NEOPROBE CORP Form 424B3 October 05, 2007

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# FIRST AMENDED PROSPECTUS NEOPROBE CORPORATION 13.440.000 Shares of Common Stock

This prospectus relates to the sale of up to 13,440,000 shares of our common stock by Fusion Capital Fund II, LLC (Fusion Capital). Fusion Capital is sometimes referred to in this prospectus as the selling stockholder. The prices at which Fusion Capital 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 Fusion Capital. Our common stock is registered under Section 12(g) of the Securities Exchange Act of 1934 and quoted on the OTC Bulletin Board under the symbol NEOP. On September 14, 2007, the last reported sale price for our common stock as reported on the OTC Bulletin Board was \$0.31 per share.

The selling stockholder is 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.

The date of this prospectus is October 2, 2007.

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Unless otherwise specified, the information in this prospectus is set forth as of October 2, 2007, 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.

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### 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 subsidiaries. This prospectus contains forward-looking statements and information relating to Neoprobe Corporation. See Cautionary Note Regarding Forward Looking Statements on page 15.

# **Our Company**

Neoprobe Corporation (Neoprobe, the company or we) is a biomedical company that develops and commercializes innovative products that enhance patient care and improve patient outcome by meeting the critical intraoperative diagnostic information needs of physicians and therapeutic treatment needs of patients. 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 1998, we devoted substantially all of our efforts and resources to the research and clinical development of radiopharmaceutical and medical device technologies related to the intraoperative diagnosis and treatment of cancers, including our proprietary radioimmunoguided surgery (RIGS®) technology. At that point, an evaluation of the status of the regulatory pathway for our **RIGS** products coupled with our limited financial resources caused us to suspend development activities related to our radiopharmaceutical business and to retrench our organization to focus on our medical device business. After achieving profitability in 2000 following this retrenchment, we set out on a growth strategy centered around medical device products. In December 2001, we acquired Biosonix Ltd., a private Israeli company limited by shares, which we subsequently renamed Cardiosonix Ltd. (Cardiosonix). Since 2001 through early 2007, we devoted substantial time and resources to commercializing Cardiosonix Quantix line of blood flow measurement devices for a variety of diagnostic and surgical applications in the cardiac and vascular management arena. The results of Cardiosonix s efforts to date have not met with our expectations and we are in the process of critically evaluating the prospects for this business line. Although our strategic focus expanded in 2001 to include blood flow measurement devices, we continued to look for other avenues to reinvigorate our radiopharmaceutical development. During 2004, our efforts resulted in a number of positive events that caused us to take steps to re-activate development of our radiopharmaceutical and therapeutic initiatives. As a result, in 2007 we have one of our radiopharmaceutical products, Lymphoseek<sup>®</sup>, involved in a variety of clinical evaluations including a recently completed successful Phase 2 multi-center clinical trial, and a second, **RIGScan®** CR, for which we are clarifying the regulatory pathway and identifying potential sources of funding. In early 2005, we also formed a subsidiary, Cira Biosciences, Inc. (Cira Bio), to evaluate the current market opportunities for another technology platform, activated cellular therapy (ACT). Our unique virtual business model combines revenue generation from medical devices that contributes to covering our corporate overhead while we devote capital raised through financing efforts to incremental development such as Lymphoseek and look for development partners to assist us in the clinical and commercial development for **RIGScan** CR and ACT.

# The Offering

Fusion Capital, the selling stockholder under this prospectus, is offering for sale up to 13,440,000 shares of our common stock hereunder. On December 1, 2006, we entered into a common stock purchase agreement with Fusion Capital, an Illinois limited liability company. Under the terms of the common stock purchase agreement we have agreed to issue Fusion Capital a commitment fee consisting of 1,440,000 shares of our common stock, of which we have issued 870,000 shares as of August 31, 2007, and we will issue the remaining 570,000 shares of the commitment fee pro rata as we sell \$6,000,000 of our common stock to Fusion Capital. We have authorized up to 12,000,000 shares of our common stock for sale to Fusion Capital under the agreement. As of August 31, 2007, there were 64,779,458 shares of our common stock outstanding (63,163,455 shares held by non-affiliates) excluding the 12,000,000 shares

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offered by Fusion Capital pursuant to this prospectus, of which it has not yet purchased 6,887,901 shares from us, and the remaining 570,000 commitment fee shares to be issued pro rata as we sell the \$6,000,000 of our common stock to Fusion Capital. If all of such 13,440,000 shares offered hereby were issued and outstanding as of the date hereof, the 12,000,000 shares would represent 17% of the total common stock outstanding or 17% of the non-affiliates shares outstanding as of the date hereof. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the agreement.

