ENPATH MEDICAL INC
Form 10-K
March 24, 2005

U.S. Securities and Exchange Commission

Washington, D.C. 20549

Form 10-K

ý Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2004

Or

o Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from to

Commission File Number 0-19467

Enpath Medical, Inc.

(Exact name of registrant as specified in its charter)

Minnesota	**41-1533300**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

15301 Highway 55 West, Plymouth, Minnesota 55447

(Address of principal executive office, including zip code)

(763) 559-2613

(Registrant s telephone number, including area code)

Securities Registered Pursuant to Section 12(b) of the Act:

None

Securities Registered Pursuant to Section 12(g) of the Act:

Common Stock, $.01 Par Value

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 ý No o

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 ý

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

Yes o No ý

The aggregate market value of the common stock held by non-affiliates of the issuer as of June 30, 2004, the last day of the second quarter of the past fiscal year, was approximately $63,071,000.

Shares of Common Stock outstanding at March 16, 2005: 5,914,029 shares

Documents incorporated by reference:

Portions of the issuer s Proxy Statement for the Annual Meeting of Shareholders scheduled for April 28, 2005 are incorporated by reference into Part III of this Form 10-K.

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PART I

Item 1 **Business**

Overview

We are a medical products company engaged in:

the design, development, manufacture and marketing of percutaneous vessel introducers, safety needles and related vascular delivery products;

the design, development, manufacture and marketing of implantable stimulation leads, lead delivery systems, and lead accessories for cardiac rhythm management (CRM) and neuromodulation markets; and

the manufacture of medical devices and components for other medical product companies on a contract basis.

During 2004, we operated as two divisions. The Enpath Delivery Systems Division (EDS), formerly Medamicus, Inc., was engaged in the design, development, manufacture and marketing of percutaneous vessel introducers, safety needles and related vascular delivery products, while the Enpath Lead Technologies Division (ELT), which consisted of assets purchased from BIOMEC Cardiovascular Inc. (BCI) in October 2003, was engaged in the design, development, manufacture and marketing of implantable stimulation leads, lead delivery systems, and lead accessories for CRM and neuromodulation markets. In addition, both divisions were engaged in the manufacture of medical devices and components for other medical products on a contract basis.

The two divisions are aggregated into one reportable segment: the manufacture and sale of medical devices. The divisions have similar technology, manufacturing, customers and regulatory activities and we have combined our sales and marketing and research and development activities to take advantage of similarities in customers and product development. Effective January 1, 2005, the divisional structure was eliminated and we now operate as one organization located in two facilities. On March 15, 2005, ELT was merged into Enpath Medical, Inc.

We were incorporated under the laws of the State of Minnesota on August 24, 1981 under the name MNM Enterprises, Inc. In March 1988, we changed our name to Medamicus, Inc. and operated under that name until February 1, 2004. On February 2, 2004 we changed our name to Enpath Medical, Inc. Our Delivery Systems office is located at 15301 Highway 55 West, Plymouth, Minnesota 55447-1418 and our telephone number is (763) 559-2613. Our Lead Technologies office is located at 7452 West 78th Street, Bloomington, Minnesota 55439-2513, and its telephone number is (952) 943-1189.

Products

Delivery Systems

We manufacture and market a family of percutaneous venous vessel introducers with proprietary features, including our own proprietary valved introducer and we will introduce an articulating guide sheath in the near future. Vessel introducers enable physicians to create a conduit through which they can insert infusion catheters, implantable ports, pacemaker leads and other therapeutic devices into a blood vessel.

In order to introduce a catheter or pacemaker lead into a vein, a hypodermic needle is first used to access the vein. A guide wire is then inserted through the hypodermic needle and the needle is removed. A vessel introducer, consisting of a hollow sheath and a dilator, is then inserted over the guide wire to expand the opening. The guide wire and dilator are then removed, leaving only the hollow sheath through which the catheter or pacemaker lead is introduced. Once the catheter or pacemaker lead is in place, the vessel introducer sheath is usually removed. This process is typically done by peeling the introducer in half or slitting it off, in the case of our proprietary introducer.

We manufacture and market both peelable introducers and our own proprietary slitter introducer in a variety of sizes and market them both (1) in a kit that contains the disposable devices necessary to do catheter or lead implant procedures, and (2) in bulk for packaging by the customer with its own devices.

We also design, manufacture and market guiding and articulating or steerable introducers. These advanced delivery systems are used by our customers to deliver therapeutic catheters to specific sites in the body. We are currently providing delivery systems to several different companies for development projects evaluating new therapies. Under the terms of our agreements with these customers, if the customer is successful in commercializing its therapy, we will be the manufacturer of its delivery system device. We expect to continue to expand this portion of our business.

We also manufacture safety products, primarily a safety needle that can be retracted into a protective sheath while still in the patient, greatly reducing the possibility of a needle stick and infection to the health care professional after the needle has been in contact with a patient s blood. Due to slow market acceptance of the safety needle, we wrote down our investment in safety needle technology and equipment in the second quarter of 2004 (see Note 11 to the consolidated financial statements in this Form 10-K for further discussion).

Finally, we perform contract manufacturing and engineering services under which we design and manufacture products at our facilities to third party customer specifications.

Lead Technologies

Our primary product line is our permanent, sutureless, epicardial (MyoPore®) leads, both bipolar and unipolar, which are used in both post open-heart surgery patients and in cardiac resynchronization therapy (CRT) procedures for heart failure. This epicardial lead technology has been on the market since 1989 and has been used in more than 20,000 implants worldwide. The CRT procedure for congestive heart failure is a relatively new procedure in which one of the lead wires needs to be positioned in a small vein on the left side of the heart, sometimes a very difficult place to reach. In 10 20% of these cases, the lead cannot be effectively placed transvenously, in which case the patient is taken to a surgical suite where a lead is placed on the outside of the heart. We manufacture one of two leads most often used for this epicardial or outside of the heart procedure.

A new steroid, sutureless, bipolar epicardial lead (Myopore Rx) has been developed to reduce cardiac stimulation thresholds and improve the energy efficiency of the pacing system. The Myopore Rx uses the mechanical structure of the bipolar Myopore lead and incorporates a steroid plug to reduce the inflammatory response of the cardiac tissue. The steroid plugs are provided by two of our major CRM customers, resulting in two distinct steroid epicardial lead models. As is the case with all Enpath products, these leads, when approved by the appropriate regulatory bodies, will be distributed by our OEM partners. The FDA and CE regulatory submissions for these leads were made in August of 2004. Based on an early indication from the FDA that such an application would be considered, we submitted a Paper PMA (a less burdensome approach that does not require prospective human clinical data) to gain marketing clearance for our epicardial steroid lead. Recently the FDA advised us that our application does not have a robust clinical argument without human clinical data. Although we are currently in negotiation with the FDA on the amount of human clinical data required for eventual PMA approval, the scope and the timing of collecting the human data along with the feasibility of conducting such a study has not yet been determined. We did receive European approval to begin selling the first steroid leads through one of our OEM partners and expect approval of the lead for the second OEM partner within the next several weeks.

We also provide a FasTac® implant tool in every MyoPore lead package to facilitate surgical placement of the leads onto the surface of the heart. The unique design of the implant tool allows for a quick, one-handed motion for release of the lead after attachment. The distal end of the tool is designed to provide simple and fast regrasping, reloading, and repositioning of the lead, if necessary.

Based on feedback from cardiac surgeons, we developed a new epicardial implant tool called the FasTac Flex delivery tool. The FasTac Flex is designed to facilitate more minimally invasive placement of epicardial leads on the ventricles of the heart. While the new tool builds on some of the patented features of the FasTac, it offers many more surgery-friendly features such as remote tip deflection, rotation, and lead release. The new device received FDA regulatory approval exemption as a Class I device, but does require a CE design dossier submission because it was classified as an active implantable medical device. Unlike the original FasTac tool which is sold as part of the epicardial lead package, the FasTac Flex will be sold as a separate device.

Adaptors are necessary when a connector on a pacing lead wire from one generation of pacemaker needs to be connected to a pacemaker from a newer generation. Although pacing lead wires are intended to stay in the body indefinitely, pacemakers need to be exchanged every five to ten years as batteries expire. Due to the advent of multi-polar lead technology and multi-chamber pacing and defibrillation, the international standard for connectors has been under review in order to accommodate this new technology. As discussed below under Research and Development, we anticipate the new IS-4 international connector standard to be implemented in 2005 or 2006. This will again create a long-term mismatch between old and new connectors. We currently produce four models of IS-1 implantable adapters. We intend to supply selected IS-4 adapters to one of the major CRM manufacturers after the connector standard has been finalized. We have also initiated development of a proprietary neurostimulation lead that incorporates previously patented fixation technology.

Finally, we perform contract manufacturing and engineering services under which we design and manufacture products at our facilities to third party customer specifications.

Markets and Marketing

We estimate that there are over 4,000,000 central venous and peripheral access procedures performed worldwide each year that use venous vessel introducers. Because the majority of vessel introducers are sold in combination with the sale of infusion catheters, implantable ports or pacing leads, we identified an opportunity to market our vessel introducer with the catheters, implantable ports or pacing leads of other medical device manufacturers. Accordingly, we have entered into agreements with Medtronic, Inc. and with Bard Access Systems, a subsidiary of C. R. Bard, Inc., for the inclusion of our introducers in kits sold in their respective markets. We also have agreements with a number of other companies in the dialysis and port markets.

We believe Medtronic has the largest worldwide market share of pacing leads. Medtronic is currently purchasing our sterilized introducer kits, which include a syringe, hypodermic needle and guide wire, as well as the vessel introducer, and are packaged by us in boxes designed by Medtronic. Medtronic markets our vessel introducer with the slitting device worldwide under the SOLO-TRAK™ trade name. We also manufacture and package a peelable introducer in similar kits for Medtronic.

In October 2002, we entered into a five-year supply agreement with Medtronic that superceded all previous supply agreements between the companies. The agreement named us as exclusive supplier of all standard right-side pacing procedure kits. There are no minimum purchase obligations associated with the agreement, but Medtronic is obligated to purchase all of its requirements for certain introducer procedure kits from us.

We estimate that approximately 110,000 CRT procedures were conducted in 2004, and in 10 20% of those cases an epicardial lead placement was necessary to complete this procedure. We estimate that CRT procedures will grow more than three-fold over the next five years. Two of the three major pacing companies offer our lead and implant tool when marketing their products for these procedures.

Our primary customers for our leads, delivery systems and adapters include the three major CRM companies: Medtronic, Guidant, Inc. and St. Jude Medical, Inc. We also package accessory products for St. Jude Medical and perform packaging and contract manufacturing for a number of other companies. We sell adaptors to all three major pacing companies and we are poised to capitalize on the opportunities presented by the adoption of the new connector standard. Our products are sold to our OEM customers by our own sales force.

For the years ended December 31, 2004, 2003 and 2002, Medtronic accounted for 41%, 44% and 67% and C.R. Bard, Inc. accounted for 16%, 18% and 13% of our sales. In addition, St. Jude Medical, Inc. accounted for 11% and 7% of our sales for the years ended December 31, 2004 and 2003.

Competition

Delivery Systems

Our vessel introducers compete with other peel-away vessel introducers manufactured by competitors. We believe that the four major competitors in the venous introducer market are Daig Corporation (owned by St. Jude Medical); B. Braun of America Company; Pressure Products, Inc., and TFX Medical, a subsidiary of Teleflex Incorporated. Daig, B. Braun, Pressure Products and TFX Medical market their vessel introducers primarily by establishing distribution arrangements with existing companies in the medical field, which is the same strategy that we follow. Many of these competitors are significantly larger and have significantly greater financial, technical, research and marketing resources than we have.

Lead Technologies

Our primary competitors in providing stimulation leads and adapters to OEM customers in the CRM market are Oscor Inc., and Osypka GMBH. Oscor, with its facility in Florida, and Osypka GMBH located in Germany, both have lines of pacing leads, adapters and other electrophysiology devices that they sell to major CRM companies, and also to end users through their own distributors worldwide.

Research and Development

Although our research and development activities are carried out primarily by our employees, we have utilized outside specialists on a contract basis and expect to continue to do so. During the past year, we significantly increased our product development activities on a number of projects. Delivery Systems broadened its venous vessel introducer product offering through the introduction of a valved introducer to minimize blood loss and reduce the possibility of an air embolism. More importantly, they have been focused on development of articulating or steerable introducers. We believe the next generation of introducers will be required to reach places inside a patient s anatomy not accessed before in order to conduct new minimally-invasive therapeutic procedures.

Lead Technologies is engaged in several projects related to new CRM and neurostimulation leads, adapters, and delivery systems. We are developing a proprietary articulating delivery tool specifically designed for surgical placement of our epicardial leads in heart-failure patients undergoing CRT. This new tool is designed to allow surgeons better control for lead placement on the left ventricular epicardial surface of the heart. We have also developed a new version of our MyoPore epicardial lead that incorporates an anti-inflammatory drug, or steroid, into the lead head. As discussed above under Products - Leads Technologies, we are currently seeking CE and FDA clearance to market this product in Europe and the United States. We are also developing IS-4 adapters that will adapt current style IS-1 leads and IPG/ICD systems (pacemakers and defibrillators) to new IS-4 compatible leads and IPG/ICD systems. The IS-4 standard is still in development and is expected to be adopted by the major CRM manufacturers by mid-2006. We have been involved with the AAMI Pacemaker Connector Standards Committee that has been working on the new IS-4 connector standard over the past four years, and are currently a member of that committee. In addition, we have initiated development of a proprietary neurostimulation lead that incorporates previously patented fixation technology and a next generation epicardial lead. Both of these leads will utilize advanced delivery catheters as part of a lead/delivery system.

For the years ended December 31, 2004, 2003 and 2002, we spent $4.7 million, $2.0 million and $1.7 million on research and development activities. As of December 31, 2004, we had 28 employees dedicated to research and development. We intend to increase our research and development spending slightly in 2005 compared to 2004 as we continue to work on these projects and begin development efforts on new projects. There can be no assurance that our development efforts will result in additional revenue.

Contract Manufacturing

Delivery Systems

Since October 1985, we have performed contract manufacturing services for a variety of medical device companies in the Minneapolis-Saint Paul metropolitan area, and currently manufacture two medical products for one company

and one medical product for another company. For the years ended December 31, 2004, 2003 and 2002, contract manufacturing sales were approximately 4-5% of our Delivery System sales. We expect contract manufacturing sales for 2005 to be less than 3% of our Delivery Systems sales.

Lead Technologies

We also perform contract development and manufacturing for medical device OEM customers, primarily in the fields of CRM and Neuromodulation. During 2004, we discontinued several contract manufacturing projects that did not fit our business model. For the years ended December 31, 2004 and 2003, contract manufacturing revenues were approximately 50% and 65% of our Lead Technologies sales, respectively. We anticipate that sales related to contract manufacturing will decline to approximately 30% of Lead Technologies sales in 2005 as we focus our sales efforts on increasing sales of our proprietary products.

Suppliers

We currently purchase, and will in the future purchase, components and raw materials from outside vendors. Although we have identified alternative suppliers for key components and raw materials, at the present time we generally use one source of supply for each component and raw material. Each supplier of raw material for the vessel introducers we sell to Medtronic is subject to the approval of Medtronic, and future customers may have a right of approval as well. At present, Medtronic has approved all of the applicable suppliers. If a key supplier is unwilling or unable to supply any such component or raw material in a timely manner, or if approval of a proposed supplier is delayed, withheld or withdrawn, we could experience delays in obtaining alternative suppliers, which may adversely affect our business.

Government Regulation

The medical devices we manufacture and market are subject to regulation by the FDA and, in some instances, by state and foreign authorities. Pursuant to the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, and related regulations, medical devices intended for human use are classified into three categories (Classes I, II and III), depending upon the degree of regulatory control to which they will be subject. Our introducer products are considered Class II devices. Our lead wires are considered Class III devices.

If a Class II device is substantially equivalent to an existing device that has been continuously marketed since the effective date of the 1976 Amendments, FDA requirements may be satisfied through a Premarket Notification Submission (510(k)) under which the applicant provides product information supporting its claim of substantial equivalence. In a 510(k) Submission, the FDA may also require that it be provided with clinical test results demonstrating the safety and efficacy of the device. Generally, Class III devices are devices that must receive pre-market approval by the FDA to ensure their safety and effectiveness. They are typically life-sustaining, life supporting, or implantable devices. Pre-market approval (PMA) is a more rigorous approval process typically requiring human clinical studies. The lead wires that we manufacture and market at our Lead Technologies facility are typically Class III devices. In August 2004, we submitted a Paper PMA (a less burdensome approach that does not require prospective human clinical data) to gain marketing clearance for our epicardial steroid lead, based on an indication from the FDA that such an application would be considered. Recently the FDA has advised us that our application does not have a robust clinical argument without human clinical data. Although we are currently in negotiation with the FDA on the amount of human clinical data required for eventual PMA approval, the scope and the timing of collecting the human data along with the feasibility of undertaking such a study has not yet been determined.

We also submitted a 510(k) application in December 2004 for marketing clearance for our steerable introducer. We are currently awaiting a response from the FDA on that submission.

