NEOPROBE CORP
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PROSPECTUS-FIRST AMENDED

NEOPROBE CORPORATION

21,817,257 SHARES OF COMMON STOCK

This prospectus relates to the sale of up to 21,817,257 shares of our common stock by persons who have purchased shares of our common stock or who may purchase shares of our common stock through the conversion of debt or the exercise of warrants as more fully described herein. The aforementioned persons are sometimes referred to in this prospectus as the selling stockholders. The prices at which the selling stockholders may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of our shares by the selling stockholders.

Our common stock is quoted on the Nasdaq Over-The-Counter Bulletin Board under the symbol NEOP. On January 14, 2005, the last reported sale price for our common stock as reported on the Nasdaq Over-The-Counter Bulletin Board was $0.575 per share.

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Each selling stockholder may be deemed to be an "underwriter" within the meaning of the Securities Act of 1933, as amended.

THE SECURITIES OFFERED IN THIS PROSPECTUS INVOLVE A HIGH DEGREE OF RISK. YOU SHOULD CONSIDER THE RISK FACTORS BEGINNING ON PAGE 4 BEFORE PURCHASING OUR COMMON STOCK.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

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The date of this prospectus is January 18, 2005.

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UNLESS OTHERWISE SPECIFIED, THE INFORMATION IN THIS PROSPECTUS IS SET FORTH AS OF JANUARY 18, 2005, AND WE ANTICIPATE THAT CHANGES IN OUR AFFAIRS WILL OCCUR AFTER SUCH DATE. WE HAVE NOT AUTHORIZED ANY PERSON TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS, OTHER THAN AS CONTAINED IN THIS PROSPECTUS, IN CONNECTION WITH THE OFFER CONTAINED IN THIS PROSPECTUS. IF ANY PERSON GIVES YOU ANY INFORMATION OR MAKES REPRESENTATIONS IN CONNECTION WITH THIS OFFER, DO NOT RELY ON IT AS INFORMATION WE HAVE AUTHORIZED. THIS PROSPECTUS IS NOT AN OFFER TO SELL OUR COMMON STOCK IN ANY STATE OR OTHER JURISDICTION TO ANY PERSON TO WHOM IT IS UNLAWFUL TO MAKE SUCH OFFER.



## PROSPECTUS SUMMARY

The following summary highlights selected information from this prospectus and may not contain all the information that is important to you. To understand our business and this offering fully, you should read this entire prospectus carefully, including the financial statements and the related notes beginning on page F-1. When we refer in this prospectus to the "company," "we," "us," and "our," we mean Neoprobe Corporation, a Delaware corporation, together with our subsidiary. This prospectus contains forward-looking statements and information relating to Neoprobe Corporation. See Cautionary Note Regarding Forward Looking Statements on page 14.

### OUR COMPANY

We are a biomedical technology company providing innovative surgical and diagnostic products that enhance patient care by meeting the critical decision-making needs of healthcare professionals. We were originally incorporated in Ohio in 1983 and reincorporated in Delaware in 1988. Our executive offices are located at 425 Metro Place North, Suite 300, Dublin, Ohio 43017. Our telephone number is (614) 793-7500. The address of our website is www.neoprobe.com. Information on our website is not part of this prospectus.

From our inception through the end of 2001, we devoted substantially all of our efforts and resources to the research and clinical development of innovative systems for the intraoperative diagnosis and treatment of cancers. Following an evaluation of our business plan during early 2001, however, we determined that we needed to expand our product portfolio and consider synergistic products outside the cancer or oncology fields.

In December 2001, we acquired Biosonix Ltd., a private Israeli company limited by shares. In February 2002, Biosonix Ltd. changed its name to Cardiosonix Ltd. (Cardiosonix). Cardiosonix is developing and commercializing a unique line of blood flow measurement devices for a variety of diagnostic and surgical applications. The decision to expand beyond our product focus on oncology was based on our belief that the Cardiosonix products would diversify our customer base through a product line we believe has great market potential and a path of market adoption similar to our gamma detection devices, but one that also has

significant operational synergies in the development, regulation and manufacture to that of our existing gamma devices.

Although we have expanded our strategic focus to include blood flow medical devices, we intend to continue to execute many of the strategies outlined in prior years related to the internal development of gamma detection medical devices and to continue supporting development of our other complementary procedural-based technologies. Based upon information that we have recently become aware of, we are considering reactivating development activities concerning radioimmuguided surgery (RIGS(R)). In addition, we are preparing to begin the pivotal stage in the development of our proprietary lymphatic tracing agent, LYMPHOSEEK(TM).

Our business goals are to maximize the market potential of Cardiosonix' blood flow products as leaders in the measurement of blood flow in both clinical and surgical settings to supplement our leadership position in the current intraoperative gamma detection market. We believe our core device business lines will provide us with a strong operating foundation and enable us to judiciously evaluate and develop complementary procedural products with a recurring revenue stream. To that end, we intend to continue to pursue the development of LYMPHOSEEK and to evaluate an appropriate development plan for RIGS.

THE OFFERING

During April 2003, we completed a bridge loan agreement with our President and CEO, David Bupp. Under the terms of the agreement, Mr. Bupp advanced us $250,000. In consideration for the loan, we issued Mr. Bupp warrants, expiring in April 2008, to purchase 375,000 shares of our common stock at an exercise price of $0.13 per share. Interest accrued on the note at the rate of 8.5% per annum, payable monthly, and the note was due on June 30, 2004. On March 8, 2004, the due date of the note to Mr. Bupp was extended to June 30, 2005. In exchange for extending the due date of the note, we issued Mr. Bupp an additional , expiring in March 2009, to purchase 375,000 shares of our common stock at an exercise price of $0.50 per share. This prospectus covers the resale of the original 375,000 shares of common stock issuable pursuant to the warrants granted to Mr. Bupp in April 2003.



During April 2003, we also completed a convertible bridge loan agreement with Donald E. Garlikov for an additional $250,000. In consideration for the loan, we issued Mr. Garlikov 500,000 warrants, expiring in April 2008, to purchase shares of our common stock at an exercise price of $0.13 per share. Under the terms of the agreement, the note bore interest at 9.5% per annum, payable monthly, and was due on June 30, 2004. During January 2004, Mr. Garlikov converted the entire balance of the note into 1.1 million shares of common stock according to the conversion terms of the agreement. Mr. Garlikov's 500,000 warrants remain outstanding. This prospectus covers the resale of the shares of common stock issued upon the conversion of the note and the 500,000 shares of common stock issuable upon the exercise of the warrants granted to Mr. Garlikov.

During the second and third quarters of 2003, we engaged the services of two investment banking firms to assist us in raising capital, Alberdale Capital, LLC (Alberdale) and Trautman Wasserman & Company, Inc. (Trautman Wasserman). In exchange for Alberdale's services, we agreed to pay them a monthly retainer of $10,000, half payable in cash and half payable in common stock, and we agreed to pay them additional compensation upon the successful completion of a private placement of our securities. We terminated the agreement with Alberdale effective September 23, 2003, but agreed to issue them a total of 150,943 shares of common stock in payment for one half of their retainer, plus warrants to purchase 78,261 shares of common stock in exchange for their assistance in

arranging an accounts receivable financing transaction. This prospectus covers the resale of these shares and the shares of common stock issuable pursuant to the warrants. The warrants have an exercise price of $0.28 per share.

In exchange for the services of Trautman Wasserman, we agreed to pay a retainer of $10,000, payable in cash and stock, and to pay further compensation on successful completion of a private placement. We issued Trautman Wasserman a total of 27,199 shares of common stock in payment for one half of their retainer. This prospectus covers the resale of these shares.

During October and November 2003, we executed common stock purchase agreements with third parties introduced to us by a third investment banking firm, Rockwood, Inc., for the purchase of 12,173,914 shares of our common stock at a price of $0.23 per share for net proceeds of $2.4 million. In addition, we issued the purchasers warrants to purchase 6,086,959 shares of common stock at an exercise price of $0.28 per share and issued the placement agents warrants to purchase 1,354,348 shares of our common stock on similar terms. All warrants issued in connection with the transaction expire in October 2008. This prospectus covers the resale of the 12,173,914 shares of common stock purchased by the purchasers and the 7,441,307 shares of common stock issuable pursuant to the warrants granted to the purchasers and the placement agents and their assignees.

AN INVESTMENT IN OUR COMMON STOCK IS HIGHLY SPECULATIVE AND INVOLVES A HIGH DEGREE OF RISK. SEE RISK FACTORS BEGINNING ON PAGE 4.



## RISK FACTORS

An investment in our common stock is highly speculative, involves a high degree of risk, and should be made only by investors who can afford a complete loss. You should carefully consider the following risk factors, together with the other information in this prospectus, including our financial statements and the related notes, before you decide to buy our common stock. Our most significant risks and uncertainties are described below; however, they are not the only risks we face. If any of the following risks actually occur, our business, financial condition, or results of operations could be materially adversely affected, the trading of our common stock could decline, and you may lose all or part of your investment therein.

WE HAVE SUFFERED SIGNIFICANT OPERATING LOSSES FOR SEVERAL YEARS IN OUR HISTORY AND WE MAY NOT BE ABLE TO AGAIN ACHIEVE PROFITABILITY.

We had an accumulated deficit of approximately $124 million as of September 30, 2004. Although we were profitable in 2000 and in 2001, we incurred substantial losses in the years prior to that, and in 2002 and 2003. The deficit resulted because we expended more money in the course of researching, developing and enhancing our technology and products and establishing our marketing and administrative organizations than we generated in revenues. We expect to continue to incur significant operating expenses in the foreseeable future, primarily related to the completion of development and commercialization of the Cardiosonix product line but also potentially related to RIGS and LYMPHOSEEK. As a result, we are sustaining substantial operating and net losses, and it is possible that we will never be able to sustain or develop the revenue levels necessary to again attain profitability.

OUR PRODUCTS MAY NOT ACHIEVE THE BROAD MARKET ACCEPTANCE THEY NEED IN ORDER TO BE A COMMERCIAL SUCCESS.

Widespread use of our gamma detection devices is currently limited to a surgical procedure (ILM) used in the treatment and diagnosis of two primary types of cancer: melanoma and breast cancer. The success of our gamma detection devices greatly depends on the medical community's acceptance of ILM, and on our devices for use in ILM as a reliable, safe and cost effective alternative to current treatments and procedures. The adoption rate for ILM appears to be leveling off and may not meet our growth expectations. Although we continue to believe that ILM has significant advantages over other currently competing procedures, broad-based clinical adoption of ILM will likely not occur until after the completion of ongoing international trials related to breast cancer. Even if the results of these trials are positive, we cannot assure you that ILM will attain rapid and widespread acceptance. Our efforts and those of our marketing and distribution partners may not result in significant demand for our products, and the current demand for our products may decline.

Our future success now also greatly depends on the success of the Cardiosonix product line. Cardiosonix' products are just beginning to be marketed commercially. The market for these products is in an early stage of development and may never fully develop as we expect. The long-term commercial success of the Cardiosonix product line will require widespread acceptance of our products as safe, efficient and cost-effective. Widespread acceptance would represent a significant change in medical practice patterns. Other cardiac monitoring procedures, such as pulmonary artery catheterization, are generally accepted in the medical community and have a long standard of use. It is possible that the Cardiosonix product line will never achieve the broad market acceptance necessary to become a commercial success.

CLINICAL TRIALS FOR OUR PRODUCT CANDIDATES WILL BE LENGTHY AND EXPENSIVE AND THEIR OUTCOME IS UNCERTAIN.

