personnel and brings to NMT a wealth of experience in the neurology and interventional cardiology area.

In the year ended December 31, 2003, CardioSEAL® and STARFlex® revenues achieved record levels, increasing approximately 11%, to \$21.4 million from \$19.3 million in the year ended December 31, 2002. We have a strong balance sheet with more than \$36 million in cash and no debt, which provides the Company with financial strength and flexibility.

Building and maintaining leadership in the early stage PFO closure opportunity is challenging. We are pioneers, and pioneers don't always have a map; pioneers don't always have all the answers. But successful pioneers have passion, perseverance, and commitment in what they believe in. My colleagues and I at NMT have that. These are exciting times.

Sincerely,



John E. Ahern

President, Chief Executive Officer & Chairman

FINANCIALS

~~This Report contains forward-looking statements, as defined by the Securities Exchange Act of 1934. We caution investors not to place undue reliance on forward-looking statements in this Report because these statements speak only as of the date when made. There are a number of factors that could cause our actual results to differ materially from those indicated by the forward-looking statements, including without limitation the factors described in this Report under the caption "Certain Factors That May Affect Future Results."~~

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934 (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, 2003

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 (I.R.S. Employer
Incorporation or Organization) Identification No.)

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

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

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

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:
Common Stock, \$.001 par value per share
Preferred Stock Purchase Rights
(Title of Class)

Indicate by check mark 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 an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes No

The aggregate market value of voting stock held by nonaffiliates of the registrant on June 30, 2003 was \$34,117,660 based on the last reported sale price of the registrant's Common Stock on the NASDAQ National Market on that date. There were 11,946,522 shares of Common Stock outstanding as of March 19, 2004.

DOCUMENTS INCORPORATED BY REFERENCE

<u>Document</u>	<u>Part of Form 10-K into which incorporated</u>
Portions of the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held on June 22, 2004	Items 10, 11, 12, 13 and 14 of Part III

PART I

FORWARD-LOOKING STATEMENTS

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

ITEM 1. BUSINESS

INTRODUCTION

NMT Medical, Inc. (together with its subsidiaries, the "Company" or "NMT"), founded in July 1986, designs, develops and markets proprietary implant technologies that allow interventional cardiologists to treat cardiac sources of stroke through minimally invasive, catheter-based procedures. The Company's products are designed to offer alternative approaches to existing complex treatments, thereby reducing patient trauma, shortening procedure, hospitalization and recovery times, and lowering overall treatment costs. The Company is a Delaware corporation, with executive offices located at 27 Wormwood Street, Boston, Massachusetts 02210-1625 and the Company's telephone number is (617) 737-0930.

Stroke is the third leading cause of death in the United States, and for some young adults, a common heart defect, called the patent foramen ovale ("PFO"), may be the primary culprit in embolic stroke. 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. For the estimated 25% of people whose PFO may not fully seal, most will never even know that they have this defect. When intracardiac pressures are increased (i.e. by strenuous activities, lifting, or straining), the PFO may open and allow blood flow to move, or shunt, from one atrial chamber to the other. On occasion, emboli present in venous blood, which are normally filtered through the lungs, can now cross through the PFO into the arterial side and travel to the brain and block essential blood flow. The result may be a stroke, causing potential loss of speech, vision, movement, and even death. For the estimated 470,000 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. Another area of increasing interest is the potential role of PFO closure in certain migraine patients.

Sales of proprietary implant technologies in the United States and Europe represent the primary current source of our revenues. For the year ended December 31, 2003, these products accounted for 99.3% of our product sales and 93.3% of our total revenues.

In the United States, the Food and Drug Administration ("FDA") classifies septal repair implant devices as Class III medical devices, which require receipt of Pre-Market Approval ("PMA"). Under the FDA's Humanitarian Device Exemption ("HDE") regulations, medical devices that provide safe treatment for limited populations of patients can be granted approval by the FDA based upon more limited clinical experience than is required for a full PMA. We currently sell our CardioSEAL[®] product in the United States under an HDE granted in 2000 by the FDA for treating PFO patients with recurrent stroke who have failed conventional drug therapy, such as Coumadin[®]. HDE regulations allow for the treatment of up to 4,000 patients per year at an approved price of \$5,500 for each device. We also sell our CardioSEAL[®] product in the United States under a PMA for patients with a ventricular septal defect ("VSD") who have high risk surgical factors. The European Union has promulgated rules governing the marketing and sale of medical products in the countries of the European Economic Area. These products must receive a CE ("Conformité Europeene") Mark indicating that the manufacturer has conformed to all of the obligations required by the legislation. We have sold our STARFlex[®] product in Europe since its awarding of the CE Marking in 1998. We also re-sell third party products for use with our CardioSEAL[®] and STARFlex[®] implant devices, specifically vascular sizing balloons and sheaths.

More than 13,000 PFOs have been successfully closed with our CardioSEAL[®] and STARFlex[®] implants worldwide and our current top strategic goal is to be the first to receive a PFO PMA. During 2001 and 2002, consistent with our strategic focus on PFO closure, we completed the divestiture of various non-strategic assets. These divestitures included the November 2001 sale of the vena cava filter product line to C.R. Bard, Inc. ("Bard") and the July 2002 sale of the neurosciences business unit to Integra LifeSciences Holding Corporation ("Integra"). Consummation of these transactions strengthened our balance sheet, providing the financial and operational flexibility to pursue the emerging opportunity of treating cardiac sources of stroke with our proprietary CardioSEAL[®] and STARFlex[®] catheter-based implant technologies.

In order to obtain study data to support a PFO PMA application, we are currently engaged in an investigational device exemption ("IDE"), FDA-approved clinical trial ("CLOSURE I") comparing our fourth generation STARFlex[®] cardiac septal repair implant with medical therapy in preventing recurrent stroke and transient ischemic attack ("TIA"). CLOSURE I, which is our primary

operating objective, is expected to enroll 1,600 patients at 100 leading stroke and interventional cardiology centers in the United States. We currently expect to complete patient enrollment in CLOSURE I by mid 2005. Total costs of CLOSURE I, including third party contracts, agreements with clinical sites and internal clinical department costs, are currently estimated to be approximately \$24 million through trial completion and FDA submission, which is currently expected to occur in 2007. Of this total, approximately \$2.5 million was incurred during 2003 and we currently project 2004 costs in the range of \$8-10 million, largely dependent upon the rate of patient enrollment. As a result of this ongoing investment, we do not expect to be profitable in 2004.

Commencing in 2003, we earned royalty income from Bard pursuant to the terms of the agreements related to our November 2001 sale of the vena cava filter product line. In addition, we earn royalty income from Boston Scientific Corporation ("BSC") pursuant to a 1994 license of our stent technology.

We also manufacture a line of aneurysm clips used for the management of intracranial aneurysms, which are marketed worldwide through a distribution agreement with Integra.

PRODUCTS

Cardiac Septal Repair Devices

In February 1996, we acquired the exclusive rights to the CardioSEAL® cardiac septal repair implant from InnerVentions, Inc., a licensee of the Children's Medical Center Corporation ("CMCC"), also known as Children's Hospital Boston. In connection with the 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 sell third party products for use with the CardioSEAL® and STARFlex® implant devices, specifically vascular sizing balloons and sheaths. These product sales accounted for 99.3%, 78.7% and 63.6% of total product sales for the years ended December 31, 2003, 2002 and 2001, respectively.

Cardiac septal repair implant devices are used for the repair of intracardiac shunts that result in abnormal blood flow through the chambers of the heart. Common cardiac septal defects include PFO, VSD and atrial septal defects ("ASD"). PFO, the most common of these defects, has been implicated as a possible cause of embolic stroke, for which current treatments include lifelong anticoagulation therapy or open heart surgery. Both of these treatments may present significant risks to the embolic stroke patient with a PFO. We believe that our catheter-based cardiac septal repair implant technologies may provide a minimally invasive and less costly treatment alternative. We estimate that the worldwide market potential for our cardiac septal repair technologies is approximately 500,000 procedures annually, with current congenital heart defect procedures (ASD, VSD etc.) accounting for about 30,000 and the balance representing the potential for the emerging PFO procedures.

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

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

During 2003, we introduced in Europe the Rapid Transport™ System ("RTS"), which allows the interventional cardiologist to more easily implant the STARFlex® device. We currently plan to initiate a clinical study in the U.S. to obtain HDE approval to market this product.

Aneurysm Clips

We manufacture aneurysm clips used for the management of intracranial aneurysms. The aneurysm clip was developed in collaboration with Bio-Tech Engineering, Inc. ("BTE") under an exclusive worldwide royalty-bearing license to the patents owned by BTE. In September 2003, as part of the settlement of an arbitration proceeding with BTE and its principals, we acquired the associated patents, executed mutual releases and paid \$950,000. See Item 3 (Legal Proceedings). The clip is CE Marked, and the products are marketed worldwide through a distribution arrangement with Integra.

ROYALTY INCOME

Vena Cava Filters

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

Stents

In November 1994, we licensed to BSC the exclusive worldwide rights to develop, manufacture, market and distribute 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.

CLOSURE I CLINICAL TRIAL

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 with experts from the neurology and interventional cardiology communities, we submitted to the FDA the clinical trial design for our PFO IDE. The trial, named CLOSURE I, for which we received full IDE approval from the FDA in June 2003, is a prospective, multi-center, randomized, controlled clinical trial designed to evaluate the safety and efficacy of our STARFlex® septal closure system versus medical therapy in patients who have had a stroke and/or a TIA due to a presumed paradoxical embolism through a PFO. The trial is expected to enroll approximately 1,600 patients at approximately 100 leading stroke and interventional cardiology centers in the United States, with half receiving a STARFlex® implant and the other half receiving drug therapy. We currently expect to complete patient enrollment in CLOSURE I by mid 2005. Patients will be evaluated periodically over a two-year period, during which time safety and efficacy data, including recurrent events rates (i.e., stroke and/or TIA), will be collected for all patients. We do not charge for the products implanted in the clinical trial. Once completed, we expect to use clinical data from this trial for the submission of PMA applications to the FDA for CardioSEAL® and STARFlex®. For more information concerning FDA regulations applicable to CLOSURE I, see “Business –Government Regulation”.

We have committed significant financial and personnel resources to the execution of this 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, which is currently expected to be in 2007. Of this total, approximately \$2.5 million was incurred during 2003 and we currently project 2004 costs in the range of \$8-10 million, largely dependent upon the rate of patient enrollment.

Accelerating patient enrollment in CLOSURE I is management’s top priority during 2004. Consistent with that objective, and to promote the education and awareness of cryptogenic stroke and TIA in young patients, we have recently entered into collaboration with the National Stroke Association.

RESEARCH AND DEVELOPMENT

Our research and development organization included 26 persons as of December 31, 2003, with departmental groups dedicated to product development, regulatory and clinical affairs, and quality assurance. Total research and development expenses were \$7.0 million, \$5.5 million and \$3.8 million for the years ended December 31, 2003, 2002 and 2001, respectively. Of these totals, approximately \$2.5 million in 2003 were CLOSURE I costs.

Research & Development

During 2003, our research and development staff worked to develop several enhancements and accessory products for the current CardioSEAL® and STARFlex® product line, which are essential to maintain and expand our technology leadership in transcatheter PFO closure. Additionally, development of next generation platforms for PFO closure devices were initiated, and efforts were continued to solidify and protect our intellectual property position in all aspects of transcatheter prevention of cardiac sources of stroke.

Our new delivery system, the RTS, was released in Europe in the fourth quarter of 2003. This system represents a significant improvement over existing technology to deliver septal repair implants, allowing single operator capability, minimizing the number of steps for implantation, and incorporating integrated safety mechanisms. The RTS system promotes 180 degrees of free movement at the implant/delivery catheter interface allowing clinicians the ability for enhanced device assessment for proper positioning prior to its release from the delivery catheter. Additional product enhancement projects focused on improving septal repair implant retrievability, thromboresistance, arm fracture resistance, and overall system compatibility and reliability.

Our next generation product development program focuses on two areas. The first relates to the continued development of a next generation STARFlex® septal repair implant incorporating an enhanced tissue scaffold by utilizing a proprietary tissue-engineered matrix. This combination was designed to optimize the biological response by promoting quicker healing and device endothelialization. The second relates to the development of next generation therapies for PFO closure by incorporating new technologies to produce novel approaches to closure of this specific defect.

Regulatory & Clinical Affairs

In 2003, our Regulatory and Clinical Affairs department designed the CLOSURE I clinical trial and consummated agreements with key third party service providers. Nearly three-quarters of the projected 100 CLOSURE I clinical sites throughout the United States have completed the Institutional Review Board ("IRB") approval process and two-thirds of those sites have concluded the initiation process allowing them to begin patient enrollment. We currently expect to complete patient enrollment in CLOSURE I by mid 2005. As part of this effort, a clinical development specialist group was created, whose primary goal is to facilitate enrollment in CLOSURE I.

Additionally, we managed ongoing enrollment in the VSD PMA post-market registry for the CardioSEAL® septal repair implants, filed regulatory submissions to obtain approval of a new accessory product line and obtained necessary regulatory approvals for septal repair implant product line modifications.

In 2004, in addition to our ongoing CLOSURE I trial, we intend to focus on three primary project activities: (i) evaluating our next generation STARFlex® cardiac septal repair implant incorporating the enhanced tissue scaffold; (ii) evaluating our new Rapid Transport™ Delivery Catheter, with resulting data to be used to support U.S. regulatory filings to the FDA; and (iii) initiating a small clinical trial to study the potential connection between PFO and migraine.

In addition, we currently anticipate receipt during 2004 of FDA clearance for the new accessory product line.

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® direct in key European markets and through select distributors in a few other markets. During 2002 and 2003, we increased worldwide sales and marketing personnel from 9 to 18, more than doubling our presence throughout Europe from 3 to 8. The Company's European employees are based in Germany, The Netherlands, France and the United Kingdom. Continued geographic expansion and coverage is being evaluated, including the merits of possible joint venture type relationships in the Asia/Pacific region.

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. Traditionally, the stroke neurologist and the interventional cardiologist have not collaborated on patient diagnosis or treatment. We believe that the PFO-stroke connection has changed that. To further facilitate what we believe to be an emerging solution to stroke, we have focused added attention 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. During 2003, we sponsored a successful joint meeting in Europe that brought together 1,400 members of the interventional cardiology and stroke neurology communities on the subject of preventing cardiac sources of stroke. This meeting included a live case, broadcast to both meeting locations by satellite, using our STARFlex® implant in combination with our new RTS product.

Our aneurysm clip products are marketed worldwide through a distribution arrangement with Integra.

CUSTOMERS

Sales of vena cava filter products to Bard and certain of its affiliates accounted for 21% of product sales for the year ended December 31, 2002 and 36% of product sales for the year ended December 31, 2001. Following the fulfillment of our obligations under the transitional manufacturing agreement with Bard, as of June 30, 2002, Bard is no longer a significant customer. No other customer accounted for greater than 10% of product sales in each of the three years in the period ended December 31, 2003.

All of our U.S. customers must have IRB approval before they are eligible to purchase the CardioSEAL® products under our PFO HDE. At December 31, 2003, we had approximately 230 active customers worldwide to whom we sell our CardioSEAL® and STARFlex® products directly.

MANUFACTURING

We manufacture the CardioSEAL® and STARFlex® cardiac septal repair implants and aneurysm clips at our headquarters facility in Boston, which includes a Class 10,000 clean room. We have received ISO 13485 and EN 46001 certifications, which are based on adherence to established standards in the areas of quality assurance and manufacturing process control, and have also received permission to affix the CE Marking to our products. We believe that our current manufacturing facilities are sufficient to accommodate potential increases in demand for our products.

COMPETITION

Three companies, AGA Medical Corp. ("AGA"), W. L. Gore and Cardia, Inc. have developed devices that compete with CardioSEAL® and STARFlex®. All three companies sell their products in Europe and other international markets, and AGA also sells in the United States. We believe that these competitors are either conducting, or are planning to conduct, clinical trials in the United States.

In addition, the clip market is currently influenced by competing devices, principally intracranial coils, to treat aneurysms.

DISCONTINUED OPERATIONS

In July 2002, we sold the remainder of our neurosciences business unit, including implantable valves (shunts) and other accessories used in the management of cerebral spinal fluid, an owned manufacturing facility located in Biot, France and a leased North American distribution facility in Atlanta, Georgia, to Integra for \$5.4 million in cash. In accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", the accompanying consolidated financial statements reflect the financial results of the neurosciences business unit as discontinued operations for all periods presented. See Note 3 of Notes to Consolidated Financial Statements.

PATENTS AND PROPRIETARY TECHNOLOGY

We seek to protect our technology through the use of patents and trade secrets. We are the owner or licensee of 17 issued United States patents, and corresponding foreign patents, relating to our cardiac septal repair implant devices, stents, distal (embolic) protection, anastomosis devices, nitinol radiopaque markers and other related inventions. In addition, we have 21 pending utility patent applications and 14 provisional patent applications in the areas of distal protection and intracardiac repair, including implants, delivery systems and accessory products. The existing patents expire at various dates ranging from 2011 to 2019. The expiration dates of our patents relating to our stents range from 2012 to 2017. The patents related to our anastomosis devices, which are minimally invasive means of attaching vascular grafts, expire from 2016 to 2017 and the patent for our radiopaque markers, which allow catheters to be more visible under x-ray, expires in 2014. In addition, we are the exclusive licensee under certain patents, expiring from 2014 to 2016, relating to the CardioSEAL® and STARFlex® cardiac septal repair implants, delivery systems and methods for repairing cardiac and vascular defects. We also hold a license to certain technology used in nitinol septal repair devices.