As a manufacturer of medical devices, we are also subject to certain other FDA regulations, and our manufacturing processes and facilities are subject to continuing review by the FDA to ensure compliance with Good Manufacturing Practices regulations. We believe that our manufacturing and quality control procedures substantially conform to the requirements of FDA regulations. In addition, our sales and marketing practices are subject to regulation by the United

States Department of Health and Human Services pursuant to federal anti-kickback laws, and are also subject to similar state laws.

Our devices may also be subject to regulation in foreign countries in order to conduct business in the European Community. Medtronic, Bard Access, St. Jude Medical, Guidant and any other entity with whom we would develop a distribution relationship, are responsible for obtaining approval from the foreign countries in which they desire to sell the vessel introducers manufactured by us. Our facilities are ISO 13485 certified and we have received approval for placement of the CE Mark on products for sale in Europe. Should we elect to use independent distributors in countries outside the European Community, we may be responsible for obtaining approval to sell in those countries.

Intellectual Property

Delivery Systems

We have made and continue to make, when appropriate, efforts to obtain patents on new products and improvements to existing products. We have nine U.S. patents on various aspects of introducer and delivery systems and a number of additional applications pending or in process.

Due to the rapid technological changes experienced in the medical device industry, we believe that the improvement of existing products, reliance upon trade secrets and unpatented proprietary know-how and the development of new products are generally as important as patent protection in establishing and maintaining a competitive advantage.

Lead Technologies

We have nine U.S. patents covering certain aspects of myocardial leads and introducers, steroid eluting myocardial leads, and other leads and lead features for CRM applications. We also have twelve registered trademarks, in the U.S. and Europe, related to our MyoPore leads, FasTac, other endocardial leads, and pending trademarks for introducers and business marketing services. We also have several invention disclosures and one provisional patent related to leads, delivery systems and other lead related technologies.

Employees

As of March 15, 2005, our Delivery Systems facility had 153 full-time employees while our Lead Technologies facility employed 72 persons, including one part-time employee.

Available Information

We maintain a website at www.enpathmedical.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, are available on our website, as soon as reasonably practicable after these documents are filed with the SEC. To obtain copies of these reports, go to www.enpathmedical.com and click

on Investor Relations, then click on SEC Filings. A copy of any report filed by the Company with the SEC will also be furnished without charge to any shareholder who requests it in writing from Michael D. Erdmann, Secretary, Enpath Medical, Inc., 15301 Highway 55 West, Plymouth, Minnesota 55447.

You may also read and copy any materials that the Company files with the SEC at the SEC s Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549 or by calling 1-800-SEC-0330. The SEC maintains an Internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Item 2 **Properties**

Our Delivery Systems administrative, manufacturing and research and development facilities are located at 15301 Highway 55 West, Plymouth, Minnesota 55447-1418. Effective February 1, 2004, we extended our lease until June 30, 2006. Under the revised lease, we occupy 38,337 square feet of space with current base rent payments of

$17,525 per month and common area maintenance expenses and real estate taxes of $8,585 per month through May 2005, increasing to $19,276 and $9,185 per month, respectively, from June 1, 2005 to the end of the lease term. The lease provides for up to three one-year extensions that are automatic if we do not give a six-month notice of evacuation. The base rent can increase yearly, after June 30, 2006, based on the consumer price index.

Delivery Systems also leased additional warehouse space on February 4, 2005 located at 2010 East Center Circle, Plymouth, Minnesota 55441. Under the new lease, we occupy 4,740 square feet of space with base rent payments of $1,876 per month and common area maintenance expenses and real estate taxes of $1,063 per month beginning March 1, 2005 and running through July 2006.

Our Lead Technologies administrative, manufacturing and research and development facilities are located at 7452 West 78th Street, Bloomington, Minnesota 55439-2513. We are leasing 27,000 square feet pursuant to a lease that commenced on June 15, 1998 and expires December 31, 2008. The lease calls for base rent payments of $14,189 per month, as well as charges for common area maintenance expenses and real estate taxes of $8,135 per month for 2005. The lease provides for up to three one-year extensions that require a six-month notice of intent to exercise that option, at which time the base rent would be established at the current market price

We are currently in the process of looking for new space that will combine both facilities into one building sometime in mid-2006. We have hired an outside firm to assist us with this process and we are currently in the planning phase of the project. We will report on our progress in this area in future filings.

Item 3 Legal Proceedings

None

Item 4 Submission of Matters to a Vote of Security Holders

None

PART II

Item 5 Market for Registrant s Common Equity and Related Stockholder Matters

The closing market price of our stock on March 21, 2005 was $8.02.

Our Common Stock was traded on the SmallCap System of the Nasdaq Stock Market under the symbol MEDM from September 1991 until October 2003 when we moved to the National Market System of The Nasdaq Stock Market. Our trading symbol changed from MEDM to NPTH on February 2, 2004 in connection with the change in our name from Medamicus, Inc. to Enpath Medical, Inc. The table below shows the high and low closing sales prices for the quarters indicated.

	First Quarter		Second Quarter		Third Quarter		Fourth Quarter	
Year	**Low**	**High**	**Low**	**High**	**Low**	**High**	**Low**	**High**
2003	$ 6.55	$ 8.41	$ 6.73	$ 8.35	$ 7.99	$ 12.18	$ 10.89	$ 14.77
2004	$ 12.53	$ 14.15	$ 11.01	$ 13.92	$ 8.43	$ 11.39	$ 8.10	$ 10.96

Holders and Dividends

As of March 15, 2005, we had approximately 275 record holders and 1,800 beneficial holders of our Common Stock. We have not paid cash dividends in the past and do not expect to do so in the foreseeable future. Under the terms of our bank credit facility, we are prohibited from paying any dividends without the consent of the bank.

Recent Sales of Unregistered Equity Securities

The Company had no unregistered sales of equity securities during the quarter ended December 31, 2004.

Issuer Repurchases of Equity Securities

We did not repurchase any of our equity securities during the quarter ended December 31, 2004.

Item 6 Selected Financial Data

Selected Income Statement Data

Year Ended December 31 Dollars in thousands	2004	2003	2002	2001	2000
	Note 7	Note 4		Notes 1,2,3	Notes 1,2
Sales	$ 29,489	$ 19,603	$ 17,879	$ 13,648	$ 7,399
Operating income (loss)	(1,784)	257	4,441	3,487	1,695
Income (loss) from continuing operations	(1,296)	309	2,859	3,541	1,580
Income (loss) from discontinued operations				3,079	(1,418)
Net income (loss)	**$ (1,296)**	**$ 309**	**$ 2,859**	**$ 6,620**	**$ 162**
				Note 6	Note 6

Selected Balance Sheet Data

As of December 31 Dollars in thousands	2004	2003	2002	2001	2000
					Note 5
Working capital	$ 5,220	$ 4,558	$ 8,858	$ 7,645	$ 1,443
Total assets	31,168	33,561	18,571	13,926	5,561
Note payable to bank	3,833				1,551
Long-term obligations, including current portion	71	6,799	215	298	273
Total liabilities	7,393	10,571	3,143	1,990	2,929
Shareholders equity	23,775	22,990	15,428	11,936	2,632

Selected Share Data

Year Ended December 31	2004	2003	2002	2001	2000
Net income (loss) per common share - Basic					
Continuing operations	$ (0.22)	$ 0.06	$ 0.61	$ 0.83	$ 0.38
Discontinued operations				0.72	(0.34)
Total net income (loss) per common share - Basic	**$ (0.22)**	**$ 0.06**	**$ 0.61**	**$ 1.55**	**$ 0.04**
Net income (loss) per common share - Diluted					
Continuing operations (Note 6)	$ (0.22)	$ 0.06	$ 0.57	$ 0.77	$ 0.36
Discontinued operations				0.67	(0.32)
Total net income (loss) per common share - Dilute	**$ (0.22)**	**$ 0.06**	**$ 0.57**	**$ 1.43**	**$ 0.04**

				Note 6	Note 6
Dividends per share	**$**	**$**	**$**	**$**	
Weighted average common and common equivalent shares outstanding (thousands)					
Basic	**5,843**	**4,918**	**4,712**	**4,275**	**4,165**
Diluted	**5,843**	**5,169**	**4,974**	**4,626**	**4,387**

Notes

(1) Years prior to 2001 have been restated to reflect only sales and operating income from continuing operations. All sales, gross profit and expenses related to the Gynecology Division are included in income (loss) from discontinued operations.

(2) Years prior to 2001 reflect no income tax expense due to the utilization of net operating tax loss carry-forwards. 2001 also includes recognition of benefit of unutilized net operating tax loss carry-forwards of $923,000.

(3) Results for 2001 include gain on sale of Gynecology Division of $2,896,610 and income from discontinued segment of $182,012.

(4) Results for 2003 include financial results from the BCI acquisition beginning October 24, 2003. Included in these results are the write-off of purchased in-process research and development costs of $2,650,000.

(5) The balance sheet for 2000 includes assets and liabilities of the Gynecology Division.

(6) The comparable pro forma net income from continuing operations would have been $979,442 or $.22 per diluted share in 2000 and $2,160,949 or $.47 per diluted share in 2001. The pro forma amounts ignore the income (loss) from discontinued operations (2000-2001), the $923,000 income tax benefit recognized in 2001 and applies a 38% tax rate on income for those three years.

(7) Results for 2004 include a safety needle impairment charge of $2,809,199 less income tax benefit of $898,944.

Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations

Overview

We are a medical products company engaged in:

the design, development, manufacture and marketing of percutaneous vessel introducers, safety needles and related vascular delivery products;

the design, development, manufacture and marketing of implantable stimulation leads, lead delivery systems, and lead accessories for cardiac rhythm management, neuromodulation, and hearing restoration markets; and

the manufacture of medical devices and components for other medical product companies on a contract basis.

On October 23, 2003, we completed our acquisition of the operating assets of BCI from BIOMEC Inc. and began to operate the BCI business through our wholly-owned subsidiary, Enpath Lead Technologies, Inc. (ELT). We paid $18 million less assumed liabilities of approximately $1 million plus a working capital adjustment of $897,000. In addition, we made a contingent payment of $3 million on March 31, 2004, based on the final 2003 sales results of the acquired BCI business. This payment consisted of $1.2 million in cash and $1.8 million in common stock (133,588 shares @ $13.62 per share). We will also make a second contingent payment on March 31, 2005, which is based on the increase in proprietary sales in 2004 over 2003, as defined in the Asset Purchase Agreement. This contingent payment totals $489,000 and will be paid out as $98,000 in cash and $391,000 in common stock. We will issue 33,831 shares valued at $11.56 per share based upon a pre-agreed formula (see Note 4 to the consolidated financial statements in this Form 10-K for further details). Under the terms of the Asset Purchase Agreement, the amount of the 2004 contingent payment is to be doubled if, on or before December 31, 2004, ELT executed supply agreements with one or more specified customers having minimum terms specified in the Asset Purchase Agreement. The Company has determined that the conditions for doubling were not met and notified BIOMEC. Under the Asset Purchase Agreement, BIOMEC has the right to review the Enpath documentation with respect to determination of the 2004 contingent payment. If BIOMEC disputes the amount due to it under the 2004 contingent payment, the Asset Purchase Agreement establishes a dispute resolution mechanism under which the matter may be referred to a third party accounting firm. BIOMEC has requested, and the Company has delivered, supporting documentation with respect to the computation of the 2004 contingent payment.

During 2004, Enpath Medical, Inc. operated as two divisions: The Enpath Delivery Systems Division (EDS , formerly Medamicus, Inc.) and the Enpath Lead Technologies Division (ELT , formerly BCI). The divisions are aggregated into one reportable segment: the manufacture and sale of medical devices. The divisions have similar technology, manufacturing, customers and regulatory activities and we have combined our sales and marketing and research and development activities to take advantage of similarities in customers and product development. Effective January 1, 2005, the divisional structure was eliminated and we now operate as one organization located in two facilities.

Our consolidated 2004 sales were $29.5 million, consisting of $20.9 million from EDS and $8.6 million from ELT. Sales at EDS increased $3.9 million compared to 2003 primarily due to increased sales of new and existing introducer products to both new and existing customers. Sales at ELT increased $6.0 million compared to 2003 due to only including two months of post acquisition revenue in our 2003 consolidated results. Comparing full-year 2004 to full-year 2003 ELT/BCI sales, sales actually declined from $10.5 million to $8.6 million, primarily due to lower sales of accessories to our largest ELT customer.

Our consolidated 2004 gross profit was $11.2 million, consisting of $9.4 million from EDS and $1.8 million from ELT. Gross profit at EDS increased $2.2 million compared to 2003 primarily due to increased sales levels and improved manufacturing efficiencies in 2004. Gross profit at ELT increased $1.0 million compared to 2003 primarily due to only including two months of post acquisition gross profit in our 2003 consolidated results. Comparing full-year 2004 to full-year 2003

ELT/BCI gross profit, gross profit actually declined from $3.5 million to $1.8 million, primarily due to lower sales and correspondingly higher amounts of unapplied overhead included in cost of goods sold.

Our consolidated 2004 expenses were $13.1 million, consisting of $4.7 million of research and development expenses, $5.4 million of sales, general and administrative expenses and $211,000 of interest and other expenses. Additionally, EDS booked a one-time impairment charge on its safety needle investment of $2.8 million to write down the value of assets related to the safety needle product line.

As a result, we had a net loss of $1.3 million or $.22 per diluted common share in 2004, compared to net income of $309,000 or $.06 per diluted common share in 2003. See the table below for a more complete summary.

Combined Summary 2004 Compared to 2003

	Year Ended December 31, 2004						YTD			
In Thousands	**EDS $**	**EDS %**	**ELT $**	**ELT %**	**Consolidated**	**Tot %**	**2003 (1)**	**Tot %**	**Change**	**% Change**
Revenues	**$ 20,941**	**100.0%**	**$ 8,548**	**100.0%**	**$ 29,489**	**100.0%**	**$ 19,603**	**100.0%**	**$ 9,886**	**50.4%**
Gross profit	**9,410**	**44.9%**	**1,760**	**20.6%**	**11,170**	**37.9%**	**7,976**	**40.7%**	**3,194**	**40.0%**
Expenses										
Research & development	2,676	12.8%	2,054	24.0%	4,730	16.0%	1,987	10.1%	2,743	138.0%
Sales & marketing	949	4.5%	898	10.5%	1,847	6.3%	1,025	5.2%	822	80.2%
General & administrative	2,602	12.4%	966	11.3%	3,568	12.1%	2,057	10.5%	1,511	73.5%
Purchased in-process R&D		0.0%		0.0%		0.0%	2,650	13.5%	(2,650)	n/a
Safety needle asset impairment	2,809	13.4%		0.0%	2,809	9.5%		0.0%	2,809	n/a
Interest, other	214	1.0%	(3)	0.0%	211	0.7%	21	0.1%	190	904.8%
Total Expenses	**9,250**		**3,915**		**13,165**		**7,740**		**5,425**	**70.1%**
Income (loss) before tax	160		(2,155)		(1,995)		236		(2,231)	-945.3%
Income tax benefit (expense)	10	0.0%	689	8.1%	699	2.4%	73	0.4%	626	-857.5%
Net income (loss)	**$ 170**		**$ (1,466)**		**$ (1,296)**	**-4.4%**	**$ 309**	**1.6%**	**$ (1,605)**	**-519.4%**

(1) YTD 2003 included ELT results from October 24, 2003 to December 31, 2003

	Year Ended December 31, 2003						YTD			
In Thousands	**EDS $**	**EDS %**	**ELT $**	**ELT %**	**Consolidated**	**Tot %**	**2002 (2)**	**Tot %**	**Change**	**% Change**
Revenues	**$ 17,055**	**100.0%**	**$ 2,548**	**100.0%**	**$ 19,603**	**100.0%**	**$ 17,879**	**100.0%**	**$ 1,724**	**9.6%**
Gross profit	**7,242**	**42.5%**	**734**	**28.8%**	**7,976**	**40.7%**	**8,376**	**46.8%**	**(400)**	**-4.8%**
Expenses										
Research & development	1,764	10.3%	223	8.8%	1,987	10.1%	1,661	9.3%	326	19.6%
Sales & marketing	835	4.9%	190	7.5%	1,025	5.2%	529	3.0%	496	93.8%

General & administrative	1,851	10.9%	206	8.1%	2,057	10.5%	1,744	9.8%	313	17.9%
Purchased in-process R&D		0.0%	2,650	104.0%	2,650	13.5%		0.0%	2,650	n/a
Safety needle asset impairment		0.0%		0.0%		0.0%		0.0%		n/a
Interest, other	20	0.1%	1	0.0%	21	0.1%	(51)	-0.3%	72	-141.2%
Total Expenses	**4,470**		**3,270**		**7,740**		**3,883**		**3,857**	**99.3%**
Income (loss) before tax	2,772		(2,536)		236		4,493		(4,257)	-94.7%
Income tax benefit (expense)	(891)	-5.2%	964	37.8%	73	0.4%	(1,634)	-9.1%	1,707	-104.4%
Net income (loss)	**$ 1,881**		**$ (1,572)**		**$ 309**	**1.6%**	**$ 2,859**	**16.0%**	**$ (2,550)**	**-89.2%**

(2) YTD 2002 consisted of the EDS division only

Delivery Systems

We manufacture and market a family of percutaneous venous vessel introducers with proprietary features, as well as our own proprietary valved introducer. Vessel introducers enable physicians to create a conduit through which they can insert infusion catheters, implantable ports and pacemaker leads into a blood vessel.