Before obtaining regulatory approval for the commercial sale of any product candidates, we must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for use in humans. Conducting clinical trials is a time consuming, expensive and uncertain process and may take years to complete. Our most advanced product candidates, LYMPHOSEEK and RIGSCAN(R) CR are preparing to enter the Phase III stage of clinical trials. Historically, the results from preclinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. Frequently, drugs that have shown promising results in preclinical or early clinical trials subsequently fail to establish sufficient safety and efficacy data necessary to obtain regulatory approval. At any time during the clinical trials, we, our collaborative partners or the FDA might delay or halt any clinical trials for our product candidates for various reasons, including:



- ineffectiveness of the product candidate;
- discovery of unacceptable toxicities or side effects;
- development of disease resistance or other physiological factors;
- delays in patient enrollment; or
- other reasons that are internal to the businesses of our potential collaborative partners, which reasons they may not share with us.

The results of the clinical trials may fail to demonstrate the safety or effectiveness of our product candidates to the extent necessary to obtain regulatory approval or such that commercialization of our product candidates is

worthwhile. Any failure or substantial delay in successfully completing clinical trials and obtaining regulatory approval for our product candidates could severely harm our business.

WE RELY ON THIRD PARTIES FOR THE WORLDWIDE MARKETING AND DISTRIBUTION OF OUR GAMMA DETECTION DEVICES, WHO MAY NOT BE SUCCESSFUL IN SELLING OUR PRODUCTS.

We currently distribute our gamma detection devices in most global markets through two partners who are solely responsible for marketing and distributing these products. The partners assume direct responsibility for business risks related to credit, currency exchange, foreign tax laws or tariff and trade regulation. While we believe that our distribution partners intend to continue to aggressively market our products, we cannot assure you that the distribution partners will succeed in marketing our products on a global basis. We may not be able to maintain satisfactory arrangements with our marketing and distribution partners, who may not devote adequate resources to selling our gamma detection devices. If this happens, we may not be able to successfully market our products, which would decrease our revenues.

IF WE FAIL TO OBTAIN COLLABORATIVE PARTNERS, OR THOSE WE OBTAIN FAIL TO PERFORM THEIR OBLIGATIONS OR DISCONTINUE CLINICAL TRIALS FOR PARTICULAR PRODUCT CANDIDATES, OUR ABILITY TO DEVELOP AND MARKET POTENTIAL PRODUCTS COULD BE SEVERELY LIMITED.

Our strategy for the development and commercialization of our product candidates depends, in large part, upon the formation of collaborative arrangements. Collaborations may allow us to:

- generate cash flow and revenue;
- offset some of the costs associated with our internal research and development, preclinical testing, clinical trials and manufacturing;
- seek and obtain regulatory approvals faster than we could on our own; and,
- successfully commercialize existing and future product candidates.

We do not currently have collaborative agreements covering LYMPHOSEEK or RIGSCAN CR. We cannot assure you that we will be successful in securing collaborative partners, or that we will be able to negotiate acceptable terms for such arrangements. The development, regulatory approval and commercialization of our product candidates will depend substantially on the efforts of collaborative partners, and if we fail to secure or maintain successful collaborative arrangements, or if our partners fail to perform their obligations, our development, regulatory, manufacturing and marketing activities may be delayed, scaled back or suspended.

WE DO NOT HAVE EXPERIENCE IN MARKETING BLOOD FLOW DEVICES AND WE HAVE NOT YET ESTABLISHED LONG-TERM STRATEGIC RELATIONSHIPS WITH A SIGNIFICANT NUMBER OF POTENTIAL MARKETING PARTNERS.

We completed the Cardiosonix acquisition on December 31, 2001, and to date we have limited marketing and distribution experience with the QUANTIX(R) line of blood flow products covering only a limited number of countries. We believe the adoption path for Cardiosonix' products will be similar to that of our gamma detection devices, but we have no direct experience in marketing or selling blood flow measurement devices and will likely be working with pricing structures such as per-use or leasing with which we have little direct experience. Further, we may not be successful in creating the necessary infrastructure, either internally or through third parties, to support the successful marketing and sales of Cardiosonix products.

WE MAY HAVE DIFFICULTY RAISING ADDITIONAL CAPITAL, WHICH COULD DEPRIVE US OF NECESSARY RESOURCES.

We expect to continue to devote capital resources to fund research and development and to maintain existing and secure new manufacturing capacity. In order to support the initiatives envisioned in our business plan, we may need to raise additional funds through the sale of assets, public or private financing, collaborative relationships or other arrangements. Our ability to raise additional financing depends on many factors beyond our control, including the state of capital markets, the market price of our common stock and the development or prospects for development of competitive technology by others. Because our common stock is not listed on a major stock market, many investors may not be willing or allowed to purchase it or may demand steep discounts. Sufficient additional financing may not be available to us or may be available only on terms that would result in further dilution to the current owners of our common stock. At current market prices, the limited number of shares we have available to sell severely limits our ability to use equity as a method of raising capital. If we are unable to raise additional funds when we need them, we may have to severely curtail our operations.

OUR RADIOPHARMACEUTICAL PRODUCTS ARE SUBJECT TO EXTENSIVE GOVERNMENT REGULATIONS AND WE MAY NOT BE ABLE TO OBTAIN NECESSARY REGULATORY APPROVALS.

We may not receive the regulatory approvals necessary to commercialize our product candidates, which could cause our business to be severely harmed. Our product candidates are subject to extensive and rigorous government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. If our potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments. None of our product candidates has been approved for sale in the United States or any foreign market. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, complex, expensive and uncertain. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish the product candidate's safety and efficacy. Data obtained from preclinical and clinical trials are susceptible to varying interpretation, which may delay, limit or prevent regulatory approval. The approval process may take many years to complete and may involve ongoing requirements for post-marketing studies. In light of the limited regulatory history of monoclonal antibody-based therapeutics, regulatory approvals for our products may not be obtained without lengthy delays, if at all. Any FDA or other regulatory approvals of our product candidates, once obtained, may be withdrawn. The effect of government regulation may be to:

- delay marketing of potential products for a considerable period of time;
- limit the indicated uses for which potential products may be marketed;
- impose costly requirements on our activities; and
- provide competitive advantage to other pharmaceutical and biotechnology companies.

We may encounter delays or rejections in the regulatory approval process because of additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other regulatory action against our product candidates or us. Outside the United States, our ability to market a product is contingent upon receiving clearances from the appropriate regulatory authorities. This foreign regulatory approval process includes similar risks to those associated with FDA approval process.

OUR PRODUCT CANDIDATES WILL REMAIN SUBJECT TO ONGOING REGULATORY REVIEW EVEN IF THEY RECEIVE MARKETING APPROVAL. IF WE FAIL TO COMPLY WITH CONTINUING REGULATIONS, WE COULD LOSE THESE APPROVALS AND THE SALE OF OUR PRODUCTS COULD BE SUSPENDED.



Even if we receive regulatory approval to market a particular product candidate, the approval could be conditioned on us conducting additional costly post-approval studies or could limit the indicated uses included in our labeling. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market or impede or delay our ability to obtain regulatory approvals in additional countries. In addition, the manufacturer of the product and its facilities will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product will remain subject to extensive regulatory requirements. We may be slow to adapt, or we may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements.

If we fail to comply with the regulatory requirements of FDA and other applicable U.S. and foreign regulatory authorities or previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;
- import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and

- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

UNFAVORABLE PRICING REGULATIONS, THIRD-PARTY REIMBURSEMENT PRACTICES OR HEALTHCARE REFORM INITIATIVES APPLICABLE TO OUR PRODUCT CANDIDATES COULD LIMIT OUR POTENTIAL PRODUCT REVENUE.

The regulations governing drug pricing and reimbursement vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed and, in many of these countries, the pricing review period begins only after approval is granted. In some countries, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Although we monitor these regulations, our product candidates are currently in the development stage and we will not be able to assess the impact of price regulations for at least several years. As a result, we may obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay the commercial launch of the product and may negatively impact the revenues we are able to derive from sales in that country.

WE MAY BE UNABLE TO ESTABLISH THE PHARMACEUTICAL MANUFACTURING CAPABILITIES NECESSARY TO DEVELOP AND COMMERCIALIZE OUR POTENTIAL PRODUCTS.

We do not have our own manufacturing facility for the manufacture of the radiopharmaceutical compounds necessary for clinical testing or commercial sale. We intend to rely in part on third-party contract manufacturers to produce sufficiently large quantities of drug materials that are and will be needed for clinical trials and commercialization of our potential products. Third-party manufacturers may not be able to meet our needs with respect to timing, quantity or quality of materials. If we are unable to contract for a sufficient supply of needed materials on acceptable terms, or if we should encounter delays or difficulties in our relationships with manufacturers, our clinical trials may be delayed, thereby delaying the submission of product candidates for regulatory approval and the market introduction and subsequent commercialization of our potential products. Any such delays may lower our revenues and potential profitability.



We may develop our manufacturing capacity in part by expanding our current facilities or building new facilities. Either of these activities would require substantial additional funds and we would need to hire and train significant numbers of employees to staff these facilities. We may not be able to develop manufacturing facilities that are sufficient to produce drug materials for clinical trials or commercial use. We and any third-party manufacturers that we may use must continually adhere to current Good Manufacturing Practices regulations enforced by FDA through its facilities inspection program. If our facilities or the facilities of third-party manufacturers cannot pass a pre-approval plant inspection, FDA will not grant approval to our product candidates. In complying with these regulations and foreign regulatory requirements, we and any of our third-party manufacturers will be obligated to expend time, money and effort on production, record-keeping and quality control to assure that our potential products meet applicable specifications and other requirements. If we or any third-party manufacturer with whom we may contract fail to maintain regulatory compliance, we or the third party may be subject to fines and/or manufacturing operations may be suspended.

THE SALE OF THE SHARES OF COMMON STOCK ACQUIRED IN PRIVATE PLACEMENTS COULD CAUSE THE PRICE OF OUR COMMON STOCK TO DECLINE.

During 2003 and 2004, we completed several financings in which we issued common stock, convertible notes, warrants and other securities convertible into common stock to certain private investors and as required under the terms of those transactions, we filed a registration statements with the United States Securities and Exchange Commission (SEC) under which the investors may resell common stock acquired in these transactions, as well as common stock acquired on the exercise of the warrants and convertible securities held by them, to the public. We have also filed a registration statement covering the resale of common stock issued to former stockholders of Cardiosonix in connection with our acquisition of that business.

The selling stockholders under these registration statements may sell none, some or all of the shares of common stock acquired from us, as well as common stock acquired on the exercise of the warrants and convertible securities held by them. We have no way of knowing whether the selling stockholders will sell the shares covered by these registration statements. Depending upon market liquidity at the time, a sale of shares covered by these registration statements at any given time could cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock under this prospectus, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

WE RELY ON THIRD PARTIES TO MANUFACTURE OUR PRODUCTS AND OUR BUSINESS WILL SUFFER IF THEY DO NOT PERFORM.

We rely on independent contract manufacturers for the manufacture of our current line of gamma detection systems and for our QUANTIX line of blood flow monitoring products. Our business will suffer if our contract manufacturers have production delays or quality problems. Furthermore, medical device manufacturers are subject to the QSR regulations of FDA, international quality standards, and other regulatory requirements. If our contractors do not operate in accordance with regulatory requirements and quality standards, our business will suffer. We use or rely on components and services used in our devices that are provided by sole source suppliers. The qualification of additional or replacement vendors is time consuming and costly. If a sole source supplier has significant problems supplying our products, our sales and revenues will be hurt until we find a new source of supply. In addition, our distribution agreement with EES for gamma devices contains failure to supply provisions, which, if triggered, could have a significant negative impact on our business.