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

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, provided for royalty payments of 7.5% of commercial net sales of our CardioSEAL® and STARFlex® septal implant devices. In addition, for each \$25 million of net sales there is an additional one-time royalty payment due of \$250,000, after which the royalty rate increases sequentially by 1%, to a maximum of 10.5%. Cumulative net commercial sales surpassed \$25 million in the fourth quarter of 2001 and \$50 million in the first quarter of 2003, resulting in the current royalty rate of 9.5%. We expect to reach \$75 million of cumulative net commercial sales during the second quarter of 2004, which will result in the final one-time additional royalty payment of \$250,000 and an increase in the royalty rate to 10.5%. Royalties continue until the end of the term of the patents (ranging from 2014 to 2016). We also have a royalty-free, worldwide sublicense under the U.S. patents entitled "System for the Percutaneous Transluminal Front-End Loading Delivery and Retrieval of a Prosthetic Occluder" (U.S. Patent No. 5,649,950) and their corresponding foreign patents and associated know-how. The sublicense is exclusive in the field of the repair of atrial septal defects and nonexclusive in certain other fields. We have also obtained an exclusive worldwide license from Lloyd A. Marks, M.D. under the United States patent entitled "Aperture Occlusion Device" (U.S. Patent No. 5,108,420). The license agreement with Dr. Marks provides for royalty payments, subject to certain annual minimums, based on net sales of nitinol septal repair implants that are covered by the patent, which expires in 2011. There have been no sales of covered nitinol septal repair implants to date.

Vena Cava Filters

In connection with the SNF, we entered into a Technology Purchase Agreement dated April 14, 1987 (the "Technology Purchase Agreement" or "TPA") with Morris Simon, M.D., our former Chief Scientific Director and co-founder and a Director of the Company until his resignation on January 22, 2002. Pursuant to the TPA, Dr. Simon assigned all the technology relating to the SNF to the Company in exchange for certain royalty payments based on our net sales of the SNF, to continue perpetually unless the agreement were to be terminated. Dr. Simon agreed not to compete with the Company in the vena cava filter market during the term of the agreement. In connection with the agreement, Beth Israel Deaconess Medical Center ("Beth Israel") granted the Company an exclusive worldwide license under the United States patent entitled "Blood Clot Filter."

On September 11, 2001, we filed against Dr. Morris Simon and Beth Israel a demand for arbitration seeking resolution of disputes over royalties payable on sales of certain existing and future products under the TPA. On October 19, 2001, the Company and Beth Israel settled their disputes by execution of a general release agreement, which became effective on November 5, 2001, coincident with the sale of the vena cava filter product line to Bard. Pursuant to this release agreement, Beth Israel assigned all of its rights with respect to the TPA to the Company. See Item 3 (Legal Proceedings).

Under the terms of our sale of the vena cava filter product line to Bard, we continue to make royalty payments to Dr. Simon based upon net sales of Bard's SNF and RNF products. Under a Royalty Agreement between the Company and Bard, commencing in 2003, we earn royalties from Bard on its sales of these vena cava filter products.

Stents

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

GOVERNMENT REGULATION

The manufacture and sale of medical devices intended for commercial distribution are subject to extensive governmental regulations in the United States. Medical devices are regulated in the United States by the FDA under the Federal Food, Drug and Cosmetic Act (the "FDC Act") and generally require pre-market clearance or pre-market approval prior to commercial distribution. In addition, certain material changes or modifications to medical devices also are 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, distribution and production 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, 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 cost of any device manufactured or distributed by the Company.

Medical devices are classified into one of three classes, Class I, II or III, on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Generally, Class III devices (e.g., life-sustaining, life-supporting and implantable devices or new devices which have not been found to be substantially equivalent to legally marketed devices) require clinical testing to

ensure safety and effectiveness and FDA approval prior to marketing and distribution. The FDA also has the authority to require clinical testing of Class I and Class II devices. A PMA application must be filed if a proposed device is not substantially equivalent to a legally marketed predicate device, or if it is a Class III device for which the FDA has called for such applications.

If human clinical trials of a device are required, and if the device presents a "significant risk", the manufacturer or distributor of the device is required to file an IDE application with the FDA prior to commencing human 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 are permitted to sell those devices distributed in the course of the study, provided that such costs do not exceed recovery of the costs of manufacture, research, development and handling. 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 sponsor of the study is not required to obtain FDA approval of an IDE application before beginning the study. However, prior IRB approval of the study is required and the study must be conducted in compliance with the applicable FDA regulations, including, but not limited to, FDA regulations regarding the protection of human subjects.

Generally, before a new device can be introduced into the market in the United States, the manufacturer or distributor must obtain FDA clearance of a pre-market notification ("510(k) notification") submission or approval of a PMA application. If a medical device manufacturer or distributor can establish that a device is "substantially equivalent" to a legally marketed Class II device, or to a Class III device for which the FDA has not called for PMAs, the manufacturer or distributor may seek clearance from the FDA to market the device by filing a 510(k) notification. The 510(k) notification may need to be supported by appropriate data establishing the claim of substantial equivalence to the satisfaction of the FDA. The FDA's Modernization Act of 1997 (the "Modernization Act") was adopted with the intent of bringing better definition to the process for clearing 510(k) submissions. Although it is expected that the Modernization Act will result in shorter timeframes for clearance of 510(k) submissions, there can be no assurance that the FDA review process will not involve delays or that such clearances will be granted on a timely basis.

If a manufacturer or distributor of medical devices cannot establish that a proposed device is substantially equivalent to a legally marketed device, the manufacturer or distributor must seek pre-market approval of the proposed device through submission of a PMA application. A PMA application must be supported by extensive data, including preclinical and clinical trial data, as well as extensive literature to prove the safety and effectiveness of the device. The Modernization Act allows the filing of a PMA to be modular, permitting the FDA to initiate review of the submission prior to completion of all sections. Under the FDC Act, the FDA has 180 days to review a filed PMA application. Although the changes in the PMA application review process are designed to shorten review times, there can be no assurance that delays will be eliminated or that PMA clearances will be granted on a timely basis.

Certain Class III devices that were on the market before May 28, 1976 ("preamendments Class III devices"), and devices that are determined to be substantially equivalent to them, can be brought to market through the 510(k) process until the FDA, by regulation, calls for PMA applications for the devices. Generally, the FDA will not grant 510(k) clearance for such devices unless the facilities at which they are manufactured successfully undergo an FDA pre-approval Good Manufacturing Practice ("GMP") inspection. In addition, the FDC Act requires the FDA either to down-classify preamendments Class III devices to Class I or Class II, or to publish a classification regulation retaining the devices in Class III. Manufacturers of preamendments Class III devices that the FDA retains in Class III must have PMA applications accepted by the FDA for filing within 90 days after the publication of a final regulation in which the FDA calls for PMAs. If the FDA calls for a PMA for a preamendments Class III device, a PMA must be submitted for the device even if the device has already received 510(k) pre-market clearance; however, if the FDA down-classifies a preamendments Class III device to Class I or Class II, a PMA application is not required. The FDA's reclassification determinations are to be based on safety and effectiveness information that manufacturers of certain preamendments Class III devices are required to submit to the FDA as set forth in two FDA orders published in August 1995.

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 HDE regulations, medical devices that provide safe treatment and a reasonable assurance of effectiveness may be made available to small numbers of patients (less than 4,000 patients in the U.S. per year) on more limited clinical experience than that required for a PMA. In addition, under HDE regulations, only one product can be approved for each indication.

The current regulatory environment in Europe for medical devices differs significantly from that in the United States. There are several different regulatory regimes operating within the different European countries. Regulatory requirements for medical devices range from no regulations in some countries to rigorous regulations approaching the requirements of the FDA's regulations for Class III medical devices. Several countries require that device safety be demonstrated prior to approval for commercialization. The regulatory environment in certain European countries has undergone major changes as a result of the creation of medical device directives by the European Union. In particular, the European Union has promulgated rules, which provide that medical products may not be marketed and sold commercially in the countries in the European Economic Area unless they receive a CE Mark. The letters "CE", an abbreviation of a French phrase "Conformité Européene", indicates that the manufacturer has conformed to all of the obligations required by the legislation. Substantially all of our products have received approval for CE Marking.

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

Mounting concerns about rising health care costs may cause more restrictive coverage and reimbursement policies to be implemented in the future. Several states and the federal government are investigating a variety of alternatives to reform the health care delivery system and to further reduce and control health care spending. These reform efforts include proposals to limit spending on health care items and services, limit coverage for new technology and limit or control directly the price health care providers and drug and device manufacturers may charge for their services and products. We believe that U.S. health care providers currently are reimbursed for the cost of purchasing our CardioSEAL® septal repair implants used in HDE and PMA procedures. In the international market, reimbursement by private third party medical insurance providers, including governmental insurers and providers, varies from country to country. In certain countries, our ability to achieve significant market penetration may depend upon the availability of third party governmental reimbursement. Our independent distributors, and the health care providers to whom such distributors sell, obtain any necessary reimbursement approvals.

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

Our CLOSURE I trial is being conducted under a FDA-approved IDE with Category B HCFA status, meaning usage under the trial is eligible for Medicare coverage.

FINANCIAL INFORMATION ABOUT GEOGRAPHIC AREAS

Please see Note 12 of Notes to Consolidated Financial Statements for certain of our financial information concerning geographic areas.

PRODUCT LIABILITY AND INSURANCE

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

EMPLOYEES

As of December 31, 2003, we had 101 full-time employees. The Company believes that it maintains good relations with its employees.

ITEM 2. PROPERTIES

We currently lease an approximately 35,000 square foot manufacturing, laboratory and administrative facility in Boston, Massachusetts, under leases that expire in September 2006. We have a renewal option for an additional 5 years on approximately 27,000 square feet of that space, which requires written notice to the landlord at any time during the period 9-12 months prior to the expiration of the lease term.

The Company's principal executive offices are located at 27 Wormwood Street, Boston, Massachusetts 02210, and its telephone number is (617) 737-0930.

ITEM 3. LEGAL PROCEEDINGS

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

In December 1998, we filed a patent infringement suit in the United States District Court for the District of Massachusetts (the "Court") against AGA Medical Corp. ("AGA"), claiming that AGA's Amplatzer aperture occlusion devices infringe U.S. Patent No. 5,108,420, which is licensed exclusively to the Company. We sought an injunction to prevent further infringement as well as monetary damages. In April 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. In May 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 patent by the United States Patent and Trademark Office, which is still ongoing. On September 30, 2003, AGA requested that the Court dismiss the suit without prejudice to our ability to refile the suit after the conclusion of the patent reexamination proceeding. On December 1, 2003, the Court granted AGA's request.

On or about September 24, 2001, the three French subsidiaries of the Company's former neurosciences business unit, NMT Neurosciences Instruments SARL, NMT Neurosciences Holdings SA and NMT Neurosciences Implants SA, each received a Notification of Reassessment Following Verification of the Accounts (*Notification de redressements suite à une verification de comptabilité*) from the French Direction de Controle Fiscal Sud-est (Nice) ("Reassessment"). The French authorities are seeking from the above-named NMT entities in excess of FF11 million, which is the currency in which the assessment was made, (approximately \$2.1 million based upon the exchange rate at December 31, 2003) in back taxes, interest and penalties. We are appealing the Reassessment. In connection with our sale of the neurosciences business unit in July 2002, we agreed to specifically indemnify Integra against any liability in connection with these tax claims. Pursuant to the terms of a settlement agreement with Elekta AB, completed in early 2002, a portion of any resulting tax claim may be recoverable from Elekta. See Note 3 of Notes to Consolidated Financial Statements.

On September 11, 2001, we filed against Dr. Morris Simon and Beth Israel a demand for arbitration before a former judge of the Massachusetts Superior Court, in Boston, Massachusetts, seeking resolution of certain disputes over royalties payable on sales of certain existing and future products under the TPA between Dr. Simon and the Company. On September 28, 2001, Dr. Simon filed a response to the demand for arbitration, which identified one additional dispute for resolution. On October 19, 2001, the Company and Beth Israel settled their disputes by execution of a general release agreement that became effective on November 5, 2001, pursuant to which we paid Beth Israel \$2.25 million and issued 40,000 shares of our common stock. Dr. Simon resigned as a Director of the Company on January 22, 2002. Following a hearing on the merits of the disputes between the Company and Dr. Simon, the arbitrator issued an award ruling that (i) we do not owe Dr. Simon past royalties with respect to our sales of the former SNF product; (ii) we are not in breach of the TPA; and (iii) we will be required to make royalty payments to Dr. Simon in accordance with the terms of the TPA in connection with future sales of Bard's Recovery™ Filter product. On November 10, 2002, after a hearing on whether either party was entitled to reimbursement of all or a portion of its legal fees from the other, the arbitrator awarded Dr. Simon \$400,000, which represented a portion of his legal fees. On or about January 2, 2003, we paid \$400,000 to Dr. Simon in accordance with the November 10, 2002 award. On February 14, 2003, the Company and Beth Israel entered into a Settlement Agreement in which Beth Israel agreed to reimburse the \$400,000 in full settlement of an indemnification agreement entered into between the Company and Beth Israel on November 5, 2001. The reimbursement consisted of cash and the return of the 40,000 shares of common stock of the Company that Beth Israel had originally received in the settlement.

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

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 fiscal year 2003.

EXECUTIVE OFFICERS OF THE COMPANY

The executive officers of the Company and their ages as of March 19, 2004 are as follows:

NAME	AGE	POSITION
John E. Ahern	59	President, Chief Executive Officer and Chairman of the Board of Directors
Richard E. Davis	45	Vice President and Chief Financial Officer

JOHN E. AHERN has served as President, Chief Executive Officer and Chairman of the Company since September 2000. Prior to joining the Company, Mr. Ahern was Vice President, Emerging Technology Investment Group at Bard, a leading medical technology company, where he was responsible for identifying, investing in and managing early-stage medical technologies and companies. In his 13 years with Bard, Mr. Ahern also held the senior marketing and strategic planning positions in three of Bard's cardiovascular divisions. Mr. Ahern's more than 35 years of medical device industry experience also includes Vice President of Worldwide Sales and Marketing at Intra-Sonix, Inc., an early stage development company focused on minimally invasive surgery, Area Manager for the Middle East and North Africa at Abbott Laboratories, a leading health care company, and various sales and marketing positions at Becton Dickinson, a major medical technology company. Mr. Ahern is also a member of the Board of Directors of Seacoast Technologies, Inc. and EndoBionics, Inc., two privately-held companies in the medical device industry.

RICHARD E. DAVIS has served as Vice President and Chief Financial Officer of the Company since February 2001. From August 2000 to February 2001, Mr. Davis served as Interim Chief Financial Officer of the Company through his employment with the consulting firm of Argus Management Corporation. From July 1998 to July 2000, Mr. Davis was Vice President and Chief Financial Officer of Q-Peak, Inc., a marketer and manufacturer of solid-state laser systems. Prior to that, Mr. Davis was employed for ten years by TJX Companies, Inc., a worldwide off-price retailer of apparel and home fashions, in various senior financial management positions where he was responsible for business and strategic planning, cash flow and expense management and accounting and operational controls.

PART II

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

Our common stock is quoted on the NASDAQ National Market under the symbol NMTI. There were approximately 100 stockholders of record of our common stock on March 19, 2004, representing approximately 1,900 shareholder accounts. The following table lists, for the periods indicated, the high and low sales prices for our common stock.

PERIOD	HIGH	LOW
2002		
First quarter	\$8.750	\$6.120
Second quarter	8.100	5.300
Third quarter	6.600	2.750
Fourth quarter	3.910	2.000
2003		
First quarter	\$3.320	\$2.650
Second quarter	4.790	2.750
Third quarter	4.805	3.640
Fourth quarter	4.920	3.160

We did not declare or pay any cash dividends on shares of our common stock during the years ended December 31, 2003 and 2002 and do not anticipate declaring or paying cash dividends in the foreseeable future. We currently expect that we will retain any earnings for use in our business.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data for each of the five years in the period ended December 31, 2003 were derived from our audited Consolidated Financial Statements. The selected consolidated financial data set forth below should be read in conjunction with the Consolidated Financial Statements and the Notes thereto, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the other financial information appearing elsewhere in this Annual Report on Form 10-K.