We do not have the right to commence any sales of our shares to Fusion Capital until the Securities & Exchange Commission has declared effective the registration statement of which this prospectus forms a part. The registration statement was declared effective on October 2, 2007. Generally we have the right but not the obligation from time to time to sell our shares to Fusion Capital in amounts between \$50,000 and \$1.0 million depending on certain conditions set forth in the common stock purchase agreement we have entered into with Fusion Capital. We have the right to control the timing and amount of any sales of our shares to Fusion Capital. The purchase price of the shares will be determined based upon the market price of our shares without any fixed discount at the time of each sale. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any business day that the price of our common stock is below \$0.20. The common stock purchase agreement may be terminated by us at any time at our discretion without any cost to us.

An investment in our common stock is highly speculative and involves a high degree of risk. See Risk Factors beginning on page 4.

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### 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 \$138 million and have an overall deficit in stockholders equity as of June 30, 2007. Although we were profitable in 2000 and in 2001, we incurred substantial losses in the years prior to that, and again in 2002 through June 30, 2007. 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 expenses in the foreseeable future, primarily related to the completion of development and commercialization of **Lymphoseek**, but also potentially related to **RIGS** and the **Quantix** product line. 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 and product candidates may not achieve the broad market acceptance they need in order to be a commercial success.

Widespread use of our handheld gamma detection devices is currently limited to one surgical procedure, Sentinel Lymph Node Biopsy (SLNB), used in the diagnosis and treatment of two primary types of cancer: melanoma and breast cancer. While the adoption of SLNB within the breast and melanoma indications appears to be widespread, expansion of SLNB to other indications such as colorectal and prostate cancers is likely dependent on a better lymphatic tissue targeting agent than is currently available. Without expanded indications in which to apply SLNB, it is likely that gamma detection devices will reach market saturation. 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.

To date, our efforts to place Cardiosonix s products have met with limited success. The long-term commercial success of the Cardiosonix product line will require much more widespread acceptance of our blood flow measurement products than we have experienced to date. Widespread acceptance of blood flow measurement would represent a significant change in current 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.

Our radiopharmaceutical product candidates, **Lymphoseek** and **RIGScan** CR, are still in the process of development, and even if we are successful in commercializing them, we cannot assure you that they will obtain significant market acceptance.

### We may have difficulty raising additional capital, which could deprive us of necessary resources.

We expect to continue to devote significant 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 will likely need to raise additional funds through the sale of assets, public or private debt or equity 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

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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.

We believe that we have access to sufficient financial resources with which to fund our operations or those of our subsidiaries through 2007. We expect to raise additional capital during 2007 in order to continue executing on our current business plan. However, if we are unsuccessful in raising additional capital, or the terms of raising such capital are unacceptable, we may have to modify our business plan and/or significantly curtail our planned development activities and other operations.

In December 2006, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC (Fusion) that allows us to sell shares of common stock for up to \$6.0 million in proceeds. We have authorized up to 12,000,000 shares of our common stock for sale to Fusion under the agreement, and have issued 720,000 shares as a commitment fee. Up to an additional 720,000 shares of our common stock may be issued to Fusion as an additional commitment fee as shares are sold to Fusion. Our right to make sales under the agreement is limited to \$50,000 every four business days, unless our stock price equals or exceeds \$0.30 per share, in which case we can sell greater amounts to Fusion as the price of our common stock increases. Fusion does not have the right or the obligation to purchase any shares on any business day that the market price of our common stock is less than \$0.20 per share. Through August 31, 2007, we have sold Fusion 5.1 million shares of common stock and issued 870,000 shares of stock as commitment fees to Fusion. Assuming the remaining 6.9 million shares are sold, the selling price per share would have to average at least \$0.69 for us to receive the maximum proceeds from this offering of \$6.0 million. Assuming a purchase price of \$0.27 per share (the closing sale price of the common stock on August 31, 2007) and the purchase by Fusion of the entire 12,000,000 shares, proceeds to us would only be \$3.2 million.