WE MAY LOSE OUT TO LARGER AND BETTER-ESTABLISHED COMPETITORS.

The medical device and biotechnology industries are intensely competitive. Some of our competitors have significantly greater financial, technical, manufacturing, marketing and distribution resources as well as greater experience in the medical device industry than we have. The particular medical conditions our product lines address can also be addressed by other medical devices, procedures or drugs. Many of these alternatives are widely accepted by physicians and have a long history of use. Physicians may use our competitors' products and/or our products may not be competitive with other technologies. If these things happen, our sales and revenues will decline. In addition, our current and potential competitors may establish cooperative relationships with large medical equipment companies to gain access to greater research and development or marketing resources. Competition may result in price reductions, reduced gross margins and loss of market share.

OUR PRODUCTS MAY BE DISPLACED BY NEWER TECHNOLOGY.

The medical device and biotechnology industries are undergoing rapid and significant technological change. Third parties may succeed in developing or marketing technologies and products that are more effective than those developed or marketed by us, or that would make our technology and products obsolete or non-competitive. Additionally, researchers could develop new surgical procedures and medications that replace or reduce the importance of the procedures that use our products. Accordingly, our success will depend, in part, on our ability to respond quickly to medical and technological changes through the development and introduction of new products. We may not have the resources to do this. If our products become obsolete and our efforts to develop new products do not result in any commercially successful products, our sales and revenues will decline.

WE ARE IN A HIGHLY REGULATED BUSINESS AND COULD FACE SEVERE PROBLEMS IF WE DO NOT COMPLY WITH ALL REGULATORY REQUIREMENTS IN THE GLOBAL MARKETS IN WHICH OUR PRODUCTS ARE SOLD.

FDA regulates our products in the United States. Foreign countries also subject our products to varying government regulations. In addition, such regulatory authorities may impose limitations on the use of our products. FDA enforcement policy strictly prohibits the marketing of FDA cleared medical devices for unapproved uses. Within the European Union, our products are required to display the CE Mark in order to be sold. We have obtained FDA clearance to market and European certification to display the CE Mark on our current line of gamma detection systems and on two of Cardiosonix' products, the QUANTIX/ND(TM) and QUANTIX/OR(TM). We may not be able to obtain clearance to market for any neW products in a timely manner, or at all. Failure to comply with these and other current and emerging regulatory requirements in the global markets in which our products are sold could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance for devices, withdrawal of clearances, and criminal prosecution.

OUR INTELLECTUAL PROPERTY MAY NOT HAVE OR PROVIDE SUFFICIENT LEGAL PROTECTIONS AGAINST INFRINGEMENT OR LOSS OF TRADE SECRETS.

Our success depends, in part, on our ability to secure and maintain patent protection, to preserve our trade secrets, and to operate without infringing on the patents of third parties. While we seek to protect our proprietary positions by filing United States and foreign patent applications for our important inventions and improvements, domestic and foreign patent offices may not issue these patents. Third parties may challenge, invalidate, or circumvent our patents or patent applications in the future. Competitors, many of which have significantly more resources than we have and have made substantial investments in competing technologies, may apply for and obtain patents that will prevent, limit, or interfere with our ability to make, use, or sell our products either in the United States or abroad.

In the United States, patent applications are secret until patents issue, and in foreign countries, patent applications are secret for a time after filing. Publications of discoveries tend to significantly lag the actual discoveries and the filing of related patent applications. Third parties may have already filed applications for patents for products or processes that will make our products obsolete or will limit our patents or invalidate our patent applications.

We typically require our employees, consultants, advisers and suppliers to execute confidentiality and assignment of invention agreements in connection with their employment, consulting, advisory, or supply relationships with us. They may breach these agreements and we may not obtain an adequate remedy for breach. Further, third parties may gain access to our trade secrets or independently develop or acquire the same or equivalent information.

Agencies of the United States government conducted some of the research activities that led to the development of antibody technology that some of our proposed antibody-based surgical cancer detection products use. When the United States government participates in research activities, it retains rights that include the right to use the technology for governmental purposes under a royalty-free license, as well as rights to use and disclose technical data that could preclude us from asserting trade secret rights in that data and software.

CONDITIONS IN ISRAEL MAY AFFECT THE OPERATIONS OF CARDIOSONIX AND MAY LIMIT OUR ABILITY TO COMPLETE DEVELOPMENT OF ITS PRODUCTS.

Our Cardiosonix subsidiary is incorporated in Israel, and its offices and research and development facilities are located there. In concert with the plan to transfer or manufacturing of the QUANTIX products to a contract manufacturer located in the United States, certain manufacturing and development activities underway in Israel have been or will be curtailed or discontinued. While we have reduced our activities in Israel, continued adverse political, economic and military conditions in Israel may directly affect our operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel. Despite past progress towards peace between Israel and its Arab neighbors, the future of these peace efforts is uncertain. Any armed conflict, political instability or continued violence in the region could have a negative effect on the activities of Cardiosonix and the completion of development and commercialization of our blood flow monitoring products.

THE GOVERNMENT GRANTS CARDIOSONIX HAS RECEIVED FOR RESEARCH AND DEVELOPMENT EXPENDITURES RESTRICT OUR ABILITY TO MANUFACTURE BLOOD FLOW MONITORING PRODUCTS AND TRANSFER TECHNOLOGIES OUTSIDE OF ISRAEL AND REQUIRE US TO SATISFY SPECIFIED CONDITIONS. IF WE FAIL TO SATISFY THESE CONDITIONS, WE MAY BE REQUIRED TO REFUND GRANTS PREVIOUSLY RECEIVED TOGETHER WITH INTEREST AND PENALTIES, AND MAY BE SUBJECT TO CRIMINAL CHARGES.

Cardiosonix received grants from the government of Israel through the Office of the Chief Scientist (OCS) of the Ministry of Industry and Trade for the financing of a portion of its research and development expenditures associated with our blood flow monitoring products. From 1998 to 2001, Cardiosonix received grants totaling $775,000 from the OCS. The terms of the OCS grants may affect our efforts to transfer manufacturing of products developed using these grants outside of Israel without special approvals. The OCS issued a letter to Neoprobe in December 2001, prior to the acquisition of Cardiosonix, consenting to the transfer of manufacturing as long as Neoprobe consented to the terms of the OCS statutes under Israeli law. As a result of our efforts to transfer a significant portion of the manufacture of our blood flow products out of Israel, we will likely be required to pay an increased amount of royalties, which may be up to 300% of the grant amount, depending on the manufacturing volume that is performed outside of Israel. This may impair our ability to effectively outsource manufacturing or engage in similar arrangements for those products or technologies. In addition, if we fail to comply with any of the conditions imposed by the OCS, we may be required to refund any grants previously received together with interest and penalties, and may be subject to criminal charges. In recent years, the government of Israel has accelerated the rate of repayment of OCS grants related to other grantees and may further accelerate them in the future.

OUR PRODUCT SALES MAY BE ADVERSELY AFFECTED BY HEALTHCARE PRICING REGULATION AND REFORM ACTIVITIES.

The healthcare industry is undergoing fundamental changes resulting from political, economic and regulatory influences. In the United States, comprehensive programs have been proposed that seek to increase access to healthcare for the uninsured, control the escalation of healthcare expenditures within the economy and use healthcare reimbursement policies to balance the federal budget.

We expect that Congress and state legislatures will continue to review and assess healthcare proposals, and public debate of these issues will likely continue. We cannot predict which, if any, of such reform proposals will be adopted and when they might be adopted. Other countries also are considering healthcare reform. Significant changes in healthcare systems could have a substantial impact on the manner in which we conduct our business and could require us to revise our strategies.



WE COULD BE DAMAGED BY PRODUCT LIABILITY CLAIMS.

Our products are used or intended to be used in various clinical or surgical procedures. If one of our products malfunctions or a physician misuses it and injury results to a patient or operator, the injured party could assert a product liability claim against our company. We currently have product liability insurance with a $10 million per occurrence limit, which we believe is adequate for our current activities. However, we may not be able to continue to obtain insurance at a reasonable cost. Furthermore, insurance may not be sufficient to cover all of the liabilities resulting from a product liability claim, and we might not have sufficient funds available to pay any claims over the limits of our insurance. Because personal injury claims based on product liability in a medical setting may be very large, an underinsured or an uninsured claim could financially damage our company.

WE MAY HAVE TROUBLE ATTRACTING AND RETAINING QUALIFIED PERSONNEL AND OUR BUSINESS MAY SUFFER IF WE DO NOT.

Our business has experienced developments the past two years that have resulted in several significant changes in our strategy and business plan, including the shifting of resources to support our current product initiatives and downsizings to what we consider to be the minimal support structure necessary to operate a publicly traded company. Our management will need to remain flexible to support our business model over the next few years. However, losing members of the Neoprobe management team could have an adverse effect on our operations. Our success depends on our ability to attract and retain technical and management personnel with expertise and experience in the medical device business. The competition for qualified personnel in the medical device industry is intense and we may not be successful in hiring or retaining the requisite personnel. If we are unable to attract and retain qualified technical and management personnel, we will suffer diminished chances of future success.

RISKS OF SECURED INDEBTEDNESS

All of our material assets, except the intellectual property associated with our Lymphoseek and RIGS products under development, have been pledged as collateral for the $8.1 million in principal amount of our 8% Series A Convertible Notes due December 12, 2008 (the "Notes"). In addition to the security interest in our assets, the Notes carry substantial covenants that impose significant requirements on us, including, among others, requirements that:

- we pay all principal, interest and other charges on the Notes when

due;

- we use the proceeds from the sale of the Notes only for permitted purposes;
- we nominate and recommend for election as a director a person designated by the holders of the Notes;
- we keep reserved out of our authorized shares of common stock sufficient shares to satisfy our obligation to issue shares on conversion of the Notes and the exercise of the warrants issued in connection with the sale of the Notes;
- we achieve annual revenues on a consolidated basis of at least $5.4 million in 2005, $6.5 million in 2006, and $9 million in each year thereafter;
- we maintain a minimum cash balances of $4.5 million at the end of first 6 months of 2005, $4 million at the end of the second six months of 2005, and $3.5 million at the end of each 6 month period thereafter; and
- that we indemnify the purchasers of the Notes against certain liabilities.



Additionally, with certain exceptions, the Notes prohibit us from:

- amending our organizational or governing agreements and documents, entering into any merger or consolidation, dissolving the Company or liquidating its assets, or acquiring all or any substantial part of the business or assets of any other person;
- engaging in transactions with any affiliate;
- entering into any agreement inconsistent with our obligations under the Notes and related agreements;
- incurring any indebtedness, capital leases, or contingent obligations outside the ordinary course of business;
- granting or permitting liens against or security interests in our assets;
- making any material dispositions of our assets outside the ordinary course of business;
- declaring or paying any dividends or making any other restricted payments; or
- making any loans to or investments in other persons outside of the ordinary course of business.

Our ability to comply with these provisions may be affected by changes in our business condition or results of our operations, or other events beyond our control. The breach of any of these covenants would result in a default under the Notes, permitting the holders of the Notes to accelerate their maturity and to sell the assets securing them. Such actions by the holders of the Notes could cause us to cease operations or seek bankruptcy protection.