In addition to this core traditional introducer product line, we have developed and manufacture advanced delivery introducers that have fixed curve or articulating distal tip sections that can be manipulated to enable the health care professional to access parts of the patient s anatomy (such as the left ventricle of the heart) that cannot be reached by traditional introducers. These sophisticated advanced delivery introducers are designed and manufactured to meet the unique needs of each procedure being performed.

We also manufacture safety products, primarily a safety needle that can be retracted into a protective sheath while still in the patient, greatly reducing the possibility of a needle stick and infection to the health care professional after the needle has been in contact with a patient s blood (see Note 11 to the consolidated financial statements in this Form 10-K for further information).

Finally, we perform contract manufacturing and engineering services under which we design and manufacture products at our facilities to third party customer specifications.

Lead Technologies

We develop and manufacture proprietary and custom designed implantable stimulation leads, adapters and delivery systems for the cardiac and neuromodulation markets. We also provide laser processing and contract manufacturing services for our medical device customers for implantable and disposable devices.

Results of Operations

Delivery Systems 2004, 2003 and 2002

Net sales were $20.9 million in 2004, $17.1 million in 2003 and $17.9 million in 2002, representing a 22.8% increase and a 4.6% decrease, respectively.

Sales of our core introducer products were $16.5 million in 2004, $12.4 million in 2003 and $11.1 million in 2002, representing a 32.4% and 12.2% increase, respectively. The increase in 2004 was primarily due to the launch of the FlowGuardTM valved introducer into the cardiac pacemaker market which included a large initial stocking order, as well as strong orders for introducers from our two largest customers during the last half of 2004. The increase in 2003 was primarily due to continued growth in sales to both new and existing customers. We had hoped to see a larger increase in our introducer product sales during 2003 with the launch of our FlowGuard valved introducer in the second quarter. Unfortunately, due to a design issue related to the handle resin, we voluntarily pulled the product off the market in June 2003 and spent the remainder of 2003 resolving the issue. We expect introducer sales in 2005 to increase slightly over the 2004 level as we continue to penetrate smaller market share customers with the FlowGuard product.

Sales of our advanced delivery products were $2.8 million in 2004, $2.5 million in 2003 and $5.5 million in 2002, representing a 10.9% increase and a 54.6% decrease, respectively. The increase in 2004 was primarily due to several special orders of Left Ventricle Lead Delivery System (LVLDS) procedural kits that shipped to Medtronic in 2004. Without these special orders, sales would have declined from 2003 primarily due to lower component sales to Medtronic for these kits. The decrease in 2003 was primarily due to Medtronic transferring the manufacturing of LVLDS kits from us to its own facility beginning in late 2002. We are continuing our work with several different customers on sophisticated delivery catheters that will have utility in the treatment of atrial fibrillation, percutaneous mitral valve repair, carotid stent placement, and a variety of renal and peripheral interventions. Each of these delivery catheters is based on our proprietary technology and could potentially be

used in new treatments being developed by our customers addressing large patient populations. Some of our partners are further along than others, and on track to bring their therapeutic device to market sometime in 2005. We expect advanced delivery product sales to increase in the second half of 2005 as our customers begin to launch their new devices into the marketplace with our delivery systems.

Sales of safety needles were $393,000 in 2004, $602,000 in 2003 and $180,000 in 2002, representing a 34.7% decrease and a 234.4% increase, respectively (see Note 11 of the consolidated financial statements in this Form 10-K for additional information). The decrease in 2004 is primarily due to the reasons described below.

During 2002 and 2003, sales of our safety needles had been growing, but at a much slower pace than we originally anticipated. We launched the safety needle in all of Medtronic s kits for United States distribution in 2003. Our initial launch strategy was to place a safety needle in all kits for United States distribution and after a period of time when all customers had been exposed to the safety needle, we would then offer an option of kits with and without safety needles. Since then, sales of kits with safety needles have dropped precipitously. Cook Incorporated launched our safety needle in February 2004 and purchased a substantial amount of inventory. We had discussions with these two customers during the second quarter of 2004 to assess their expectations in the marketplace regarding safety needles. Cook advised us that it had experienced only modest sales of safety needles. While we remain cautiously optimistic that the federal mandate requiring the use of safety needles in all health care related procedures will result in a future favorable revenue stream for our safety needle, the market s slow adoption rate no longer justified the level of investment we had in safety needle intellectual property rights and equipment. As a result, we determined, with the assistance of an independent valuation firm, that the current fair value of our safety needle assets at June 30, 2004 was $315,000. This resulted in a one-time impairment charge of approximately $2.8 million which we reflected in the results from operations for the three months ended June 30, 2004. We expect sales of safety needles to remain soft for the foreseeable future and we are continuing to evaluate our options for this product. On December 31, 2004, we had inventory of safety needles totaling $308,000 which amounted to 6.6% of total inventory. We continue to sell safety needles on a monthly basis, reducing the inventory levels of these products. We estimate that we have a 12-18 month supply of safety needle inventory on hand and will not be purchasing any additional components or manufacturing any additional needles in the near future.

Other sales, consisting of contract manufacturing, engineering services and freight charges were $1.3 million in 2004, $1.5 million in 2003 and $1.1 million in 2002. Because of the small number of contract manufacturing customers we serve and the volatility of engineering service projects, this category of sales will vary from one year to the next. The decrease in 2004 was primarily due to decreased engineering service sales, partially off-set by increases in contract manufacturing sales during the comparable periods. The increase in 2003 was primarily due to increased engineering service sales, partially off-set by decreases in contract manufacturing sales during the comparable periods.

Gross profit totaled $9.4 million in 2004, $7.2 million in 2003 and $8.4 million in 2002, representing a 29.9% increase and a 13.5% decrease, respectively. Gross profit as a percent of sales was 44.9% in 2004, 42.5% in 2003 and 46.9% in 2002. Gross profit as a percent of sales increased in 2004 compared to 2003 primarily due to the resolution of several issues that impacted 2003. These issues included the recall of the FlowGuard product due to resin issues that have been resolved, the manufacturing by hand of safety needles which are now made on automated equipment, and the high levels of depreciation and amortization on our safety needle assets related to the sales of safety needles. Gross profit as a percent of sales decreased in 2003 compared to 2002 primarily due to the drastic reduction in our high gross profit Medtronic advanced delivery product sales. In addition, we made a conscious decision to retain all of our production staff while we resolved the FlowGuard resin issue and we used the time to conduct training and rearrange our production floor for greater efficiency. As a result, we had higher manufacturing overhead costs than would be typical for the lower level of production we generated. We also had relatively high fixed costs related to the amortization of our investment in obtaining the rights to the arterial safety needle market, as well as depreciation on the automated safety needle assembly equipment (beginning in April 2003), as compared to sales of safety needles. We also incurred additional costs in the first quarter of 2003 when we manually assembled safety needles, as well as additional costs in the second quarter of 2003 when we wrote off inventory associated with the FlowGuard valved introducer. We expect our margins to approximate 42%-44% in 2005 as we continue to launch the smaller sizes of FlowGuard and other new products to the marketplace.

Lead Technologies 2004, 2003 and 2002

Because we did not acquire the assets of this division until October 23, 2003, the comparative numbers shown for 2003 were taken directly from the unaudited records of BCI and the comparative numbers for 2002 were taken from the audited financial statements of BCI. These figures are shown in order to give a point of reference to the current year

results. The percent changes are shown in the table below in order to help clarify the comparative results. The amounts for 2004 and from October 23 to December 31, 2003 were included in our consolidated results.

Sales Category (in thousands)	Full Year 2004	Pro Forma Full Year 2003	October 23 to December 31 2003	Full Year 2002
Proprietary Products	$ 3,880	$ 3,391	$ 723	$ 1,622
Contract Manufacturing	4,336	6,783	1,699	2,562
Contract Development/Other	332	344	126	25
Total Sales	**$ 8,548**	**$ 10,518**	**$ 2,548**	**$ 4,209**
Gross Profit	**$ 1,791**	**$ 3,466**	**$ 734**	**$ 780**
Gross Profit as Percent of Sales	**21.0%**	**33.0%**	**28.8%**	**18.5%**

Percent Change	Full Yr 2004 to Full Yr 2003	Full Yr 2004 to Partial Yr 2003	Full Yr 2003 to Full Yr 2002
Total Sales	-18.7%	235.5%	149.9%
Proprietary Product Sales	14.4%	436.7%	109.1%
Contract Manufacturing Sales	-36.1%	155.2%	164.8%
Contract Development/Other Sales	-3.5%	163.5%	1276.0%
Gross Profit	-48.3%	144.0%	344.4%

Total sales were $8.6 million in 2004, $10.5 million in 2003 ($2.5 million included in consolidated sales) and $4.2 million in 2002 (not included in consolidated sales).

Sales of proprietary products, consisting of implantable stimulation leads, lead delivery systems and adaptors were $3.9 million in 2004, $3.4 million in 2003 ($723,000 included in consolidated sales) and $1.6 million in 2002 (not included in consolidated sales). The increase in 2004 was primarily due to increased sales of epicardial leads into the growing CRT market and the launch of several IS-1 adaptors for a key customer. The increase in 2003 was primarily due to a three-fold growth in our proprietary Myopore epicardial lead sales and increased demand for our IS-1 adapters. High growth in the Myopore lead sales was driven by the rapid growth of the CRT market and the demand for sutureless epicardial leads for left ventricular pacing in failed transvenous left ventricular placements. We expect that sales in 2005 will increase due to European approval of our Myopore Rx epicardial steroid lead. The launch of our Fastac Flex delivery tool for improved efficiency when placing the epicardial lead will also help to increase sales in 2005.

Sales of contract manufacturing products, consisting primarily of lead accessories were $4.3 million in 2004, $6.8 million in 2003 ($1.7 million included in consolidated sales), and $2.6 million in 2002 (not included in consolidated sales). The decrease in 2004 was primarily due to our largest customer continuing to adjust an inventory overstock situation and we look for reduced orders to continue through the first quarter of 2005. Additionally, as part of our overall strategy to focus on higher margin proprietary products, we discontinued several low margin contract manufacturing projects. The increase in 2003 was primarily due to the growth in pacing accessories driven by our largest customer s increase in stocking levels and higher demand due to that customer s sales force expansion. Additional revenue growth was due to increased demand for OEM procedure kits, laser processing of prosthetic discs, and the successful start-up of a hemostatic powder filling operation. We expect that contract manufacturing sales in 2005 will be lower than 2004 due to the shift to proprietary products and the continued reduced orders for accessory products from our largest customer.

Other sales consisting of our contract development work and freight were $332,000 in 2004, $344,000 in 2003 ($126,000 included in consolidated sales) and $25,000 in 2002 (not included in consolidated sales). Contract development work in 2004 and 2003 was primarily related to development of stimulation leads for a variety of emerging neurostimulation applications. These co-development efforts have been initiated to fuel longer-term manufacturing growth tied to development and supply arrangements with emerging therapy start-up companies.

Gross profit totaled $1.8 million in 2004, $3.5 million in 2003 ($734,000 included in consolidated results) and $780,000 in 2002 (not included in consolidated results). Gross profit as a percent of sales was 21.0% in 2004, 33.0% in 2003 (28.8% included in consolidated results) and 18.5% in 2002 (not included in consolidated results). The decrease in gross profit as a percentage of sales was primarily due to the low level of sales during the year, causing our manufacturing staff to be underutilized which resulted in a significant portion of our overhead not being allocated to production. Gross profits were also affected by the amortization of identifiable intangible assets totaling $219,000 in 2004 compared to $36,000 in 2003. Without the amortization charge, gross profits as a percent of sales for 2004 would have been 23.5%. Gross profit grew in 2003 primarily because of increased sales of our higher-margin proprietary products. Other changes that helped improve gross profit in 2003 included the implementation of cost reduction efforts in strategic supply, manufacturing processing improvements and increased efficiencies in the production work force due to hiring, training, and retention programs. We were also able to pass on price increases to customers of our proprietary products that had not seen price increases in several years. We do not expect margins to increase substantially until we launch our new Fastac Flex and Myopore Rx products to the market in 2005.

Combined Expenses 2004, 2003 and 2002

Research and Development

Research and development expenses were $4.7 million in 2004 ($2.6 million for EDS, $2.1 million for ELT), $2.0 million in 2003 ($1.8 million for EDS, $223,000 for ELT) and $1.7 million in 2002 (all EDS) totaling 16.0%, 10.1% and 9.3% of sales, respectively. The large increase in 2004 was primarily due to inclusion of the ELT expenses for all of 2004 compared to only two months in 2003 and none in 2002. Included in the amounts was $260,000 and $43,000 for 2004 and 2003, respectively, of identifiable intangible asset amortization related to the BCI acquisition.

The increase in 2004 over 2003 for Delivery Systems was due to development work on its family of proprietary advanced delivery introducers, as well as development work related to partnerships with a number of other medical device companies working on therapies that will utilize our delivery systems. The increase in 2003 over 2002 was due to increasing our engineering staff and continuing expenditures on a variety of new product development activities.

The increase in 2004 over 2003 for Lead Technologies was primarily due to activities related to validating the improved performance of our anti-inflammatory steroid epicardial lead and the submission of our application to the FDA for marketing clearance (approximately $1 million). Recent discussions with the FDA have indicated that they consider the original least burdensome approach (i.e. a Paper PMA with no requirement for prospective human clinical data) as not being a robust clinical argument for the approval of this lead. We are attempting to clarify the scope and timing of a human clinical that the FDA would find acceptable and then assess the feasibility of conducting such a clinical trial. In addition to the steroid epicardial lead activities, we also spent approximately $500,000 on continued development of the FasTac Flex tool and new IS-4 adaptors.

We expect research and development expenditures for 2005 to be approximately 14% of sales as we continue our efforts to develop and launch these new products. Our long-term goal is to spend approximately 10-12% of our sales on research and development activities.

Sales and Marketing

Sales and marketing expenses were $1.8 million in 2004, $1.0 million in 2003 and $529,000 in 2002 totaling 6.3%, 5.2% and 3.0% of sales, respectively. The large increase in 2004 was primarily due to the inclusion of the ELT expenses for all of 2004 compared to only two months in 2003 and none in 2002. Had we included ELT expenses for all of 2003, the 2003 amount of spending would have totaled approximately $1.6 million. Included in the amounts was $18,000 and $3,000 for 2004 and 2003, respectively, of identifiable intangible

asset amortization related to the BCI acquisition.

The increase in 2004 from 2003 was primarily due to the costs associated with combining our sales and marketing group for the two divisions. On March 31, 2004 we announced the formation of a single sales and marketing group for our two divisions and named James Mellor as Senior Vice President with overall responsibility for that effort. James Reed was appointed to the new position of Director of Sales for the combined group. We did not expect cost savings as a result of putting the two groups together, but rather a more focused and effective sales effort, especially with the large

cardiac rhythm management companies. We incurred some significant expenses related to web-site and marketing material development that increased expenses in 2004 (approximately $100,000). We also added one additional person to the group in 2004. The increase in 2003 from 2002 was primarily due to increased spending on salaries, trade shows and travel, partially off-set by a decrease in commission expense. We had been developing an internal sales and marketing department over the past two years and added a number of positions since January of 2002 to help drive the sales and marketing efforts for our new products while eliminating our independent sales representative relationships. With the addition of these positions, we attended more trade shows to build awareness of our products and incurred higher travel costs than in past years. We expect sales and marketing expenses to be approximately 6% of sales for 2005.

General and Administrative

General and administrative expenses were $3.6 million in 2004, $2.1 million in 2003 and $1.7 million in 2002 totaling 12.1%, 10.5% and 9.8% of sales, respectively. The large increase in 2004 was primarily due to several factors. First, we included the ELT expenses for all of 2004 compared to only 2 months in 2003 and none in 2002. Had we included ELT expenses for all of 2003, the 2003 amount of spending would have totaled approximately $3.0 million. Included in the amounts was $118,000 and $20,000 for 2004 and 2003, respectively, of identifiable intangible asset amortization related to the BCI acquisition. Second, we increased spending on salaries, accounting and legal services, investor relations, name change and corporate integration activities. Compliance with Sarbanes-Oxley Section 404 requirements increased our accounting and legal costs significantly, and we expect these higher costs to continue for all of 2005 and beyond. We also have increased our investor relations activities in conjunction with our acquisition of BCI in order to expand awareness to a growing group of investors. Finally, we have incurred additional costs and expenses in connection with the integration of our new ELT division and the name change to Enpath Medical. The increase in 2003 from 2002 was primarily due to increased spending on salaries, accounting and legal fees associated with Sarbanes-Oxley compliance, investor relations, depreciation, consulting services and insurance. We expect general and administrative expenses to total approximately 11% of sales for 2005.