FOR THE YEARS ENDED DECEMBER 31,	2003	2002	2001	2000	1999
STATEMENT OF OPERATIONS DATA:					
(In thousands, except per share data)					
Revenues:					
Product sales	\$21,574	\$24,546	\$22,501	\$17,785	\$13,280
Net royalty income	1,387	413	546	811	1,778
Total revenues	<u>22,961</u>	<u>24,959</u>	<u>23,047</u>	<u>18,596</u>	<u>15,058</u>
Costs and Expenses:					
Cost of product sales	5,303	6,606	7,436	6,308	5,887
Research and development	6,961	5,544	3,801	4,548	4,014
General and administrative	5,546	5,496	6,080	5,222	3,929
Selling and marketing	5,614	5,446	3,619	2,945	1,919
Settlement of litigation	1,216	—	—	—	—
Write-down of note receivable from Image Technologies Corporation	—	—	—	—	1,364
Total costs and expenses	<u>24,640</u>	<u>23,092</u>	<u>20,936</u>	<u>19,023</u>	<u>17,113</u>
Gain on sale of product line	—	7,000	20,257	—	—
(Loss) income from operations	<u>(1,679)</u>	<u>8,867</u>	<u>22,368</u>	<u>(427)</u>	<u>(2,055)</u>
Other Income (Expense):					
Currency transaction gain (loss)	81	81	(36)	124	(237)
Interest expense	(5)	(10)	(698)	(1,169)	(2,426)
Interest income	558	691	176	199	480
Loss on early extinguishment of debt	—	—	(402)	—	(2,598)
Equity in net loss of Image Technologies Corporation	—	—	—	—	(489)
Gain on sale of investment in Image Technologies Corporation	—	—	—	440	—
Total other income (expense), net	<u>634</u>	<u>762</u>	<u>(960)</u>	<u>(406)</u>	<u>(5,270)</u>
(Loss) income before provision for income taxes	<u>(1,045)</u>	<u>9,629</u>	<u>21,408</u>	<u>(833)</u>	<u>(7,325)</u>
Provision for income taxes	105	3,424	2,630	—	75
Net (loss) income from continuing operations	<u>(1,150)</u>	<u>6,205</u>	<u>18,778</u>	<u>(833)</u>	<u>(7,400)</u>
Discontinued operations:					
(Loss) income from discontinued operations	—	(40)	417	(9,107)	(8,121)
Gain (loss) on sale of discontinued operations	—	4,914	—	345	(3,532)
Net gain (loss) from discontinued operations	—	<u>4,874</u>	<u>417</u>	<u>(8,762)</u>	<u>(11,653)</u>
Net (loss) income	<u>\$(1,150)</u>	<u>\$11,079</u>	<u>\$19,195</u>	<u>\$(9,595)</u>	<u>\$(19,053)</u>
Basic net (loss) income per share:					
Continuing operations	\$(0.10)	\$0.54	\$1.71	\$(0.08)	\$(0.69)
Discontinued operations	—	0.42	0.04	(0.80)	(1.08)
Net (loss) income	<u>\$(0.10)</u>	<u>\$0.96</u>	<u>\$1.74</u>	<u>\$(0.88)</u>	<u>\$(1.77)</u>
Diluted net (loss) income per share:					
Continuing operations	\$(0.10)	\$0.51	\$1.61	\$(0.08)	\$(0.69)
Discontinued operations	—	0.40	0.04	(0.80)	(1.08)
Net (loss) income	<u>\$(0.10)</u>	<u>\$0.91</u>	<u>\$1.65</u>	<u>\$(0.88)</u>	<u>\$(1.77)</u>
Weighted average common shares outstanding:					
Basic	<u>11,808</u>	<u>11,542</u>	<u>11,013</u>	<u>10,909</u>	<u>10,751</u>
Diluted	<u>11,808</u>	<u>12,119</u>	<u>11,657</u>	<u>10,909</u>	<u>10,751</u>

AT DECEMBER 31, 2003 2002 2001 2000 1999

BALANCE SHEET DATA:

(In thousands)

Cash, cash equivalents and marketable securities	\$36,725	\$36,244	\$ 7,837	\$ 4,415	\$ 407
Working capital	37,396	37,807	23,168	6,410	17,149
Total assets	44,122	45,093	38,434	19,091	44,547
Long-term obligations	—	—	32	4,248	5,934
Stockholders' equity	38,236	38,956	24,402	4,326	14,161

The following table presents our unaudited consolidated statements of operations data for each quarter in the two years ended December 31, 2003. 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 12/31/2003 9/30/2003 6/30/2003 3/31/2003 12/31/2002 9/30/2002 6/30/2002 3/31/2002

STATEMENT OF OPERATIONS DATA:

(In thousands, except per share data) (unaudited)

Revenues:								
Product Sales	\$6,015	\$ 5,368	\$5,276	\$4,915	\$5,515	\$5,008	\$7,231	\$6,792
Net royalty income	643	499	138	107	90	118	135	70
Total revenues	<u>6,658</u>	<u>5,867</u>	<u>5,414</u>	<u>5,022</u>	<u>5,605</u>	<u>5,126</u>	<u>7,366</u>	<u>6,862</u>
Costs and Expenses:								
Cost of product sales	1,699	1,236	1,219	1,149	1,342	1,418	2,052	1,794
Research and development	1,962	2,031	1,791	1,177	1,301	1,488	1,534	1,221
General and administrative	1,332	1,286	1,649	1,279	1,315	887	1,639	1,655
Selling and marketing	1,362	1,375	1,726	1,151	1,583	1,439	1,200	1,224
Settlement of litigation	(29)	1,245	—	—	—	—	—	—
Total costs and expenses	<u>6,326</u>	<u>7,173</u>	<u>6,385</u>	<u>4,756</u>	<u>5,541</u>	<u>5,232</u>	<u>6,425</u>	<u>5,894</u>
Gain on sale of product line	—	—	—	—	3,000	4,000	—	—
Income (loss) from operations	332	(1,306)	(971)	266	3,064	3,894	941	968
Total other income, net	161	82	162	229	245	212	231	74
Income (loss) before provision for income taxes	493	(1,224)	(809)	495	3,309	4,106	1,172	1,042
Provision for income taxes	105	—	—	—	1,146	1,572	466	240
Net income (loss) from continuing operations	<u>388</u>	<u>(1,224)</u>	<u>(809)</u>	<u>495</u>	<u>2,163</u>	<u>2,534</u>	<u>706</u>	<u>802</u>
Discontinued operations:								
Income (loss) from discontinued operations	—	—	—	—	—	145	(131)	(54)
Gain on sale of discontinued operations	—	—	—	—	874	4,040	—	—
Net gain (loss) from discontinued operations	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>874</u>	<u>4,185</u>	<u>(131)</u>	<u>(54)</u>
Net income (loss)	<u>\$ 388</u>	<u>\$(1,224)</u>	<u>\$(809)</u>	<u>\$ 495</u>	<u>\$3,037</u>	<u>\$6,719</u>	<u>\$ 575</u>	<u>\$ 748</u>
Basic net income (loss) per share:								
Continuing operations	\$0.03	\$(0.10)	\$(0.07)	\$0.04	\$0.18	\$0.22	\$0.06	\$0.07
Discontinued operations	—	—	—	—	0.07	0.36	(0.01)	—
Net income (loss)	<u>\$0.03</u>	<u>\$(0.10)</u>	<u>\$(0.07)</u>	<u>\$0.04</u>	<u>\$0.26</u>	<u>\$0.58</u>	<u>\$0.05</u>	<u>\$0.07</u>
Diluted net income (loss) per share:								
Continuing operations	\$0.03	\$(0.10)	\$(0.07)	\$0.04	\$0.18	\$0.21	\$0.06	\$0.07
Discontinued operations	—	—	—	—	0.07	0.34	(0.01)	—
Net income (loss)	<u>\$0.03</u>	<u>\$(0.10)</u>	<u>\$(0.07)</u>	<u>\$0.04</u>	<u>\$0.25</u>	<u>\$0.55</u>	<u>\$0.05</u>	<u>\$0.07</u>
Weighted average common shares outstanding:								
Basic	<u>11,863</u>	<u>11,812</u>	<u>11,794</u>	<u>11,761</u>	<u>11,696</u>	<u>11,620</u>	<u>11,545</u>	<u>11,302</u>
Diluted	<u>12,213</u>	<u>11,812</u>	<u>11,794</u>	<u>12,022</u>	<u>12,024</u>	<u>12,221</u>	<u>12,307</u>	<u>12,235</u>

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

The following discussion of the financial condition and results of operations of the Company should be read in conjunction with the Consolidated Financial Statements and Notes thereto included elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains forward-looking statements based on our current expectations, assumptions, estimates and projections about the Company and our industry. These forward-looking statements are usually accompanied by words such as "believes," "anticipates," "plans," "expects" and similar expressions. Forward-looking statements involve risks and uncertainties, and our actual results may differ materially from the results anticipated in these forward-looking statements as a result of certain factors, as more fully described in this section under the caption "Certain Factors That May Affect Future Results".

OVERVIEW

During 2001 and 2002, we completed the divestiture of certain non-strategic assets. These divestitures included the November 2001 sale of the vena cava filter product line to Bard and the July 2002 sale of the neurosciences business unit to Integra. These sales provided aggregate cash proceeds of approximately \$38.8 million, of which approximately \$5.0 million was used in 2001 to repay outstanding subordinated debt. These divestitures strengthened our balance sheet, providing the financial and operational flexibility to pursue the emerging opportunity of treating cardiac sources of stroke and to evaluate other potential opportunities, such as the treatment of migraines, with our proprietary CardioSEAL® and STARFlex® catheter-based implant technologies.

Our 2003 revenues were primarily derived from sales of our CardioSEAL® and STARFlex® products in the U.S. and Europe and the commencement of royalties earned from Bard pursuant to agreements related to the November 2001 sale of the vena cava filter product line to Bard. CardioSEAL® and STARFlex® product sales increased by approximately 11% from 2002 to 2003, and we currently expect an approximate 10% increase from 2003 to 2004. The Bard royalties, which apply to its worldwide sales of SNF and RNF products, are reported net of certain royalties which we pay to the original inventor. Bard received FDA regulatory approval for commercial sales and use of its RNF product as of December 31, 2002. As a result, future royalties earned on RNF product sales could increase significantly, dependent upon continued market acceptance and penetration. We continue to earn royalties from BSC in connection with the 1994 exclusive license of our stent technology. We believe that future royalties earned from BSC will remain flat or decline from 2003 levels. We currently do not anticipate any other material sources of revenues in 2004.

In 2003, we launched our clinical trial, CLOSURE I, 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. During the second half of 2003, we initiated site selection, site initiation and the process of patient enrollment. At December 31, 2003, nearly three-quarters of the 100 CLOSURE I clinical sites have completed the IRB process and approximately two-thirds of those sites have completed the initiation process allowing them to begin patient enrollment. Although the initial rate of enrollment has been disappointing, we are encouraged by the level of commitment shown by our clinical centers and currently expect that the enrollment phase of CLOSURE I will be completed by mid 2005. We currently expect that total costs for CLOSURE I will be approximately \$24 million through completion of the trial and submission to the FDA, which is currently expected to be in 2007. Of this total, approximately \$2.5 million was incurred during 2003 and we currently project 2004 costs in the range of \$8-10 million, largely dependent upon the rate of patient enrollment. As a result of the ongoing costs of CLOSURE I, we do not expect to be profitable in 2004.

We ended 2003 with \$36.7 million in cash, cash equivalents and marketable securities, providing the Company with what we believe is the financial strength and flexibility to complete CLOSURE I and to continue to invest in additional research and development programs, regulatory activities and commercial sales efforts, including potential geographical expansion to the Asia/Pacific region. Another area of significant interest that we expect to investigate is the potential role of PFO closure in the treatment of certain migraine patients.

CRITICAL ACCOUNTING POLICIES

Our significant accounting policies are more fully described in Note 2 of Notes to Consolidated Financial Statements. However, certain of our accounting policies are particularly important to the portrayal and understanding of our financial position and results of operations and require the application of significant judgment by our management. As a result, these policies are subject to an inherent degree of uncertainty. In applying these policies, we use our judgment in making certain assumptions and estimates. Our critical accounting policies include:

Revenue Recognition

We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 101 ("SAB 101"), "Revenue Recognition in Financial Statements", as amended by SABs 101A, 101B and 104. SAB 101/104 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 the collectibility of those fees. Should changes in conditions cause us to determine that these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

We require receipt of official purchase orders for all customer orders for our products. Prior to fulfillment of a customer order, we review that customer's account history and outstanding balances to determine if we believe that collectibility of the order value is reasonably assured. We recognize product revenues upon shipment unless customer purchase orders specifically designate that title to the products transfers upon receipt. Products sold to distributors, which account for approximately 2% of our product sales in 2003, 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 reserves level. The amount of reserves 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 record a provision for estimated sales returns and allowances on product sales in the same period as we record the related revenues. We base these estimates on historical sales returns, analysis of credit memo data and other known factors. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowances would be made in the period in which such a determination is made and revenues in that period could be adversely affected.

Inventories

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

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

Income Taxes

We account for income taxes under SFAS No. 109, "Accounting for Income Taxes". As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process requires us to estimate our actual current tax exposure together with an assessment of temporary differences resulting from differing treatment of items, such as deferred revenue or installment sales, for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent that we believe that recovery is not probable, we must establish a valuation allowance. To the extent that we establish a valuation allowance, or increase this allowance in a period, we must include a provision for income taxes in our consolidated statements of operations.

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance to be recorded against our net deferred tax assets. We have recorded a valuation allowance of approximately \$1.4 million as of December 31, 2003, due to uncertainties relating to our ability to utilize some of our deferred tax assets, primarily consisting of certain tax credits, before they expire. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates, or if we adjust these estimates in future periods, we may need to establish an additional valuation allowance which could materially impact our reported operating results.

The net deferred tax asset at December 31, 2003 of \$282,000, which is net of the \$1.4 million valuation allowance, is included in prepaid expense and other current assets in our consolidated balance sheets.

Legal Contingencies

We are currently involved in certain legal proceedings, which are described in Note 14 of Notes to Consolidated Financial Statements. In connection with these legal proceedings, we periodically review estimates of potential costs that we may incur in connection with the adjudication or settlement, if any, of these proceedings. We develop these estimates in consultation with outside counsel and they are based on an analysis of potential litigation outcomes and settlement strategies. In accordance with FASB Statement No. 5, "Accounting for Contingencies", loss contingencies are accrued if, in the opinion of management, an adverse outcome is probable and such outcome can be reasonably estimated. We do not currently believe that any of these proceedings will have a material adverse effect on our financial position; however, it is possible that future results for any particular quarter or annual period may be materially affected by changes in our assumptions or the effectiveness of our strategies relating to these proceedings.

Expenses Associated With Clinical Trial

During the second quarter ended June 30, 2003, we received full IDE approval from the FDA for, and commenced, CLOSURE I. Including contracts with third party providers, agreements with participating clinical sites and internal clinical department costs, we currently expect total costs for CLOSURE I to be approximately \$24 million through completion of the trial and submission to the FDA, which is currently expected to be in 2007. Of this amount, we incurred costs of approximately \$2.5 million in 2003 and we currently project 2004 costs in the range of \$8-10 million, largely dependent upon the rate of patient enrollment. Our judgment is required in determining methodologies used to recognize various costs. We will expense certain costs as patients are enrolled or upon the occurrence of other specific events during the clinical trial. We will expense certain other estimated costs, principally related to project management and data analysis, ratably over the estimated period in which the related services will be provided. Additional STARFlex[®] products manufactured to accommodate the expected requirements of CLOSURE I are included in inventory because they are saleable units with alternative use outside of the trial. These units will be expensed as a cost of CLOSURE I as they are implanted. All expenses related to CLOSURE I are included in research and development in our consolidated statements of operations.

Comparison of Years Ended December 31, 2003, 2002 and 2001

The following two tables present consolidated statements of operations information as a reference for management's discussion which follows thereafter. The first table presents dollar and percentage changes for each listed line item for 2003 compared with 2002 and for 2002 compared with 2001. The second table presents consolidated statements of operations information for each of the three years ended December 31, 2003 as a percentage of total revenues (except for cost of product sales, which is stated as a percentage of product sales).

(In thousands, except percentages)	YEARS ENDED DECEMBER 31,			INCREASE (DECREASE)		% CHANGE	
	2003	2002	2001	2002 to 2003	2001 to 2002	2002 to 2003	2001 to 2002
Revenues:							
Product sales	\$21,574	\$24,546	\$22,501	\$ (2,972)	\$ 2,045	(12.1)%	9.1%
Net royalty income	1,387	413	546	974	(133)	235.8%	(24.4)%
	<u>22,961</u>	<u>24,959</u>	<u>23,047</u>	<u>(1,998)</u>	<u>1,912</u>	<u>(8.0)%</u>	<u>8.3%</u>
Costs and expenses:							
Cost of product sales	5,303	6,606	7,436	(1,303)	(830)	(19.7)%	(11.2)%
Research and development	6,961	5,544	3,801	1,417	1,743	25.6%	45.9%
General and administrative	5,546	5,496	6,080	50	(584)	0.9%	(9.6)%
Selling and marketing	5,614	5,446	3,619	168	1,827	3.1%	50.5%
Settlement of litigation	1,216	—	—	1,216	—	—	—
Total costs and expenses	<u>24,640</u>	<u>23,092</u>	<u>20,936</u>	<u>1,548</u>	<u>2,156</u>	<u>6.7%</u>	<u>10.3%</u>
Gain on sale of product line	—	7,000	20,257	(7,000)	(13,257)	(100.0)%	(65.4)%
(Loss) income from operations	(1,679)	8,867	22,363	(10,546)	(13,501)	(118.9)%	(60.4)%
Other Income (Expense):							
Currency transaction gain (loss)	81	81	(35)	—	117	—	(325.0)%
Interest expense	(5)	(10)	(693)	5	688	(50.0)%	(98.6)%
Interest income	558	691	176	(133)	515	(19.2)%	292.6%
Loss on early extinguishment of debt	—	—	(402)	—	402	—	(100.0)%
Total other income (expense), net	<u>634</u>	<u>762</u>	<u>(960)</u>	<u>(128)</u>	<u>1,722</u>	<u>(16.8)%</u>	<u>(179.4)%</u>
(Loss) income before provision for income taxes	(1,045)	9,629	21,408	(10,674)	(11,779)	(110.9)%	(55.0)%
Provision for income taxes	105	3,424	2,630	(3,319)	794	(96.9)%	30.2%
Net (loss) income from continuing operations	<u>(1,150)</u>	<u>6,205</u>	<u>18,778</u>	<u>(7,355)</u>	<u>(12,573)</u>	<u>(118.5)%</u>	<u>(67.0)%</u>
Discontinued operations:							
(Loss) income from discontinued operations	—	(40)	417	40	(457)	(100.0)%	(109.6)%
Gain on sale of discontinued operations	—	4,914	—	(4,914)	4,914	(100.0)%	—
Net gain from discontinued operations	<u>—</u>	<u>4,874</u>	<u>417</u>	<u>(4,874)</u>	<u>4,457</u>	<u>(100.0)%</u>	<u>1068.8%</u>
Net (loss) income	<u>\$ (1,150)</u>	<u>\$11,079</u>	<u>\$19,195</u>	<u>\$ (12,229)</u>	<u>\$ (8,116)</u>	<u>(110.4)%</u>	<u>(42.3)%</u>

YEARS ENDED DECEMBER 31,	2003	2002	2001
Revenues:			
Product sales	94.0%	98.3%	97.6%
Net royalty income	6.0%	1.7%	2.4%
	<u>100.0%</u>	<u>100.0%</u>	<u>100.0%</u>
Costs and expenses:			
Cost of product sales	24.6%	26.9%	33.0%
Research and development	30.3%	22.2%	16.5%
General and administrative	24.2%	22.0%	26.4%
Selling and marketing	24.5%	21.8%	15.7%
Settlement of litigation	5.3%	—	—
Total costs and expenses	<u>107.3%</u>	<u>92.5%</u>	<u>90.8%</u>
Gain on sale of product line	—	28.0%	87.9%
(Loss) income from operations	(7.3)%	35.5%	97.1%
Other Income (Expense):			
Currency transaction gain (loss)	0.4%	0.3%	(0.2)%
Interest expense	—	—	(3.0)%
Interest income	2.4%	2.8%	0.8%
Loss on early extinguishment of debt	—	—	(1.7)%
Total other income (expense), net	<u>2.8%</u>	<u>3.1%</u>	<u>(4.2)%</u>
(Loss) income before provision for income taxes	(4.6)%	38.6%	92.9%
Provision for income taxes	0.5%	13.7%	11.4%
Net (loss) income from continuing operations	(5.0)%	24.9%	81.5%
Discontinued operations:			
(Loss) income from discontinued operations	—	(0.2)%	1.8%
Gain on sale of discontinued operations	—	19.7%	—
Net gain from discontinued operations	—	19.5%	1.8%
Net (loss) income	<u>(5.0)%</u>	<u>44.4%</u>	<u>83.3%</u>

RESULTS OF OPERATIONS YEAR ENDED DECEMBER 31, 2003 COMPARED WITH YEAR ENDED DECEMBER 31, 2002

Revenues. Revenues for the years ended December 31, 2003 and 2002 were as follows:

	2003	2002
(In thousands, except per share data)		
Product sales:		
CardioSEAL® and STARFlex®:		
North America	\$17,853	\$16,962
Europe	3,564	2,355
	<u>21,417</u>	<u>19,317</u>
Vena cava filter	—	5,156
Other	157	73
Total product sales	<u>21,574</u>	<u>24,546</u>
Net royalty income:		
Bard	1,028	—
BSC	359	413
Total net royalty income	<u>1,387</u>	<u>413</u>
Total revenues	<u>\$22,961</u>	<u>\$24,959</u>

CardioSEAL® and STARFlex® product sales increased by approximately \$2.1 million, or 10.9%, in 2003 compared to 2002. We believe that North American product sales, which increased by 5.3% from 2002 to 2003, benefited from continued growing awareness within the medical community that closing a PFO in certain stroke patients offers an alternative to drug therapy. Additionally, we believe that North American product sales may have been negatively impacted by the combination of CLOSURE I and competing trials and commercial sales efforts.