OUR COMMON STOCK IS TRADED OVER THE COUNTER, WHICH MAY DEPRIVE STOCKHOLDERS OF THE FULL VALUE OF THEIR SHARES.

Our common stock is quoted via the National Association of Securities Dealers' Over The Counter Bulletin Board (OTCBB). As such, our common stock may have fewer market makers, lower trading volumes and larger spreads between bid and asked prices than securities listed on an exchange such as the New York Stock Exchange or the Nasdaq Stock Market. These factors may result in higher price volatility and less market liquidity for the common stock.

A LOW MARKET PRICE MAY SEVERELY LIMIT THE POTENTIAL MARKET FOR OUR COMMON STOCK.

Our common stock is currently trading at a price substantially below $5.00 per share, subjecting trading in the stock to certain SEC rules requiring additional disclosures by broker-dealers. These rules generally apply to any non-NASDAQ equity security that has a market price share of less than $5.00 per share, subject to certain exceptions (a "penny stock"). Such rules require the delivery, prior to any penny stock transaction, of a disclosure schedule explaining the penny stock market and the risks associated therewith and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and institutional or wealthy investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to the sale. The broker-dealer also must disclose the commissions payable to the broker-dealer, current bid and offer quotations for the penny stock and, if the broker-dealer is the sole market maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Such information must be provided to the customer orally or in writing before or with the written confirmation of trade sent to the customer. Monthly statements must be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. The additional burdens imposed upon broker-dealers by such requirements could discourage broker-dealers from effecting transactions in our common stock.

THE PRICE OF OUR COMMON STOCK HAS BEEN HIGHLY VOLATILE DUE TO SEVERAL FACTORS THAT WILL CONTINUE TO AFFECT THE PRICE OF OUR STOCK.

Our common stock has traded as low as $0.25 per share and as high as $1.11 per share in the last twelve months. Some of the factors leading to the volatility include:



- price and volume fluctuations in the stock market at large which do not relate to our operating performance;
- fluctuations in our operating results;
- financing arrangements we may enter that require the issuance of a significant number of shares in relation to the number of shares currently outstanding;
- announcements of technological innovations or new products which we or our competitors make;
- FDA and/or international regulatory actions;
- developments with respect to patents or proprietary rights;

- public concern as to the safety of products that we or others develop; and

- fluctuations in market demand for and supply of our products.

AN INVESTOR'S ABILITY TO TRADE OUR COMMON STOCK MAY BE LIMITED BY TRADING VOLUME.

Until recently, the trading volume for our common stock has been relatively limited. A consistently active trading market for our common stock may not occur on the OTCBB. The average daily trading volume for our common stock on the OTCBB for the twelve-month period ended December 20, 2004 was approximately 508,000 shares. Daily volume during that period ranged from 0 shares to 4.4 million shares.

OUR STOCKHOLDER RIGHTS PLAN, SOME PROVISIONS OF OUR ORGANIZATIONAL AND GOVERNING DOCUMENTS AND AN AGREEMENT WITH SELLING STOCKHOLDERS, MAY HAVE THE EFFECT OF DETERRING THIRD PARTIES FROM MAKING TAKEOVER BIDS FOR CONTROL OF OUR COMPANY OR MAY BE USED TO HINDER OR DELAY A TAKEOVER BID.

Our certificate of incorporation authorizes the creation and issuance of "blank check" preferred stock. Our Board of Directors may divide this stock into one or more series and set their rights. The Board of Directors may, without prior stockholder approval, issue any of the shares of "blank check" preferred stock with dividend, liquidation, conversion, voting or other rights, which could adversely affect the relative voting power or other rights of the common stock. Preferred stock could be used as a method of discouraging, delaying, or preventing a take-over of our company. If we issue "blank check" preferred stock, it could have a dilutive effect upon our common stock. This would decrease the chance that our stockholders would realize a premium over market price for their shares of common stock as a result of a takeover bid.

BECAUSE WE WILL NOT PAY DIVIDENDS, STOCKHOLDERS WILL ONLY BENEFIT FROM OWNING COMMON STOCK IF IT APPRECIATES.

We have never paid dividends on our common stock and we do not intend to do so in the foreseeable future. We intend to retain any future earnings to finance our growth. Accordingly, any potential investor who anticipates the need for current dividends from his investment should not purchase our common stock.



## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things:

- general economic and business conditions, both nationally and in our markets,

- our history of losses,

- our expectations and estimates concerning future financial performance, financing plans and the impact of competition,

- our ability to implement our growth strategy,
- anticipated trends in our business,
- advances in technologies, and
- other risk factors set forth under "Risk Factors" in this prospectus.

In addition, in this prospectus, we use words such as "anticipates," "believes," "plans," "expects," "future," "intends," and similar expressions to identify forward-looking statements.

We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

## USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by the selling stockholders. We will receive no proceeds from the sale of shares of common stock in this offering.



## MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock trades on the OTCBB under the trading symbol NEOP. The prices set forth below reflect the quarterly high, low and closing sales prices for shares of our common stock during the last three fiscal years as reported by Reuters Limited. These quotations reflect inter-dealer prices, without retail markup, markdown or commission, and may not represent actual transactions.

| | HIGH | LOW | CLOSE |
|---|---|---|---|
| Fiscal Year 2004 | | | |
| First Quarter | $ 1.10 | $ 0.28 | $ 0.90 |
| Second Quarter | $ 1.11 | $ 0.41 | $ 0.60 |
| Third Quarter | $ 0.60 | $ 0.35 | $ 0.53 |
| Fourth Quarter through December 20, 2004 | $ 0.61 | $ 0.37 | $ 0.59 |
| Fiscal Year 2003 | | | |
| First Quarter | $ 0.17 | $ 0.10 | $ 0.11 |
| Second Quarter | $ 0.26 | $ 0.10 | $ 0.17 |
| Third Quarter | $ 0.50 | $ 0.14 | $ 0.29 |
| Fourth Quarter | $ 0.43 | $ 0.24 | $ 0.31 |
| Fiscal Year 2002 | | | |
| First Quarter | $ 0.55 | $ 0.35 | $ 0.38 |
| Second Quarter | $ 0.42 | $ 0.25 | $ 0.28 |
| Third Quarter | $ 0.30 | $ 0.08 | $ 0.12 |
| Fourth Quarter | $ 0.31 | $ 0.05 | $ 0.13 |

As of December 20, 2004, we had approximately 827 holders of common stock of record.

We have not paid any dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future. We intend to retain any earnings to finance the growth of our business. We cannot assure you that we will ever pay cash dividends. Whether we pay cash dividends in the future will be at the discretion of our Board of Directors and will depend upon our financial condition, results of operations, capital requirements and any other factors that the Board of Directors decides is relevant. See Management's Discussion and Analysis of Financial Condition and Results of Operations below.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF
FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read together with our Financial Statements and the Notes related to those statements, as well as the other financial information included in the Form SB-2 Registration Statement, of which this prospectus is a part. Some of our discussion is forward-looking and involves risks and uncertainties. For information regarding risk factors that could have a material adverse effect on our business, refer to the Risk Factors section of this prospectus beginning on page 4.

THE COMPANY

Neoprobe Corporation is a biomedical technology company that provides innovative surgical and diagnostic products that enhance patient care by meeting the critical decision-making needs of physicians. The December 2001 acquisition of Cardiosonix expanded our potential product offerings beyond the neo2000 gamma detection device which is marketed in the oncology arena into the area of blood flow measurement and cardiac care. Cardiosonix is in the process of developing and commercializing a unique line of proprietary blood flow monitoring devices for a variety of diagnostic and surgical applications and has received marketing clearance for two of its products, QUANTIX/ND and QUANTIX/OR, in Europe and in the U.S. In addition to our medical device products, we have two radiopharmaceutical products, RIGSCAN CR and Lymphoseek, in the advanced phases of clinical development.



YEARS ENDED DECEMBER 31, 2003 AND 2002

RESULTS OF OPERATIONS

Net Sales and Margins. Net sales increased $2.2 million, or 64%, to $5.6 million in 2003 from $3.4 million in 2002. Gross margins on net sales increased to 44% of net sales for 2003 compared to 30% of net sales for 2002. During the third quarter of 2002, we recorded an inventory impairment charge of $214,000 related to our BLUETIP probe product. This charge adversely affected our gross margins for 2002 by 7 percentage points.

Approximately $1.9 million of the increase in net sales was the result of increased revenue related to our gamma detection products with the remaining $245,000 generated from our blood flow products. We had only $59,000 in revenues from blood flow products during 2002. Of the increased revenue from gamma detection products, approximately 20% was due to increased prices realized on our NEO2000(R) Control unit and 14mm probes, with approximately 70% due to increased sales volumes of these products. The remaining 10% was due to various changes in other products and product mix. The price at which we sell our gamma detection products to Ethicon Endo-Surgery, Inc., (EES) is based on a percentage of the global average selling price (ASP) received by EES on sales of Neoprobe products to end customers, subject to a minimum floor price. The increase in gross margins was primarily due to the higher recorded revenue per gamma

detection system combined with lower internal manufacturing costs as a result of headcount reductions during the third and fourth quarters of 2002 that contributed to lower average costs.

License and Other Revenue. License and other revenue for 2003 and 2002 included $800,000 from the pro-rata recognition of license fees related to the distribution agreement with EES and $146,000 and $520,000, respectively, from the reimbursement by EES of certain product development costs. License and other revenue in 2002 also included $218,000 from EES' waiver of certain warranty costs due from us in exchange for a release from contractual minimum purchase requirements.

Research and Development Expenses. Research and development expenses decreased $430,000, or 19%, to $1.9 million during 2003 from $2.3 million in 2002. The decrease was primarily due to $425,000 in lower compensation costs resulting from headcount reductions of gamma product line personnel in the third and fourth quarters of 2002, coupled with decreased use of external design consultants and decreased prototype expenses related to the blood flow product line. 2003 and 2002 also included $27,000 and $50,000, respectively, of license fees related to the LYMPHOSEEK tracing agent.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $165,000, or 5%, to $3.1 million during 2003 from $3.3 million during 2002. The decrease was primarily due to $232,000 in lower compensation costs resulting from headcount reductions of gamma product line personnel in the third and fourth quarters of 2002, offset by increases in certain overhead costs such as bad debts and insurance and increased selling, general and administrative expenses incurred in the operation and support of Cardiosonix. Selling, general and administrative expenses in 2003 and 2002 included $30,000 and $138,000, respectively, in impairment expense related to production equipment and intellectual property that we did not believe had ongoing value to our business. Selling, general and administrative expenses in 2002 also included $79,000 for the transfer of manufacturing of certain components of the NEO2000 gamma detection system to UMM.

Other Income (Expenses). Other income decreased $217,000 resulting in other expenses of $188,000 during 2003 compared to other income of $29,000 during 2002. Other expenses during 2003 consisted primarily of interest expense, amortized discount on our notes payable and interest expense related to the financing of our accounts receivable. Other income during 2002 consisted primarily of interest income. Our interest income decreased because we maintained a lower balance of cash and investments during 2003 as compared to 2002.



NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

RESULTS OF OPERATIONS

Net Sales and Margins. Net sales, primarily of our gamma detection systems, increased $230,000, or 6%, to $4.1 million during the first nine months of 2004 from $3.9 million during the same period in 2003. Gross margins on net sales increased to 59% of net sales for the first nine months of 2004 compared to 45% of net sales for the same period in 2003.