The extent to which we rely on Fusion as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources, such as through the sale of our products. Specifically, Fusion does not have the right or the obligation to purchase any shares of our common stock on any business day that the market price of our common stock is less than \$0.20 per share. To the extent that we are unable to make sales to Fusion to meet our capital needs, or to the extent that we decide not to make such sales because of excessive dilution or other reasons, and if we are unable to generate sufficient revenues from sales of our products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$6.0 million potentially available under the agreement with Fusion, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

# Clinical trials for our radiopharmaceutical 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. We recently completed patient enrollment in a Phase 2 clinical trial for our most advanced radiopharmaceutical product candidate, **Lymphoseek**, and are preparing to commence two pivotal Phase 3 trials for this product in breast cancer and melanoma. We are also taking steps to obtain FDA approval of a Phase 3 clinical protocol for our next radiopharmaceutical candidate, **RIGScan** CR. 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, the participating institutions or FDA might delay or halt any clinical trials for our product candidates for various reasons, including:

ineffectiveness of the product candidate;

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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.

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 recently executed a non-binding term sheet for the distribution of **Lymphoseek** in the United States. We do not currently have collaborative agreements covering **Lymphoseek** in other areas of the world or for **RIGScan** CR or ACT. We cannot assure you that we will be successful in reaching definitive terms with the potential U.S. distribution partner for **Lymphoseek** or in securing collaborative partners for other markets or radiopharmaceutical products, 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 rely on third parties for the worldwide marketing and distribution of our gamma detection and blood flow.

We rely on third parties for the worldwide marketing and distribution of our gamma detection and blood flow measurement 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. Our blood flow products are marketed and sold in the U.S. and a number of foreign markets through other distribution partners specific to those markets. Further, we have had only limited success to date in marketing or selling our **Quantix** line of blood flow products. 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 products. If this happens, we may not be able to successfully market our products, which would decrease our revenues.

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Our radiopharmaceutical product candidates 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 **Lymphoseek** and **RIGScan** product candidates, which could cause our business to be severely harmed. Our product candidates are subject to extensive and rigorous government regulation. 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 in 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 clearance to market requires the submission of extensive preclinical and clinical data and supporting information to FDA for each indication to establish the product candidate 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 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 risks similar to those associated with FDA approval process.

Our radiopharmaceutical 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 clearance 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 clearance, 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;

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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.

Our existing products are highly regulated and we could face severe problems if we do not comply with all regulatory requirements in the global markets in which these products are sold.

FDA regulates our gamma detection and blood flow measurement products in the United States. Foreign countries also subject these products to varying government regulations. In addition, these 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 blood flow products, the **Quantix/ND** and **Quantix/OR**. We may not be able to obtain clearance to market 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.

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 neo2000 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 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 Ethicon Endo-Surgery, Inc. (EES) for gamma detection devices contains failure to supply provisions, which, if triggered, could have a significant negative impact on our business.

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.

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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.

# Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives applicable to our radiopharmaceutical products and 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 may delay the commercial launch of the product and may negatively impact the revenues we are able to derive from sales in that country.

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.

# The sale of our common stock to Fusion may cause dilution and the sale of common stock acquired by Fusion could cause the price of our common stock to decline.

In connection with our agreement with Fusion, we have authorized the sale of up to 12,000,000 shares of our common stock and the issuance of 1,440,000 shares in commitment fees, and we filed a registration statement with the SEC for the sale to the public of the entire 13,440,000 shares. The number of shares ultimately offered for sale to the public will be dependent upon the number of shares purchased by Fusion under the agreement. It is anticipated that these shares will be sold over a period of up to 24 months from the date of the agreement, at prices that will fluctuate based on changes in the market price of our common stock over that period. Depending upon market liquidity at the times sales are made, these sales could cause the market price of our common stock to decline. Consequently, sales to Fusion may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Fusion, 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. However, we have the right to control the timing and amount of any sales of our shares to Fusion and the agreement may be terminated by us at any time at our discretion without any cost to us.

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# 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 registration statements with the Securities and Exchange Commission (SEC) under which the investors may resell to the public common stock acquired in these transactions, as well as common stock acquired on the exercise of the warrants and convertible securities held by them.