European sales increased by approximately 51% from 2002 to 2003, although the strengthening of the euro accounted for approximately \$500,000, or 40%, of this increase. European sales have been positively impacted by our increased investments in that region since the second half of 2002. Direct sales personnel have more than doubled to a total of eight at the end of 2003 compared to three at the end of 2001. European sales represented approximately 16.6% and 12.2% of total CardioSEAL® and STARFlex® product sales in 2003 and 2002, respectively.

Management currently anticipates approximately 10% growth in CardioSEAL® and STARFlex® product sales in 2004 compared to 2003, with European sales projected to approximate 20% of the total. It is uncertain if, and to what extent, our anticipated acceleration of CLOSURE I patient enrollment in 2004 will affect the level of North American sales. Continued strengthening or weakening of the euro against the U.S. dollar will have a favorable or unfavorable impact, respectively, on the trend of European product sales.

There were no vena cava filter product sales in 2003. In connection with the 2001 sale of the vena cava filter product line to Bard, we completed, as of June 2002, our transitional manufacturing agreement under which we had continued to sell vena cava filter products to Bard.

The substantial increase in net royalty income for the year ended December 31, 2003 was directly attributable to the commencement of royalties from Bard on its sales of vena cava filter products (see Note 4 of Notes to Consolidated Financial Statements). The Bard royalties, which were recorded net of royalties payable to the original inventor of these products, were approximately \$1.0 million for the year ended December 31, 2003. A substantial majority of the Bard royalties related to sales of its RNF product, for which it received FDA regulatory for commercial sale and use as of December 31, 2002. Royalties from BSC in connection with its exclusive license of our stent technology were approximately \$359,000 for the year ended December 31, 2003 compared to royalties and manufacturing cost sharing incentives totaling approximately \$413,000 for the prior year. Although we believe that royalties earned from Bard will increase in the future, that result is largely dependent upon continued market acceptance and penetration of their new generation RNF product. We currently anticipate that future royalties earned from BSC will remain flat or decline compared to 2003 levels.

Cost of Product Sales. The decrease in cost of sales as a percentage of product sales for the year ended December 31, 2003 was largely attributable to completion of vena cava filter product sales during 2002, which products historically had a higher cost as a percentage of product sales than our CardioSEAL® and STARFlex® products. This decrease in cost of sales as a percentage of product sales for the year ended December 31, 2003 was partially offset by a 1% increase in the CardioSEAL® and STARFlex® royalty rate, effective in February 2003, and the impact of proportionately higher international sales, which have a lower average selling price than U.S. sales. Included in cost of product sales were royalty expenses of approximately \$2.1 million and \$1.9 million for the years ended December 31, 2003 and 2002, respectively. We currently expect cost of sales as a percentage of product sales to be approximately 25% in 2004, primarily as a result of higher projected international sales as a percentage of total sales and the higher unit manufacturing cost of our RTS product, which was launched in Europe during the second half of 2003.

Research and Development. The approximately \$1.4 million increase in research and development expense in 2003 compared to 2002 was directly related to the launch of our PFO IDE clinical trial. CLOSURE I costs of approximately \$2.5 million for the year ended December 31, 2003 were partially offset by cost reductions related to the substantial completion during 2002 of the RTS development project, the winding down of older clinical trials and the 2002 purchase of PFO study data used in the design of the CLOSURE I trial. We continued to invest heavily to protect and expand our intellectual property positions, having filed in excess of 30 utility and provisional patent applications in 2003 compared to 16 in 2002.

We currently expect 2004 research and development expense to increase by more than 100% compared to 2003, primarily attributable to an estimated \$8-10 million of costs for CLOSURE I. As a result of the recent execution of certain third party contracts and the expected effects of the extended duration of CLOSURE I, we have increased our current estimate of total CLOSURE I costs to approximately \$24 million through the end of the clinical trial and submission to the FDA, currently expected to occur in 2007. In addition to third party contracts, CLOSURE I costs include the personnel and operating expense of our clinical department and the cost of STARFlex® products implanted. Research and development expense as a percentage of total revenues is expected to be approximately 45-50% in 2004.

General and Administrative. General and administrative expense was essentially unchanged from 2002 to 2003. Increases in stock-based compensation associated with our 2001 stock option re-pricing, higher insurance premiums and the commencement of annual retainer fees for outside directors were largely offset by decreases in audit fees related to the mandated re-audits performed in 2002, lower corporate legal fees and reduced travel costs, primarily related to the period prior to the July 2002 sale of the neurosciences business unit. General and administrative expense is expected to increase by less than 10% in 2004 compared to 2003, primarily related to anticipated insurance premium increases and professional fees necessary to comply with increased corporate governance requirements of the Sarbanes-Oxley Act.

Selling and Marketing. The increase in selling and marketing expense in 2003 compared to 2002 was primarily attributable to our European investments, including additional personnel and associated costs related to the doubling of headcount during the second half of 2002, increased awareness marketing programs in that region and the effect of increased product sales on commission costs. In addition, the strengthening of the euro throughout 2003 had the effect of increasing reported international costs, primarily denominated in euros, by approximately \$300,000. These cost increases were partially offset by reduced U.S. selling and marketing costs, principally related to travel and marketing programs. We currently expect selling and marketing expense to increase by approximately 15% in 2004 compared to 2003, primarily related to the establishment of a more formalized product management function and anticipated costs to initiate geographical expansion into the Asia/Pacific region.

Settlement of Litigation. During the year ended December 31, 2003, we incurred a charge of approximately \$1.2 million in connection with the settlement of an arbitration proceeding with BTE. The charge consisted of a \$950,000 settlement payment to BTE plus legal costs (See Note 14 of Notes to Consolidated Financial Statements).

Gain on Sale of Product Line. For the year ended December 31, 2002, we recorded a gain on sale of product line of \$7.0 million related to the achievement of certain performance and delivery milestones in connection with our sale of assets comprising the vena cava filter product line to Bard on November 5, 2001. The \$7.0 million gain consisted of (i) \$4.0 million resulting from the transfer of manufacturing responsibilities to Bard as of September 30, 2002, which occurred following the completion of the transitional manufacturing agreement under which we continued to manufacture vena cava filter products for Bard through June 2002; and (ii) \$3.0 million upon the receipt by Bard of FDA regulatory approval for the commercial sale and use of its Recovery™ Filter (See Note 4 of Notes to Consolidated Financial Statements).

Interest Income. The decrease in interest income in 2003 compared to 2002 was primarily attributable to a reduction in weighted average interest rates earned, partially offset by an increase in the amount of interest bearing assets. The increased assets were primarily attributable to the proceeds from our sale of the neurosciences business unit and the contingent consideration received in connection with the sale of the vena cava filter product line to Bard. At December 31, 2003, approximately \$8.0 million of interest-bearing funds remain invested in U.S. Government agency debt securities, with a scheduled maturity of April 2004. An additional \$25.6 million of interest-bearing funds are invested in an institutional money market fund, earning approximately 0.96% per annum based upon the daily rate at December 31, 2003. Average interest bearing deposits during 2004 are expected to decrease as a result of the significant ongoing costs of CLOSURE I. As a result, we currently expect interest income to decrease by approximately \$50,000, or 10%, compared to net interest income recorded in fiscal 2003, assuming interest rates remain the same.

Income Tax Provision. Our income tax provision in 2003 of \$105,000, or approximately 10.0% of loss before income taxes, compares to approximately \$3.4 million, or 35.6% of income before income taxes from continuing operations, in 2002. The significant decrease in our 2003 tax provision compared to 2002 was directly attributable to an approximately \$10.5 million reduction in income (loss) from operations. This reduction consisted primarily of the \$7.0 million gain from sale of product line in 2002 in connection with our 2001 sale of the vena cava filter product line to Bard, the 2003 settlement of litigation charge of approximately \$1.2 million and approximately \$2.5 million of CLOSURE I costs associated with the 2003 commencement of that clinical trial. The 2003 tax provision was primarily attributable to the \$3.0 million of taxable income recognized upon receipt of the final Bard milestone payment in January 2003, which was recognized for financial statement purposes in 2002, partially offset by approximately \$1.0 million of remaining tax loss carryforwards for which tax benefit had not been previously provided, and operating losses incurred in 2003. The current provision of approximately \$387,000 has been partially offset by a \$282,000 deferred tax benefit attributable to the projected carryback of expected 2004 operating losses. We currently expect to incur operating losses in 2004, primarily due to the projected \$8-10 million cost associated with CLOSURE I. Accordingly, we expect a minimal tax provision for the year ending December 31, 2004.

Net Gain from Discontinued Operations. For the year ended December 31, 2002, net gain from discontinued operations was approximately \$4.9 million, which consisted primarily of a \$248,000 pre-tax loss on the sale of our neurosciences business unit in July 2002 and a tax benefit of approximately \$5.2 million attributable to the utilization of prior years' losses, for which tax benefit had not been previously provided for in our financial statements. These un-benefited losses were largely attributable to approximately \$14 million of asset impairment charges in fiscal 2000 and 1999 (See Note 3 of Notes to Consolidated Financial Statements).

YEAR ENDED DECEMBER 31, 2002 COMPARED WITH YEAR ENDED DECEMBER 31, 2001

Revenues. Revenues for the years ended December 31, 2002 and 2001 were as follows:

	2002	2001
(In thousands of dollars)		
Product sales:		
CardioSEAL® and STARFlex®:		
North America	\$16,962	\$12,130
Europe	2,355	2,188
	<u>19,317</u>	<u>14,318</u>
Vena cava filter	5,156	8,183
Other	73	—
Total product sales	<u>24,546</u>	<u>22,501</u>
Net royalty income:		
Bard	—	—
BSC	413	546
Total net royalty income	<u>413</u>	<u>546</u>
Total revenues	<u>\$24,959</u>	<u>\$23,047</u>

CardioSEAL® and STARFlex® product sales increased by approximately \$5.0 million, or 34.9%, in 2002 compared to 2001. We believe that this increase resulted primarily from (i) the growing awareness within the medical community that closing a PFO in certain stroke patients offers an alternative to ongoing drug therapy; (ii) the granting of a PMA by the FDA in December 2001 for the VSD indication; and (iii) an increase in our direct sales headcount during fiscal 2002 from 9 to 17. The approximate \$3.0 million decrease in vena cava filter product sales was primarily attributable to completion of our transitional manufacturing agreement with Bard as of June 30, 2002 in connection with our November 2001 sale of the vena cava filter product line to Bard.

Net royalty income, related to the exclusive license of our stent technology to BSC, included \$355,000 and \$421,000 of royalties and \$58,000 and \$125,000 of cost-sharing payments for the years ended December 31, 2002 and 2001, respectively. The \$66,000 decrease in royalty payments was attributable to reduced BSC sales of the stent products manufactured using our technology.

Cost of Product Sales. The decrease in cost of product sales as a percentage of product sales was primarily attributable to the completion of the transitional manufacturing agreement with Bard as of June 2002, accentuating the historical shift of the product sales mix in favor of our CardioSEAL® and STARFlex® products, which have a lower product cost as a percentage of sales than the vena cava filter products. Included in cost of product sales were royalty expenses of approximately \$1.9 million and \$1.5 million for the years ended December 31, 2002 and 2001, respectively, related to acquired technologies and technology rights associated with our products.

Research and Development. The increase in research and development expense for the year ended December 31, 2002 compared to 2001 was primarily attributable to a combination of increased headcount and related personnel costs, contract product development for ongoing research and development programs related to CardioSEAL® and STARFlex® enhancements and accessories, next generation PFO closure platforms and research into the use of novel materials, and related patent legal costs. We filed more than 20 patent applications and disclosures during 2002, with a large number in the fourth quarter.

General and Administrative. The decrease in general and administrative expense for the year ended December 31, 2002 compared to 2001 was primarily attributable to decreased legal fees associated with ongoing litigation and general corporate matters and reduced stock-based compensation charges associated with our 2001 stock option re-pricing, partially offset by one-time costs of a required re-audit of our fiscal year 2000 and 2001 financial statements. The 2002 sale of our neurosciences business unit, as a discontinued operation, required restatement of our consolidated financial statements and a re-issuance of our prior auditor's report. Because our prior auditor, Arthur Andersen LLP, ceased operations, our new auditors had to re-audit those years.

Selling and Marketing. The increase in selling and marketing expenses for the year ended December 31, 2002 compared to 2001 was primarily attributable to (i) an increase in worldwide headcount from 9 to 17, including associated increases in benefits and travel costs; (ii) higher sales commissions related to the 35% increase in CardioSEAL® and STARFlex® products sales; (iii) increased marketing program costs; and (iv) European marketing consulting services. Selling and marketing expense as a percentage of total revenues increased to approximately 21.8% in 2002 from approximately 15.7% in 2001.

Gain on Sale of Product Line. For the years ended December 31, 2002 and 2001, we recorded a gain on sale of product line of \$7.0 million and \$20.3 million, respectively. These gains resulted from the sale of assets comprising our vena cava filter product line to Bard on November 5, 2001. In exchange for these assets, we received \$8.5 million at closing and \$18.5 million in January 2002

and the right to receive up to an additional \$7 million tied to certain performance and delivery milestones.

The 2001 gain of \$20.3 million consisted of proceeds of \$27 million less costs of approximately \$6.7 million, which consisted of the purchase of royalty and other technology rights from Beth Israel, deferred revenue estimates related to the transitional manufacturing agreement, accruals for ongoing arbitration proceedings, the net book value of assets sold and legal and other costs of the sale. The 2002 gain of \$7.0 million consisted of (i) \$4.0 million resulting from the transfer of manufacturing responsibilities to Bard as of September 30, 2002, which occurred following the completion of the transitional manufacturing agreement under which we continued to manufacture vena cava filter products for Bard through June 2002; and (ii) \$3.0 million upon the receipt by Bard of FDA regulatory approval for the commercial sale and use of its Recovery™ vena cava filter (See Note 4 of Notes to Consolidated Financial Statements).

Interest Expense. Interest expense was substantially eliminated in 2002 as a result of the complete repayment during 2001 of our \$5.5 million subordinated debt, principally from the proceeds of the sale of the vena cava filter product line to Bard. Interest expense for the year ended December 31, 2002 was attributable to outstanding capital lease obligations, which were paid in full during 2003.

Interest Income. The increase in interest income for the year ended December 31, 2002 was primarily attributable to increases in interest bearing deposits resulting from the \$27.0 million of net proceeds from the sale of the vena cava filter product line in November 2001 and January 2002, the \$4.0 million contingent consideration received in September 2002 from that transaction and the \$5.4 million proceeds from the sale of the remainder of our neurosciences business unit on July 31, 2002, partially offset by a significant reduction in interest rates from 2001 to 2002.

Loss on Early Extinguishment of Debt. The loss on early extinguishment of debt of approximately \$402,000 for the year ended December 31, 2001 consisted of the write-off of the remaining balances of original issue discount and deferred loan costs in connection with the repayment in full of our subordinated debt in November 2001.

Income Tax Provision. Our income tax provision in 2002 of approximately \$3.4 million or 35.6% of income before income taxes from continuing operations, compared to an income tax provision of approximately \$2.6 million, or 12.3% of income before income taxes from continuing operations in 2001. The income tax provision as a percentage of income before income taxes from continuing operations in 2001 was less than what would be expected using the statutory federal tax rate of 34% primarily due to the utilization of net operating loss carryforwards.

Income (Loss) from Discontinued Operations. In accordance with SFAS No. 144, the accompanying consolidated financial statements reflect the financial results of the neurosciences business unit, which was sold on July 31, 2002, as discontinued operations for all periods presented. Loss from discontinued operations of approximately \$40,000 for the year ended December 31, 2002 compared to income from discontinued operations of approximately \$417,000 for the year ended December 31, 2001. The 2002 decrease was primarily attributable to a charge of approximately \$373,000, recorded in the first quarter of 2002, for a settlement of litigation with Elekta, from whom we purchased the original neurosciences business unit in July 1998 (See Note 3 of Notes to Consolidated Financial Statements).