The increase in net sales was primarily a result of a $302,000 increase in gamma device sales and a $126,000 increase in gamma device service revenue, offset by a $198,000 decrease in sales of our blood flow measurement devices. We expect gamma device revenue for 2004 to be generally consistent with gamma device sales

for 2003. During the fourth quarter of 2003 and the first half of 2004, we identified a market need for certain product enhancements to our blood flow measurement devices that we are in the process of implementing. As a result, our sales efforts will be affected until the enhancements can be launched, which we expect to occur in the fourth quarter of this year. We expect blood flow sales to begin to pick up during the first quarter of 2005.

The increase in gross margins was primarily due to decreases in the unit costs to manufacture our neo2000 control unit resulting from internal design changes and a lower cost structure at the new contract manufacturer. Cost of goods sold for 2004 included a $78,000 charge for inventory obsolescence primarily related to design changes in our QUANTIX product line.

License and Other Revenue. License and other revenue in the first nine months of 2004 and 2003 included $600,000 from the pro-rata recognition of license fees related to the distribution agreement with EES. License and other revenue in the first nine months of 2003 also included $146,000 from the reimbursement by EES of certain product development costs.

Research and Development Expenses. Research and development expenses increased $401,000 or 29% to $1.8 million during the first nine months of 2004 from $1.4 million during the same period in 2003. Research and development expenses in the first nine months of 2004 included approximately $270,000 in gamma detection drug development costs, $159,000 related to our gamma detection devices and $792,000 related to the QUANTIX products. This compares to expenses of $28,000, $39,000 and $899,000 in these relative segment categories in the same period in 2003. The changes in each segment were primarily due to (i) efforts to support the re-initiation of our RIGSCAN CR research effort and to move our development of LYMPHOSEEK forward, (ii) development activities related to updated versions of our neo2000 control unit and detector probes, and (iii) the costs of product refinement activities related to the QUANTIX/OR offsetting cost savings from headcount reductions at our facility in Israel, respectively.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $131,000 or 6% to $2.4 million during the first nine months of 2004 from $2.2 million during the same period in 2003. The increase was primarily due to increases of $125,000 in marketing expenses related to the marketing activities in support of the launch of our QUANTIX line of blood flow products, $81,000 in increased wages and benefits, and $58,000 in professional services coupled with increased investor relations services costs and board meeting expenses, offset by decreases of $81,000 in depreciation and amortization expenses, $51,000 in consulting services as well as decreases in space costs and bad debt expense. Selling, general and administrative expenses in the first nine months of 2003 also included $30,000 in impairment of intellectual property that we did not believe had ongoing value to the business.

Other Income (Expenses). Other expenses increased $12,000 to $136,000 during the first nine months of 2004 from $123,000 during the same period in 2003. The primary reason for the increase was an increase in interest expense on debt financings entered into during 2003. Of this interest expense, $132,000 and $62,000 in the first nine months of 2004 and 2003, respectively, was non-cash in nature related to the amortization of debt discounts resulting from the warrants and beneficial conversion feature issued in connection with the underlying debt agreements. Other expenses during the first nine months of 2004 also included $17,000 in income related to miscellaneous refunds. Other expenses during the first nine months of 2003 included $30,000 in interest expense related to the factoring of our accounts receivable.

LIQUIDITY AND CAPITAL RESOURCES

Operating Activities. Cash used in operations decreased $295,000 to $625,000 used during the first nine months of 2004 from $919,000 used during the same period in 2003. Working capital increased $1.4 million to $4.0 million at September 30, 2004 as compared to $2.5 million at December 31, 2003. The current ratio increased to 5.4:1 at September 30, 2004 from 2.6:1 at December 31, 2003. The increase in working capital was primarily related to cash generated from the sale of our common stock and the exercise of warrants combined with recognition of non-cash license fees related to our distribution agreement with EES.

Cash balances increased to $3.0 million at September 30, 2004 from $1.6 million at December 31, 2003, primarily due to the cash generated from the sale of our common stock and the exercise of warrants, offset by increased operating expenses during the first nine months of 2004.

Accounts receivable decreased to $746,000 at September 30, 2004 from $1.1 million at December 31, 2003. We expect receivable levels to continue to fluctuate over the remainder of 2004 as the level of accounts receivable is greatly dependent on the timing of purchases and payments by EES as well as the potential effect of sales of blood flow products.

Inventory levels decreased to $947,000 at September 30, 2004 as compared to $1.0 million at December 31, 2003. We expect inventory levels to increase over the remainder of 2004 as we re-establish our gamma device safety stock and build finished units of our blood flow products in preparation for broader distribution.

Investing Activities. Cash used in investing activities remained constant at $84,000 during the first nine months of 2004 and 2003. Capital expenditures in the first nine months of 2004 were primarily related to purchases of technology infrastructure. Capital expenditures in the first nine months of 2003 were primarily purchases of production tools and equipment in preparation for the manufacture of our Quantix line of blood flow measurement devices. Capital needs for the remainder of 2004 are expected to be consistent with 2003.

Financing Activities. Financing activities generated $2.1 million in cash in the first nine months of 2004 versus $725,000 provided during the same period in 2003.

On November 19, 2001, we entered into a common stock purchase agreement with an investment fund, Fusion Capital Fund II, LLC (Fusion) for the issuance and purchase of our common stock. Under the stock purchase agreement, Fusion committed to purchase up to $10 million of our common stock over a forty-month period that commenced in May 2002. A registration statement registering for resale up to 5 million shares of our common stock became effective on April 15, 2002. Under the terms of the agreement, we can request daily drawdowns, subject to a daily base amount currently set at $12,500. The number of shares we are to issue to Fusion in return for that money is based on the lower of (a) the closing sale price for our common stock on the day of the draw request or (b) the average of the three lowest closing sales prices for our common stock during a twelve-day period prior to the draw request. However, no shares may be sold to Fusion at lower than a floor price currently set at $0.30, which may be reduced by us, but in no case below $0.20 without Fusion's prior consent. Upon execution of the common stock purchase agreement, we issued 449,438 shares of our common stock to Fusion as a commitment fee. During the second half of 2003, we sold Fusion a total of 473,869 shares of common stock and realized net proceeds of $143,693. We issued Fusion 6,462 shares of common stock for commitment fees related to the sales of our common stock to them during 2003. During the first nine months of 2004, we sold Fusion a total of 2,350,000 shares of common stock and realized net proceeds of $1,468,874. We also issued Fusion 66,129 shares of common stock for commitment fees related to the sales of our common stock to

them during the first nine months of 2004.

During April 2003, we completed a bridge loan agreement with our President and CEO, David Bupp. Under the terms of the agreement, Mr. Bupp advanced us $250,000. In consideration for the loan, we issued a note to Mr. Bupp in the principal amount of $250,000. The note was secured by general assets of the company, excluding accounts receivable. In addition, we issued Mr. Bupp 375,000 warrants to purchase shares of our common stock at an exercise price of $0.13 per share, expiring in April 2008. The per share value of these warrants was $0.10 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 2.9%, volatility of 139% and no expected dividend rate. Interest accrues on the note at 8.5% per annum, payable monthly, and the note was originally due on June 30, 2004. On March 8, 2004, at the request of the Board of Directors, Mr. Bupp agreed to extend the due date of the note from June 30, 2004 to June 30, 2005. In exchange for extending the due date of the note, we issued Mr. Bupp an additional 375,000 warrants to purchase our common stock at an exercise price of $0.50 per share, expiring in March 2009. The per share value of these warrants was $0.46 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 2.7%, volatility of 152% and no expected dividend rate. Mr. Bupp's 750,000 warrants remain outstanding. The note was repaid with proceeds from the $8.1 million convertible note financing that we closed in December 2004.



During April 2003, we also completed a convertible bridge loan agreement with an investor for an additional $250,000. In consideration for the loan, we issued a note to the investor in the principal amount of $250,000. The note was secured by general assets of the company, excluding accounts receivable. In addition, we issued the investor 500,000 warrants to purchase shares of our common stock at an exercise price of $0.13 per share, expiring in April 2008. The per share value of these warrants was $0.10 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 2.9%, volatility of 139% and no expected dividend rate. Under the terms of the agreement, the note bore interest at 9.5% per annum, payable monthly, was convertible into common stock and was due on June 30, 2004. During January 2004, the investor converted the entire balance of the note into 1.1 million shares of common stock according to the conversion terms of the agreement. The investor's 500,000 warrants remain outstanding.

During 2003, an investment banking firm, Alberdale Capital, LLC (Alberdale), assisted us in arranging an accounts receivable financing transaction. In exchange for Alberdale's services, we issued them warrants to purchase 78,261 shares of our common stock. During the first quarter of 2004, Alberdale exercised these warrants on a cashless basis in exchange for 53,500 shares of common stock.

During October and November 2003, we executed common stock purchase agreements with third parties introduced to us by another investment banking firm, Rockwood, Inc., for the purchase of 12,173,914 shares of our common stock at a price of $0.23 per share for net proceeds of $2.4 million. In addition, we agreed to issue the purchasers warrants to purchase 6,086,959 shares of common stock at an exercise price of $0.28 per share and agreed to issue the placement agents warrants to purchase 1,354,348 shares of our common stock on similar terms. All warrants issued in connection with the transaction expire in October 2008. The per share value of these warrants was $0.31 on the date of issuance using the Black-Scholes option pricing model with the following assumptions: an average risk-free interest rate of 3.2%, volatility of 151% and no expected dividend rate. During the first nine months of 2004, investors and placement

agents who participated in this placement exercised warrants representing a total of 3,308,327 shares of common stock resulting in net proceeds of $865,563.

During December 2004, we completed a private placement of 8% Series A Convertible Notes due December 12, 2008 in an aggregate principal amount of $8.1 million with Biomedical Value Fund, L.P. (BVF), Biomedical Offshore Value Fund, Ltd. (BOVF) and David C. Bupp (Neoprobe's President and CEO) resulting in proceeds to us of approximately $7.4 million, net of investment banking and legal fees. BVF and BOVF are investment funds managed by Great Point Partners, LLC. The notes will bear interest at 8% per annum and are freely convertible into shares of our common stock at a price of $0.40 per share. We may force conversion of the notes prior to their stated maturity under certain circumstances. The conversion price represents the 10-day volume weighted average trading price of our common stock through December 10, 2004. The notes are callable by the holders in the event we do not meet certain revenue, cash balance and other covenants. As part of this transaction, we issued five-year warrants to the investors to purchase 10,125,000 shares of our common stock at an exercise price of $0.46. In connection with this financing, we have also issued warrants to purchase 1,600,000 shares of the Company's common stock to placement agents, containing substantially identical terms to the warrants issued to the note holders. Proceeds from the notes will be used primarily to fund late stage clinical development of our most advanced radiopharmaceutical agent, Lymphoseek, for the assessment of the spread of breast cancer and melanoma to the lymphatic system and to complete the commercial launch of Neoprobe's blood flow measurement products, the Quantix/OR and the Quantix/ND.