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 or when 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 these registration statements, 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 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 may not have sufficient legal protection against infringement or loss of our intellectual property, and we may lose rights to our licensed intellectual property if diligence requirements are not met.

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.

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In the United States, patent applications are secret until patents are issued, 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.

The patents underlying our radiopharmaceutical products and ACT technology are exclusively licensed to us by third parties, and the relevant license agreements require us to use diligence in the development and commercialization of products using the licensed patents. Our failure to meet the diligence requirements in any license agreement may result in our loss of some or all of our license rights to the patents licensed thereunder.

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. In January 2006, the OCS consented to the transfer of manufacturing as long as Neoprobe complies with the terms of the OCS statutes under Israeli law. As long as we maintain at least 10% Israeli content in our blood flow devices, we will pay a royalty rate of 4% on sales of applicable blood flow devices and must repay the OCS a total of \$1.2 million in royalties. However, should the amount of Israeli content of our blood flow device products decrease below 10%, the royalty rate could increase to 5% and the total royalty payments due could increase to \$2.3 million. 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.

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We may lose the license rights to certain in-licensed products if we do not exercise adequate diligence.

Our license agreements for **Lymphoseek**, **RIGS**, and ACT contain provisions that require that we demonstrate ongoing diligence in the continuing research and development of these potential products. Cira Bio s rights to certain applications of the ACT technology may be affected by its failure to achieve certain capital raising milestones by December 31, 2006 although no such notices to that effect have been received to-date. We have provided information, as required or requested, to the licensors of our technology indicating the steps we have taken to demonstrate our diligence and believe we are adequately doing so to meet the terms and/or intent of our license agreements. However, it is possible that the licensors may not consider our actions adequate in demonstrating such diligence. Should we fail to demonstrate the requisite diligence required by any such agreements or as interpreted by the respective licensors, we may lose our development and commercialization rights for the associated product.

# 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 challenges 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.

Our secured indebtedness imposes significant restrictions on us, and a default could cause us to cease operations. All of our material assets, except the intellectual property associated with our Lymphoseek, RIGS and ACT products under development, have been pledged as collateral for the remaining \$6.2 million in principal amount of our Series A Convertible Notes, issued to funds managed by Great Point Capital Partners and to our CEO under an agreement dated December 13, 2004, as amended November 30, 2006, and a Series B Convertible Note issued to our CEO and members of his family dated July 3, 2007 (collectively, 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 (as of August 31, 2007: \$1,500,000 due January 7, 2008, \$2,000,000 due July 7, 2008, \$1 million due July 8, 2008 and \$2,600,000 due January 7, 2009), interest (10 -12% per annum, payable on March 31, June 30, September 30, and December 31 of each year) and other charges on the Notes when due:

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we use the proceeds from the sale of the Notes only for permitted purposes, such as **Lymphoseek** development and general corporate purposes;

we nominate and recommend for election as a director a person designated by the holders of the Series A Notes (as of August 31, 2007, the holders of the Series A Notes have not designated a potential board member);

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 indemnify the purchasers of the Notes against certain liabilities; and

we use our best efforts to offer and sell equity securities with gross proceeds of up to \$10 million and apply not less than 50% of the net proceeds of such sales to the repayment of principal on the Series A Notes.

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. Further, the Series A Notes require us to apply at least 50% of the proceeds of any equity financing, permitted asset disposition or licensing, distribution or similar strategic alliance agreement to the repayment of principal on the Notes. 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 OTC Bulletin Board. 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.

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### 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 traded as low as \$0.19 per share and as high as \$0.50 per share during the twelve-month period ended August 31, 2007. The market price of our common stock has been and is expected to continue to be highly volatile. Factors, including announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by the company and by stockholders, and subsequent sale of common stock by the holders of warrants and options could have an adverse effect on the market price of our shares.

Some additional factors which could lead to the volatility of our common stock include:

price and volume fluctuations in the stock market at large which do not relate to our operating performance;

financing arrangements we may enter that require the issuance of a significant number of shares in relation to the number of shares currently outstanding;

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.

Generally, 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 12-month period ended August 31, 2007 was approximately 120,000 shares.