Gain on Sale of Discontinued Operations. For the year ended December 31, 2002, gain on sale of discontinued operations was approximately \$4.9 million, which consisted of a \$248,000 pre-tax loss on the sale our neurosciences business unit in July 2002 and a tax benefit of approximately \$5.2 million attributable to the utilization of prior years' losses, for which tax benefit had not been previously provided for in the Company's financial statements. These un-benefited losses were largely attributable to approximately \$14 million of asset impairment charges in fiscal 2000 and 1999. There was no gain on sale of discontinued operations for the year ended December 31, 2001 (See Note 3 of Notes to Consolidated Financial Statements).

LIQUIDITY AND CAPITAL RESOURCES

FOR THE YEARS ENDED DECEMBER 31,	2003	2002	2001
(In thousands)			
Cash, cash equivalents and marketable securities	\$36,725	\$36,244	\$ 7,837
Cash provided by continuing operations	865	17,322	7,930
Cash (used in) provided by discontinued operations	(411)	5,608	989
Cash provided by (used in) investing activities	7,930	(11,806)	(140)
Cash provided by (used in) financing activities	406	1,011	(5,342)

Cash Provided by Continuing Operations:

Cash provided by continuing operations for the year ended December 31, 2003 totaled \$865,000 and was comprised of (a) a net loss of approximately \$1.1 million; (b) various non-cash charges to operations of approximately \$1.2 million; and (c) net changes in components of working capital of approximately \$845,000.

Net cash provided by continuing operations for 2003 decreased by approximately \$16.5 million from 2002. This decrease was primarily attributable to the following:

- (a) We received a total of \$22.5 million cash consideration from Bard during 2002 in connection the sale of the vena cava filter product line, including the first \$4.0 million milestone payment, an increase of \$19.5 million compared to \$3.0 million cash consideration received during 2003, representing the final milestone payment under the Bard agreement.
- (b) At December 31, 2001, we had recorded a deferred gain of \$3.4 million relating to the sale of the vena cava filter product line to Bard, which consisted of (i) an estimated \$2.4 million of aggregate price discounts to be applied against invoices due from Bard for the sales of vena cava filter products during the transitional manufacturing period; and (b) an estimated \$1.0 million accrual for costs associated with an ongoing arbitration proceeding related to the sale of the vena cava filter product line. During 2002, we recorded a \$3.4 million reduction of the deferred gain balance down to zero as we transferred manufacturing capabilities of filter products to Bard and settled the arbitration proceeding.

The non-cash charges of approximately \$1.2 million in 2003 included depreciation of property, plant and equipment, amortization of bond premium related to our investments in U.S. government agency securities, provisions for bad debts and sales returns and stock-based compensation principally related to our stock option re-pricing in 2001. Unless we purchase additional marketable securities at a premium, amortization of bond premium will not re-occur in 2004.

The primary elements of the \$845,000 net change in working capital items in 2003 consisted of the following:

- (a) We received the final \$3.0 million milestone payment from Bard in January 2003, which had been recognized as a receivable as of December 31, 2002.
- (b) Net trade accounts receivable increased by approximately \$480,000, primarily due to increased product sales in the fourth quarter of 2003 compared to the fourth quarter of 2002. Gross trade accounts receivable increased by approximately \$200,000, or 7.2%, at December 31, 2003 compared to 2002. This increase was less than the approximate \$500,000, or 9.1%, increase in fourth quarter 2003 product sales compared to that of the prior year as days sales outstanding (DSO) improved to approximately 45 days at the end of 2003 compared to approximately 49 days at the end of the prior year. Our European sales increased by approximately 51% in 2003 compared to 2002 and, although European customers generally are slower payers than U.S. customers, we achieved better DSO due to improved collection efforts.
- (c) Our inventories increased by approximately \$753,000 during 2003, primarily in anticipation of CLOSURE I patient enrollment requirements, initial stocking levels of the new RTS product and also as a result of higher projected sales growth than was realized. Based upon our 2004 production plan and expected acceleration of CLOSURE I patient enrollment, we currently anticipate that inventory balances will trend downward during 2004.
- (d) Prepaid expenses and other current assets increased during 2003 by approximately \$1.1 million. Of this total, approximately \$730,000 represented fourth quarter royalties due from Bard that commenced in 2003 as a result of our sale of the filter product line to Bard. The remainder of this increase related primarily to increased annual insurance premiums paid in advance at renewal and increased deposits associated with committed marketing events and capital equipment purchases, partially offset by reduced levels of interest income receivable. To the extent that increases in Bard royalties and insurance renewal premiums are currently anticipated, we expect that the level of prepaid expenses and other current assets will trend upward in 2004.
- (e) Current liabilities increased by approximately \$190,000 during 2003, primarily related to CLOSURE I cost accruals, increased royalty accruals and current income taxes payable, partially offset by reductions in accounts payable and the completion of the re-audit of the years ended December 31, 2001 and 2000 that was required to reflect our sale of the neurosciences business unit as a discontinued operation. We currently expect that CLOSURE I costs and accruals will increase substantially during 2004. Royalty expense accruals are also currently expected to increase, but will be partially offset by the anticipated payment of the last \$250,000 balloon royalty to CMCC during 2004.

Net cash provided by continuing operations for 2002 increased by approximately \$9.4 million compared to 2001. This increase was largely attributable to a \$14.0 million increase in cash consideration from Bard for the sale of the vena cava filter product line, net of a \$3.4 million reduction of the deferred gain balance down to zero as we transferred manufacturing capabilities of filter products to Bard and settled the arbitration proceeding.

Cash (Used In) Provided By Discontinued Operations

Cash used in discontinued operations of approximately \$411,000 during 2003 related to the payment of a judgment against the Company related to the termination of a former European employee of the neurosciences business unit. This compared to cash provided by discontinued operations of approximately \$5.6 million during 2002, which consisted primarily of a \$5.2 million tax benefit attributable to the utilization of losses, not previously benefited for financial statement purposes, in connection with the July 2002 sale of our neurosciences business unit. These losses substantially offset the taxable income recognized in 2002 from the sale of the vena cava filter product line to Bard.

Cash Provided By (Used In) Investing Activities

Cash provided from investing activities of approximately \$7.9 million in 2003 consisted primarily of \$8.0 million proceeds from maturities of U.S. government agency debt instruments. This compared to cash used from investing activities of approximately \$11.8 million in 2002, which consisted primarily of \$16.2 million of purchases of U.S. government agency debt instruments, offset by \$4.8 million proceeds from the sale of our neurosciences business unit, net of cash balances sold. Purchases of property and equipment for use in our manufacturing, research and development and general and administrative activities amounted to approximately \$150,000, \$418,000 and \$149,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

Cash Provided By (Used In) Financing Activities

Net cash provided by financing activities decreased by approximately \$605,000 from 2002 to 2003. This decrease was primarily attributable to an approximate \$707,000 reduction of proceeds from the exercise of common stock options and issuance of common stock under our employee stock purchase plan ("ESPP"), offset by an approximate \$102,000 reduction in payment of capital lease obligations, which were repaid in full during 2003. Net cash provided by financing activities of approximately \$1.0 million in 2002 represented a net \$6.4 million increase compared to net cash used in financing activities of approximately \$5.3 million in 2001. This increase was primarily attributable to the repayment in 2001 of \$5.5 million of a subordinated note, predominantly from the initial proceeds of our sale of the vena cava filter product line to Bard. Additionally, proceeds from the exercise of stock options and issuance of ESPP shares increased by approximately \$730,000 in 2002 compared to 2001 and payments of capital lease obligations decreased by approximately \$123,000 in 2002 compared to 2001. At December 31, 2003, we had no outstanding debt financing.

Primarily as a result of the ongoing costs of CLOSURE I, we expect to incur operating losses at least through 2004. The total cost of our CLOSURE I clinical trial is currently estimated to be approximately \$24 million through completion of the trial and submission to the FDA, which is currently expected to be in 2007. Of this amount, approximately \$2.5 million was incurred in 2003 and we currently expect to incur approximately \$8-10 million in 2004, largely dependent upon the rate of patient enrollment.

Capital expenditures are projected to total approximately \$500,000 during 2004, primarily for manufacturing and research and development equipment.

We currently believe that aggregate cash, cash equivalents and marketable securities balances of approximately \$36.7 million at December 31, 2003 will be sufficient to meet our working capital, financing and capital expenditure requirements through at least 2006. Based upon current projections of CLOSURE I costs during 2004, we expect that cash, cash equivalents and marketable securities will exceed \$29 million at the end of 2004.

We may require additional funds for our research and product development programs, regulatory processes, preclinical and clinical testing, sales and marketing infrastructure and programs and potential licenses and acquisitions. Any additional equity financing may 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

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 2006, include one 5-year renewal option on a majority of this space. Exercise of this option requires written notice to the landlord at any time during the period 9-12 months prior to the expiration of the lease term.

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 original inventor of certain vena cava filter products on sales of those products by Bard; and (iii) to Lloyd Marks on sales of CardioSEAL® and STARFlex® products to the extent that technology licensed to us is incorporated into these products, subject to a minimum annual royalty of \$150,000 to maintain exclusivity. Royalty expenses in 2003 totaled approximately \$2.7 million and are expected to increase in the future.

In connection with CLOSURE I, we have entered into various contractual obligations with third party service providers and the participating clinical sites. Including the internal costs of the Company's clinical department and the manufacturing costs of the STARFlex® products to be implanted, total CLOSURE I costs are currently estimated to be approximately \$24 million through the completion of the trial and submission to the FDA, which is currently expected to be in 2007. Of this total, approximately \$2.5 million of costs were incurred in 2003 and we currently project 2004 costs in the range of \$8-10 million, largely dependent upon the rate of patient enrollment. The ultimate timing and amounts of these obligations are dependent upon various factors, including the timing of patient enrollment and patient monitoring. 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.

The following table summarizes our estimated minimum future contractual commitments at December 31, 2003, excluding royalty and CLOSURE I obligations because they are variable and/or subject to uncertain timing:

	AMOUNTS DUE IN				
	TOTAL	LESS THAN ONE YEAR	1-3 YEARS	4-5 YEARS	AFTER 5 YEARS
Operating Leases	\$2,649,000	\$ 992,000	\$1,657,000	\$ —	\$ —

OFF-BALANCE SHEET FINANCING

During the year ended December 31, 2003, we have not engaged in material off-balance sheet activities, including the use of structured finance or specific purpose entities.

RECENT ACCOUNTING PRONOUNCEMENTS

In January 2003, the FASB issued Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities". FIN 46 expands upon existing accounting guidance that addresses when a company should include in its financial statements the assets, liabilities and activities of another entity. In general, a variable interest entity is a corporation, partnership, trust or any other legal structure used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. FIN 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or is entitled to receive a majority of the entity's residual returns, or both. In December 2003, the FASB revised FIN 46 ("FIN46-R") to address certain FIN 46 implementation issues. The consolidation requirements of FIN 46 apply immediately to variable interest entities created after January 31, 2003. For pre-existing entities, these requirements must be applied in the first interim reporting period ending after March 15, 2004. The adoption of these provisions did not have a material impact on our financial statements.

CERTAIN FACTORS THAT MAY AFFECT FUTURE RESULTS

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

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

Upon receipt of final FDA approval, we commenced CLOSURE I in June 2003. Although nearly three-quarters of the 100 clinical sites have completed the IRB approval process and two-thirds of those sites have concluded the initiation process allowing them to begin patient enrollment, the initial rate of patient enrollment has been disappointing. As a result, and based upon our current estimates, we expect that enrollment of all 1,600 patients will be completed by mid 2005. We currently estimate the total costs of CLOSURE I to be approximately \$24 million through completion of the clinical trial and submission to the FDA, which is currently expected to be in 2007. We have no direct experience conducting a clinical trial of this magnitude. We cannot be certain that patient enrollment will be completed within our revised time expectation or at all. We cannot be certain that the projected costs of CLOSURE I will not need to be adjusted upwards further. 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 would impact our ability to be profitable.

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

All of our U.S. commercial sales of CardioSEAL® are made pursuant to either (a) the PMA granted by the FDA in December 2001 covering the VSD indication; or (b) the HDE granted by the FDA in February 2000 covering the PFO indication. To the extent that we believe that PFO is the much larger market opportunity, a substantial majority of our U.S. sales are made under the PFO HDE. If the first PMA for the PFO indication were to be granted by the FDA to one of our competitors, our HDE approval for PFO would be deactivated by the FDA. Such a loss of our PFO HDE would cause a very material reduction in U.S. sales, resulting in significant operating losses based upon our current operational structure. Under these circumstances, and in the absence of substantial sources of new financing, our future prospects would be severely limited, including our ability to complete the CLOSURE I clinical trial that is required to apply for a PFO PMA.

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

During 2001 and 2002, we completed the divestiture of non-strategic businesses through the sale of the vena cava filter product line to Bard and the sale of the remainder of the neurosciences business unit to Integra. We derive a substantial portion of our ongoing revenues from sales of our CardioSEAL® and STARFlex® products. In the United States, the FDA limits sales under an HDE to 4,000 units per year. As demand for, and costs associated with, these products fluctuates, including the potential impact of our non-revenue producing PFO IDE clinical trial 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 will 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 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 additional products. Even if we determine that a product candidate has medical benefits, the cost of commercializing that product candidate may be too high to justify development. In addition, competitors may develop products that are more effective, cost less or are ready for commercial introduction before our products. If we are unable to develop additional, commercially viable products, our future prospects will be limited.

WE MAY FACE CHALLENGES IN EXECUTING OUR FOCUSED BUSINESS STRATEGY.

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

- o achieving a successful CLOSURE I clinical trial;
- o improving our sales and marketing capabilities;
- o continuing to train, motivate and manage our employees; and
- o 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:

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

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

Our issued U.S. patents, and corresponding foreign patents, expire at various dates ranging from 2011 to 2019. 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.

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

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

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

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

Our cardiac septal repair implant devices are marketed primarily through our direct sales force. We have increased our combined U.S. and European sales and marketing organization headcount from 9 to 18 during the two years ended December 31, 2003. Due to our relatively new sales staff, and because we have 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 into Asia/Pacific or other potential markets for our products. In order to market directly the CardioSEAL® and STARFlex® septal implants and any related products, we will have to continue to develop a marketing and sales organization with technical expertise and distribution capabilities.

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

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

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

We are currently involved in the litigation of disputes as described in Item 3 (Legal Proceedings). An adverse outcome in any one of these disputes could result in substantial monetary damages 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.

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

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

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

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

WE 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, this would materially adversely affect our ability to sell our products. Moreover, mounting concerns about rising health care costs may cause the government or private insurers to implement more restrictive coverage and reimbursement policies in the future. In the international market, reimbursement by private third party medical insurance providers and by governmental insurers and providers varies from country to country. In certain countries, our ability to achieve significant market penetration may depend upon the availability of third party governmental reimbursement.

THE SIGNIFICANT CONCENTRATION OF OWNERSHIP OF OUR COMMON STOCK COULD LIMIT INVESTORS' ABILITY TO INFLUENCE CORPORATE ACTIONS.

A few of our stockholders, including Whitney & Co. and related entities, own a significant percentage of our outstanding common stock. As a result, these stockholders may be able to influence the outcome of matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership of our common stock may have the effect of impacting the probability and timing of a change in control of the Company. This could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company and might otherwise affect the market price of our common stock.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2003 and 2002, 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 debt instruments that are carried on our books at cost, increased or decreased by unrealized gains or losses, net of tax, respectively, which amounts are recorded as a component of stockholders' equity in our consolidated financial statements. Accordingly, we have no quantitative information concerning the market risk of participating in such investments.

We are subject to market risk in the form of interest rate risk and foreign currency risk. Interest rate risk is immaterial to the Company. Although we have decreased the scope of our international operations following the sale of the neurosciences business unit in July 2002, we continue to denominate certain 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". Prior to the sale of the neurosciences business unit, the assets and liabilities of these foreign subsidiaries were translated from their local currency into U.S. dollars at the rate of exchange in effect at the end of each reporting period, while stockholders' equity was translated at historical rates. We recorded the effects of changes in balance sheet items (i.e., cumulative foreign currency translation gains and losses) as a component of consolidated stockholders' equity. The functional currency of our remaining 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

The information required by this Item was previously disclosed in a Current Report on Form 8-K, which the Company filed with the Securities and Exchange Commission on July 1, 2002.

ITEM 9A. 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 defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) (the "Exchange Act") as of December 31, 2003. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2003, our disclosure controls and procedures were (1) designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to our chief executive officer and chief financial officer by others within those entities, particularly during the period in which this report was being prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The response to this Item is contained in part under the caption "Executive Officers of the Company" in Part I of this Annual Report on Form 10-K and in part in our Proxy Statement for the 2004 Annual Meeting of Stockholders to be held on June 22, 2004 (the "2004 Proxy Statement") under the captions "Proposal 1 — Election of Directors" and "Information Relating to the Board of Directors and Certain of its Committees", which sections are incorporated herein by this reference.

Officers are elected on an annual basis and serve at the discretion of the Board.

The information required by this Item regarding compliance with Section 16(a) of the Securities Exchange Act of 1934, as amended, is contained in the 2004 Proxy Statement under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" and is incorporated herein by this reference.

ITEM 11. EXECUTIVE COMPENSATION

The response to this Item is contained in the 2004 Proxy Statement under the caption "Proposal 1 — Election of Directors", which section is incorporated herein by this reference.

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

The response to this Item is contained in the 2004 Proxy Statement under the caption "Stock Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information", which sections are incorporated herein by this reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The response to this Item is contained in the 2004 Proxy Statement under the caption "Certain Transactions", which section is incorporated herein by this reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The response to this Item is contained in the 2004 Proxy Statement under the caption "Independent Auditors", which section is incorporated herein by this reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

- (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 Auditors

Consolidated Balance Sheets at December 31, 2003 and 2002

Consolidated Statements of Operations for the years ended December 31, 2003, 2002 and 2001

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2003, 2002 and 2001

Consolidated Statements of Cash Flows for the years ended December 31, 2003, 2002 and 2001

Notes to Consolidated Financial Statements

- (b) Reports on Form 8-K.

On November 4, 2003, we furnished a Current Report on Form 8-K containing a copy of our earnings release for the quarter ended September 30, 2003 (including financial statements) pursuant to Item 12 (Results of Operations and Financial Condition).