Our future liquidity and capital requirements will depend on a number of factors, including our ability to raise additional capital in a timely manner through additional investment, expanded market acceptance of our current products, our ability to complete the commercialization of new products, our ability to obtain milestone or development funds from potential development and distribution partners, regulatory actions by FDA and other international regulatory bodies, and intellectual property protection. We believe we have adequate capital to assure that we can properly support our current business goals and objectives through 2006. Our near-term priorities include preparation for Phase III clinical trials for two radiopharmaceutical products in our pipeline, RIGScan CR and Lymphoseek and the identification of a potential development partner to assist and fund RIGS development. In addition, we are moving forward with improvements to the Quantix products based on thought leader feedback received in the US and EU. We believe this will position us for improved commercial viability of the Quantix products by the beginning of 2005. We intend to fund the estimated $5 million development of Lymphoseek internally; however, the decision as to how much, if any, of the estimated total of $15 million in RIGS development costs to fund internally versus through a potential development partner has not yet been determined. We believe our recently completed convertible promissory note financing will provide us with adequate capital to complete the Phase III trial for Lymphoseek and should free up our existing capital to support some incremental development for RIGS and support the launch activities surrounding the Quantix products. However, the conversion features of the notes along with the warrants issued in the transaction have committed substantially all of our available shares of common stock. As such, we cannot assure you that we will be able to obtain additional authorized shares from our shareholders or that we will be able to raise capital, if such shares are approved, on terms acceptable to us, or at all. We also cannot assure you that we will be able to achieve significant product revenues from our current or potential new products. In addition, we cannot assure you that we will achieve profitability in 2005 or in the future.

CONTRACTUAL OBLIGATIONS AND COMMERCIAL COMMITMENTS

The following table presents our contractual obligations and commercial commitments as of December 31, 2003.

| | | PAYMENTS DUE BY PERIOD | | |
|---|---|---|---|---|
| CONTRACTUAL CASH OBLIGATIONS | TOTAL | LESS THAN 1 YEAR | 1 - 3 YEARS | 4 - 5 YEARS |
| Capital Leases | $ 74,854(1) | $ 21,436 | $ 36,616 | $ 16,802 |
| Operating Leases | 283,916(2) | 138,610 | 145,306 | -- |
| Unconditional Purchase Obligations | 2,147,220(3) | 2,147,220 | -- | -- |
| Long-Term Debt | 500,000 | 250,000(4) | 250,000(5) | -- |
| Total Contractual Cash Obligations | $3,005,990 | $2,557,266 | $ 431,922 | $ 16,802 |



(1) In February 2004, we entered into two (2) three-year capital lease agreements for office equipment. The lease payments total approximately $10,000 per year.

(2) In February 2004, we entered into a six-month operating lease agreement for storage space. The lease payments total approximately $17,000 in 2004.

(3) This amount represents purchases under binding purchase orders for which we are required to take delivery of the product under the terms of the underlying supply agreements going out approximately one year.

(4) In January 2004, Mr. Garlikov converted the entire balance of the note into 1.1 million shares of common stock according to the conversion terms of the agreement.

(5) In March 2004, the due date of the note to Mr. Bupp was extended to June 30, 2005 under the same terms.

CRITICAL ACCOUNTING POLICIES

The following accounting policies are considered by us to be critical to our results of operations and financial condition.

Revenue Recognition Related to Net Sales. We currently generate revenue primarily from sales of our gamma detection products; however, sales of blood flow products constituted approximately 1% of total revenues for the first nine months of 2004 and are expected to increase in the future. We generally recognize sales revenue related to sales of our products when the products are shipped and the earnings process has been completed. Our customers have no right to return products purchased in the ordinary course of business. However, in

cases where product is shipped but the earnings process is not yet completed, revenue is deferred until it has been determined that the earnings process has been completed. We also generate revenue from the service and repair of out-of-warranty products. Fees charged for service and repair on products not covered by an extended service agreement are recognized on completion of the service process when the serviced or repaired product has been returned to the customer. Fees charged for service or repair of products covered by an extended warranty agreement are deferred and recognized as revenue ratably over the life of the extended service agreement. The prices we charge our primary customer, EES, related to sales of products are subject to retroactive annual adjustment based on a fixed percentage of the actual sales prices achieved by EES on sales to end customers made during each fiscal year. To the extent that we can reasonably estimate the end-customer prices received by EES, we record sales to EES based upon these estimates. If we are unable to reasonably estimate end customer sales prices related to certain products sold to EES, we record revenue related to these product sales at the minimum (i.e., floor) price provided for under our distribution agreement with EES.

Impairment or Disposal of Long-Lived Assets. We account for long-lived assets in accordance with the provisions of SFAS No. 144. This Statement requires that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. As of September 30, 2004, the most significant long-lived assets on our balance sheet relate to assets recorded in connection with the acquisition of Cardiosonix and gamma detection device patents related to ILM. The recoverability of the capitalized cost of these assets is based on the financial projections and models related to the future sales success of Cardiosonix' products and the continuing success of our gamma detection product line. As such, these assets could be subject to significant adjustment should the Cardiosonix technology not be successfully commercialized or the sales amounts in our current projections not be realized.



Inventory Valuation. We value our inventory at the lower of cost (first-in, first-out method) or market. Our valuation reflects our estimates of excess, slow moving and obsolete inventory as well as inventory with a carrying value in excess of its net realizable value. Write-offs are recorded when product is removed from saleable inventory. We review inventory on hand at least quarterly and record provisions for excess and obsolete inventory based on several factors, including current assessment of future product demand, anticipated release of new products into the market, historical experience and product expiration. Our industry is characterized by rapid product development and frequent new product introductions. Uncertain timing of product approvals, variability in product launch strategies, product recalls and variation in product utilization all impact the estimates related to excess and obsolete inventory.

Allowance for Doubtful Accounts. We maintain an allowance for doubtful accounts receivable to cover estimated losses resulting from the inability of our customers to make required payments. We determine the adequacy of this allowance by regularly reviewing our accounts receivable aging and evaluating individual customer receivables, considering customers' credit and financial condition,

payment history and relevant economic conditions. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances for doubtful accounts may be required.

OTHER ITEMS AFFECTING FINANCIAL CONDITION

At December 31, 2003, we had U.S. net operating tax loss carryforwards and tax credit carryforwards of approximately $90.6 million and $4.3 million, respectively, available to offset or reduce future income tax liability, if any, through 2023. However, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, use of prior tax loss and credit carryforwards may be limited after an ownership change. As a result of ownership changes as defined by Sections 382 and 383, which have occurred at various points in our history, we believe utilization of our tax loss carryforwards and tax credit carryforwards may be significantly limited.

## DESCRIPTION OF BUSINESS

DEVELOPMENT OF THE BUSINESS

We are a biomedical technology company providing innovative surgical and diagnostic products that enhance patient care by meeting the critical decision-making needs of healthcare professionals. We were originally incorporated in Ohio in 1983 and reincorporated in Delaware in 1988. Our executive offices are located at 425 Metro Place North, Suite 300, Dublin, Ohio 43017. Our telephone number is (614) 793-7500.

From our inception through the end of 2001, we devoted substantially all of our efforts and resources to the research and clinical development of innovative systems for the intraoperative diagnosis and treatment of cancers. Following an evaluation of our business plan during early 2001, however, we determined that we needed to expand our product portfolio and consider synergistic products outside the cancer or oncology fields.

In December 2001, we acquired Biosonix Ltd., a private Israeli company limited by shares. In February 2002, Biosonix Ltd. changed its name to Cardiosonix Ltd. (Cardiosonix). Cardiosonix is developing and commercializing a unique line of blood flow measurement devices for a variety of diagnostic and surgical applications. The decision to expand beyond our product focus on oncology was based on our belief that the Cardiosonix products would diversify our customer base through a product line we believe has great market potential and a path of market adoption similar to our gamma detection devices, but one that also has significant operational synergies in the development, regulation and manufacture to that of our existing gamma devices.

Although we have expanded our strategic focus to include blood flow medical devices, we intend to continue to execute many of the strategies outlined in prior years related to the internal development of gamma detection medical devices and to continue supporting development of our other complementary procedural-based technologies. Based upon information that we have recently become aware of, we are considering reactivating development activities concerning radioimmuguided surgery (RIGS(R)). In addition, we are preparing to begin the pivotal stage in the development of our proprietary lymphatic tracing agent, LYMPHOSEEK(TM).



Our business goals are to maximize the market potential of Cardiosonix' blood flow products as leaders in the measurement of blood flow in both clinical and surgical settings to supplement our leadership position in the current intraoperative gamma detection market. We believe our core device business lines

will provide us with a strong operating foundation and enable us to judiciously evaluate and develop complementary procedural products with a recurring revenue stream. To that end, we intend to continue to pursue the development of LYMPHOSEEK and to evaluate an appropriate development plan for RIGS.

OUR TECHNOLOGY

GAMMA DETECTION DEVICES

Through the third quarter of 2004, substantially all of our revenue has been generated from the sale of a line of gamma radiation detection devices and related products used by surgeons in the diagnosis and treatment of cancer and related diseases. Our currently-marketed line of gamma detection devices has been cleared by the U.S. Food and Drug Administration (FDA) and other international regulatory agencies for marketing and commercial distribution throughout most major global commercial markets.

Our patented gamma detection devices consist of hand-held detector probes and a control unit. The detection device in the tip of the probe is a highly radiosensitive crystal that relays a signal through a preamplifier to the control unit to produce both a digital readout and an audible signal. The detector element fits into a housing approximately the size of a pocket flashlight. The NEO2000(R) Gamma Detection System, originally released in 1998, is the third generation of our gamma detection systems. The NEO2000 is designed as a platform for future growth of our instrument business. The neo2000 is software upgradeable and is designed to support future surgical targeting probes without the necessity of costly remanufacture. Since 1998, we have developed and released three major software upgrades for customer units designed to improve the utility of the system and/or offer the users additional features.

Surgeons are using our gamma detection devices in a surgical application referred to as sentinel lymph node biopsy (SLNB) or intraoperative lymphatic mapping (lymphatic mapping or ILM). ILM helps trace the lymphatic patterns in a cancer patient to evaluate potential tumor drainage and cancer spread in lymphatic tissue. The technique does not detect cancer; rather it helps surgeons identify the lymph node(s) to which a tumor is likely to drain and spread. The lymph node(s) (sometimes referred to as the "sentinel" node(s)) may provide critical information about the stage of a patient's disease. ILM begins when a patient is injected at the site of the main tumor with a commercially available radioactive tracing agent. The agent is intended to follow the same lymphatic flow as the cancer would if it had metastasized. The surgeon may then track the agent's path with a hand-held gamma-radiation-detection probe, thus following the potential avenues of metastases and identifying lymph nodes to be biopsied for evaluation and determination of cancer spread.

Numerous clinical studies, involving a total of nearly two thousand patients and published in peer-reviewed medical journals such as Oncology (January 1999) and The Journal of The American College of Surgeons (December 2000), have indicated ILM is approximately 97% accurate in predicting the presence or absence of disease spread in melanoma and breast cancers. Consequently, it is estimated that more than 80% of breast cancer patients who would otherwise have undergone full axillary lymph node dissections (ALND), involving the removal of as many as 20 - 30 lymph nodes, might be spared this radical surgical procedure if the sentinel node was found to be free of cancer. Surgeons practicing ILM have found that our gamma-detection probes are well suited to the procedure.



Lymphatic mapping has become the standard of care for treating patients with melanoma at many institutions. For breast cancer, the technique appears to be

moving toward standard of care status at major cancer centers. Our marketing partner has seen continued growth in sales due partially to increased adoption of the ILM procedure and changes in the competitive landscape. Lymphatic mapping in breast cancer is the subject of national and international clinical trials, including studies sponsored by the U.S. Department of Defense, the National Cancer Institute (NCI) and the American College of Surgeons. Although we have been selling gamma detection devices for use in surgical oncology for over seven years, we believe many surgeons, both in the U.S. and the rest of the world have delayed adoption of lymphatic mapping pending the outcome of these important trials. We believe that once data from these trials are published; there will be an additional demand for our devices. We continue to monitor these trials and to work with our marketing partners and thought leaders in the surgical community to set up and support training courses internationally for lymphatic mapping. We also believe, based on anecdotal market intelligence, that over half of the potential global market for devices such as ours remains untapped. Courses showcasing our instruments continue to be held at many nationally and internationally renowned cancer-specializing and teaching institutions. These courses appear to be positively impacting the adoption of lymphatic mapping, albeit not as rapidly as we would like to see.