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Some provisions of our organizational and governing documents 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 of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements include statements regarding, among other things, (a) our projected sales and profitability, (b) our growth strategies, (c) anticipated trends in our industry, (d) our future financing plans, and (e) our anticipated needs for working capital. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words may, will. should. expect. anticipate. or the negative of these words or other variations on these words or comparable terminology. This information may involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from the future results, performance, or achievements expressed or implied by any forward-looking statements. These statements may be found under Management's Discussion and Analysis of Financial Condition and Results of Operations and Business, as well as in this prospectus generally. Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks outlined under Risk Factors and matters described in this prospectus generally. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this filing will in fact occur.

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 stockholder. We will receive no proceeds from the sale of shares of common stock in this offering. However, we may receive up to \$6.0 million in proceeds from the sale of our common stock to Fusion Capital under the common stock purchase agreement. Any proceeds from Fusion Capital we receive under the common stock purchase agreement will be used for working capital and general corporate purposes.

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### 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 two completed fiscal years, and for the current fiscal year through September 14, 2007, 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 2007			
First Quarter	\$0.28	\$0.20	\$0.24
Second Quarter	0.32	0.19	0.27
Third Quarter through September 14, 2007	0.50	0.20	0.31
Fiscal Year 2006:			
First Quarter	\$0.36	\$0.25	\$0.29
Second Quarter	0.30	0.23	0.26
Third Quarter	0.33	0.23	0.33
Fourth Quarter	0.34	0.22	0.24
Fiscal Year 2005:			
First Quarter	\$0.72	\$0.37	\$0.46
Second Quarter	0.46	0.30	0.35
Third Quarter	0.40	0.25	0.30
Fourth Quarter	0.32	0.20	0.25

As of September 14, 2007, we had approximately 796 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 are relevant. See Management s Discussion and Analysis of Financial Condition and Results of Operations, below.

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# 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 this Post-effective Amendment No. 1 to Registration Statement on Form SB-2, 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. We currently market two lines of medical devices; our **neo2000**® gamma detection systems and the **Quantix**® line of blood flow measurement devices of our subsidiary, Cardiosonix. In addition to our medical device products, we have two radiopharmaceutical products, **RIGScan**® CR and **Lymphoseek**®, in the advanced phases of clinical development. We are also exploring the development of our activated cellular therapy (ACT) technology for patient-specific disease treatment through our majority-owned subsidiary, Cira Biosciences, Inc. (Cira Bio).

# **Executive Summary**

This Executive Summary section contains a number of forward-looking statements, all of which are based on current expectations. Actual results may differ materially. Our financial performance is highly dependent on our ability to continue to generate income and cash flow from our gamma device product line and on our ability to successfully commercialize the blood flow products of our subsidiary, Cardiosonix. We cannot assure you, however, that we will achieve the volume of sales anticipated, or if achieved, that the margin on such sales will be adequate to produce positive operating cash flow. We continue to be optimistic about the longer-term potential for our other proprietary, procedural-based technologies such as Lymphoseek and RIGS® (radioimmunoguided surgery); however, these technologies are not anticipated to generate any significant revenue for us during 2007. In addition, we cannot assure you that these products will ever obtain marketing clearance from the appropriate regulatory bodies. We believe that the future prospects for Neoprobe continue to improve as we make progress in all of our lines of business. We expect revenue from our gamma device line to continue to provide a strong revenue base during 2007. Sales of our blood flow measurement devices also continue to be below our expectations. While we have seen enough instances of success when the products have been demonstrated to cardiovascular surgeons to give us cause for optimism, these product demonstrations have not yet translated into significant sales for the Company. As a result, we currently expect that blood flow-related revenue for 2007 may fall below 2006 levels. Over the past few years, we have also made progress on our oncology drug development initiatives. We recently completed patient enrollment in a Phase 2 clinical trial for Lymphoseek in breast cancer and melanoma.

The majority of our development expenses over the next 12 to 18 months will be devoted to our **Lymphoseek** efforts to complete manufacturing validation and scale-up, to complete Phase 3 clinical trials and to prepare for the submission of a new drug application to the U.S. Food and Drug Administration (FDA) which we expect to submit in 2008 subject to clearance from FDA to commence the Phase 3 studies in a timely fashion. We anticipate the total outsourced out-of-pocket costs for **Lymphoseek** to be approximately \$9 10 million. We also expect to incur development expenses in 2007 as we continue to innovate our device product lines, although we do not currently expect our out-of-pocket expenses to exceed \$1 million related to these projects in 2007. We are currently devoting minimal incremental resources and funding to support our blood flow measurement business beyond that needed to support our gamma device line and believe we are not far from a breakeven point for the blood flow line based on the incremental investment anticipated in our current expectations. We will continue to monitor the state of market development and success for our blood flow measurement business and

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adjust our business plans accordingly. We may also incur some minor development expenses in 2007 related to our RIGS radiopharmaceutical product development although we intend to defer any major expenses until we identify a partner to assist us in the development and commercialization of **RIGScan** CR. We will likely show a loss for fiscal year 2007 primarily due to our drug product development efforts.