- (c) Exhibits. The exhibits filed as part of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding such exhibits, and are incorporated herein by this reference. We have identified with asterisks in the Exhibit Index each management contract and compensation plan filed as an exhibit to this Annual Report on Form 10-K in response to Item 15(c) of Form 10-K.
- (d) 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 24, 2004

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
<u>/s/ JOHN E. AHERN</u> John E. Ahern	President, Chief Executive Officer, and Chairman of the Board (Principal Executive Officer)	March 24, 2004
<u>/s/ RICHARD E. DAVIS</u> Richard E. Davis	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 24, 2004
<u>/s/ ROBERT G. BROWN</u> Robert G. Brown	Director	March 24, 2004
<u>/s/ CHERYL L. CLARKSON</u> Cheryl L. Clarkson	Director	March 24, 2004
<u>/s/ R. JOHN FLETCHER</u> R. John Fletcher	Director	March 24, 2004
<u>/s/ DANIEL F. HANLEY</u> Daniel F. Hanley, M.D.	Director	March 24, 2004
<u>/s/ JAMES E. LOCK</u> James E. Lock, M.D.	Director	March 24, 2004
<u>/s/ FRANCIS J. MARTIN</u> Francis J. Martin	Director	March 24, 2004
<u>/s/ HARRY A. SCHULT</u> Harry A. Schult	Director	March 24, 2004

APPENDIX

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

Report of Independent Auditors	A-2
Consolidated Balance Sheets at December 31, 2003 and 2002	A-3
Consolidated Statements of Operations for the Years Ended December 31, 2003, 2002 and 2001	A-4
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2003, 2002 and 2001	A-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2003, 2002 and 2001	A-6
Notes to Consolidated Financial Statements	A-7

REPORT OF INDEPENDENT AUDITORS

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

We have audited the accompanying consolidated balance sheets of NMT Medical, Inc. (a Delaware corporation) and subsidiaries as of December 31, 2003 and 2002 and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2003. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of NMT Medical, Inc. and subsidiaries as of December 31, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

Ernst & Young LLP

Boston, Massachusetts
February 12, 2004

NMT MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

AT DECEMBER 31,	2003	2002
Assets		
Current assets:		
Cash and cash equivalents	\$28,724,767	\$19,933,931
Marketable securities	8,000,000	16,310,152
Receivable from sale of product line	—	3,000,000
Accounts receivable, net of reserves of \$385,000 in 2003 and \$265,000 in 2002	2,546,846	2,457,322
Inventories	1,931,941	1,178,949
Prepaid expenses and other current assets	2,078,531	1,063,463
Total current assets	<u>43,282,085</u>	<u>43,943,817</u>
Property and equipment, at cost:		
Laboratory and computer equipment	2,100,975	1,961,165
Leasehold improvements	1,136,859	1,134,545
Equipment under capital lease	1,188,902	1,188,902
Office furniture and equipment	483,395	475,648
	<u>4,910,131</u>	<u>4,760,260</u>
Less-Accumulated depreciation and amortization	<u>4,128,323</u>	<u>3,779,300</u>
	<u>781,808</u>	<u>980,960</u>
Other assets	<u>58,557</u>	<u>167,850</u>
	<u>\$44,122,450</u>	<u>\$45,092,627</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,275,781	\$ 2,233,443
Accrued expenses	4,110,525	2,964,641
Capital lease obligations	—	27,865
Discontinued operations liabilities	500,000	910,505
Total current liabilities	<u>5,886,306</u>	<u>6,136,454</u>
Commitments and Contingencies (Notes 7 and 14)		
Stockholders' equity:		
Preferred stock, \$.001 par value		
Authorized—3,000,000 shares		
Issued and outstanding—none	—	—
Common stock, \$.001 par value		
Authorized—30,000,000 shares		
Issued—11,914,787 shares in 2003 and 11,712,877 shares in 2002	11,915	11,713
Additional paid-in capital	45,395,546	44,728,424
Less—Treasury stock - 40,000 shares at cost	(119,600)	—
Unrealized gain on marketable securities	—	118,000
Accumulated deficit	<u>(7,051,717)</u>	<u>(5,901,964)</u>
Total stockholders' equity	<u>38,236,144</u>	<u>38,956,173</u>
	<u>\$44,122,450</u>	<u>\$45,092,627</u>

See accompanying notes.

NMT MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE YEARS ENDED DECEMBER 31,	2003	2002	2001
Revenues:			
Product sales	\$21,573,769	\$24,545,551	\$22,500,983
Net royalty income	1,387,590	413,074	546,279
Total revenues	<u>22,961,359</u>	<u>24,958,625</u>	<u>23,047,262</u>
Costs and Expenses:			
Cost of product sales	5,302,700	6,605,861	7,436,627
Research and development	6,961,391	5,543,868	3,800,741
General and administrative	5,545,302	5,495,758	6,079,607
Selling and marketing	5,614,397	5,446,548	3,618,977
Settlement of litigation	1,216,357	—	—
Total costs and expenses	<u>24,640,147</u>	<u>23,092,035</u>	<u>20,935,952</u>
Gain on sale of product line	—	7,000,000	20,256,879
(Loss) income from operations	(1,678,788)	8,866,590	22,368,189
Other Income (Expense):			
Currency transaction gain (loss)	81,399	80,840	(35,819)
Interest expense	(5,361)	(10,013)	(698,602)
Interest income	557,997	691,171	175,783
Loss on early extinguishment of debt	—	—	(401,740)
Total other income (expense), net	<u>634,035</u>	<u>761,998</u>	<u>(960,378)</u>
(Loss) income before provision for income taxes	(1,044,753)	9,628,588	21,407,811
Provision for income taxes	105,000	3,424,000	2,630,000
Net (loss) income from continuing operations	<u>(1,149,753)</u>	<u>6,204,588</u>	<u>18,777,811</u>
Discontinued operations:			
(Loss) income from discontinued operations	—	(39,653)	417,000
Gain on sale of discontinued operations, including income tax benefit of \$5,162,000	—	4,914,355	—
Net gain from discontinued operations	<u>—</u>	<u>4,874,702</u>	<u>417,000</u>
Net (loss) income	<u>\$ (1,149,753)</u>	<u>\$11,079,290</u>	<u>\$19,194,811</u>
Basic net (loss) income per common share:			
Continuing operations	\$(0.10)	\$0.54	\$1.71
Discontinued operations	—	0.42	0.04
Net (loss) income	<u>\$(0.10)</u>	<u>\$0.96</u>	<u>\$1.74</u>
Diluted net (loss) income per common share:			
Continuing operations	\$(0.10)	\$0.51	\$1.61
Discontinued operations	—	0.40	0.04
Net (loss) income	<u>\$(0.10)</u>	<u>\$0.91</u>	<u>\$1.65</u>
Weighted average common shares outstanding:			
Basic	11,808,071	11,542,099	11,013,335
Diluted	<u>11,808,071</u>	<u>12,119,248</u>	<u>11,657,270</u>

See accompanying notes.

NMT MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	COMMON STOCK			TREASURY STOCK		Unrealized Gain (Loss) on Marketable Securities	Cumulative Translation Adjustment	Accumulated Deficit	Total Stockholders' Equity	Comprehensive Income (Loss)
	Number of Shares	\$0.001 Par Value	Additional Paid-In Capital	Number of Shares	Cost					
Balance, December 31, 2000	10,954,463	\$10,955	\$42,031,096	—	\$ —	\$ —	\$(1,539,595)	\$(36,176,065)	\$ 4,326,391	\$ —
Common stock issued under the employee stock purchase plan	63,099	63	135,231	—	—	—	—	—	135,294	—
Exercise of common stock options	121,264	121	276,230	—	—	—	—	—	276,351	—
Stock-based compensation	—	—	275,476	—	—	—	—	—	275,476	—
Common stock issued in connection with repurchase of technology rights	40,000	40	245,960	—	—	—	—	—	246,000	—
Change in cumulative translation adjustment	—	—	—	—	—	—	(52,000)	—	(52,000)	(52,000)
Net income	—	—	—	—	—	—	—	19,194,811	19,194,811	19,194,811
Total comprehensive income	—	—	—	—	—	—	—	—	—	<u>\$19,142,811</u>
Balance, December 31, 2001	11,178,826	11,179	42,963,993	—	—	—	(1,591,595)	(16,951,254)	24,402,323	\$ —
Common stock issued under the employee stock purchase plan	68,721	69	203,800	—	—	—	—	—	203,869	—
Exercise of common stock options	465,330	465	936,874	—	—	—	—	—	937,339	—
Stock-based compensation	—	—	(31,243)	—	—	—	—	—	(31,243)	—
Tax benefit from exercise of stock options	—	—	655,000	—	—	—	—	—	655,000	—
Unrealized gain on marketable securities	—	—	—	—	—	118,000	—	—	118,000	118,000
Change in cumulative translation adjustment	—	—	—	—	—	—	271,000	—	271,000	—
Write-off of cumulative translation adjustment	—	—	—	—	—	—	1,320,595	—	1,320,595	—
Net income	—	—	—	—	—	—	—	11,079,290	11,079,290	11,079,290
Total comprehensive income	—	—	—	—	—	—	—	—	—	<u>\$11,197,290</u>
Balance, December 31, 2002	11,712,877	11,713	44,728,424	—	—	118,000	—	(5,901,964)	38,956,173	\$ —
Common stock issued under the employee stock purchase plan	52,669	53	154,611	—	—	—	—	—	154,664	—
Exercise of common stock options and warrants	149,241	149	279,396	—	—	—	—	—	279,545	—
Stock-based compensation	—	—	192,115	—	—	—	—	—	192,115	—
Tax benefit from exercise of stock options	—	—	41,000	—	—	—	—	—	41,000	—
Treasury stock received	—	—	—	(40,000)	(119,600)	—	—	—	(119,600)	—
Unrealized loss on marketable securities	—	—	—	—	—	(118,000)	—	—	(118,000)	(118,000)
Net loss	—	—	—	—	—	—	—	(1,149,753)	(1,149,753)	(1,149,753)
Total comprehensive loss	—	—	—	—	—	—	—	—	—	<u>\$(1,267,753)</u>
Balance, December 31, 2003	<u>11,914,787</u>	<u>\$11,915</u>	<u>\$45,395,546</u>	<u>(40,000)</u>	<u>\$(119,600)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$(7,051,717)</u>	<u>\$38,236,144</u>	

See accompanying notes.

NMT MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31,	2003	2002	2001
Cash flows from operating activities:			
Net (loss) income	\$ (1,149,753)	\$11,079,290	\$19,194,811
Net gain from discontinued operations	—	(4,874,702)	(417,000)
Net (loss) income from continuing operations	(1,149,753)	6,204,588	18,777,811
Adjustments to reconcile net income (loss)			
to net cash provided by (used in) operating activities—			
Depreciation and amortization	570,469	588,845	582,444
Noncash interest expense	—	—	271,179
Increase (decrease) in accounts receivable reserves	392,000	(42,045)	117,500
Common shares issued in connection with repurchase of technology rights	—	—	246,000
Net book value of product line assets sold	—	—	242,910
Stock-based compensation	192,115	(31,243)	217,803
Tax benefit from exercise of stock options	41,000	655,000	—
Noncash interest expense relating to early extinguishment of debt	—	—	401,740
Deferred tax (benefit) provision	(282,000)	(2,902,000)	2,515,000
Changes in assets and liabilities—			
Accounts receivable	(481,524)	2,937	(170,067)
Receivable from sale of product line	3,000,000	15,500,000	(18,500,000)
Inventories	(752,992)	236,820	(31,648)
Prepaid expenses and other current assets	(852,668)	(468,948)	(177,945)
Accounts payable	(957,662)	371,238	150,011
Accrued expenses	1,145,883	625,508	(131,675)
Deferred gain	—	(3,419,200)	3,419,200
Net cash provided by continuing operations	864,868	17,321,500	7,930,263
Net cash (used in) provided by discontinued operations	(410,505)	5,607,508	989,488
Cash flows from investing activities:			
Purchases of property, plant and equipment	(149,871)	(417,667)	(148,490)
Decrease (increase) in other assets	80,000	(29,326)	8,000
Proceeds from sale of discontinued operations, net of cash sold	—	4,833,000	—
Purchase of marketable securities	—	(16,192,152)	—
Maturities of marketable securities	8,000,000	—	—
Net cash provided by (used in) investing activities	7,930,129	(11,806,145)	(140,490)
Cash flows from financing activities:			
Proceeds from exercise of common stock options and warrants	279,545	937,339	276,351
Proceeds from issuance of common stock under the employee stock purchase plan	154,664	203,869	135,295
Payments of subordinated note payable	—	—	(5,500,000)
Payments of capital lease obligations	(27,865)	(129,987)	(253,345)
Net cash provided by (used in) financing activities	406,344	1,011,221	(5,341,699)
Effect of exchange rate changes on cash	—	(37,649)	(15,210)
Net increase in cash and cash equivalents	8,790,836	12,096,435	3,422,352
Cash and cash equivalents, beginning of period	19,933,931	7,837,496	4,415,144
Cash and cash equivalents, end of period	\$28,724,767	\$19,933,931	\$ 7,837,496

See accompanying notes.

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) OPERATIONS

NMT Medical, Inc. (the "Company" or "NMT") designs, develops and markets proprietary implant technologies that allow interventional cardiologists to treat cardiac sources of stroke through minimally invasive, catheter-based procedures. Our products are designed to offer alternative approaches to existing complex treatments, thereby reducing patient trauma, shortening procedure, hospitalization and recovery times and lowering overall treatment costs. These products also serve the pediatric interventional cardiologist with a broad range of cardiac septal repair implants delivered with nonsurgical catheter techniques.

On July 31, 2002, we sold the neurosciences business unit to a wholly-owned subsidiary of Integra LifeSciences Holding Corporation ("Integra") for \$5.4 million in cash (see Note 3). In accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", the accompanying consolidated financial statements of the Company reflect the financial results of the neurosciences business unit as discontinued operations for all periods presented.

On November 5, 2001, we sold the vena cava filter product line to C.R. Bard, Inc. ("Bard") for \$27 million in up front cash payments plus up to \$7 million tied to certain performance and delivery milestones. Pursuant to the asset purchase agreement with Bard, we continued to manufacture the filter products for Bard through June 30, 2002 and, upon final transfer of manufacturing to Bard, received an additional \$4 million on September 30, 2002. In addition, in the fourth quarter of 2002, upon Bard's receipt of FDA approval for the commercial sale and use of its Recovery™ Filter product, we recognized the final \$3 million milestone payment, which was received in January 2003. Commencing in 2003, we received royalty payments from Bard on its manufacture and sales of the vena cava filter products and we continued to pay certain royalties to the original inventor (see Notes 4 and 14).

As a result of our sale of the neurosciences business unit in July 2002, our continuing operations are represented by one operating segment as defined in SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information".

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation

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

(b) Management Estimates

The preparation of financial statements in conformity with 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 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 less from the date of purchase to be cash equivalents and all investments with original maturity dates greater than 90 days to be marketable securities.

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

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.

Marketable securities at December 31, 2003 consisted of one U.S. Government agency debt instrument scheduled to mature in April 2004. There was no unrealized gain or loss recorded at December 31, 2003. Accrued interest of approximately \$61,000 was included in prepaid expenses and other current assets in the accompanying consolidated balance sheet at December 31, 2003.

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

(d) Inventories

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

AT DECEMBER 31,	2003	2002
Components	\$1,065,377	\$ 290,927
Finished goods	866,564	888,022
	<u>\$1,931,941</u>	<u>\$1,178,949</u>

Finished goods are comprised of 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, accounts receivable and debt obligations. The estimated fair value of these financial instruments approximates their carrying value at December 31, 2003 and 2002, respectively. The estimated fair values have been determined through information obtained from market sources and management estimates. We do not have any derivative or any other financial instruments as defined by SFAS No. 133, "Accounting for Derivative and Hedging Instruments".

(f) Concentration of Credit Risk and Significant Customers

SFAS No. 105, "Disclosure of Information About Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentrations of Credit Risk", as amended by SFAS No. 133, requires disclosure of any significant off-balance-sheet and credit risk concentrations. Financial instruments that subject the Company to the potential for 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.

Prior to the sale of the filter product line to Bard, Bard was the primary distributor for sales of filter products (see Note 4). Bard accounted for approximately 21% and 36% of product revenues for the years ended December 31, 2002 and 2001, respectively. No other customer accounted for greater than 10% of product sales in each of the three years ended December 31, 2003.

At December 31, 2003, approximately 22% of gross accounts receivable represent accounts denominated in foreign currencies that are translated at year-end exchange rates. For the years ended December 31, 2003, 2002 and 2001, revenues from non U.S. customers accounted for approximately 17%, 10% and 10% of total revenues, 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, 2003 or 2002.

(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	Life of Lease
Laboratory and computer equipment	3-7 Years
Equipment under capital lease	Life of Lease
Office furniture and equipment	5-10 Years

Depreciation and amortization expense was \$349,000, \$551,000 and \$570,000 for the years ended December 31, 2003, 2002 and 2001, respectively. Maintenance and repairs are charged to expense when incurred. Additions and improvements are capitalized.

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

(i) Revenue Recognition

In accordance with Staff Accounting Bulletin ("SAB") No. 101, as amended by SAB 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 and Potential 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 (loss) by the weighted average common shares outstanding, including potential common shares from exercise of stock options and warrants using the treasury stock method, if dilutive. Options and warrants to purchase a total of 2,028,836, 713,399, and 307,894 common shares have been excluded from the computation of diluted weighted average shares outstanding for the years ended December 31, 2003, 2002 and 2001, respectively, because they were not dilutive.