In addition to lymphatic mapping, surgeons are investigating the use of our device for other gamma guided surgery applications, such as evaluating the thyroid function, in determining the state of disease in patients with vulvar and penile cancers, and in SLNB in gastric and non-small cell lung cancers. Expanding the application of ILM beyond the current primary uses in the treatment of breast cancer and melanoma is the primary focus of our strategy regarding our gamma guided surgery products. To support that expansion, we continue to work with our marketing and distribution partners to develop software-based enhancements to the NEO2000 platform as well as probes such as the laparoscopic probe introduced in 2002 that supports the minimally invasive emphasis in today's practice of surgery. To that end, our primary goals for our gamma device business for 2004 center around working with our marketing partners to improve the market position of our laparoscopic approach and increase awareness of independent research being done to expand the application of ILM to other indications.

BLOOD FLOW MEASUREMENT DEVICES

Accurate blood flow measurement is required for various clinical needs, including:

- real-time monitoring;
- intra-operative quantification;
- non-invasive diagnostics; and
- evaluation of cardiac function.

Currently, the medical community has no simple, immediate, real-time means to quantify the adequacy of organ perfusion, that is, the direct measurement of blood flow into the organ. Devices do exist that visually show perfusion of a target organ. We are unaware, however, of any device that provides an accurate, real-time measurement of blood flow in as many applications without having to isolate target vessels or conduct other invasive procedures.

In addition, blood flow velocity measurements are often confused with volume blood flow. These two variables, however, are normally different parameters that respond differently to pathological conditions and provide different data. Blood flow velocity is used primarily for determining the existence of a stenosis (narrowing or obstruction) in the vascular surgery setting, while the applications of blood flow volume have potential impact across a much broader

range of medical disciplines.

Cardiosonix is developing and commercializing the QUANTIX(R) line of products that employ a unique and proprietary Angle-independent Doppler Blood Flow (ADBF(TM)) technology that allows for blood flow volume and velocity readings. Most current applications of Doppler technology to blood flow measurement are angle-dependent and therefore more prone to estimation errors and potential inaccuracy. ADBF eliminates calculation estimation and permits real-time measurement of volume blood flow.



The ADBF technology utilizes a special application of the Doppler method through simultaneous projection of a combination of narrow beams with a known angle between them. Thus, based on trigonometric and Doppler considerations, the angle of insonation can be obtained, resulting in accurate, angle-independent blood flow velocity measurements that do not require the use of complicated, expensive imaging systems. In order to obtain high-resolution velocity profiles, the QUANTIX devices use a multi-gated pulse wave Doppler beam. With this method, specific sample volumes along the ultrasound beam can be separately evaluated, and the application of a flow/no flow criterion can be made. The Cardiosonix technology applies a special use of digital Doppler technology, which with the digital signal processing power of the system allows hundreds of sample volumes to be sampled and processed simultaneously, thus providing high resolution velocity profiles for both angle and vascular diameter calculations, and subsequently volume blood flow measurements. At present, Cardiosonix has two products in the early stages of commercialization and one still in development that are designed to provide blood flow measurement and cardiac output information to physicians in cardiac/vascular surgery, neurosurgery and critical care settings.

QUANTIX/ND(TM) is designed to allow neurosurgeons and neurologists, as well as intensive care unit or emergency room physicians, to non-invasively measure carotid artery blood flow in a simple and real-time manner. QUANTIX/ND consists of a control unit and an angle-independent ultrasound probe that obtains signals directly from the carotid artery in a non-invasive manner. QUANTIX/ND is designed primarily for use in monitoring head trauma patients in neuro-intensive care units and emergency rooms. Periodic blood flow measurements minimize the risk of brain impairment. We are unaware of any measurement system on the market today that provides real-time, bedside, non-invasive, continuous, direct and accurate measurements of complete hemodynamic parameters including blood flow. Other modalities that do monitor capabilities of the brain are significantly more invasive, expose the patient to incremental risk or are inherently complicated, offering only indirect estimation of perfusion conditions. Some medical devices use an estimated measurement of blood flow velocity to create an index of blood flow but do not account for instantaneous changes in vascular cross-sectional area. In most competing devices, however, blood flow velocity is angle-dependent and cannot be measured accurately. The QUANTIX/ND device, as well as its predecessor device, the FLOWGUARD(TM), has received CE mark regulatory clearance for marketing in the European Union (EU) as well as FDA 510(k) clearance for marketing in the United States.

QUANTIX/OR(TM) is designed to permit cardiovascular surgeons and assisting physicians to obtain intraoperative volume blood flow readings in various targeted blood vessels within seconds. The system consists of an angle-independent ultrasound probe and digital numerical displays of blood flow rate. Thus, the surgeon obtains immediate, real-time and quantitative readings while focused on the target vessel. Quantifying blood flow is crucial during anastomostic or other bypass graft procedures to determine adequate blood flow. While measurement is advisable whenever a blood vessel is exposed

intra-operatively, generally this is not the current practice.

Ultimately, in practice, the surgeon generally resorts to using his eyes and fingers in a process called finger palpation to qualitatively assess vessel flow. The QUANTIX/OR offers the surgeon immediate and simple quantitative assessment of blood flow in multiple blood vessels and grafts. The primary advantage of finger palpation is that it is fast and simple; the disadvantages are that it requires a good deal of experience, it is difficult to perform in vessels embedded in tissue, it can become difficult to interpret in large vessels, and it permits only a very qualitative and subjective assessment. A significant partial occlusion (or even a total occlusion) will result in significant vessel "inflation" and strong palpations that could mislead the surgeon. Instead of such a subjective clinical practice that is highly experience-dependent, the QUANTIX/OR is designed to allow the surgeon to rely on more evidence-based medicine.

We believe that QUANTIX/OR represents a significant improvement over existing technologies to directly measure blood flow intraoperatively. Other technologies that attempt to measure intraoperative blood flow directly are generally more invasive and are impractical when multiple vessel measurements are required. They are, therefore, not used routinely in the operating room, so surgeons most often resort to finger palpation to qualitatively, rather than quantitatively, measure vessel perfusion. The QUANTIX/OR device has received CE mark regulatory clearance for marketing in the EU and FDA 510(k) clearance for marketing in the United States.



QUANTIX/TE(TM) is being designed as a transesophageal cardiac function monitor for measuring blood flow in the descending aorta in critical care settings. The system employs a special transesophageal catheter for quantitative assessment of blood flow in the descending aorta for cardiac output calculations. The system is designed for bedside use in intensive care settings. Cardiac output and function monitoring is essential in critical care and trauma patients. The procedure of transesophageal monitoring is a well-recognized clinical modality, particularly for echocardiography of the heart. Only highly invasive methods of cardiac output via thermodilution techniques are currently available, or indirect and non-invasive methods such as bioimpedance with an unknown degree of clinical significance. The QUANTIX/TE is still in the early stages of development and is not currently cleared for commercial sale in any market.

Our strategy related to Cardiosonix products for 2004 continues to emphasize the three primary objectives we established in 2003:

- to promote and expand the clinical evaluation of the QUANTIX/ND and QUANTIX/OR with thought leaders in the neurosurgical and cardiac arenas;
- to secure and train additional marketing and distribution partners for key global markets for the QUANTIX/ND and QUANTIX/OR devices; and
- to achieve commercial sales of Cardiosonix' QUANTIX products beyond demonstration unit sales that would demonstrate the initial market acceptance of the products.

We cannot assure you, however, that any of Cardiosonix' products will achieve market acceptance. See also Risk Factors.

LYMPHOSEEK

Our gamma detection devices are primarily capital in nature; as such, they generate revenue only on the initial sale. To complement the one-time revenue stream related to capital products, we are working on developing recurring revenue or "procedural" products that would generate revenue based on each procedure in which they were used. Our primary efforts in this area involve an exclusive worldwide license agreement with the University of California, San Diego (UCSD) for a proprietary compound we refer to as LYMPHOSEEK. We believe LYMPHOSEEK, if proven effective, could be used as a lymph node locating agent in ILM procedures. Neoprobe and UCSD completed pre-clinical evaluations of LYMPHOSEEK in 2001 and completed a Phase I trial in the treatment of breast cancer in humans. The initial Phase I studies of LYMPHOSEEK in breast cancer were funded through a research grant from the Susan G. Komen Breast Cancer Research Foundation. Preliminary results from the Phase I breast trial were presented at the Spring 2002 meeting of the Society of Nuclear Medicine.
A Phase I/II clinical trial in melanoma patients was completed during the third quarter of 2003. The Phase I/II melanoma trial was funded through a research grant from the American College of Surgeons. Our discussions held to date in the further development and commercialization of LYMPHOSEEK have focused on gaining a better understanding of the regulatory approval process related to LYMPHOSEEK. To that end, we held a meeting in November 2003 with the Interagency Council on Biomedical Imaging in Oncology (Interagency Council), an organization representing FDA, the NCI and the Centers for Medicare and Medicaid Services to discuss the regulatory approval process and to determine the objectives for the next clinical trial involving LYMPHOSEEK. As a result of that meeting, we prepared and submitted a clinical protocol to FDA for a pivotal trial to support the marketing approval of LYMPHOSEEK at the third quarter of 2004. We are in discussion with the FDA regarding the final design of the trial and hope to commence the multi-center trials late in the first quarter of 2005. We cannot assure you, however, that this product will achieve regulatory approval, or if approved, that it will achieve market acceptance. See also Risk Factors.

RIGS

From inception until 1998, Neoprobe devoted significant efforts and resources to the development of its proprietary RIGS technology. The RIGS system combines a patented hand-held gamma radiation detection probe, proprietary radiolabeled cancer-specific targeting agents, and patented surgical methods to provide surgeons with real-time information to locate tumor deposits not detectable by conventional methods, and to assist in more thorough removal of the cancer. The RIGS system is designed to assist the surgeon in the more thorough removal of the cancer, thereby leading to improved surgical treatment of the patient. The targeting agents used in the RIGS process are monoclonal antibodies, labeled with a radioactive isotope that emits low energy gamma rays. The device used is a very sensitive radiation detection instrument that is capable of detecting small amounts of radiation bound to the targeting agent. Before surgery, a cancer patient is injected with one of the targeting agents which circulates throughout the patient's body and binds specifically to cancer cell antigens or receptors. Concentrations of the targeting agent are then located during surgery by Neoprobe's gamma-detection device, which emits an audible tone to direct the surgeon to targeted tissue.



RIGSCAN(R) CR is an intraoperative radiodiagnostic agent consisting of a radiolabeled murine monoclonal antibody (MAb CC49). The radiolabel used is 125I, a 27 - 35 KeV emitting isotope. The MAb used in RIGSCAN CR is the CC49 MAb developed by the NCI and licensed to Neoprobe by the National Institutes of Health (NIH). The CC49 MAb is produced from a murine cell line generated by the fusion of splenic lymphocytes from mice immunized with tumor-associated

glycoprotein-72 (TAG-72) with non-immunoglobulin secreting P3-NS-1-Ag4 myeloma cells. The CC49 MAb localizes or binds to TAG-72 and shows a strong reactivity with both LS-174T colon cancer extract and to a breast cancer extract.