Other Expenses

Interest income was $2,000 in 2004, $40,000 in 2003 and $78,000 in 2002 and interest expense was $206,000, $52,000, and $23,000 during the same respective periods. Interest income decreased primarily due to lower cash balances resulting from the use of excess cash to fund the acquisition of BCI in 2003, as well as lower interest rates compared to 2002. Interest expense increased primarily due to the interest on the $5.0 million note payable that was put in place in October 2003 to help fund the BCI acquisition, as well as interest payments on our line of credit borrowings.

Liquidity and Capital Resources

As of December 31, 2004, we had unrestricted cash and cash equivalents of $363,000, compared to $1.1 million as of December 31, 2003. Net cash provided by operating activities during 2004 was $3.1 million, consisting of a net loss of $1.3 million, adjusted for non-cash items of depreciation and amortization of $2.4 million, safety needle asset impairment charge of $2.8 million, non-cash consulting services of $7,000 offset in part by the net change in our deferred tax asset of $600,000. We also had a net change in operating assets and liabilities of $212,000.

Net cash used in investing activities during 2004 was $3.8 million, consisting primarily of the purchase of equipment totaling $1.4 million, additions to intangible assets totaling $411,000 and cash paid for the BCI acquisition of $2.0 million.

Net cash used in financing activities during 2004 was $38,000. We made principal payments on capital leases of $75,000 and payments on our note payable to bank of $1.0 million. This was offset by proceeds from option exercises of $155,000 and proceeds on our line of credit totaling $882,000.

On October 23, 2003, we entered into a financing arrangement with a bank that included a five-year term loan of $5 million, which was used to finance a portion of the BCI acquisition, and a $3 million line of credit, $2.1 million of which was available at December 31, 2004. The borrowings are secured by substantially all of our assets and also contain financial covenants that must be met on a quarterly basis. The agreement also prohibits the payment of

dividends without the consent of the lender. At December 31, 2004, we were in violation of certain of these covenants, due to the $2.8 million safety needle asset impairment charge (see Note 11 to the consolidated financial statements in this Form 10-K). These violations were subsequently waived by the bank on February 9, 2005.

Payments on the term loan consist of monthly principal payments of $83,334 plus interest at Libor plus 2.5%. These payments commenced in November 2003. The line of credit bears interest at Libor plus 2.25% with no minimum interest due and expires on April 30, 2005. The availability under the line is subject to borrowing base requirements, and advances are at the discretion of the lender. There were borrowings of $882,000 under the line of credit at December 31, 2004.

As of December 31, 2004, our working capital was $5.2 million, or a current ratio of 2.3 to 1, compared to working capital of $4.6 million or a current ratio of 1.9 to 1 as of December 31, 2003. Accounts receivable decreased $463,000 primarily due to faster collections at our ELT facility in 2004 (45 days in 2004 versus 79 days in 2003). Inventory increased $885,000 during 2004 as we moved to a new distribution strategy of maintaining higher levels of finished goods for our customers. While this strategy has the short-term impact of increasing our inventories, it significantly simplifies the process our customers go through when they order our products. We had cash totaling $363,000 as of December 31, 2004. Because we have been utilizing our bank line of credit, we have been using excess cash to pay down the credit line in order to minimize interest expense. We will continue to maintain a small cash balance while we utilize our line of credit.

A summary of our contractual cash obligations at December 31, 2004 is as follows:

			Payments due by period			
Contractual Obligations	**Total**	**2005**	**2006**	**2007**	**2008**
Long-term debt, including interest	$ 4,264,156	$ 1,229,819	$ 1,117,577	$ 1,065,319	$ 851,441
Operating leases	1,134,679	438,698	323,918	191,108	180,955
Total contractual cash obligations	**$ 5,398,835**	**$ 1,668,517**	**$ 1,441,495**	**$ 1,256,427**	**$ 1,032,396**

We also have a commercial commitment as described below:

Other Commercial Commitment	**Total Amount Committed**	**Outstanding at December 31, 2004**	**Date of Expiration**
Line of credit	$ 3,000,000	$ 881,652	April 30, 2005

We had $362,625 in cash and cash equivalents as of December 31, 2004. In connection with our acquisition of BCI, we are required to make an additional payment of $488,856 related to the 2004 Contingent Payment that is due on March 31, 2005. In February 2004, we entered into an amendment to the Asset Purchase Agreement with BIOMEC Inc., under which we agreed to pay the 2004 Contingent Payment as 80% stock and 20% cash. In addition, the value of the stock to be issued in conjunction with the contingent payment would be valued at no less than $11.56 or more than $15.63 per share. Based on these parameters, the 2004 Contingent Payment will be made in the form of $97,771 in cash and $391,085 in common stock (an estimated 33,831 shares). Under the terms of the Asset Purchase Agreement, the amount of the 2004 contingent payment is to be doubled if, on or before December 31, 2004, ELT executed supply agreements with one or more specified customers having minimum terms specified in the Asset Purchase Agreement. The Company has determined that the conditions for doubling were not met and notified BIOMEC. Under the Asset Purchase Agreement, BIOMEC has the right to review the Enpath documentation with respect to determination of the 2004 contingent payment. If BIOMEC disputes the amount due to it under the 2004 contingent payment, the Asset Purchase Agreement establishes a dispute resolution mechanism under which the matter may be referred to a third party accounting firm. BIOMEC has requested, and the Company has delivered, supporting documentation with respect to the computation of the 2004 contingent payment.

While we believe that we have sufficient resources with our current cash and credit facility to make payments required under the acquisition, to meet our long-term debt obligations and fund our planned operations for fiscal 2005, there is no assurance that we will not need additional capital in the future. Sources of additional capital may include additional debt

financing or the sale of debt or equity securities. There can be no assurance that we will be able to successfully obtain additional capital on favorable terms.

Critical Accounting Policies and Estimates

Our significant accounting policies and estimates are summarized in the footnotes to our annual consolidated financial statements. Some of our accounting policies require management to exercise significant judgment in selecting the appropriate assumptions for calculating financial estimates. These judgments are subject to an inherent degree of uncertainty and are based on our historical experience, known trends in our industry, terms of existing contracts and other information from outside sources, as appropriate. Actual results may differ from these estimates under different assumptions and conditions. Certain of the most critical policies that require significant judgment are as follows:

Revenue Recognition

We recognize revenue in accordance with Staff Accounting Bulletin 104, *Revenue Recognition* when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the selling price is fixed or determinable and collectability is reasonably assured.

Allowance for Doubtful Accounts

We establish estimates of the uncollectability of accounts receivable. Our management analyzes accounts receivable, historical write-offs as bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. We maintain an allowance for doubtful accounts at an amount that we estimate to be sufficient to provide adequate protection against losses resulting from collecting less than full payment on receivables. A considerable amount of judgment is required when assessing the realizability of receivables, including assessing the probability of collection and the current credit-worthiness of each customer. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, an additional provision for doubtful accounts may be required. We have not experienced significant bad debt expense and our reserve for doubtful accounts of $69,000 should be adequate for any exposure to loss in our December 31, 2004 accounts receivable.

Allowance for Excess and Slow-Moving Inventory

Inventories, which are composed of purchased parts and subassemblies, work in process and finished goods, are valued at the lower of cost or market with cost being determined by the first-in, first-out method. On a periodic basis, we analyze the level of inventory on hand, its cost in relation to market value and estimated customer requirements to determine whether write-downs for excess or slow-moving inventory are required. Actual customer requirements in any future periods are inherently uncertain and thus may differ from estimates. If actual or expected requirements were significantly greater or lower than the established reserves, a reduction or increase to the obsolescence allowance would be recorded in the period in which such a determination was made. We have established reserves for excess and slow-moving inventories and believe the reserve of $124,000 at December 31, 2004 is adequate.

Valuation of Goodwill and Long-Lived Assets including Intangible Assets with Finite Lives

As a matter of policy, we review our major assets for impairment at least annually, and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. The test for impairment of finite life assets requires us to make estimates of the fair value of our long-lived assets, primarily based on projected future cash flows using discount rates determined by management to be commensurate with the

risk inherent in the current business model or another valuation technique. For indefinite life intangibles, we determine whether the carrying amount of the reporting unit s net assets exceeds its expected future cash flows. If we determine that the carrying value of these assets may not be recoverable, we will be required to reduce the valuation of these assets on our financial statements. Significant intangible assets include the following:

Goodwill

The estimate of the fair value of the goodwill that resulted from our recent acquisition of BCI and the annual impairment test of this asset are significant estimates and require judgment in projecting future cash flows as well as considering the current amount recorded of $9.6 million.

Safety Needle

The determination of the safety needle intangible and equipment impairments during 2004 was a significant estimate in 2004. In addition, the realization of our remaining investment in the license agreement and manufacturing equipment related to the safety needle (aggregate net balance of $263,250 at December 31, 2004) is dependent upon attaining a sustained level of sales of this product. We currently are comfortable projecting a level of future sales that is sufficient to allow us to fully realize the adjusted investment we have remaining in the safety needle inventory and equipment. However, if actual sales fail to reach these levels, our adjusted investment in this product may not be fully realizable in the future (see Note 11 to the consolidated financial statements in this Form 10-K).

Other Intangibles with Finite Lives

Other intangibles with finite lives consist primarily of purchased technology, trade name, patents, customer relationships and trademarks (aggregate net balance of $5.9 million at December 31, 2004) are being amortized on a straight-line method over their estimated useful lives, ranging from 5 to 30 years (see Note 3 to the consolidated financial statements in this Form 10-K).

Allocation of Purchase Price Paid for the BCI Acquisition

As a result of our acquisition of BCI, (see Note 4 to the consolidated financial statements in this Form 10-K), we were required to allocate the consideration paid for BCI between tangible assets, identifiable intangible assets, including in-process research and development (IPR&D), and goodwill. The value assigned to IPR&D was determined by identifying those acquired specific in-process research and development projects that would be continued and for which (a) technological feasibility had not been established at the acquisition date, (b) there was no alternative future use, and (c) the fair value was estimable with reasonable reliability. We were required to make significant estimates to determine the portion of the purchase price allocated to IPR&D and other intangible assets. We engaged an independent valuation firm to assist in the determination of the fair values of the intangible assets. The amount of the purchase price allocated to IPR&D and other intangible assets was determined by estimating the future cash flows of each project or technology and discounting the net cash flows back to their present values. The discount rates used in calculating the present value of the various intangibles were in accordance with accepted valuation methods and for IPR&D also included the consideration of the risks of not achieving commercial feasibility. The goodwill that resulted from this acquisition represents the excess of the total purchase price over the fair value of the total tangible and identifiable intangible net assets acquired.

In-Process Research and Development (IPR&D)

Development projects, that had not yet reached technological feasibility and had no alternative future use, were classified as in-process research and development. The purchase price assigned to those projects was immediately expensed on the acquisition date and was reflected as an expense in the 2003 consolidated statements of operations. The in-process research and development projects were as follows: steroid leads ($1.3 million), adapters ($1 million) and an implant tool ($350,000). The estimated value of these projects was determined using a discounted cash flow model. The discount rates used considered the stage of completion and the risk surrounding the successful development and commercialization of each of the purchased in-process technology projects. Some of the original assumptions related to these projects were as follows:

Initial Assumptions October 23, 2003

	Leads	Tool	Adaptor
Costs incurred as of 10/23/03	$ 47,000	$ 203,000	$ 75,000
Estimated cost to complete	$ 602,000	$ 658,000	$ 529,000
Percent complete (dollars)	7.2%	23.6%	12.4%
Months spent up to 10/23/03	12	12	12
Estimated months to complete	24	12	12
Percent complete (months)	33.3%	50.0%	50.0%
Year revenues estimated to begin	2005	2004	2004
Regulatory approval received	No	No	No

The discount rates used in valuing the developed, core and in-process technologies ranged from 26% to 50%. A higher discount rate was used to value the in-process research and development, due to the inherent uncertainties surrounding the successful development of the in-process projects, FDA approval, and the market acceptance of the products. The percentage of completion for each of the in-process projects was determined using costs incurred to date on each project as compared to the remaining estimated costs to be incurred to bring each of the projects to technological feasibility.

We believe that the three in-process projects described above will reach technological feasibility. However, because of the risks associated with the commercial viability of these products, there can be no assurance that these projects will actually achieve commercialization. These risks include the delay or failure to obtain the necessary regulatory approvals or the failure to achieve market acceptance. As of March 21, 2005, we had received European approval to begin selling the steroid lead through one OEM partner, but had not yet obtained regulatory approvals to market the other products. Updated information related to these three projects is summarized below:

Status On December 31, 2004

	Leads	Tool	Adaptor
Costs incurred as of 12/31/04	$ 1,038,000	$ 686,000	$ 85,000
Estimated cost to complete	$ 350,000	$ 132,000	$ 153,000
Percent complete (dollars)	74.8%	83.9%	35.7%
Months spent up to 12/31/04	26	26	26
Estimated months to complete	9	7	7
Percent complete (months)	74.3%	78.8%	78.8%
Year revenues estimated to begin	2005	2005	2005
Regulatory approval received	No	No	No

The scope of the adaptor project has been significantly reduced due to entering into an exclusive arrangement with a major CRM company for IS-4 adaptors.

Recently Issued Accounting Pronouncements

In November 2004, FASB issued Statement No. 151, *Inventory Costs*. Statement No 151 amends the guidance in ARB No. 43, Chapter 4, *Inventory Pricing*, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material (spoilage). In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of

the production facilities. The application of Statement No. 151 did not have any effect on our consolidated financial statements.

In December 2004, the Financial Accounting Standards Board (FASB) published FASB Statement No. 123 (revised 2004), *Share-Based Payment* (FAS 123(R) or the Statement). FAS 123(R) requires that the compensation cost relating to share-based payment transactions, including grants of employee stock options, be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instruments issued. FAS 123(R) covers a wide range of share-based compensation arrangements including stock options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. FAS 123(R) is a replacement of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, and

supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related interpretive guidance (APB 25).

The effect of the Statement will be to require entities to measure the cost of employee services received in exchange for stock options based on the grant-date fair value of the award, and to recognize the cost over the period the employee is required to provide services for the award. FAS 123(R) permits entities to use any option-pricing model that meets the fair value objective in the Statement. We will be required to apply FAS 123(R) beginning July 1, 2005.

Forward Looking Statements

Statements included in this Annual Report on Form 10-K, in the letter to shareholders, in our quarterly reports, in filings by us with the Securities and Exchange Commission, in our press releases, and oral statements made with the approval of an authorized executive officer that are not historical or current facts are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Certain important factors could cause results to differ materially from those anticipated by some of these statements. Investors are cautioned that all forward-looking statements involve risks and uncertainties. A number of factors that could cause results to differ materially are those discussed in the section of this Annual Report on Form 10-K entitled Risk Factors. Additional factors that could cause results to differ materially are the following: our ability to complete the integration of the ELT operation; our dependence upon a limited number of key customers for our revenue; our ability to complete development of our Myopore Rx steroid epicardial lead and Fastac Flex delivery tool and obtain all necessary FDA and European approval to market these devices; our ability and our distribution partners ability to successfully introduce the Myopore Rx and Fastac Flex; the ability of our customers to successfully develop and market therapies that utilize our advanced delivery systems; our dependence upon licensing agreements with third parties for the technology underlying some of our products, our ability to effectively manufacture our products, including the new Myopore Rx steroid lead and the Fastac Flex delivery tool in anticipated required quantities; our ability to develop or acquire new products to increase revenues; our ability to attract and retain key personnel; introduction of competitive products; our ability to successfully protect our intellectual property against misappropriation or claims of infringement by third parties; government regulatory matters; economic conditions; and our ability to raise capital. All our forward-looking statements, whether written or oral are expressly qualified by these cautionary statements. In addition, we disclaim any obligation to update forward-looking statements to reflect events or circumstances after the date hereof.

Risk Factors

The following are important factors that could cause actual results to differ materially from those anticipated in any forward-looking statements made by or on behalf of the Company.

We have three major customers and depend on these customers for a significant portion of our revenues.

Medtronic accounted for approximately 41%, 44% and 67%; C.R. Bard accounted for approximately 16%, 18% and 13%; and St. Jude Medical accounted for approximately 11%, 7% and 0% of our total sales from operations in 2004, 2003 and 2002, respectively. We anticipate that our expected near-term future growth in sales will be tied in part to these customers sales of their existing products, as well as new products incorporating our products as components. Because we anticipate that sales of our components and kits to Medtronic for use in Medtronic s Left Ventricle Lead Delivery Systems (LVLDS) will continue to decrease, we are attempting to expand our customer base and our product offerings. We cannot ensure that we will be successful in making sales to new customers, increasing sales to existing customers other than Medtronic or developing and marketing new products. To the extent that we do not expand our customer base and product offerings, sales to Medtronic and our other key customers will continue to account for a major portion of our revenues, making us vulnerable to the risks described below. We anticipate that our concentration of business with Medtronic will approximate 40% in 2005 with our other two customers making up approximately 14% and 8%, respectively.