A reconciliation of the number of shares used in the calculation of basic and diluted net income (loss) per share is as follows:

	2003	2002	2001
Weighted average common shares outstanding	11,808,071	11,542,099	11,013,335
Dilutive effect of assumed exercise of stock options and warrants	—	577,149	643,935
Weighted average common shares outstanding assuming exercise of stock options and warrants	11,808,071	12,119,248	11,657,270

(k) Stock-Based Compensation

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

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

	2003	2002	2001
Risk-free interest rates	2.84%-3.79%	3.50%-5.14%	4.31%-5.14%
Expected dividend yield	—	—	—
Expected lives	7 years	7 years	7 years
Expected volatility	67.5%-75.5%	73%	74%
Weighted average grant-date fair value of options granted during the period	\$2.59	\$4.40	\$1.74

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

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

	2003	2002	2001
Net (loss) income as reported	\$(1,149,753)	\$11,079,290	\$19,194,811
Add: Stock-based compensation included in net income (loss) as reported	192,115	(31,243)	217,803
Less: Total stock-based employee compensation expense determined under fair value based method for all awards	(1,332,167)	(1,151,672)	(436,508)
Pro forma net (loss) income	<u>\$(2,289,805)</u>	<u>\$ 9,896,375</u>	<u>\$18,976,106</u>
Basic net (loss) income per common share:			
As reported	<u>\$(0.10)</u>	<u>\$0.96</u>	<u>\$1.74</u>
Pro forma	<u>\$(0.19)</u>	<u>\$0.86</u>	<u>\$1.72</u>
Diluted net (loss) income per common share:			
As reported	<u>\$(0.10)</u>	<u>\$0.91</u>	<u>\$1.65</u>
Pro forma	<u>\$(0.19)</u>	<u>\$0.82</u>	<u>\$1.63</u>

Our stock option grants vest over several years and we intend to grant varying levels of stock options in future periods. Therefore, the effects indicated above of applying SFAS No. 123 are not necessarily representative of the effects on similar illustrated disclosures in future years.

(l) Foreign Currency

The accounts of our foreign subsidiaries are translated in accordance with SFAS No. 52, "Foreign Currency Translation". Prior to our July 2002 sale of the neurosciences business unit, the balance sheet accounts of those foreign subsidiaries were translated from their local currency into U.S. dollars using the exchange rate at the balance sheet date and we recorded the effects of changes in balance sheet items (i.e. cumulative foreign currency translation gains and losses) as a component of stockholders' equity. The functional currency of our current 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 exchange transaction gains of approximately \$81,000 for each of the years ended December 31, 2003 and 2002, and a foreign currency exchange transaction loss of approximately \$36,000 for the year ended December 31, 2001. 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.

(n) Recent Accounting Pronouncements

In January 2003, the FASB issued Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities". FIN 46 expands upon existing accounting guidance that addresses when a company should include in its financial statements the assets, liabilities and activities of another entity. In general, a variable interest entity is a corporation, partnership, trust or any other legal structure used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. FIN 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or is entitled to receive a majority of the entity's residual returns, or both. In December 2003, the FASB revised FIN 46 ("FIN 46-R") to address certain FIN 46 implementation issues. The consolidation requirements of FIN 46 apply immediately to variable interest entities created after January 31, 2003. For pre-existing entities, these requirements must be applied in the first interim reporting period ending after March 15, 2004. The adoption of these provisions did not have a material impact on our financial statements.

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

(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. We did not make any employer matching or other discretionary contributions to the 401(k) Plan for the years ended December 31, 2003, 2002 and 2001.

(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,	2003	2002	2001
Supplemental disclosure of cash flow information:			
Cash paid during the period for—			
Interest	\$ 5,361	\$ 10,013	\$426,030
Income and franchise taxes	\$111,880	\$160,104	\$ —
Supplemental disclosure of noncash financing and investing transactions:			
Receipt of treasury stock	\$119,600	\$ —	\$ —

(q) Expenses Associated With Clinical Trial

Upon receipt of U.S. Food and Drug Administration ("FDA") approval in June 2003, we commenced a clinical trial, CLOSURE I. Including contracts with third party providers, agreements with participating clinical sites and internal clinical department costs, we currently expect total costs for CLOSURE I to be approximately \$24 million through completion of the clinical trial and submission to the FDA, which we currently expect to be in 2007. Our judgment is required in determining methodologies used to recognize various costs. We will expense certain costs as patients are enrolled or upon the occurrence of other specific events during the clinical trial. We will expense certain other estimated costs, principally related to project management and data analysis, ratably over the estimated period during which the related services are expected to be provided. Additional STARFlex® products that we manufacture to accommodate the expected requirements of CLOSURE I are included in inventory because they are saleable units with alternative use outside of the trial. These units will be expensed as a cost of CLOSURE I as they are used in the trial. We incurred costs of approximately \$2.5 million in 2003 related to CLOSURE I, which are included in research and development expense in our consolidated statements of operations.

(3) DISCONTINUED OPERATIONS

(a) Sale of Neurosciences Business Unit

On July 31, 2002, we sold all of the outstanding stock of the companies comprising the neurosciences business unit to Integra for \$5.4 million in cash, resulting in a pre-tax loss from the sale of discontinued operations of approximately \$248,000. Although the disposition of the neurosciences business unit resulted in a nominal loss for financial reporting purposes, on a tax basis the disposition resulted in a significant capital loss. This capital loss was largely attributable to the realization, for tax purposes, of the \$6.8 million goodwill write-off and the \$7.1 million asset impairment charge related to other long-lived assets of this business unit recorded in fiscal 1999 and 2000, respectively, for financial statement purposes. Accordingly, we recorded a tax benefit on the sale of approximately \$5.2 million attributable to utilization of losses not previously benefited, resulting in a net gain on sale of discontinued operations of approximately \$4.9 million for the year ended December 31, 2002.

Revenues for the neurosciences business unit were approximately \$8.6 million for the seven months ended July 31, 2002 (date of sale) and approximately \$16.2 million for the year ended December 31, 2001.

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(3) DISCONTINUED OPERATIONS (CONTINUED)

The determination of the pre-tax loss on the sale of the neurosciences business unit is summarized as follows:

Cash proceeds	<u>\$5,400,000</u>
Net assets sold:	
Current assets	5,590,704
Property, plant and equipment, net	87,741
Other assets	300,000
Current liabilities	(2,870,754)
Long-term debt obligation	<u>(12,000)</u>
Net assets sold	3,095,691
Write-off of cumulative translation adjustment	1,320,595
Transaction costs and related accruals	<u>1,231,359</u>
	<u>5,647,645</u>
Pre-tax loss	<u>\$ (247,645)</u>

(b) Settlement of Litigation

Effective April 4, 2002, we settled an arbitration proceeding with Elekta, resulting in a net payment by the Company of approximately \$388,000. The charge of approximately \$373,000 included the settlement amount plus legal costs, reduced by the elimination of net accounts payable balances due Elekta. The net settlement charge was included in net income (loss) from discontinued operations for the year ended December 31, 2002.

(4) SALE OF VENA CAVA FILTER PRODUCT LINE

On November 5, 2001, we sold the assets comprising our vena cava filter product line to Bard pursuant to an asset purchase agreement. In exchange for these assets, we received \$8.5 million at closing and \$18.5 million in January 2002 and the right to receive up to an additional \$7 million tied to certain performance and delivery milestones. We continued to manufacture the products for Bard through June 30, 2002 pursuant to the agreement and completed the transfer of manufacturing responsibilities to Bard in the third quarter of 2002, resulting in receipt of a \$4 million milestone payment from Bard on September 30, 2002. In the fourth quarter of 2002, we recognized an additional \$3 million gain, representing the final contingent consideration under the asset purchase agreement related to the receipt by Bard, as of December 31, 2002, of FDA regulatory approval for commercial sale and use of its Recovery™ Filter. The aggregate \$7 million of contingent consideration has been recorded as additional gain on sale of product line for the year ended December 31, 2002.

Under the transitional manufacturing agreement, we agreed to sell vena cava filter products to Bard at a discounted price and we recorded the estimated aggregate discount as deferred gain that was amortized to revenue over the production and sales period. Total vena cava filter product sales were approximately \$5.2 million for the year ended December 31, 2002. The original deferred gain at December 31, 2001 also included estimated costs associated with certain arbitration proceedings directly attributable to the sale of the vena cava filter product line. The final arbitration ruling was issued in October 2002 (see Note 14). Our aggregate costs associated with these legal proceedings reduced the deferred gain balance to zero at December 31, 2002.

Commencing in 2003, we received royalty payments from Bard on its manufacture and sales of the vena cava filter products. We continue to pay certain royalties to the original inventor (see Note 14).

The gain on sale of product line for the years ended December 31, 2002 and 2001 consisted of the following:

	<u>2002</u>	<u>2001</u>
Cash proceeds received	\$4,000,000	\$ 8,500,000
Cash proceeds received subsequent to year-end	3,000,000	18,500,000
Repurchase of royalty and other rights	—	(2,496,000)
Legal and other closing costs and deferrals	—	(4,004,211)
Book value of net assets sold	—	(242,910)
Net gain on sale of product line	<u>\$7,000,000</u>	<u>\$20,256,879</u>

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(5) 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 (benefit) for income taxes in the accompanying consolidated statements of operations for the years ended December 31, 2003, 2002 and 2001 consisted of the following:

FOR THE YEARS ENDED DECEMBER 31,	2003	2002	2001
Foreign - current	\$ (38,000)	\$ 24,000	\$ —
Federal - current	386,000	5,539,000	115,000
State - current	39,000	763,000	—
	<u>387,000</u>	<u>6,326,000</u>	<u>115,000</u>
Foreign - deferred	—	—	—
Federal - deferred	(282,000)	(2,576,000)	1,918,000
State - deferred	—	(326,000)	597,000
	<u>(282,000)</u>	<u>(2,902,000)</u>	<u>2,515,000</u>
	<u>\$105,000</u>	<u>\$3,424,000</u>	<u>\$2,630,000</u>

We have tax credit carryforwards of approximately \$560,000 to reduce federal and state taxable income in future periods, if any. These carryforwards are subject to review and possible adjustment by the Internal Revenue Service and their utilization may be limited by aggregate changes in significant ownership of the Company over a three year period as prescribed by Section 382 of the Internal Revenue Code. These carryforwards expire on various dates through 2023.

The tax effects of temporary differences that give rise to significant portions of the current deferred tax asset at December 31, 2003 and 2002 are as follows:

	2003	2002
Net operating loss carryforwards	\$ —	\$ 165,000
Tax credit carryforwards	560,000	662,000
Timing differences, including reserves, accruals and write-offs	1,079,000	1,042,000
	<u>1,639,000</u>	<u>1,869,000</u>
Less - Valuation allowance	(1,357,000)	(836,000)
Deferred tax asset	282,000	1,033,000
Deferred tax liability related to sale of product line	—	(1,033,000)
Net deferred tax asset	<u>\$ 282,000</u>	<u>\$ —</u>

We have provided a partial valuation allowance for our gross deferred tax asset due to the uncertainty surrounding 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,	2003	2002	2001
Statutory federal income tax rate (benefit)	(34.0)%	34.0%	34.0%
State income taxes, net of federal income tax benefit	2.5	3.0	6.0
Change in valuation allowance/utilization of net operating loss and tax credit carryforwards	38.7	—	(28.0)
Other	2.8	(1.4)	—
	<u>10.0%</u>	<u>35.6%</u>	<u>12.0%</u>

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(6) NET ROYALTY INCOME

In connection with our November 2001 sale of the vena cava filter product line, we entered into a royalty agreement pursuant to which Bard commenced payment of royalties in 2003. 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. Under these agreements, we earned approximately \$1,388,000, \$413,000 and \$546,000 during the years ended December 31, 2003, 2002 and 2001, respectively. Royalties for the year ended December 31, 2003 have been reported net of related royalty obligations to third parties.

(7) COMMITMENTS

(a) Operating Leases

We have operating leases for office and laboratory space and motor vehicle leases expiring through 2006. We have a renewal option for an additional 5 years on approximately 27,000 square feet of that space, which requires written notice to the landlord at any time during the period 9-12 months prior to the expiration of the lease term. The office leases require payment of a pro rata share of operating expenses of the building, including real estate taxes and utilities in excess of base year amounts.

Future minimum rental payments due under operating lease agreements at December 31, 2003 are approximately as follows:

YEARS ENDING DECEMBER 31,	
2004	\$ 992,000
2005	960,000
2006	697,000
	<u>\$ 2,649,000</u>

Rent expense for the years ended December 31, 2003, 2002 and 2001 amounted to approximately \$975,000, \$922,000 and \$891,000, respectively.

(b) Royalties

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 \$2,730,000, \$2,074,000 and \$1,507,000 for the years ended December 31, 2003, 2002 and 2001, respectively. For the year ended December 31, 2003, approximately \$484,000 of these royalties was included as a reduction of related royalty income earned from third parties.

(c) Employment Agreements

We have employment agreements with our CEO through December 2005 and with our CFO through April 2005. 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 0% to 3.5% for our CEO and from 0% to 0.875% for our CFO.

(d) CLOSURE I

In connection with CLOSURE I, we have entered into various contractual obligations with third party service providers and the participating clinical sites. Including the internal costs of the Company's clinical department and the manufacturing costs of the Company's STARFlex® products to be implanted, total CLOSURE I costs are currently estimated to be approximately \$24 million through the completion of the clinical trial and submission to the FDA, which is currently expected to be in 2007. Of this total, approximately \$2.5 million of costs were incurred in 2003. The timing and amount of these obligations are dependent on various factors, including the timing of patient enrollment and patient monitoring. 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.

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(8) STOCKHOLDERS' EQUITY

(a) Preferred Stock

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

(b) Rights Agreement

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

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

(9) STOCK OPTIONS AND WARRANTS

(a) Stock Options

Our 1996 Stock Option Plan (the "1996 Plan"), 1998 Stock Incentive Plan (the "1998 Plan") and 2001 Stock Incentive Plan (the "2001 Plan") (collectively, the "Plans") generally provide for the grant of incentive stock options, nonstatutory stock options and restricted stock awards, as appropriate, to eligible employees, officers, directors, consultants and advisors of the Company. The Compensation Committee of the Board of Directors administers the Plans, subject to the terms and conditions of the respective Plans. Options granted generally vest in equal annual installments over a four-year period from the date of grant. At December 31, 2003 there were 1,720,059 options outstanding and 120,833 options available for grant under the Plans.

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 directors of the Company who are not employees of the Company and who do not otherwise receive compensation from the Company. Under terms of the Directors Plan, as amended, each new non-employee director not otherwise compensated by the Company 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 the Company's 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

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(9) STOCK OPTIONS AND WARRANTS (CONTINUED)

not serve as chairperson of such committee. At December 31, 2003 there were 184,834 options outstanding and 132,000 options available for grant under the Directors Plan.

On March 1, 2001, our Board of Directors authorized an offer for employees to exchange certain Plan options outstanding. Under this exchange offer, certain employees elected to have a total of 322,521 existing options cancelled in exchange for 131,558 new options. The new options were granted at \$2.19 per share, which was the fair market value of the common stock as of the date of grant. These options are subject to variable accounting as defined in FASB Interpretation No. 44 ("FIN 44"), "Accounting for Certain Transactions Involving Stock Compensation". In addition, we granted 83,450 additional options to employees who participated in the option exchange program, which are subject to variable accounting under FIN 44. We have followed the provisions of FIN 44 and have revalued to market the re-priced options, through the date of exercise, cancellation or expiration, at each reporting date. As of December 31, 2003, 83,968 options subject to variable accounting have been cancelled or exercised and 131,040 were outstanding. Compensation (benefit) expense related to the re-priced options was approximately \$159,000, \$(127,000) and \$188,000 for the years ended December 31, 2003, 2002 and 2001, respectively. Based upon our closing stock price at December 31, 2003, approximately \$103,000 of additional compensation expense would be recognized over the remainder of the four year vesting period of the re-priced options.

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. In accordance with FIN 44, we remeasured this stock option. Based upon our stock price on the date of remeasurement, approximately \$74,000 of compensation expense was recognized in fiscal 2002 for the vested shares at December 31, 2002, approximately \$33,000 of compensation expense was recognized in fiscal 2003 and \$24,000 of additional compensation expense will be recognized over the remaining vesting period of the option during fiscal 2004.

At December 31, 2003 there are 103,943 nonqualified options outstanding to purchase shares of common stock issued to former officers and directors, most of which were granted prior to our 1996 initial public offering.

All unexercised options expire ten years from date of grant.

The following table summarizes a reconciliation of all stock option activity for each of the three years during the period ended December 31, 2003:

FOR THE YEARS ENDED DECEMBER 31,	2003		2002		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding:						
Beginning balance	1,725,574	\$4.43	1,571,522	\$2.91	2,239,868	\$4.30
Granted	441,000	3.80	725,750	6.20	704,058	2.72
Cancelled	(91,826)	5.46	(106,368)	4.62	(1,251,140)	5.32
Exercised	(65,912)	1.54	(465,330)	2.01	(121,264)	2.28
Ending balance	<u>2,008,836</u>	<u>\$4.34</u>	<u>1,725,574</u>	<u>\$4.43</u>	<u>1,571,522</u>	<u>\$2.91</u>
Exercisable	<u>866,478</u>	<u>\$3.89</u>	<u>471,712</u>	<u>\$3.52</u>	<u>608,502</u>	<u>\$2.52</u>

For various price ranges, information for options outstanding and exercisable at December 31, 2003 was as follows:

	OUTSTANDING OPTIONS			EXERCISABLE OPTIONS	
	Shares	Weighted Average Remaining Life (in years)	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
\$0.94 - 1.56	121,939	5.38	\$1.26	83,917	\$1.27
1.76 - 2.38	396,316	6.34	2.05	249,605	2.07
2.50 - 3.40	389,937	8.09	2.91	167,993	2.81
3.72 - 5.03	423,344	8.82	4.30	119,966	4.47
5.18 - 7.50	556,300	8.18	6.53	203,747	6.57
7.70 - 13.13	121,000	5.47	9.63	41,250	9.63
\$0.94 - 13.13	<u>2,008,836</u>	<u>7.60</u>	<u>\$4.34</u>	<u>866,478</u>	<u>\$3.89</u>

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(9) STOCK OPTIONS AND WARRANTS (CONTINUED)

(b) Warrants

The following table summarizes our warrant activity:

	Shares	Weighted Average Exercise Price
Balance, December 31, 2000	162,081	\$2.62
Cancelled	<u>(58,752)</u>	<u>2.50</u>
Balance, December 31, 2001 and 2002	103,329	2.69
Exercised	<u>(83,329)</u>	<u>2.15</u>
Balance, December 31, 2003	<u>20,000</u>	<u>\$4.94</u>
Exercisable, December 31, 2003	<u>20,000</u>	<u>\$4.94</u>

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

(c) Employee Stock Purchase Plan

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

Under the 1997 ESPP, the stockholders authorized 90,000 shares of common stock to be reserved for issuance. We issued 38,008 shares of common stock to participating employees under the 1997 ESPP during the year ended December 31, 2001. On June 7, 2001, the stockholders adopted the 2001 ESPP, and a total of 275,000 common shares have been reserved for issuance under the 2001 ESPP, as amended. The 2001 ESPP has substantially the same terms and conditions as the 1997 ESPP, which was terminated as of June 7, 2001. Employees purchased 52,669, 68,721 and 25,091 shares of common stock under the 2001 ESPP during the years ended December 31, 2003, 2002 and 2001, respectively. The average purchase prices for total ESPP shares acquired were \$2.94, \$2.97 and \$2.14 for the years ended December 31, 2003, 2002 and 2001, respectively.