RIGSCAN CR is the biologic component for the RIGS system to be used in patients with colon or rectal cancer. The RIGS system is designed to be a diagnostic aid in the intraoperative detection of clinically occult disease. RIGSCAN CR is intended to be used in conjunction with other diagnostic methods, for the detection of the extent and location of tumor in patients with colorectal cancer. The detection of clinically occult tumor provides the surgeon with a more accurate assessment of the extent of disease and, therefore, may impact the surgical and therapeutic management of the patient. Clinical trials suggest that RIGSCAN CR provides additional information outside that provided by standard diagnostic modalities (including surgical exploration) that may aid in patient management. Specifically, RIGSCAN CR used as a component of the RIGS system confirms the location of surgically suspicious metastases, evaluates the margins of surgical resection, and detects occult tumor in perihepatic (portal and celiac axis) lymph nodes.

Neoprobe conducted two Phase III studies, NEO2-13 and NEO2-14, of RIGSCAN CR in patients with colorectal cancer. Both studies were multi-institutional involving cancer treatment institutions in the United States, Israel, and Europe. The primary endpoint of both studies was to demonstrate that RIGSCAN CR detected pathology-confirmed disease that had been undetected by traditional preoperative (i.e., CT Scans) or intraoperative (i.e., surgeon's visual observations and palpation) means. That is, the trials were intended to show that the use of RIGSCAN CR assisted the surgeon in the detection of occult tumor. In 1996, Neoprobe submitted applications to the European Agency for the Evaluation of Medicinal Products (EMEA) and FDA for marketing approval of RIGSCAN CR for the detection of metastatic colorectal cancer.

Clinical study NEO2-14, which was submitted to FDA in the RIGSCAN CR Biologic License Application (BLA), enrolled 151 colorectal cancer patients with either suspected metastatic primary colorectal disease or recurrent colorectal disease. During FDA's review of the BLA, 109 of the enrolled patients were determined to be evaluable patients. Clinical study NEO2-13 was conducted in 287 enrolled patients with primary colorectal disease. The primary end-point for clinical study NEO2-13 was the identification of occult tumor.

NEO2-14 was the pivotal study submitted with Neoprobe's referenced BLA. Two additional studies evaluating patients with either primary or metastatic colorectal disease, NEO2-11 (a multi-center study) and NEO2-18 (a single institution study), were included in the BLA and provided supportive proof of concept (i.e., localization and occult tumor detection) and safety data. A study summary report for NEO2-13 was submitted under the BLA; however, FDA undertook no formal review of the study.

Following review of its applications, we received requests for further information from FDA and from the European Committee for Proprietary Medicinal Products (CPMP) on behalf of the EMEA. Both FDA and EMEA acknowledged that our studies met the diagnostic endpoint of the Phase III clinical study, which was to provide incremental information to the surgeon regarding the location of hidden tumor. However, both agencies wanted to know how the finding of additional tumor provided clinical benefit that altered patient management or outcome. In a series of conversations with FDA the product claims were narrowed to the intraoperative detection of hepatic and perihepatic disease in patients with advanced colorectal cancer and patients with recurrent colorectal cancer.

FDA determined during its review of the BLA review that the clinical studies of RIGSCAN CR needed to demonstrate clinical utility in addition to identifying additional pathology confirmed disease. In discussions between Neoprobe and the agency, an FDA driven post hoc analysis plan was developed to limit the evaluation of RIGSCAN CR to patients with hepatic and perihepatic disease with known metastasis to the liver. Findings of "occult" disease and subsequent changes in patient management (i.e., abandoning otherwise risky hepatic resections) in this limited population would serve as a measure of patient benefit. FDA's analysis of the patients enrolled in NEO2-14 matching the limited criteria was evaluated with a determination to confirm the surgical resection abandonment outcome. The number of evaluable patients in this redefined patient population was deemed too small by the agency and the lack of pre-stated protocol guidance precluded consistent sets of management changes given similar occult findings. The number of evaluable patients for any measure of clinical utility, therefore, was too small to meet relevant licensing requirements and FDA ultimately issued a not approvable letter for the BLA on December 22, 1997, describing certain clinical and manufacturing deficiencies. Neoprobe also withdrew its application to the EMEA in November 1997.

We developed a clinical response plan for both agencies during the first half of 1998. However, following our analysis of the regulatory pathways for approval that existed at that time, we determined that we did not have sufficient financial resources to conduct the additional studies requested and sought to identify others with an interest in continuing the development process.

Over the last several years, we have held preliminary discussions with several parties potentially interested in continuing the RIGS development; however, only one of those discussions resulted in an arrangement that attempted to restart the development of RIGS. During 2000, we executed and amended an agreement with OncoSurg Ltd. (OncoSurg, formerly NuRIGS Ltd.), that provided OncoSurg with an option exercisable through December 31, 2001 to license the RIGS technology for use in the diagnosis and treatment of colorectal cancer. During 2001, OncoSurg conducted pre-clinical testing and sponsored a Phase I physician's Investigational New Drug (IND) clinical trial for colorectal cancer using a second-generation humanized version of our RIGSCAN CR antibody. However, OncoSurg did not exercise its option to continue development at the end of 2001 due to a lack of funding which we believe is unrelated to the clinical results of the Phase I trial. The physician-IND researchers reported favorable results of the Phase I trial during fourth quarter of 2003.

We recently obtained results of a third party's survival analysis suggesting that RIGSCAN CR may be predictive of, or actually contribute to, a positive outcome when measuring survival of the patients that participated in our original BLA studies. The data or its possible significance was unknown at the time of the BLA review given the limited maturity of the follow-up experience. The data includes publication by some of the primary investigators involved in the Phase III RIGS trials who have independently conducted survival follow-up analyses to their own institution's RIGS trial patients with apparently favorable results relating to the long-term survival prognosis of patients who were treated with RIGS. In addition, we have recently learned that FDA has held the BLA originally filed with FDA in 1996 open. Based primarily on these pieces of information, we requested, a meeting with FDA to discuss the possible next steps for evaluating the survival related to our previous Phase III clinical trials as well as the possible submission of this data, if acceptable, as a prospective analysis in response to questions originally asked by FDA in response to our original BLA. This meeting with FDA took place in April 2004.

The April 2004 meeting with FDA was an important event in the re-activation of the RIGS program. The meeting was very helpful from a number of aspects: we confirmed that the RIGS BLA remains active and open. We believe this will improve both the cost effectiveness and timeliness of future regulatory submissions for RIGSSCAN CR. Additionally, FDA preliminarily confirmed that the

BLA may be applicable to the general colorectal population; and not just the recurrent colorectal market as applied for in 1996. Applicability to a general colorectal population could result in a greater market potential for the product than if applicable to just the recurrent population. During the meeting, FDA indicated that it would consider possible diagnostic/prognostic indications for RIGSCAN CR and that survival data from one of our earlier Phase III studies could be supportive of a prognostic indication. We believe that approval for a diagnostic indication prior to the submission of additional prognostic data from a new trial could positively impact the approval timeline for RIGSCAN CR. In June 2004 we submitted a Phase III protocol to FDA for their comment and review. The protocol included a proposed clinical plan that included a near term diagnostic endpoint for the study and a long term prognostic endpoint.



We have received a formal response from FDA to the Phase III protocol submitted in late June 2004. The response indicates that FDA would be receptive to a clinical trial design that would incorporate both near term disease progression and long term survival prognostic endpoints. Further, the response provides us with guidance for the development of the clinical data sheets and investigator training programs for the conduct of the Phase III study in primary colorectal patients as well as for the further development of the study design. We intend to request a meeting with FDA to review the Phase III study materials, to provide materials requested by FDA for diagnostic endpoints of the study and to prepare for the initiation of the Phase III study in 2005. In addition, we intend to meet with FDA to review the company's biologic and radio labeling production plans. It is possible that the regulatory pathway may evolve as we seek to reach a consensus with the agency on the reactivation of the RIGS filing.

If our plan for evaluating the survival data is received positively, we intend to engage the services of a clinical research organization (CRO) to review these survival findings related to all evaluable patients from our Phase III primary and metastatic colorectal cancer clinical trials. The analysis of this data may answer some of the questions raised by FDA in response to our original application; however, the RIGSCAN CR drug has not been produced for several years and we believe it is likely we would have to perform some additional work related to ensuring the drug cell line is still viable and submit this data to FDA for their evaluation before approval could be considered. We have initiated discussions with established biologic manufacturing organizations to determine the costs and timelines associated with the production of commercial quantities of the CC49 antibody. In addition, we will need to establish a process for radiolabeling the CC49 antibody in order to meet the regulatory needs for the RIGSCAN CR product. We have met with the centralized European regulatory agency, the EMEA, to discuss development plans for RIGS. The EMEA indicated that they were receptive to a similar diagnostic and prognostic clinical plan that is being reviewed with FDA. In addition, the EMEA indicated that they would encourage us to conduct the next clinical study on the RIGS technology with the humanized version of the RIGSSCAN CR.

We are encouraged by the recent developments regarding RIGS. We believe we would need to obtain additional funding and/or identify a development partner in order to carry out all the activities necessary for commercialization. We do not have any agreements in place or pending with third parties that would ensure the continued development of the RIGS process and the completion of the survival analysis proposed to FDA at the April 2004 meeting. In addition, even if we are able to make such arrangements on satisfactory terms, we believe that the time required for continued development, regulatory approval and commercialization of a RIGS product would likely be a minimum of two years before we receive any significant product-related royalties or revenues. However, we cannot assure you

that we will be able to complete definitive agreements with a development partner for the RIGS technology and do not know if a partner will be obtained on a timely basis on terms acceptable to us, or at all. We cannot assure you that FDA or the EMEA will approve our RIGS products for marketing, or that any such products will be successfully introduced or achieve market acceptance. See also Risk Factors.

ACTIVATED CELLULAR THERAPY

We have performed early stage research on another technology platform, activated cellular therapy (ACT), based on work originally done in conjunction with the RIGS technology. ACT is intended to boost the patient's own immune system by removing lymph nodes identified during surgery and then, in a cell processing technique, activating and expanding "helper" T-cells found in the nodes. Within 10 to 14 days, the patient's own immune cells, activated and numbering more than 20 billion, are infused into the patient in an attempt to trigger a more effective immune response to the cancer.

During the second quarter of 2001, we announced a research collaboration with Aastrom Biosciences, Inc. (Aastrom) intended to determine whether Aastrom's ReplicellTM system would be able to duplicate cell expansion results experienced in previous Phase I clinical testing of our ACT technology for oncology. Unfortunately, we experienced delays in completing the evaluation in 2001 due to a lack of available tissue for testing purposes and since that time have not had the funding available to move the research forward. From time to time, we have engaged investment banking firms as we did for the RIGS technology to assist us in identifying parties to license or purchase the ACT technology. However, these efforts have not resulted in the identification of a development partner, purchaser or licensee to date. We do not know if a partner will be identified on a timely basis, on terms acceptable to us, or at all. Although the prospects for ACT may be improved depending on the outcome of a decision to renew development efforts for RIGS, we currently do not intend to fund any significant ACT-related research and development without a partner. We cannot assure you that any ACT products will be successfully developed, tested or licensed, or that any such products will gain market acceptance. See also Risk Factors.



MARKET OVERVIEWS

The medical device marketplace is a fast growing market. Medical Device & Diagnostic Industry magazine reports an annual medical device and diagnostic market of $75 billion in the U.S. and $169 billion internationally.

CANCER MARKET OVERVIEW

Cancer is the second leading cause of death in the U.S. and Western Europe and is responsible for over half a million deaths annually in the U.S. alone. The NI