On October 11, 2002, we entered into a supply agreement with Medtronic that requires Medtronic to purchase exclusively from us all of its requirements for introducer kits manufactured by us for a period of five years. There are no minimum purchase obligations under the supply agreement for our current products or any future products we may develop. If sales of Medtronic s products that incorporate our products as components decrease or if Medtronic does not develop new products incorporating our products as components, future sales of our products to Medtronic and our

results of operations would be adversely affected. Further, any action by Medtronic to discontinue any of its products that incorporate our products, to redesign or change the technical requirements for its products so that our products would not meet those requirements, or to otherwise limit or discontinue its purchases from us would have a material adverse impact on sales of our products and, consequently, our financial results.

In addition, under the supply agreement, if we fail to supply certain products, Medtronic may manufacture and sell these products or have these products manufactured by another party. Our failure to supply these products would result in a loss of sales to Medtronic and would have a material adverse impact on our revenues. Moreover, the supply agreement establishes the pricing Medtronic receives with respect to each product and provides that if we extend more favorable pricing to any other customer, that same pricing will also be extended to Medtronic. A reduction in our pricing with Medtronic would likely result in a decline in our overall revenue.

We may need additional capital in the future.

We had $362,625 in cash and cash equivalents as of December 31, 2004. In connection with our acquisition of BCI, we are required to make an additional payment of $488,856 related to the 2004 Contingent Payment that is due on March 31, 2005. In February 2004, we entered into an amendment to the Asset Purchase agreement with BIOMEC Inc., under which we agreed to pay the 2004 Contingent Payment as 80% stock and 20% cash. In addition, the value of the stock to be issued in conjunction with the contingent payment would be valued at no less than $11.56 or more than $15.63 per share. Based on these parameters, the 2004 Contingent Payment will be made in the form of $97,771 in cash and $391,085 in common stock (an estimated 33,831 shares). Under the terms of the Asset Purchase Agreement, the amount of the 2004 contingent payment is to be doubled if, on or before December 31, 2004, ELT executed supply agreements with one or more specified customers having minimum terms specified in the Asset Purchase Agreement. The Company has determined that the conditions for doubling were not met and notified BIOMEC. Under the Asset Purchase Agreement, BIOMEC has the right to review the Enpath documentation with respect to determination of the 2004 contingent payment. If BIOMEC disputes the amount due to it under the 2004 contingent payment, the Asset Purchase Agreement establishes a dispute resolution mechanism under which the matter may be referred to a third party accounting firm. BIOMEC has requested, and the Company has delivered, supporting documentation with respect to the computation of the 2004 contingent payment.

On October 23, 2003, we entered into a financing arrangement with a bank that included a five-year term loan of $5 million, which was used to finance a portion of the BCI acquisition, and a $3 million line of credit, $2.1 million of which was available at December 31, 2004. The borrowings are secured by substantially all of our assets and also contain financial covenants that must be met on a quarterly basis. The agreement also prohibits the payment of dividends without the consent of the lender. At December 31, 2004, we were in violation of certain of these covenants, due to the $2.8 million safety needle asset impairment charge (see Note 11 to the consolidated financial statements in this Form 10-K). These violations were subsequently waived by the bank on February 9, 2005.

While we believe that we have sufficient resources with our current cash and the new credit facility to make payments required under the acquisition, meet our long-term debt obligations and fund our planned operations for fiscal 2005, there is no assurance that we will not need additional capital in the future. Sources of additional capital may include additional debt financing or the sale of debt or equity securities. There can be no assurance that we will be able to successfully obtain additional capital on favorable terms.

We have only attained profitability recently and had a net loss of $1.3 million in 2004.

We became a publicly traded company in 1991 and incurred losses in each of the years from 1991 to 1999. For the years ended December 31, 2000, 2001, 2002, 2003 and 2004, we reported net income of $162,000; $6.6 million; $2.9 million, $309,000 and a net loss of $1.3 million, respectively. Net income for 2001 included $3.1 million related to the sale of the gynecology division, as well as recognition of income tax benefit of $923,000 resulting from the elimination of the valuation allowance on deferred tax assets. In 2003, ELT/BCI was profitable for the first time in many years. However, our 2003 results only included income from ELT from October 24, 2003 to December 31, 2003 and included a one-time write-off of $2.7 million related to the purchase of in-process research and development costs associated with the acquisition. The net loss for 2004 included a one-time charge of $2.8 million related to safety needle asset impairment. There is no assurance that we will be able

to effectively integrate the operation of ELT and regain and maintain profitable operations in the future.

The government heavily regulates our business.

The medical products that we sell and propose to sell are subject to regulation by the FDA and by comparable agencies in certain states and foreign countries. The process of complying with requirements of the FDA and other agencies can be costly and time consuming. We have received clearance from the FDA to market our vessel introducer products, safety needle, epicardial lead and implant tool. As discussed above in Products Lead Technologies, we currently have a PMA submission pending with the FDA related to our epicardial steroid lead, and a 510k submission related to our steerable introducer product. There is no assurance that any future additional clearance can be obtained. In addition, once obtained, these clearances are subject to review, and later discovery of previous unknown problems may result in restrictions on the marketing of a product or withdrawal of the product from the market. We are also subject to certain FDA regulations governing manufacturing practices, packaging and labeling. Non-compliance with these regulations can result in product recalls or other sanctions which could have a material adverse effect on the Company.

We depend on patents and proprietary technology.

Our success may depend on our ability to obtain patent protection for our products and processes, to preserve our trade secrets and to operate without infringing on the proprietary rights of third parties. We have 18 United States and foreign patents issued related to various aspects of vessel introducers and stimulation leads. There can be no assurance that any future patent protection will be granted, that the scope of any patent protection will exclude competitors or that any of our patents will be held valid if subsequently challenged. The validity and breadth of claims covered in medical technology patents involve complex legal and factual questions and therefore may be highly uncertain. We also rely upon unpatented trade secrets, and no assurance can be given that others will not independently develop or otherwise acquire substantially equivalent trade secrets or otherwise gain access to our proprietary technology.

We depend on our key personnel.

Failure to attract and retain skilled personnel could hinder our research and development and manufacturing efforts. Our future success depends to a significant degree upon the continued services of key technical and senior management personnel. Our future success also depends on our continuing ability to attract, retain and motivate highly qualified managerial and technical personnel. The inability to retain or attract qualified personnel could have a significant negative effect upon our efforts and thereby materially harm our business and financial condition.

We face intense competition and rapid technological change.

We are faced with intense competition and rapid technological and industry change and, if our competitors existing products or new products are more effective or superior to our products, the commercial opportunity for our products will be reduced or eliminated. We face intense competition from other device manufacturers, many of whom are significantly larger and have greater financial, technical, research, marketing, sales, distribution and other resources than we do. We believe there will be intense price competition for products developed in our markets. Our competitors may develop or market technologies and products that are more effective or commercially attractive than any we are developing or marketing. Our competitors may succeed in obtaining regulatory approval and introducing or commercializing products before we do. Such developments could have a significant negative effect on our financial condition. Even if we are able to compete successfully, we may not be able to do so in a profitable manner. The medical device industry is generally characterized by rapid technological change, changing customer needs, and frequent new product introductions. Our products may be rendered obsolete as a result of future innovations.

We risk product liability claims and product recalls.

The manufacture and sale of medical products entails significant risk of product liability claims or product recalls. Our existing insurance coverage limits may not be adequate to protect us from any liabilities we might incur in connection with the clinical trials or sales of our products. We may require increased product liability coverage as our products are commercialized. Insurance is expensive and may not be available on acceptable terms, or at all. A successful product liability claim or series of claims brought against us in excess of our insurance coverage, or a recall of our products, could have a significant negative effect on our business and financial condition. Even unsuccessful claims

could result in the expenditure of funds and management time and could have a negative impact on our business.

We have limited sources of supply for our products.

We currently purchase, and will in the future purchase, components and raw materials from outside vendors. Although we have identified alternative suppliers for key components and raw materials, at the present time we generally use one source of supply for each component and raw material. If a key supplier becomes unwilling or unable to supply any such component or raw material in a timely manner, or if approval of a proposed supplier is delayed, withheld or withdrawn, we could experience delays in obtaining alternative suppliers, which may adversely affect our business.

We have a limited public market for our common stock.

As of March 16, 2005, we had 5,914,029 shares of common stock outstanding. The average daily trading volume approximated 47,000 shares per day in 2001, 26,000 shares per day in 2002, 18,000 shares per day in 2003, 14,000 shares per day in 2004 and 13,000 shares per day through March 15, 2005. There can be no assurance that an active market will exist for our common stock, or that our common stock could be sold without a significant negative impact on the publicly quoted price per share.

Our future operating results may fluctuate.

If our revenue declines in a quarter compared to the revenue in the previous quarter, our earnings will likely decline as well, due to the fact that many of our expenses are relatively fixed. In particular, research and development, sales and marketing and general and administrative expenses are not affected directly by variations in revenue. In some future quarter or quarters, due to a decrease or shortfall in revenue or for some other reason, our operating results likely will be below the expectations of securities analysts or investors. In this event, the market price of our common stock may fall abruptly and significantly.

Our research and development projects may not reach technological feasibility.

We are planning on spending approximately $4.8 million in 2005 to continue the development of several new products. These products include the epicardial steroid lead, the implant tool, the next generation of adaptors, steerable delivery sheaths and ergonomic handle and steerable catheters. While we believe that these products will reach technological feasibility, because of the risks associated with the commercial viability of these products, there can be no assurance that these projects will actually achieve commercialization. Such risks include the delay or failure to obtain the necessary regulatory approvals or the failure to achieve market acceptance.

Item 7A Quantitative and Qualitative Disclosures About Market Risk

We are exposed to changes in interest rates primarily as a result of our borrowing activities used to maintain liquidity. Our earnings have not been materially affected by changes in interest rates on our floating interest rate debt (less than $50,000 for 2004) because interest rates remained fairly stable during the year and we only started utilizing our line of credit beginning in June 2004. Based on our current borrowings and anticipated line of credit requirements in 2005, an increase of 100 basis points in prevailing interest rates would increase our annual interest expense by less than $100,000.

Item 8 **Financial Statements and Supplementary Data**

Quarterly Financial Data

The consolidated statements of operations, shareholders equity and cash flows for each of the years in the three-year period ended December 31, 2004, and the related consolidated balance sheets of the Company as of December 31, 2004 and 2003, together with the related notes thereto and the report of independent registered public accounting firm appear on pages 27 through 47 hereof.

The following tabulation presents the Company s unaudited quarterly results of operations for 2004 and 2003:

In thousands except for per share data

	2004				
	Q1	**Q2 (A)**	**Q3**	**Q4**	**Total**
Net sales	$ 7,297	$ 7,295	$ 7,064	$ 7,833	$ 29,489
Gross profit	2,768	2,745	2,806	2,851	$ 11,170
Operating income (loss)	445	(2,620)	363	28	$ (1,784)
Net income (loss)	**$ 273**	**$ (1,816)**	**$ 209**	**$ 38**	**$ (1,296)**
Basic net income (loss) per common share	$ 0.05	$ (0.31)	$ 0.04	$ 0.01	$ (0.22)
Diluted net income (loss) per common share	$ 0.05	$ (0.31)	$ 0.03	$ 0.01	$ (0.22)

	2003				
	Q1	**Q2**	**Q3**	**Q4 (B)**	**Total**
Net sales	$ 4,667	$ 4,338	$ 4,042	$ 6,556	$ 19,603
Gross profit	2,071	1,820	1,632	2,453	$ 7,976
Operating income (loss)	993	745	601	(2,082)	$ 257
Net income (loss)	**$ 632**	**$ 474**	**$ 381**	**$ (1,178)**	**$ 309**
Basic net income (loss) per common share	$ 0.13	$ 0.10	$ 0.08	$ (0.22)	$ 0.06
Diluted net income (loss) per common share	$ 0.13	$ 0.10	$ 0.08	$ (0.22)	$ 0.06

Notes

(A) The second quarter of 2004 includes a $2.81 million safety needle asset impairment charge (see Note 11 to the consolidated financial statements in this Form 10-K)

(B) The fourth quarter of 2003 includes a $2.65 million charge for the purchased in-process research and development that resulted from the acquisition of BCI in the 4th quarter (see Note 4 to the consolidated financial statements in this Form 10-K).

Audited Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of

Enpath Medical, Inc.

Minneapolis, Minnesota

We have audited the accompanying consolidated balance sheets of Enpath Medical, Inc. (formerly Medamicus, Inc.) and Subsidiary, as of December 31, 2004 and 2003, and the related consolidated statements of operations, shareholders equity, and cash flows for each year in the three year period ended December 31, 2004. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall 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 financial position of Enpath Medical, Inc. and Subsidiary, as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each year in the three year period ended December 31, 2004 in conformity with U.S. generally accepted accounting principles.

/s/ McGLADREY & PULLEN, LLP

Minneapolis, Minnesota
January 18, 2005 (except for Note 6,
as to which the date is February 9, 2005)

Consolidated Balance Sheets

	December 31, 2004	December 31, 2003
ASSETS (Note 6)		
Current assets:		
Cash and cash equivalents	$ 362,625	$ 1,067,935
Accounts receivable, less allowance for doubtful accounts of $69,000 and $70,000, respectively (Note 9)	3,660,049	4,122,570
Inventories, less allowance for slow-moving inventory of $124,000 and $155,000, respectively (Note 2)	4,624,183	3,738,853
Prepaid expenses and other assets	230,443	215,377
Income taxes receivable	310,683	99,931
Deferred income taxes (Note 5)	194,000	156,000
Total current assets	**9,381,983**	**9,400,666**
Property and equipment: (Notes 7 and 11)		
Equipment	6,148,662	7,162,779
Office furniture, fixtures and computers	1,736,531	1,426,714
Leasehold improvements	1,576,759	1,448,678
	9,461,952	**10,038,171**
Less accumulated depreciation and amortization	(4,285,866)	(3,176,423)
Net property and equipment	**5,176,086**	**6,861,748**
Goodwill (Note 4)	9,593,662	8,984,824
Intangible assets with finite lives, net (Notes 3, 4 and 11)	5,861,045	7,717,656
Deferred income taxes (Note 5)	1,154,964	596,000
TOTAL ASSETS	**$ 31,167,740**	**$ 33,560,894**
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Bank line of credit payable (Note 6)	$ 881,652	$
Current maturities of note payable to bank (Note 6)	1,000,000	1,000,000
Current installments of capital lease obligations (Note 7)	64,420	70,793
Accounts payable	927,196	731,390
Accrued compensation	810,016	642,536
Other accruals	260,946	287,102
Accrued acquisition payments (Note 4)	217,771	2,110,476
Total current liabilities	**4,162,001**	**4,842,297**
Long-term liabilities:		
Notes payable to bank, less current maturities (Note 6)	2,833,324	3,833,332
Capital lease obligations, less current installments (Note 7)	6,473	75,498
Accrued acquisition payments (Note 4)	391,085	1,819,473
Total long-term liabilities	**3,230,882**	**5,728,303**
Total liabilities	**7,392,883**	**10,570,600**
Commitments and contingencies (Notes 4,7,10 and 11)		
Shareholders equity: (Note 8)		
Preferred stock-undesignated, authorized 1,000,000 shares		
Common stock-$.01 par value, authorized 20,000,000 shares; issued and outstanding 5,887,929 and 5,703,526 shares, respectively	58,879	57,035
Additional paid-in capital	21,283,676	19,204,591
Retained earnings	2,432,302	3,728,668
Total shareholders equity	**23,774,857**	**22,990,294**
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	**$ 31,167,740**	**$ 33,560,894**

See accompanying notes to consolidated financial statements

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Consolidated Statements of Operations

Years Ended December 31,	2004	2003	2002
Net sales (Note 9)	$ 29,489,034	$ 19,603,441	$ 17,879,234
Cost of sales	18,318,793	11,626,944	9,503,690
Gross profit	**11,170,241**	**7,976,497**	**8,375,544**
Operating expenses:			
Research and development	4,730,013	1,987,122	1,661,373
Selling, general and administrative	5,415,287	3,082,446	2,272,717
Purchased in-process research and development (Note 4)		2,650,000	
Impairment charge on safety needle investment (Note 11)	2,809,199		
Total operating expenses	**12,954,499**	**7,719,568**	**3,934,090**
Operating income (loss)	**(1,784,258)**	**256,929**	**4,441,454**
Other income (expense):			
Interest expense	(205,636)	(51,727)	(22,918)
Interest income	1,613	39,787	78,233
Other	(6,907)	(8,873)	(4,196)
Total other income (expense)	**(210,930)**	**(20,813)**	**51,119**
Income (loss) before income taxes	**(1,995,188)**	**236,116**	**4,492,573**
Income tax expense (benefit) (Note 5)	(698,822)	(72,641)	1,633,939
Net income (loss)	**$ (1,296,366)**	**$ 308,757**	**$ 2,858,634**
Earnings (loss) per common share:			
Basic	$ (0.22)	$ 0.06	$ 0.61
Diluted	$ (0.22)	$ 0.06	$ 0.57
Weighted average common and common equivalent shares outstanding:			
Basic	5,843,103	4,917,623	4,711,634
Diluted	5,843,103	5,168,675	4,973,966