As of June 30, 2007 our cash on hand totaled \$1.2 million. We believe our currently available capital resources will be adequate to sustain our operations at planned levels through the end of 2007. We intend to raise additional funds through our stock purchase agreement with Fusion to supplement our capital needs until we are able to generate positive cash flow from **Lymphoseek** and our medical device product lines. However, the extent to which we rely on Fusion as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources, such as through the sale of our products. Specifically, Fusion does not have the right or the obligation to purchase any shares of our common stock on any business day that the market price of our common stock is less than \$0.20 per share. If we decide to seek additional funding from other sources to support the development of our products and additional financing is not available when required or is not available on acceptable terms, or we are unable to arrange a suitable strategic opportunity, we may need to modify our business plan. We cannot assure you that the additional capital we require will be available on acceptable terms, if at all. We cannot assure you that we will be able to successfully commercialize products or that we will achieve significant product revenues from our current or potential new products. In addition, we cannot assure you that we will achieve or sustain profitability in the future.

Our Outlook for our Gamma Detection Device Products

We believe our core gamma detection device business line will continue to achieve positive results. Our belief is based on continued interest in the research community in lymphatic mapping. The National Cancer Institute (NCI) has sponsored two large randomized clinical trials (research studies) for breast cancer comparing sentinel lymph node biopsy (SLNB) with conventional axillary lymph node dissection. The trials were conducted by the National Surgical Adjuvant Breast and Bowel Project (NSABP) and the American College of Surgeons Oncology Group (ACOSOG). NSABP and ACOSOG are both NCI-sponsored Clinical Trials Cooperative Groups, which are networks of institutions and physicians across the country who jointly conduct trials. Although several studies have examined the correlation between the sentinel node and the remaining axillary nodes, these are the first two large randomized multi-center trials that will compare the long-term results of sentinel lymph node removal with full axillary node dissection. While both of these trials are now closed, final data from these studies likely will not be presented for another year or so. We expect the results from these clinical trials, when announced, will have a positive impact on helping us to penetrate the remaining market for breast cancer and melanoma. We also believe that the surgical community will continue to adopt the SLNB application while a standard of care determination is still pending. We also believe that Lymphoseek, our lymphatic targeting agent, should it become commercially available, could significantly improve the adoption of SLNB in future years in areas beyond melanoma and breast cancer. To that end, we are supporting the clinical evaluation of **Lymphoseek** in patients with either prostate or colon cancers. We believe that most of the leading cancer treatment institutions in the U.S. and other major global markets have adopted SLNB and purchased gamma detection systems such as the neo2000. As a result, we may be reaching saturation within this segment of the market, except for potential replacement sales. As such, our marketing focus in all major global markets for gamma detection devices will continue to be among local/regional hospitals, which typically lag behind leading research centers and major hospitals in adapting to new technologies. A decline in the adoption rate of SLNB at these institutions or the development of alternative technologies by competitors may negatively impact our sales volumes, and therefore, revenues and net income in future years. In order to address the issue of potential saturation as well as to continue to provide our customers with the highest quality tools for performing SLNB, we introduced a new gamma detection probe at the American College of Surgeons 92<sup>nd</sup> Annual Clinical Congress meeting in Chicago in October 2006. The new probe uses Bluetooth® wireless technology to communicate gamma radiation counts to our **neo2000** control unit. The wireless probe eliminates cumbersome cables that can complicate the surgical field and provides the surgeon with operative field flexibility. The new probe is designed to be used with all existing models of our neo2000 system (Models 2000, 2100 and 2200). The wireless probe is available with either a straight or angled detection tip.