(10) RELATED PARTY TRANSACTIONS

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

In connection with certain consulting services provided by Fletcher Spaght, Inc. ("Fletcher Spaght") to the Company, we extended the exercise period of the warrant, dated July 1, 1998, issued to Fletcher Spaght for the purchase of 83,329 shares of common stock, from February 14, 2001 to February 14, 2003. In connection with this extension, we incurred a one-time charge to earnings of \$57,673 during the year ended December 31, 2001. In connection with this charge, Fletcher Spaght issued a note in favor of the Company in the amount of \$57,673, bearing interest at 5% per annum, and payable on or before February 14, 2003. On January 20, 2003, Fletcher Spaght exercised this warrant and repaid in full the remaining balance of the note. R. John Fletcher, a member of our Board of Directors, is currently the Chief Executive Officer and a significant stockholder of Fletcher Spaght.

During the year ended December 31, 2001, one stockholder provided consulting services to the Company at a rate of \$100,000 per annum. That annual agreement was terminated effective December 31, 2001.

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(11) ACCRUED EXPENSES

Accrued expenses consisted of the following:

AT DECEMBER 31,	2003	2002
Payroll and payroll related	\$1,070,476	\$ 929,905
Taxes	452,958	195,660
Royalties	1,018,604	807,159
Professional fees	466,305	580,245
Clinical trials	796,680	106,551
Other accrued expenses	305,502	345,121
	<u>\$4,110,525</u>	<u>\$2,964,641</u>

(12) FINANCIAL INFORMATION BY GEOGRAPHIC AREA

Revenues by destination country for the years ended December 31, 2003, 2002 and 2001 were as follows:

	2003	2002	2001
United States	\$19,137,000	\$22,368,000	\$20,647,000
Germany	1,658,000	1,135,000	1,118,000
Other	2,166,359	1,455,625	1,282,262
	<u>\$22,961,359</u>	<u>\$24,958,625</u>	<u>\$23,047,262</u>

Net book value of long-lived assets by country at December 31, 2003 and 2002 were as follows:

	2003	2002	2001
United States	\$763,057	\$957,429	\$1,049,017
Other	18,751	23,531	40,779
	<u>\$781,808</u>	<u>\$980,960</u>	<u>\$1,089,796</u>

(13) VALUATION OF QUALIFYING ACCOUNTS

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

FOR THE YEARS ENDED DECEMBER 31,	2003	2002	2001
Balance at beginning of period	\$265,000	\$566,000	\$484,000
Provision for bad debt and sales returns adjustments	392,000	(42,000)	117,000
Write-offs and returns	(272,000)	(259,000)	(35,000)
Balance at end of period	<u>\$385,000</u>	<u>\$265,000</u>	<u>\$566,000</u>

(14) LEGAL PROCEEDINGS

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

In December 1998, we filed a patent infringement suit in the United States District Court for the District of Massachusetts (the "Court") against AGA Medical Corp. ("AGA"), claiming that AGA's Amplatzer aperture occlusion devices infringe U.S. Patent No. 5,108,420, which is licensed exclusively to the Company. We sought an injunction to prevent further infringement as well as monetary damages. In April 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. In May 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 patent by the United States Patent and Trademark Office, which is still ongoing. On September 30, 2003, AGA requested that the Court dismiss the suit without prejudice to our ability to refile the suit after conclusion of the patent reexamination proceeding. On December 1, 2003, the Court granted AGA's request.

NMT MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(14) LEGAL PROCEEDINGS (CONTINUED)

On or about September 24, 2001, the three French subsidiaries of the Company's former neurosciences business unit, NMT Neurosciences Instruments SARL, NMT Neurosciences Holdings SA and NMT Neurosciences Implants SA, each received a Notification of Reassessment Following Verification of the Accounts (*Notification de redressements suite à une vérification de comptabilité*) from the French Direction de Contrôle Fiscal Sud-est (Nice) ("Reassessment"). The French authorities are seeking from the above-named NMT entities in excess of FF11 million, which is the currency in which the assessment was made, (approximately \$2.1 million based upon the exchange rate at December 31, 2003) in back taxes, interest and penalties. We are appealing the Reassessment. In connection with our sale of the neurosciences business unit in July 2002, we agreed to specifically indemnify Integra against any liability in connection with these tax claims. Pursuant to the terms of a settlement agreement with Elekta AB, completed in early 2002, a portion of any resulting tax claim may be recoverable from Elekta (see Note 3).

On September 11, 2001, we filed against Dr. Morris Simon and Beth Israel Deaconess Medical Center ("Beth Israel") a demand for arbitration before a former judge of the Massachusetts Superior Court, in Boston, Massachusetts, seeking resolution of certain disputes over royalties payable on sales of certain existing and future products under the Technology Purchase Agreement ("TPA") between Dr. Simon and the Company. On September 28, 2001, Dr. Simon filed a response to the demand for arbitration, which identified one additional dispute for resolution. On October 19, 2001, the Company and Beth Israel settled their disputes by execution of a general release agreement that became effective on November 5, 2001, pursuant to which we paid Beth Israel \$2.25 million and issued 40,000 shares of our common stock. Dr. Simon resigned as a Director of the Company on January 22, 2002. Following a hearing on the merits of the disputes between the Company and Dr. Simon, the arbitrator issued an award ruling that (i) we do not owe Dr. Simon past royalties with respect to our sales of the former Simon Nitinol Filter® product; (ii) we are not in breach of the TPA; and (iii) we will be required to make royalty payments to Dr. Simon in accordance with the terms of the TPA in connection with future sales of Bard's Recovery™ Filter product. On November 10, 2002, after a hearing on whether either party was entitled to reimbursement of all or a portion of its legal fees from the other, the arbitrator awarded Dr. Simon \$400,000, which represented a portion of his legal fees. On or about January 2, 2003, we paid \$400,000 to Dr. Simon in accordance with the November 10, 2002 award. On February 14, 2003, the Company and Beth Israel entered into a Settlement Agreement in which Beth Israel agreed to reimburse the \$400,000 in full settlement of an indemnification agreement entered into between the Company and Beth Israel on November 5, 2001. The reimbursement consisted of cash and the return of the 40,000 shares of common stock of the Company that Beth Israel had originally received in the settlement.

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

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

EXHIBIT INDEX

Exhibit No.

- 2.1(2) Asset Purchase Agreement, dated as of October 19, 2001, between the Company and C. R. Bard, Inc. (12)
- 2.2 Stock Purchase Agreement, dated as of July 31, 2002, between the Company and Integra LifeSciences Corporation. (13)
- 3.1 Second Amended and Restated Certificate of Incorporation. (4)
- 3.2 Certificate of Amendment to the Company's Second Amended and Restated Certificate of Incorporation, as filed with the office of the Secretary of State of the State of Delaware on June 3, 1999. (8)
- 3.3 Amended and Restated By-laws. (1)
- 4.1 Form of Common Stock Certificate. (1)
- 4.2 Rights Agreement, dated as of June 7, 1999, between the Company and American Stock Transfer & Trust Company, as Rights Agent, which includes as Exhibit A, the form of Certificate of Designation, as Exhibit B the form of Rights Certificate, and as Exhibit C, the Summary of Rights to Purchase Preferred Stock. (7)
- 10.1 Stock Purchase Agreement by and among the Company, Whitney Equity Partners, L.P., Boston Scientific Corporation, David J. Morrison, Corporate Decisions, Inc., dated as of February 16, 1996. (1)
- 10.2 Agreement and Plan of Merger by and among the Company, NMT Heart, Inc., InnerVentions, Inc. and Fletcher Spaght, Inc., dated as of January 25, 1996. (1)
- 10.3 License and Development Agreement by and between the Company and Boston Scientific Corporation, dated as of November 22, 1994. (1)
- 10.4(2) Technology Purchase Agreement by and between the Company and Morris Simon, M.D., dated as of April 14, 1987. (1)
- 10.5 Asset and Technology Donation and Transfer Agreement by and between C.R. Bard, Inc. and Children's Medical Center Corporation dated as of May 12, 1995. (1)
- 10.6 Stock Transfer Agreement by and between Children's Medical Center Corporation and InnerVentions, Inc., dated as of June 19, 1995. (1)
- 10.7(2) License Agreement by and between Children's Medical Center Corporation and InnerVentions, Inc., dated June 19, 1995. (1)
- 10.8 Sublicense Agreement by and between Children's Medical Center Corporation and InnerVentions, Inc., dated June 19, 1995. (1)
- 10.9 Assignment Agreement by and between the Company and The Beth Israel Hospital Association, dated June 30, 1994. (1)
- 10.10(2) License Agreement by and between the Company and Lloyd A. Marks, dated as of April 15, 1996. (1)
- 10.11 Agreement of Lease by and between the Company and the Trustees of Wormwood Realty, dated as of May 8, 1996. (1)
- 10.12 Company 1994 Stock Option Plan. (1)(**)
- 10.13 Company 1996 Stock Option Plan. (1)(**)
- 10.14 Amendment No. 1 to 1996 Stock Option Plan. (4)(**)
- 10.15 Company 1996 Stock Option Plan for Non-Employee Directors, as amended. (15)(**)
- 10.16 Company 1998 Stock Incentive Plan. (4)(**)
- 10.17 Company 2001 Stock Incentive Plan, as amended. (15)(**)
- 10.18 Company 2001 Employee Stock Purchase Plan, as amended. (15)(**)
- 10.19 Common Stock Purchase Warrant No. BBH-1. (10)
- 10.20 License Agreement, dated as of October 2000, by and between the Company and Children's Medical Center Corporation. (11)
- 10.21(2) Royalty Agreement, dated as of October 19, 2001, between the Company and C. R. Bard, Inc. (12)
- 10.22 Registration Rights Agreement among the Company, Whitney Equity Partners, Boston Scientific Corporation, David J. Morrison and Corporate Decisions, Inc. of February 16, 1996. (6)
- 10.23 Registration Rights Agreement by and between the Company and Fletcher Spaght, Inc., dated as of February 14, 1996. (1)
- 10.24 Amendment No. 1, dated July 1, 1998 to the Registration Rights Agreement by and between the Company and Fletcher Spaght, Inc., dated as of February 14, 1996. (9)

- 10.25 Registration Rights Agreement by and between the Company and Thomas M. Tully, dated as of February 13, 1996. (1)
- 10.26 Form of Registration Rights Agreement between the Company and certain of its existing stockholders, dated as of February 14, 1996. (1)
- 10.27 Registration Rights Agreement among the Company, Whitney Subordinated Debt Fund, L.P. and J.H. Whitney & Co., dated as of July 8, 1998. (3)
- 10.28 Registration Rights Agreement entered into by and among the Company and Morris Simon, M.D., dated February 27, 1998. (5)
- 10.29 Registration Rights Agreement dated as of March 30, 1999 by and among the Company and the individuals listed on Schedule A thereto. (6)
- 10.30 Amendment No. 1 dated as of March 30, 1999 to Registration Rights Agreement among the Company, Whitney Equity Partners, Boston Scientific Corporation, David J. Morrison and Corporate Decisions, Inc. of February 16, 1996. (6)
- 10.31 Amendment No. 1 dated as of March 30, 1999 to Registration Rights Agreement among the Company, Whitney Subordinated Debt Fund, L.P. and J.H. Whitney & Co. of July 8, 1998. (6)
- 10.32 Stock Option Agreement evidencing grant by the Company to John Ahern, dated as of September 21, 2000. (14)(**)
- 10.33 Employment Agreement by and between the Company and Richard E. Davis, dated as of February 14, 2000. (11)(**)
- 10.34(2) Amended and Restated Employment Agreement by and between the Company and John E. Ahern, dated as of December 31, 2002. (14)(**)
- 10.35 Amendment dated as of December 31, 2002 to Stock Option Agreement evidencing grant by the Company to John E. Ahern of September 21, 2000. (14)(**)
- 10.36 Stock Option Agreement evidencing grant by the Company to John E. Ahern, dated as of December 31, 2002. (14) (**)
- 10.37(2) Amendment No.1 dated as of April 28, 2003 to Employment Agreement by and between the Company and Richard E. Davis, dated as of February 14, 2000. (14)(**)
- 14.1 Code of Business Conduct and Ethics of the Company. Filed herewith.
- 21.1 Subsidiaries of the Registrant. Filed herewith.
- 23.1 Consent of Ernst & Young LLP. Filed herewith.
- 31.1 Certification pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended. Filed herewith.
- 31.2 Certification pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended. Filed herewith.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.
- 32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.

- (1) Incorporated by reference to Exhibits to the Registrant's Registration Statement on Form S-1 (File No. 333-06463).
- (2) Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Commission.
- (3) Incorporated by reference to Exhibits to the Registrant's Current Report on Form 8-K, dated July 8, 1998 (File No. 000-21001).
- (4) Incorporated by reference to Exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998 (File No. 000-21001).
- (5) Incorporated by reference to Exhibits to the Registrant's Amended Quarterly Report on Form 10-Q/A for the quarter ended March 31, 1998 (File No. 000-21001).
- (6) Incorporated by reference to Exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999 (File No. 000-21001).
- (7) Incorporated by reference to Exhibits to the Registrant's Current Report on Form 8-K, dated June 7, 1999 (File No. 000-21001).
- (8) Incorporated by reference to Exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999 (File No. 000-21001).
- (9) Incorporated by reference to Exhibits to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1998 (File No. 000-21001).
- (10) Incorporated by reference to Exhibits to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999 (File No. 000-21001).
- (11) Incorporated by reference to Exhibits to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File No. 000-21001).
- (12) Incorporated by reference to Exhibits to the Registrant's Current Report on Form 8-K, dated November 5, 2001 (File No. 000-21001).
- (13) Incorporated by reference to Exhibits to the Registrant's Current Report on Form 8-K, dated July 31, 2002 (File No. 000-21001).
- (14) Incorporated by reference to Exhibits to the Registrant's Annual Report on Form 10-K/A for the year ended December 31, 2002 (File No. 000-21001).
- (15) Incorporated by reference to Exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003 (File No. 000-21001).
- (**) Management contract or compensatory plan or arrangement required to be filed as an Exhibit to this Annual Report on Form 10-K.

BOARD OF DIRECTORS	CORPORATE OFFICERS	CORPORATE HEADQUARTERS
John F. Abern Chairman of the Board,	John F. Abern Chairman of the Board,	27 Wormwood Street Boston, Massachusetts
President and Chief Executive Officer of the Company	President and Chief Executive Officer of the Company	02210-1625 (617) 737-0930
Robert G. Brown⁽¹⁾ Director, Private Investor	Richard E. Davis Vice President and Chief Financial Officer	FORM 10-K AVAILABILITY A copy of the Annual Report on Form 10-K for the year ended December 31, 2003 may be obtained at no charge by writing to the Company.
Sheryl L. Clarkson^(1,3) Chairman of the Board, Chief Executive Officer SkinHealth, Inc.,	ORGANIZATION Richard E. Davis Vice President of Clinical Development	TRANSFER AGENT American Stock Transfer & Trust 59 Maiden Lane Plaza Level New York, NY 10038
John Fletcher⁽²⁾ Chief Executive Officer Director, Stought, Inc., management consulting company	Carol A. Devellian Vice President of Research and Development	INDEPENDENT AUDITORS Ernst & Young LLP Boston, Massachusetts
Samuel E. Hanley, MD⁽¹⁾ Professor of Neurology, Neurosurgery and Anesthesia/Critical Medicine, Professor of School of Nursing, the Jeffrey and Harriett Legum Professor of Acute Care Neurology and Director of Brain Injury Outcome Program, Johns Hopkins Medical Institutions	Jay S. Dion Vice President of Manufacturing and Facilities Geoff Fournie Director, Commercial Development – Europe	
James F. Lock, MD Chair, Department of Cardiology and Physician-in-Chief, Children's Hospital, Boston Madras Professor of Pediatrics Harvard Medical School	Paul A. Garant Vice President of Quality Assurance Anne M. Kulis Vice President of Clinical and Regulatory Affairs Brad Ryno Director, Commercial Development – North America	COUNSEL Hale and Dorr LLP 60 State Street Boston, Massachusetts 02109
Francis J. Martin^(1,2,3) Chairman and Chief Executive Officer Genzyme Medical Ltd., cardiovascular products company	Holly Whitin Director, Worldwide Market Development	ANNUAL MEETING The Annual Meeting of Stockholders will be held on Tuesday, June 22, 2004 at 10:00 a.m. at the Seaport Hotel, One Seaport Lane, Boston.
Harry A. Schult^(2,3) Chief Financial Officer and Treasurer Watch Hill Partners, Inc., customer relationship management consultancy company		COMMITTEES OF THE BOARD Member of the Joint Compensation and Stock Options Committee Member of the Audit Committee Member of the Nominating and Corporate Governance Committee

MMR Medical, Inc.

1111 Northwood Street
Boston, MA 02210-1625
508-752-0930

www.mmrmedical.com