See accompanying notes to consolidated financial statements

Consolidated Statements of Shareholders Equity

Years Ended December 31, 2004, 2003 and 2002	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Retained Earnings	Total
Balances at December 31, 2001	**4,601,567**	**$ 46,016**	**$ 11,328,818**	**$ 561,277**	**$ 11,936,111**
Options exercised (Note 8)	36,600	366	83,592		83,958
Tax benefit from options exercised (Note 5)			52,000		52,000
Warrants exercised (Note 8)	88,426	884	495,186		496,070
Warrants issued to consultant for services			1,139		1,139
Net income for the year ended December 31, 2002				2,858,634	2,858,634
Balances at December 31, 2002	**4,726,593**	**$ 47,266**	**$ 11,960,735**	**$ 3,419,911**	**$ 15,427,912**
Options exercised (Note 8)	43,600	436	180,937		181,373
Common stock issued in connection with acquisition (Note 4)	933,333	9,333	6,862,818		6,872,151
Tax benefit from options exercised (Note 5)			141,000		141,000
Options issued to consultant for services			7,000		7,000
Warrants issued in connection with acquisition (Notes 4 and 8)			52,101		52,101
Net income for the year ended December 31, 2003				308,757	308,757
Balances at December 31, 2003	**5,703,526**	**$ 57,035**	**$ 19,204,591**	**$ 3,728,668**	**$ 22,990,294**
Options exercised (Note 8)	50,815	508	154,944		155,452
Common stock issued in connection with acquisition (Note 4)	133,588	1,336	1,818,137		1,819,473
Tax benefit from options exercised (Note 5)			99,504		99,504
Options issued to consultant for services			6,500		6,500
Net loss for the year ended December 31, 2004				(1,296,366)	(1,296,366)
Balances at December 31, 2004	**5,887,929**	**$ 58,879**	**$ 21,283,676**	**$ 2,432,302**	**$ 23,774,857**

See accompanying notes to consolidated financial statements

Consolidated Statements of Cash Flows

Years Ended December 31,	2004	2003	2002
Cash flows from operating activities:			
Net income (loss)	$ (1,296,366)	$ 308,757	$ 2,858,634
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation	1,538,341	988,497	492,008
Amortization	883,550	411,773	406,259
Write-off of purchased in-process research and development (Note 4)		2,650,000	
Impairment charge on safety needle investment (Note 11)	2,809,199		
Loss on disposal of equipment		4,220	383
Non-cash consulting services	6,500	7,000	1,139
Deferred income taxes	(596,964)	(802,000)	225,000
Changes in operating assets and liabilities:			
net of effect of acquisition			
Accounts receivable	462,521	(446,594)	(204,916)
Inventories	(885,330)	465,519	(153,430)
Prepaid expenses and other assets	(15,066)	(44,640)	(47,618)
Income taxes receivable	(111,248)		
Accounts payable	195,806	(602,534)	(197,917)
Accrued liabilities	141,324	(277,974)	115,843
Income taxes payable		(1,206,913)	1,219,827
Net cash provided by operating activities	**3,132,267**	**1,455,111**	**4,715,212**
Cash flows from investing activities:			
Purchase of property and equipment	(1,397,598)	(1,184,531)	(3,161,159)
Proceeds from disposal of property and equipment		10,720	384
Additions to intangible assets	(411,201)	(251,001)	(98,224)
Net cash paid for acquisition (Note 4)	(1,990,476)	(11,212,310)	
Net cash used in investing activities	**(3,799,275)**	**(12,637,122)**	**(3,258,999)**
Cash flows from financing activities:			
Principal payments on capital lease obligations	(75,398)	(69,121)	(82,356)
Proceeds from long-term debt		5,000,000	
Principal payments on long-term debt	(1,000,008)	(166,668)	
Net proceeds on line of credit	881,652		
Proceeds from exercise of stock options and warrants	155,452	181,373	580,028
Net cash provided by (used in) financing activities	**(38,302)**	**4,945,584**	**497,672**
Net increase (decrease) in cash and cash equivalents	**(705,310)**	**(6,236,427)**	**1,953,885**
Cash and cash equivalents, beginning of year	**1,067,935**	**7,304,362**	**5,350,477**
Cash and cash equivalents, end of year	**$ 362,625**	**$ 1,067,935**	**$ 7,304,362**
Supplemental disclosure of cash flow information:			
Cash paid during the period for interest	$ 204,984	$ 51,727	$ 22,918
Cash paid during the period for income taxes	$ 9,500	$ 1,937,154	$ 189,112
Supplemental schedule of non-cash investing and financing activities:			
Equity increase from tax benefit from stock option exercises (Note 5)	$ 99,504	$ 141,000	$ 52,000
Common stock issued in payment of contingent purchase price	$ 1,819,473	$ 6,872,151	$
Accrued acquisition payments not yet paid (Note 4)	$ 488,856	$ 2,110,476	$

See accompanying notes to consolidated financial statements

Notes To Consolidated Financial Statements

1. NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

NATURE OF BUSINESS

The Company is a medical products company engaged in:

designing, developing, manufacturing and marketing percutaneous vessel introducers, safety needles and related vascular delivery products;

designing, developing, manufacturing and marketing implantable stimulation leads, lead delivery systems, and lead accessories for cardiac rhythm management and neuromodulation markets; and

manufacturing medical devices and components for other medical product companies on a contract basis.

On October 23, 2003, the Company completed the acquisition of the net operating assets of BIOMEC Cardiovascular Inc. (BCI) from BIOMEC Inc. (see Note 4 for further details). The Company has included BCI s results in its consolidated financial statements from October 24, 2003 forward. As a result of this transaction, Enpath Medical, Inc. operated with two divisions from October 24, 2003 through December 31, 2004: The Enpath Delivery Systems Division (EDS , formerly Medamicus, Inc.) and the Enpath Lead Technologies Division (ELT , formerly BCI). The divisions are aggregated into one reportable segment: the manufacture and sale of medical devices. The divisions have similar technology, manufacturing, customers and regulatory activities and the Company has combined the sales and marketing and research and development activities to take advantage of similarities in customers and product development. Revenues are primarily derived from designing, developing, manufacturing and marketing medical devices. Net sales by product line for the years ended December 31, 2004 and 2003 were as follows:

		2004		2003
Delivery Systems Product Line	$	20,941,027	$	17,055,674
Lead Technologies Product Line		8,548,007		2,547,767
Total	**$**	**29,489,034**	**$**	**19,603,441**

On February 2, 2004, the Company changed its name from Medamicus, Inc. to Enpath Medical, Inc. The name Enpath reflects the Company s mission to create pathways that enable the delivery of essential medical therapies.

A summary of the Company s significant accounting policies follows:

PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include the accounts of Enpath Medical, Inc. and its wholly owned subsidiary Enpath Lead Technologies, Inc. All material intercompany accounts and transactions have been eliminated in consolidation.

REVENUE RECOGNITION

The Company recognizes revenue upon shipment of products to its customers, FOB shipping point. Shipping and handling charges billed to customers are included in net sales, and shipping and handling costs incurred by the Company are included in cost of sales.

RECENT PRONOUNCEMENTS

In November 2004, FASB issued Statement No. 151, *Inventory Costs*. Statement No 151 amends the guidance in ARB No. 43, Chapter 4, *Inventory Pricing*, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material (spoilage). In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The application of Statement No. 151 did not have any effect on the Company s consolidated financial statements.

In December 2004, the Financial Accounting Standards Board (FASB) published FASB Statement No. 123 (revised 2004), *Share-Based Payment* (FAS 123(R) or the Statement). FAS 123(R) requires that the compensation cost relating to share-based payment transactions, including grants of employee stock options, be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instruments issued. FAS 123(R) covers a wide range of share-based compensation arrangements including stock options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. FAS 123(R) is a replacement of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related interpretive guidance (APB 25).

The effect of the Statement will be to require entities to measure the cost of employee services received in exchange for stock options based on the grant-date fair value of the award, and to recognize the cost over the period the employee is required to provide services for the award. FAS 123(R) permits entities to use any option-pricing model that meets the fair value objective in the Statement. The Company will be required to apply FAS 123(R) as of the beginning of its third quarter in 2005.

FAS 123(R) allows two methods for determining the effects of the transition: the modified prospective transition method and the modified retrospective method of transition. The Company has not yet completed its study of the transition methods or made any decisions about how it will adopt FAS 123(R). However, the pro forma net income effect of using the fair value method for the past three fiscal years is presented in the table under employee stock based compensation below. The pro forma compensation costs presented below and in prior filings for the Company have been calculated using a Black-Scholes option pricing model and may not be indicative of amounts which should be expected in future years. No decisions have been made by management as to which option-pricing model is most appropriate for the Company for future awards.

ESTIMATES

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

DISCLOSURES ABOUT FAIR VALUE OF FINANCIAL INSTRUMENTS

The following methods and assumptions were used to estimate the fair value of each class of certain financial instruments for which it is practicable to estimate that value:

Cash equivalents: The carrying amount approximates fair value because of the short maturity of these instruments.

Notes payable: The fair value of the Company s notes payable are estimated based on the quoted market prices for the same or similar issues or on the current rates offered to the Company for debt of the same remaining maturities with similar collateral requirements. At December 31, 2004 and 2003, the fair value of the Company s notes payable approximated their carrying value.

CASH AND CASH EQUIVALENTS

Cash equivalents consist of highly liquid investments, primarily United States money market securities, with an original maturity of three months or less. The Company maintains its cash in bank accounts, which, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts.

ACCOUNTS RECEIVABLE

Accounts receivable are carried at original invoice amount less an estimate made for doubtful receivables based on a review of all outstanding amounts on a monthly basis. Management determines the allowance for doubtful accounts after reviewing individual customer accounts as well as considering both historical and expected credit loss experience. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

INVENTORIES

Inventories, which are composed of purchased parts and subassemblies, work in process and finished goods, are valued at the lower of cost or market with cost being determined by the first-in, first-out method. On a periodic basis, the Company reviews the level of inventory on hand, its cost in relation to market value and estimated customer requirements to determine whether write-downs for excess or slow-moving inventory are required. If actual or expected requirements were significantly greater or lower than the established reserves, a reduction or increase to the obsolescence allowance would be recorded in the period in which such a determination was made.

PROPERTY AND EQUIPMENT

Property and equipment are stated at cost and depreciated or amortized on a straight-line basis over a period of three to seven years. Leasehold improvements are amortized over the remaining term of the related lease. Repair and maintenance costs are charged to operations as incurred.

INTANGIBLE ASSETS WITH FINITE LIVES

Intangible assets are amortized on a straight-line basis over their estimated useful lives or contractual lives, whichever are shorter (see Note 3). For a description of the intangible assets acquired in the BCI transaction, see Note 4.

GOODWILL

In accordance with Financial Accounting Standards Board (FASB) Statement No. 142, goodwill is tested for impairment annually and additionally if an event occurs or circumstances change that would indicate the carrying amount may be impaired. An impairment loss would generally be recognized when the carrying amount of the reporting unit s net assets exceeds the estimated fair value of the reporting unit. The Company determined that no impairment existed at December 31, 2004 or 2003.

IMPAIRMENT OF LONG-LIVED ASSETS

The Company periodically reviews long-lived assets to determine any potential impairment. The asset carrying values are compared with the expected future cash flows resulting from their use. The expected future cash flows include cash flows resulting from the asset s disposition. The Company would recognize an impairment loss if an asset s carrying value exceeded its expected future cash flow. In 2004, management recorded an impairment charge of approximately $2.8 million related to its investment in the safety needle (see Note 11).

INCOME TAXES

Deferred taxes are provided on an asset and liability method under which deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry-forwards and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax basis. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

EMPLOYEE STOCK-BASED COMPENSATION

At December 31, 2004, the Company has two stock-based employee compensation plans (see Note 8). The Company accounts for those plans under APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. No stock-based employee compensation cost is reflected in net income, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

The Company also grants options and warrants to non-employees for goods and services and in conjunction with certain agreements. These grants are accounted for under FASB Statement No. 123 based on the grant date fair values.

The following table illustrates the effect on net income (loss) and net income (loss) per common share if the Company had applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

	2004	2003	2002
Net income (loss) - as reported	$ (1,296,366)	$ 308,757	$ 2,858,634
Deduct: Total stock-based employee compensation (expense determined under the fair value based method for all awards)	(624,686)	(415,273)	(267,622)
Pro forma net income (loss)	**$ (1,921,052)**	**$ (106,516)**	**$ 2,591,012**
Net income (loss) per common share:			
Basic net income (loss) per share - as reported	$ (0.22)	$ 0.06	$ 0.61
Basic net income (loss) per share - pro forma	$ (0.33)	$ (0.02)	$ 0.55
Diluted net income (loss) per share - as reported	$ (0.22)	$ 0.06	$ 0.57
Diluted net income (loss) per share - pro forma	$ (0.33)	$ (0.02)	$ 0.52
Weighted average common shares outstanding			
Basic	5,843,103	4,917,623	4,711,634
Diluted	5,843,103	5,168,675	4,973,966

The above pro forma effects on net income (loss) and net income (loss) per common share are not likely to be representative of the effects on reported net income (loss) for future years because options vest over several years and additional awards generally are made each year.

RESEARCH AND DEVELOPMENT EXPENSES

The Company incurred research and development expenses of $4,730,013, $1,987,122 and $1,661,373 in 2004, 2003 and 2002, respectively, as well as $2,650,000 of expense from the write-off of purchase price assigned to in-process technology in 2003. The value assigned to purchased in-process technology was determined by identifying those acquired specific in-process research and development projects that would be continued and for which (a) technological feasibility had not been established at the acquisition date, (b) there was no alternative future use, and (c) the fair value was estimable with reasonable reliability. The fair value was estimated using the present value of future estimated cash flows of each project. The discount rate used in calculating the present value included the consideration of the risks of not achieving commercial feasibility (see Note 4).

PRODUCT WARRANTIES

The Company provides a limited warranty for the replacement of defective products. The Company has never incurred any significant costs associated with this warranty and therefore has not provided any estimated liability for these warranties.

CONCENTRATION OF SUPPLY

The Company generally uses one source of supply for key components and raw materials. The Company has identified alternate sources for these components and raw materials.

BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE

Basic per-share amounts are computed by dividing net income (loss) by the weighted average number of common shares outstanding. Diluted per-share amounts are computed similar to basic per-share amounts except that the weighted average shares outstanding are increased to include additional shares for the assumed exercise of stock options and warrants, if dilutive. The number of additional shares is calculated by assuming the outstanding stock options and warrants were exercised and that the proceeds from such exercises were used to acquire shares of common stock at the average market price during the year. The dilutive effect of these additional shares for the years ended December 31, 2003 and 2002 was to increase the weighted average shares outstanding by 251,052 and

262,332 shares, respectively. Because the Company had a loss in 2004, diluted shares were the same as basic shares since the effect of options and warrants would have been anti-dilutive.

2. INVENTORIES

Inventories at December 31, 2004 and 2003 consisted of the following:

	2004	2003
Purchased parts and subassemblies	$ 3,326,998	$ 2,284,699
Work in process	513,608	921,934
Finished goods	783,577	532,220
Total Inventory	**$ 4,624,183**	**$ 3,738,853**

3. INTANGIBLE ASSETS WITH FINITE LIVES

Finite life intangible assets at December 31, 2004 and 2003 were as follows:

	Estimated Lives (Years)	Gross Carrying Amount	December 31, 2004 Accumulated Amortization	Net Value
License technology (Note 11)	2	$ 115,000	$ 28,750	$ 86,250
Core technology	12	2,650,000	257,642	2,392,358
Developed technology	8	1,500,000	218,750	1,281,250
Customer relationships	6	615,000	119,588	495,412
Patents and inventions	5 to 9	1,346,676	338,756	1,007,920
Trade name	30	545,000	21,196	523,804
Other	5 to 10	93,085	19,034	74,051
Totals		**$ 6,864,761**	**$ 1,003,716**	**$ 5,861,045**

	Estimated Lives (Years)	Gross Carrying Amount	December 31, 2003 Accumulated Amortization	Net Value
License technology	8	$ 2,047,894	$ 543,224	$ 1,504,670
Core technology	12	2,650,000	36,806	2,613,194
Developed technology	8	1,500,000	31,250	1,468,750
Customer relationships	6	615,000	17,084	597,916
Patents and inventions	5 to 9	1,060,146	154,813	905,333
Trade name	30	545,000	3,028	541,972
Other	5 to 10	88,395	2,574	85,821
Totals		**$ 8,506,435**	**$ 788,779**	**$ 7,717,656**

Amortization expense related to these assets is as follows:

Year ended December 31, 2004	$	883,550
Year ended December 31, 2003	$	411,773
Year ended December 31, 2002	$	275,356

Estimated annual amortization expense for these assets over the next five years is as follows:

Year		Amount
2005	$	814,000
2006	$	783,000
2007	$	754,000
2008	$	714,000
2009	$	585,000

4. ACQUISITION OF BCI

On October 23, 2003, the Company purchased substantially all of the operating assets of BCI, a company that developed and manufactured medical products, specializing in pacing-lead products and pacing accessories. The primary reasons for the acquisition of BCI included the following: allow the Company to diversify its product base and increase its customer base; obtain an intellectual property portfolio covering various products; acquire potential products that are currently in the development stage, and certain future synergies that are anticipated to be realized in the combined Company after the acquisition.