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During March 2006, our primary gamma device marketing partner, Ethicon Endo-Surgery, Inc. (EES), a Johnson & Johnson company, exercised the second of its two options to extend the termination date of our distribution agreement with them through the end of 2008. We believe that total quantities of base **neo2000** systems expected to be purchased by EES during 2007 should be consistent with 2005 and 2006 purchase levels. We cannot assure you, however, that EES product purchases beyond those firmly committed through late 2007 will indeed occur or that the prices we realize will not be affected by increased competition.

Under the terms of our distribution agreement with EES, the transfer prices we receive on product sales to EES are based on a fixed percentage of their end-customer sales price, subject to a floor transfer price. Throughout their sales history, our products have generally commanded a price premium in most of the markets in which they are sold, which we believe is due to their superior performance and ease of use. The average end-customer sales prices received by EES for our gamma detection devices declined less than 3% in 2006 as compared to 2005; however, the transfer price that we received from selling to EES during 2006 remained approximately 18% above the floor pricing for the base system configuration. While we continue to believe in the technical and user-friendly superiority of our products, the competitive landscape continues to evolve and we may lose market share or experience price erosion as a result. A loss of market share or significant price erosion would have a direct negative impact on net income. If price erosion continues into 2007, there is a risk associated with future sales of our gamma detection devices to EES that may erode some or all of the premium we received in prior years in excess of the floor price. We anticipate generating a net profit from the sale of our gamma detection devices in 2007, excluding the allocation of any corporate general and administrative costs. We also believe the anticipated volumes would result in continued profitability for our gamma device business line for 2007, even at floor prices. However, we cannot assure you that sales will occur at the expected levels or prices or that such sales will ultimately result in profitability of the product line. Our Outlook for our Drugs and Therapeutics

The primary focus of our drug and therapeutic development efforts through mid-2007 has centered around completing the Phase 2 clinical trial for **Lymphoseek** for patients with breast cancer or melanoma. **Lymphoseek** is intended to be used in biopsy procedures for the detection of cancer cells in lymph nodes in a variety of tumor types including breast, melanoma, prostate, gastric and colon cancers. If approved, **Lymphoseek** would be the first radiopharmaceutical specifically designed to target lymphatic tissue.

Based on recent discussions with FDA, we plan to propose to the agency that we conduct two separate Phase 3 studies, each of which would involve approximately 200 evaluable patients with either melanoma or breast cancer. We expect the study protocol to provide for patients in these trials to receive both **Lymphoseek** and a non-radiopharmaceutical agent that is currently used as a marker in lymphatic mapping procedures. Our discussions with FDA also suggest that the Phase 3 trials will be structured to support a specific intended use of Lymphoseek in SLNB procedures. We believe such an indication would be beneficial to the marketing and commercial adoption of **Lymphoseek**.

We will hold an end of Phase 2 meeting with FDA before the Phase 3 trials can be initiated. This will likely mean that, although we continue to project that the Phase 3 trials will commence during the fourth quarter of 2007, it will likely be closer to the end of the year than previously thought. We plan to have approximately 35 participating institutions in each Phase 3 trial, which should enable us to enroll patients at a more rapid rate than we experienced with the Phase 2 study. Our goal is to file the new drug application for Lymphoseek during the second half of 2008, which will be dependent upon our ability to commence and conclude the Phase 3 clinical studies in a timely fashion. Depending on the timing and outcome of the FDA regulatory review cycle, we believe that **Lymphoseek** can be commercialized in 2009.

In early 2005, we formed a new subsidiary, Cira Bio, to explore the development of ACT. Neoprobe owns approximately 90% of the outstanding shares of Cira Bio with the remaining shares being held by the principals of a private holding company, Cira LLC. In conjunction with the formation of Cira Bio, an amended technology license agreement also was executed with The Ohio State University, from whom

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both Neoprobe and Cira LLC had originally licensed or optioned the various cellular therapy technologies. As a result of the cross-license agreements, Cira Bio has the development and commercialization rights to three issued U.S. patents that cover the oncology and autoimmune applications of its technology. In addition, Cira Bio has licenses to several pending patent applications.