The initial aggregate purchase price of approximately $18 million consisted of approximately $10 million in cash, the issuance of 933,333 shares of Company common stock with a market value of approximately $7 million and the assumption of short-term liabilities with a fair value of approximately $1 million. The number of shares to be issued was determined per the asset purchase agreement that was signed on July 21, 2003. The stock price per share was determined under the agreement by using the average closing stock price for the last five trading days prior to and including July 21, 2003 which amounted to an average price of $8.358 per share. The Company then applied a 10% discount to this amount because under the agreement, trading in these shares was restricted until at least March 2004 and under certain circumstances until March 2005 without the Company s consent, which brought the amount down to $7.52 per share. The Company settled on $7.50 per share as a value to arrive at the 933,333 shares.

The asset purchase agreement required an additional payment of $897,495 to be made in 2004 based on the final working capital of BCI on the date of acquisition. This payment was made in cash in February 2004. In addition, the Company was required to make a contingent payment of $3,032,454 on March 31, 2004, based on BCI s final 2003 sales results. This payment was made in the form of 40% cash ($1,212,981) and 60% common stock ($1,819,473 or 133,588 shares of common stock, valued at $13.62 per share). There is also a second contingent payment due on March 31, 2005, which is based on the increase in BCI s proprietary sales in 2004 over 2003. The second contingent payment amounts to $488,856 and will be paid as 20% cash ($97,771) and 80% stock ($391,085) per the amended agreement and was included in liabilities at December 31, 2004. This contingent purchase price was recorded as an increase to goodwill, with the stock to be issued in conjunction with this payment to be valued at no less than $11.56 (33,831 shares) and no more than $15.63 (25,021 shares). Under the terms of the Asset Purchase Agreement, the amount of the 2004 contingent payment is to be doubled if, on or before December 31, 2004, ELT executed supply agreement with one or more specified customers having minimum terms specified in the Asset Purchase Agreement. The Company has determined that the conditions for doubling were not met and notified BIOMEC. Under the Asset Purchase Agreement, BIOMEC has the right to review the Enpath documentation with respect to determination of the 2004 contingent payment. If BIOMEC disputes the amount due to it under the 2004 contingent payment, the Asset Purchase Agreement establishes a dispute resolution mechanism under which the matter may be referred to a third party accounting firm. BIOMEC has requested, and the Company has delivered, supporting documentation with respect to the computation of the 2004 contingent payment. The results of operations of BCI and the estimated fair value of the assets acquired and liabilities assumed are included in the Company s consolidated financial statements beginning October 24, 2003.

The Company accounted for the acquisition under the purchase method of accounting in accordance with SFAS 141. Accordingly, the purchase price was allocated to the tangible and intangible assets acquired and liabilities assumed based on the Company s estimates of fair value at the acquisition date. The Company engaged an independent valuation firm to assist in the determination of the fair values. The initial purchase price exceeded the amounts allocated to the tangible and identified intangible assets by approximately $9 million, and this excess was classified as goodwill.

The following tables provide further information on the acquisition of BCI and allocations:

Purchase Price Summary

Category		Amount
Cash paid at closing by Company	$	10,010,000
Value of Common Stock issued		7,000,000
Accrued payments:		
Working capital adjustment		897,000
Contingent payment based on BCI 2003 sales:		
Portion paid in cash		1,213,000
Portion paid with common stock		1,819,000
Contingent payment based on BCI 2004 sales:		
Portion to be paid in cash		98,000
Portion to be paid with common stock		391,000
Direct acquisition costs		1,249,000
Total Consideration	**$**	**22,677,000**

Values Assigned to Assets & Liabilities

Category		Amount
Current assets	$	3,756,000
Property & equipment		1,733,000
Acquired in-process R&D		2,650,000
Intangible assets:		
Developed technology		1,500,000
Customer relationships		615,000
Tade name		545,000
Patents		415,000
Core technology		2,650,000
Non competition agreement		75,000
Inventions		155,000
Goodwill		9,594,000
Current liabilities		(1,011,000)
Net Assets Acquired	**$**	**22,677,000**

A portion of the purchase price was allocated to developed and core technology, and in-process research and development. These intangible assets were identified and valued through the analysis of data concerning the underlying technology of the Company and its existing products, development projects, their stage of development, the time and resources to complete them, if applicable, their expected income generating ability and associated risks. The income approach, which includes an analysis of cash flows and related risks, was the primary method used in valuing the developed and core technology, and in-process research and development. Developed technology

represents projects that had attained technological feasibility and their value has accordingly been capitalized. Core technology has value through its use or re-use in many products or future generations of products.

In-Process Research and Development (IPR&D)

Development projects, which had not yet reached technological feasibility and had no alternative future use, were classified as in-process research and development. Accordingly, the purchase price assigned to those projects was immediately expensed on the acquisition date and was reflected as an expense in the 2003 consolidated statements of operations. The in-process research and development projects were as follows: Steroid Leads ($1.3 million), Adapters ($1 million) and an Implant Tool ($350,000). The estimated value of these projects was determined using a discounted cash flow model. The discount rates used considered the stage of completion and the risk surrounding the successful development and commercialization of each of the purchased in-process technology projects. Some of the original assumptions related to these projects were as follows.

Initial Assumptions October 23, 2003

	Leads	Tool	Adaptor
Costs incurred as of 10/23/03	$ 47,000	$ 203,000	$ 75,000
Estimated cost to complete	$ 602,000	$ 658,000	$ 529,000
Percent complete (dollars)	7.2%	23.6%	12.4%
Months spent up to 10/23/03	12	12	12
Estimated months to complete	24	12	12
Percent complete (months)	33.3%	50.0%	50.0%
Year revenues begin	2005	2004	2004
Regulatory approval received	No	No	No

The discount rates used in valuing the developed, core and in-process technologies ranged from 26% to 50%. A higher discount rate was used to value the in-process research and development, due to the inherent uncertainties surrounding the successful development of the in-process projects, FDA approval, and the market acceptance of the products. The percentage of completion for each of the in-process projects was determined using costs incurred to date on each project as compared to the remaining estimated costs to be incurred to bring each of the projects to technological feasibility.

The Company believes that the three in-process projects will reach technological feasibility. However, because of the risks associated with the commercial viability of these products, there can be no assurance that these projects will actually achieve commercialization. Such risks include the delay or failure to obtain the necessary regulatory approvals or the failure to achieve market acceptance. As of March 21, 2005, we had received European approval to begin selling the steroid lead through one OEM partner, but had not yet obtained the necessary regulatory approvals to market the other products. Updated information related to these three projects is summarized below:

Status On December 31, 2004

	Leads	Tool	Adaptor
Costs incurred as of 12/31/04	$ 1,038,000	$ 686,000	$ 85,000
Estimated cost to complete	$ 350,000	$ 132,000	$ 153,000
Percent complete (dollars)	74.8%	83.9%	35.7%
Months spent up to 12/31/04	26	26	26
Estimated months to complete	9	7	7
Percent complete (months)	74.3%	78.8%	78.8%
Year revenues begin	2005	2005	2005
Regulatory approval received	No	No	No

The scope of the adaptor project has been significantly reduced due to entering into an exclusive arrangement with one of the major CRM companies for IS-4 adaptors.

The intangible assets acquired in the acquisition, with the exception of goodwill and the in-process research and development, are being amortized on a straight line basis over their estimated lives ranging from 5 to 30 years (see Note 3). For tax purposes these assets, including goodwill and in-process research and development, are deductible over a 15-year period. This difference gives rise to deferred income taxes disclosed in Note 5.

The acquisition transaction had the following net effect on the accompanying 2003 consolidated statement of cash flows:

Fair value of net working capital acquired	$	2,743,387
Fair value of property and equipment acquired		1,733,300
Purchase price assigned to:		
Goodwill		8,984,824
Identifiable intangibles		8,605,000
Stock issued in connection with acquisition, net of registration costs		(6,872,151)
Warrants issued in connection with acquisition		(52,101)
Accrued payment on acquisition		(3,929,949)
Cash Purchase Price	**$**	**11,212,310**

The following unaudited pro forma summary represents the consolidated results of operations as if the BCI acquisition had occurred at the beginning of 2002 and excludes the write-off of the purchased in-process research and development. This presentation does not purport to be indicative of what would have occurred had the acquisition been made as of that date or of results which may occur in the future.

Pro forma results for the years ended December 31:

		2003		2002
Net sales	$	27,574,422	$	22,088,095
Net income	$	1,259,854	$	1,820,647
Basic income per share	$	0.22	$	0.32
Diluted income per share	$	0.21	$	0.31

5. INCOME TAXES

Significant components of the provisions (benefit) for income taxes are as follows:

		2004		2003		2002
Current:						
Federal	$	(92,000)	$	634,000	$	1,249,000
State		(10,000)		95,000		160,000
		(102,000)		729,000		1,409,000
Deferred		(597,000)		(802,000)		225,000
	$	**(699,000)**	**$**	**(73,000)**	**$**	**1,634,000**

The appropriate deferred tax effect of each type of temporary difference and carry-forward is:

	2004	2003
Deferred tax assets		
Intangible assets	$ 1,176,000	$ 1,053,000
Vacation accrual	78,000	61,000
Inventory	65,000	68,000
Other	51,000	27,000
	$ 1,370,000	**$ 1,209,000**
Deferred tax liabilities		
Property and equipment	(21,000)	(457,000)
Net deferred tax assets	**$ 1,349,000**	**$ 752,000**

The components giving rise to the net deferred income tax assets described above have been included in the accompanying balance sheets as follows:

	2004	2003
Current assets	$ 194,000	$ 156,000
Long-term assets	1,155,000	596,000
Net deferred tax assets	**$ 1,349,000**	**$ 752,000**

The total tax expense (benefit) differs from the expected tax expense (benefit), computed by applying the federal statutory rate to the Company s net income (loss), as follows:

	2004	2003	2002
Expected income tax expense (benefit)	$ (678,000)	$ 83,000	$ 1,572,000
State tax (benefit), net of federal affect	(65,000)	4,000	170,000
Income tax credits	(40,000)	(205,000)	(148,000)
Other, including non-deductible expenses	84,000	45,000	40,000
Net tax expense (benefit)	**$ (699,000)**	**$ (73,000)**	**$ 1,634,000**

6. FINANCING ARRANGEMENTS

On October 23, 2003, the Company entered into a financing arrangement with a bank that included a five-year term loan of $5,000,000, which was used to finance a portion of the BCI acquisition, and a $3,000,000 line of credit, $2,118,348 of which was available at December 31, 2004. The borrowings are secured by substantially all Company assets and also contain financial covenants that must be met on a quarterly basis. The agreement also prohibits the payment of dividends without the consent of the lender. At December 31, 2004, the Company was in violation of certain of these covenants, due to the $2.8 million safety needle asset impairment charge (see Note 11). These violations were subsequently waived by the bank on February 9, 2005.

The current line of credit bears interest at Libor plus 2.25% with no minimum interest due and expires on April 30, 2005. The availability under the line is subject to borrowing base requirements, and advances are at the discretion of the lender. There was $881,652 borrowed under the agreement at December 31, 2004.

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		2004
Term loan payable to bank in monthly installments of $83,334 plus interest at Libor plus 2.5% (3.67% at December 31, 2004), commencing November 2003 with balance due October 2008	$	3,833,324
Less current maturities		(1,000,000)
	$	**2,833,324**

Approximate maturities of long-term debt at December 31, 2004, are as follows:

Years ending December 31,		**Amount**
2005		1,000,000
2006		1,000,000
2007		1,000,000
2008		833,324
Total	**$**	**3,833,324**

7. LEASES

The Company is obligated under capital lease agreements for equipment. Future minimum payments under capital leases are as follows:

Years ending December 31,		**Amount**
2005	$	69,499
2006		4,758
Total minimum lease payments		74,257
Less amounts representing interest imputed at 8.0% to 11.6%		3,364
Present value of net minimum lease payments		70,893
Less current installments		64,420
	$	**6,473**

Capital leases are secured by the equipment underlying the lease. Equipment under capital leases as of December 31, 2004 and 2003 is as follows:

		2004		**2003**
Equipment	$	433,482	$	433,482
Less accumulated depreciation		(324,252)		(258,173)
	$	**109,230**	**$**	**175,309**

The Company has separate operating leases related to its two facilities. The Delivery Systems facility is under an operating lease that expires June 30, 2006, related to 38,337 square feet with a monthly base rent of $17,525 per month thru May 2005 and increasing June 2005 to $19,276 per month to the end of the lease term. The Lead Technologies facility is under an operating lease that expires December 31, 2008, related to 27,000 square feet with a monthly base rent of $14,189. This rent expense is being recognized on a straight-line basis over the term of the lease. Delivery Systems also leased an additional 4,740 square feet of warehouse space on February 4, 2005. The lease begins March 1, 2005 and expires on July 30, 2006 with a monthly base rent of $1,876 per month.

The Company also leases certain office equipment under operating leases. Approximate future minimum payments under operating leases are as follows:

Years ending December 31,		Amount
2005		457,000
2006		337,000
2007		191,000
2008		181,000
Total minimum lease payments	**$**	**1,166,000**

Total rent expense, including operating expenses and real estate taxes, was approximately $589,000, $299,000 and $237,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

8. SHAREHOLDERS EQUITY

Warrants

In connection with the acquisition of the operating assets of BCI, the Company issued warrants to an agent to purchase 10,000 shares of common stock at an exercise price of $8.36 per share that expire on October 23, 2008. The fair value of those warrants, estimated using the Black-Scholes Model, of approximately $52,000 was treated as a cost directly related to the acquisition (see Note 4).

Stock Options

The Company has four stock option plans: the 1989 Stock Option Incentive Plan, the 1992 Non-Qualified Plan, the 1999 Non-Employee Director and Medical Advisory Board Stock Option Plan and the 1999 Incentive Stock Option Plan. Under the four plans, a maximum of 1,780,000 options were designated for grant at prices not less than 85% of fair market value at date of grant if a non-qualified option, or 100% if an incentive option as defined under the Internal Revenue Code. Of these options, approximately 318,700 remain available for future grants. Options vest over periods ranging from two years to five years and the options expire over periods ranging from six to fifteen years after the date of grant.

As discussed in Note 1 to the financial statements, the Company accounts for employee stock-based compensation under the APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. The pro forma fair value of each option grant as presented in Note 1 to the financial statements is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions used for grants in 2004, 2003 and 2002:

	2004	2003	2002
Expected dividend yield	0%	0%	0%
Expected stock price volatility	26.7%	44.1%	61.3%
Risk-free interest rate	3.3%	3.2%	4.0%
Expected life of options (years)	6	6	6
Weighted average fair value of options granted	$ 3.95	$ 2.62	$ 4.41

Additional information relating to all outstanding options as of December 31, 2004, 2003 and 2002 is as follows:

	2004		2003		2002	
	# Shares	Weighted Avg Exercise Price	# Shares	Weighted Avg Exercise Price	# Shares	Weighted Avg Exercise Price
Options outstanding, beginning of year	802,700	$ 7.07	542,900	$ 5.34	428,900	$ 2.69
Options granted	178,100	12.25	338,500	9.63	179,600	11.37
Options exercised	(52,273)	3.31	(43,600)	4.16	(36,600)	2.29
Options surrendered	(94,300)	11.04	(35,100)	8.53	(29,000)	7.41
Options outstanding, end of year	**834,227**	**$ 7.96**	**802,700**	**$ 7.07**	**542,900**	**$ 5.34**
Options available for grant at end of year	318,700		390,500		204,100	
Total reserved shares	**1,152,927**		**1,193,200**		**747,000**	
Options exercisable, end of year	**451,227**	**$ 5.77**	**361,525**	**$ 4.45**	**286,650**	**$ 3.18**

The following table summarizes information about stock options outstanding at December 31, 2004:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at 12/31/04	Weighted Avg Remaining Contractual Life Years	Weighed Avg Exercise Price	Number Exercisable at 12/31/04	Weighed Avg Exercise Price
$1.03 to $1.50	145,975	0.88	$ 1.31	145,975	$ 1.31
$1.51 to $4.63	139,450	1.86	3.03	108,250	2.83
$4.64 to $8.40	146,401	4.78	7.52	75,101	7.59
$8.41 to $10.37	36,001	4.77	9.09	12,501	8.99
$10.38 to $10.93	139,200	5.03	10.93	41,400	10.93
$10.94 to $18.65	227,200	4.54	13.56	68,000	14.29
$1.03 to $18.65	**834,227**	**3.59**	**$ 7.96**	**451,227**	**$ 5.77**

9. SIGNIFICANT CUSTOMERS

The Company currently has three major customers that account for more than 10 percent of net sales. The information below includes the customers percent of sales for the years ended December 31, 2004, 2003 and 2002 and the related percent of accounts receivable at December 31, 2004, 2003 and 2002.

	December 31, 2004		December 31, 2003		December 31, 2002	
Customer	% Sales	% A/R	% Sales	% A/R	% Sales	% A/R
A	41%	35%	44%	24%	67%	67%
B	16%	15%	18%	8%	13%	6%
C	11%	7%	7%	38%	N/A	N/A

10. RETIREMENT PLAN

The Company has a profit-sharing plan (the Plan) classified as a defined contribution plan under Section 401(k) of the Internal Revenue Code. The Plan allows employees to defer a portion of their annual compensation through pre-tax contributions to the Plan. The Company matches 25% of an employee s contribution, up to a maximum of 5% of the employee s compensation. Matching contributions for the years ended December 31, 2004, 2003 and 2002 were $84,844, $52,732 and $42,852, respectively. The Company s Board of Directors may approve discretionary contributions to the Plan. No discretionary contribution has been made since the Plan s inception.

11. LICENSE AGREEMENT AND SAFETY NEEDLE ASSET IMPAIRMENT

In August 2000, the Company entered into an agreement with Med-Design Corporation for the right to manufacture and distribute Med-Design s center-line retractable Safety Seldinger Introducer Needle (the Safety Needle) exclusively in the venous access market. The Safety Needle can be retracted into a protective sheath while still in the patient, greatly reducing the possibility of a needle stick after the needle has been in contact with a patient s blood.

On September 7, 2001, the Company amended its Development and Licensing Agreement with Med-Design Corporation to obtain exclusive marketing rights to Med-Design s center-line retractable safety needle technology for the arterial access market in exchange for a payment of $2,000,000. The $2,000,000 payment to Med-Design consisted of $1,000,000 in cash and $1,000,000 worth of Enpath stock, or 68,027 shares based on the market value of the stock on the effective date of the amendment. The cost of the licensing rights was being amortized over the estimated useful life of the exclusive rights acquired.

The agreement, as amended, requires the Company to pay Med-Design royalties on sales of the safety needle product. The royalty fees range varies as a percent of the net sales price, depending on the sales volume achieved. In order to maintain exclusive rights, the Company must pay royalties on an increasing number of safety needles each year per the Licensing Agreement. The Company paid royalty fees of $79,000 and $169,000 and $160,000 for 2004, 2003 and 2002, respectively, of which $4,068 and $91,759 was included in current liabilities at December 31, 2004 and 2003, respectively. Med-Design agreed to waive the minimum sales targets for 2004 and the Company is currently in discussions with Med-Design about either revising the Licensing Agreement or possibly selling the safety needle business to it. The Company will continue to pay the royalty fee on needle sales in 2005, but does not anticipate that it will need to meet a minimum sales target in 2005 from a royalty standpoint in order to maintain exclusivity.

In order to meet anticipated demand, the Company invested $2,174,000 to purchase automated equipment and tooling to manufacture the safety needle. The Company also entered into a supply agreement with Medtronic in October 2002 that set forth terms under which Medtronic would begin including the Company s Axia RSN retractable guidewire introducer safety needle as part of Medtronic s introducer kits in the venous access market. In April 2003, the Company entered into a supply agreement with Cook Incorporated under which the Company appointed Cook the exclusive distributor of our single pack Axia RSN safety needles in the United States for the arterial market.

In June 2004, the Company held discussions with both Medtronic and Cook related to the lack of safety needle volume. Both customers indicated that physicians have been slow to adopt the use of safety needles and they were skeptical as to the potential growth of this product in the near future. Based on this information, the Company determined that the market s slow adoption rate no longer justified the level of investment the Company had in safety needle intellectual property rights and equipment.

As a result, the Company hired an independent valuation firm to help determine the current fair value of the license agreement and safety needle equipment and tooling. The Company s management group put together revised estimates of future sales for the next four years and performed additional analysis. With this information and the independent valuation firm s assistance, management determined that the current fair value of the safety needle assets at June 30, 2004 was $315,000. This resulted in a one-time impairment charge of approximately $2.8 million which was reflected in the results from operations for the three months ended June 30, 2004. In addition, the Company re-evaluated the future estimated lives of the safety needle assets and the reduced costs basis of these assets is being depreciated using the straight-line method over the terms shown below.

Item	Original Cost	Accumulated Depr/Amort	Preimpairment Net Book Value June 30, 2004	Impairment Write-Off	June 30, 2004 Adjusted Book Value	Revised Life (Years)
License Agreement	$ 2,047,894	$ (668,613)	$ 1,379,280	$ 1,264,280	$ 115,000	2
Automation Equipment for Safety Needle	1,771,528	(221,312)	1,550,215	1,370,215	180,000	5
Safety Needle Molds and Tooling	402,290	(207,586)	194,704	174,704	20,000	2
Totals	**$ 4,221,712**	**$ (1,097,511)**	**$ 3,124,199**	**$ 2,809,199**	**$ 315,000**	

On December 31, 2004, the Company had inventory of safety needles totaling $308,000 which amounted to 6.6% of total inventory. The Company continues to sell safety needles on a monthly basis and is reducing the inventory levels of these products. The Company estimates that it has 12-18 months of safety needle inventory on hand and will not be purchasing any additional components or manufacturing any additional needles in the near future.

Item 9 Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None

Item 9A Controls and Procedures

The Company s Chief Executive Officer and Chief Financial Officer, James D. Hartman, has reviewed the Company s disclosure controls and procedures at the end of the period covered by this report. Based upon this review, this officer believes that the Company s disclosure controls and procedures are effective in ensuring that material information related to the Company is made known to him by others within the Company.

We are currently in the process of reviewing and formalizing our internal controls and procedures for financial reporting in accordance with Securities and Exchange Commission s rules implementing the internal control reporting requirements included in Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404). Changes have been and will be made to our internal controls over financial reporting as a result of these efforts. We are dedicating significant resources, including senior management time and effort, and incurring substantial costs in connection with our ongoing Section 404 assessment. We are currently documenting and testing our internal controls and considering whether any improvements are necessary for maintaining an effective control environment at our Company. The evaluation of our internal controls is being conducted under the direction of our senior management in consultation with an independent third party consulting firm. In addition, our senior management is regularly discussing the results of our testing and any proposed improvements to our control environment with our Audit Committee. We expect to assess our controls and procedures on a regular basis. We will continue to work to improve our controls and procedures and to educate and train our employees on our existing controls and procedures in connection with our efforts to maintain an effective controls infrastructure at our Company.

Item 9B Other Information

At Enpath Compensation Committee and Board meetings held on February 16, 2005, the following persons were elected to the positions set forth below and their 2005 salaries and stock option grants were established as follows:

Name	Position		Salary	Stock Options Granted
James D. Hartman	Chief Executive Officer	$	215,000	10,000
Mark C. Kraus	Senior President and Chief Technology Officer	$	173,000	15,000
James L. Mellor	Senior Vice President of Marketing and Sales	$	168,000	15,000
James M. Reed	Vice President of Sales	$	117,000	3,000
Michael D. Erdmann	Secretary and Controller	$	115,000	4,000
James E. McCrave	Vice President of Administration	$	110,000	3,000

In addition, on that date the Compensation Committee and Board authorized the following payments under the Company s salaried bonus plan based upon the Company s overall performance plus the completion of certain agreed-upon goals in the Plan: Mr. Hartman - $9,176; Mr. Kraus - $16,820, Mr. Mellor - $4,144; Mr. Reed - $14,000; Mr. Erdmann - $8,053; and Mr. McGrave - $2,681.

PART III

Item 10 Directors and Executive Officers of the Registrant

The information required by Item 10 concerning the executive officers and directors of the Company is incorporated herein by reference to the following sections of the Company s definitive Proxy Statement for its 2005 Annual Meeting of Shareholders to be held on April 28, 2005 (the 2005 Proxy Statement), which will be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the close of the fiscal year for which this report is filed:

Ownership of Voting Securities by Principal Holders and Management

Proposal one Election of Directors

Nominees for Election to Board of Directors

Audit Committee

Executive Officers of the Company

Section 16(a) Beneficial Ownership Reporting Compliance

Corporate Governance and Board Matters Code of Ethics and Business Conduct.

A copy of our Code of Ethics and Business Conduct is available by writing to our Investor Relations Department at:

Enpath Medical, Inc.

Investor Relations Department

15301 Highway 55 West

Plymouth, Minnesota 55447

investorrelations@enpathmed.com

Item 11 Executive Compensation

The information required by Item 11 is incorporated herein by reference to the section of the Company s 2005 Proxy Statement titled Executive Compensation and Other Information, except that information under the subsections titled Compensation Committee Report, Comparative Stock Performance and Compensation Committee Interlocks and Insider Participation in Compensation Decisions is not incorporated by reference.

Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by Item 12 is incorporated herein by reference to the section of the Company s 2005 Proxy Statement titled Security Ownership of Certain Beneficial Owners and Management Summary Ownership Table.

Item 13 Certain Relationships and Related Transactions

None

Item 14 Principal Accountant Fees and Services

The information required by Item 14 is incorporated by reference to the section of the Company s 2005 Proxy Statement titled Principal Accountant Fees and Services.

PART IV

Item 15 Exhibits and Financial Statement Schedules

(a) Documents Filed as Part of This Report

1. FINANCIAL STATEMENTS. See Item 8 above.

2. FINANCIAL STATEMENT SCHEDULES:

Opinion on financial statement schedules

Schedule II Valuation and Qualifying Accounts

3. EXHIBITS. See Exhibit Index on page following signatures.

SIGNATURES

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

Enpath Medical, Inc.

Date: March 22, 2005

By: /s/ James D. Hartman
Chairman, Chief Executive Officer and Chief Financial Officer

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

Name	Title	Date
/s/ James D. Hartman	Chairman, Chief Executive Officer and Chief Financial Officer	March 22, 2005

/s/ Thomas L. Auth	Director	March 22, 2005
/s/ Michael D. Dale	Director	March 22, 2005
/s/ Albert Emola	Director	March 22, 2005
// Trevor O. Jones	Director	March 22, 2005
/s/ Richard F. Sauter	Director	March 22, 2005

EXHIBIT INDEX

Exhibit #	Description
3.1	Articles of Incorporation of the Company.
3.2	By-laws of the Company (incorporated by reference to Exhibit 3.3 to the Form 10-K for the year ended December 31, 2003).
*10.1	Employment Agreement dated February 19, 1996, between the Company and James D. Hartman (incorporated by reference to Exhibit 10.3 to the Form 10-KSB for the year ended December 31, 1995).
*10.2	Employment Agreement dated August 22, 2003 between the Company and James L. Mellor (incorporated by reference to Exhibit 10.3 to the Form 10-Q for the quarter ended September 30, 2003).
*10.3	Enpath Medical, Inc. 1991 Non-Statutory Stock Option Plan (incorporated by reference to Exhibit 4.1 to the Company s Registration Statement on Form S-8 (File No. 333-57944)).
*10.4	Enpath Medical, Inc. 1999 Incentive Stock Option Plan (incorporated by reference to Exhibit 4.1 to the Company s Registration Statement on Form S-8 (File No. 333-109875).
*10.5	Enpath Medical, Inc. 1996 Non-Employee Director and Medical Advisory Board Stock Option Plan (incorporated by reference to Exhibit 4.1 to the Company s Registration Statement on Form S-8 (File No. 333-57942)).
*10.6	Enpath Medical, Inc. 1999 Non-Employee Director and Medical Advisory Board Stock Option Plan (incorporated by reference to Exhibit 4.1 to the Company s Registration Statement on Form S-8 (File No. 333-62560)).
**10.7	Supply Agreement, dated October 11, 2002, between the Company and Medtronic, Inc. (incorporated by reference to Exhibit 10.3 to the Form 10-QSB for the quarter ended September 30, 2002).
10.8	Lease Agreement, dated January 31, 2004, between the Company and Jagodzinski Properties for premises at 15301 Highway 55 West, Plymouth, Minnesota.
10.9	Lease agreement for premises at 7452 West 78th Street, Bloomington, Minnesota as amended and assigned thought October 23, 2003.
*10.10	Form of Incentive Stock Option Agreement.
*10.11	Form of Non-Employee Director Agreement.
10.12	Revolving Credit and Term Loan Agreement dated October 17, 2003 between the Company and M&I Marshall & Ilsley Bank (incorporated by reference to Exhibit 10.4 to the Form 10-Q for the quarter ended September 30, 2003).
10.12.1	Letter Amendment No. 1 dated March 18, 2004, to the Revolving Credit and Term Loan Agreement dated as of October 17, 2003 between the Company and M&I Marshall & Ilsley Bank (incorporated by reference to Exhibit 10.17 to the Form 10-K for the year ended December 31, 2003).
10.12.2	Letter Amendment No. 2 dated July 19, 2004, to the Revolving Credit and Term Loan Agreement dated as of October 17, 2003 between the Company and M&I Marshall & Ilsley Bank (incorporated by reference to Exhibit 10.1 to the Form 10-Q for the quarter ended June 30, 2004).
10.12.3	Letter Amendment No. 3 dated October 13, 2004, to the Revolving Credit and Term Loan Agreement dated as of October 17, 2003 between the Company and M&I Marshall & Ilsley Bank (incorporated by reference to Exhibit 10.1 to the Form 10-Q for the quarter ended September 30, 2004).
10.12.4	Letter Amendment No. 4 dated February 9, 2005, to the Revolving Credit and Term Loan Agreement dated as of October 17, 2003 between the Company and M&I Marshall & Ilsley Bank.
10.13	Term Promissory Note dated October 17, 2003 in favor of M&I Marshall & Ilsley Bank (incorporated by reference to Exhibit 10.5 to the Form 10-Q for the quarter ended September 30, 2003).
10.14	Revolving Promissory Note dated October 17, 2003 in favor of M&I Marshall & Ilsley Bank (incorporated by reference to Exhibit 10.6 to the Form 10-Q for the quarter ended September 30, 2003).
10.15	Security Agreement dated October 17, 2003 between the Company and M&I Marshall & Ilsley Bank (incorporated by reference to Exhibit 10.7 to the Form 10-Q for the quarter ended September 30, 2003).

10.16	Third Party Security Agreement dated October 17, 2003 between the Company s wholly owned subsidiary and M&I Marshall & Ilsley Bank (incorporated by reference to Exhibit 10.1 to the Form 10-Q for the quarter ended September 30, 2003).
10.17	Asset Purchase Agreement among Medamicus, Inc., Medacquisition, Inc., BIOMEC Inc. and BIOMEC Cardiovascular Inc. dated as of July 21, 2003 (attached as Annex A to the Form S-4 Joint Proxy Statement/Prospectus, File No 333-108404.)
10.17.1	Amendment No 1 dated March 14, 2005 to Asset Purchase Agreement dated July 21, 2003.
10.18	Letter agreement dated March 15, 2005 between Enpath Medical Inc, BIOMEC, Inc and Biomec Technology, Inc.
21.1	The Company has no subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
31	Certification of principal executive and financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Rules 13a-14 and 15d-14 of the Securities Exchange Act of 1934).
32	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350).

*Indicates a management contract or compensatory plan or arrangement

** Certain portions of this Exhibit have been deleted and filed separately with the Commission pursuant to a request for confidential treatment under Rule 24b-2. Spaces corresponding to the deleted portions are represented by brackets with asterisks.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of

Enpath Medical, Inc.

Minneapolis, Minnesota

Our audits were made for the purpose of forming an opinion on the basic consolidated financial statements of Enpath Medical, Inc. and subsidiary taken as a whole. The consolidated supplemental schedule II is presented for purposes of complying with the Securities and Exchange Commission s rules and is not a part of the basic consolidated financial statements. This schedule has been subjected to the auditing procedures applied in our audits of the basic consolidated financial statements and, in our opinion, is fairly stated in all material respects in relation to the basic consolidated financial statements taken as a whole.

/s/ McGLADREY & PULLEN, LLP

Minneapolis, Minnesota

January 18, 2005 (except for Note 6, as to

which the date is February 9, 2005)

Enpath Medical, Inc. and Subsidiary

Schedule II Valuation and Qualifying Accounts

Description	Balance at Beginning Of Period	Additions Charged to Costs and Expenses	Additions Charged to Other Accounts	Deductions	Balance at End of Period
Year ended December 31, 2002:					
Accounts receivable allowances:					
Allowance for doubtful accounts	$ 21,944	$ 38,056	$ 0	$ 0	$ 60,000
Inventory allowance					
Allowance for slow-moving inventory	$ 91,100	$ 12,000	$ 0	$ 44,201	$ 58,899
Year ended December 31, 2003:					
Accounts receivable allowances:			**Note 1**		
Allowance for doubtful accounts	$ 60,000	$ 0	$ 20,407	$ 10,417	$ 69,990
Inventory allowance			**Note 1**		
Allowance for slow-moving inventory	$ 58,899	$ 24,321	$ 72,175	$ 0	$ 155,395
Year ended December 31, 2004:					
Accounts receivable allowances:					
Allowance for doubtful accounts	$ 69,990	$ 0	$ 0	$ 1,384	$ 68,606
Inventory allowance					
Allowance for slow-moving inventory	$ 155,395	$ 0	$ 0	$ 31,413	$ 123,982

Notes

1. Acquired in acquisition of BCI