Cira Bio intends to raise the necessary capital to move this technology platform forward; however, Cira Bio has not yet identified a potential source of capital. Obtaining this funding would likely dilute Neoprobe s ownership interest in Cira Bio; however, we believe that moving forward such a promising technology will only yield positive results for the Neoprobe stockholders and the patients who could benefit from these treatments. However, we do not know if we will be successful in obtaining funding on terms acceptable to us, or at all. In addition, because Cira Bio was not successful in obtaining sufficient capital by December 31, 2006, the technology rights for the oncology applications of ACT may revert back to Neoprobe and the technology rights for the viral and autoimmune applications may revert back to Cira LLC upon notice by either party.

Our Outlook for our Blood Flow Measurement Products

We have two blood flow measurement devices, the **Quantix/OR**<sup>TM</sup> and the **Quantix/ND**<sup>TM</sup>, that have regulatory clearance to market in the U.S. and European Union (EU) as well as certain other foreign markets. The **Quantix/OR** is primarily intended to measure blood flow in cardiac bypass graft and other similar procedures while the **Quantix/ND** is designed to measure blood flow in neurovascular settings. Currently, we have in place or have executed or reached agreement in principle with distributors and/or master distributors for the **Quantix/OR** covering the United States, all major market countries in the EU, and substantially all countries that comprise the Pacific Rim of Asia. In addition, we have distribution arrangements in place covering major portions of Central and South America. Our goal is to secure and maintain marketing and distribution arrangements with partners who possess appropriate expertise in marketing medical devices, preferably ultrasound or cardiac care devices, into our primary target markets, the cardiovascular, vascular surgery and neurosurgical markets.

Our strategy related to Cardiosonix products for the remainder 2007 is to close on sales leads generated over the course of the year and to work to increase the number of competitive product evaluations to which we are invited. The sales cycle for medical devices such as our blood flow products is typically a four to six month cycle. This sales cycle, coupled with the timetable necessary to train the new distributors we engaged during 2006 has resulted in disappointing sales levels of our blood flow measurement equipment to date. We are also investigating alternative pricing strategies such as per-use fees or leasing that may affect the adoption rates for our blood flow measurement devices. However, we anticipate that the product development and market support costs we will incur in 2007 will be greater than the revenue we generate from the sales of blood flow devices. As a result, we expect to show a loss for our blood flow measurement device product line for 2007 due to ongoing development and marketing support that is required to expand market acceptance for the product line. We are currently devoting minimal incremental resources and funding to support our blood flow measurement business and believe we are not far from a breakeven point for the blood flow line based on the incremental investment anticipated in our current expectations. We will continue to monitor the state of market development and success for our blood flow measurement business and adjust our business plans accordingly.

# Summary

The strength of our oncology product (device and drug) portfolio should position us to eventually achieve profitable operating performance for our device product lines. However, overall profitable operational results will be significantly affected by our decision to fund drug and therapeutic development activities internally.

We anticipate generating a net profit from the sale of our gamma detection devices in 2007, excluding the allocation of any corporate general and administrative costs; however, we expect to show a loss for our blood flow device product line for 2007 due to ongoing research and development and increased marketing and administrative support costs that may be required to expand market acceptance for the product line. Our overall operating results for 2007 will also be greatly affected by the amount of development of our radiopharmaceutical products.

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Primarily as a result of the significant development costs we expect to incur related to the continued clinical development of Lymphoseek, we do not expect to achieve operating profit during 2007. In addition, our net loss and loss per share will likely be significantly impacted by the non-cash interest expense we expect to record related to the accounting treatment for the beneficial conversion feature of the convertible debt and for the warrants issued in connection with the private placement we completed in December 2004 and modified in November 2006. We cannot assure you that our current or potential new products will be successfully commercialized, that we will achieve significant product revenues, or that we will achieve or be able to sustain profitability in the future.

# YEARS ENDED DECEMBER 31, 2006 AND 2005

### **Results of Operations**

Revenue for 2006 increased to \$6.1 million from \$5.9 million in the prior year. The increase was due to increased blood flow device sales of \$263,000, offset by a decrease of \$134,000 in sales of gamma detection devices and extended service contracts.

Gross profit for 2006 decreased \$124,000 or 4% as compared to 2005. The decrease in gross profit on net sales of our medical devices in 2006 was primarily due to the decline in gross margin percentage related to our blood flow product line. The decline in blood flow gross margin percentage resulted from \$129,000 of inventory impairments related to design changes to our **Quantix** products in 2006 coupled with lower margins on blood flow sales due to a greater proportion of blood flow devices being sold on a wholesale basis to distributors as opposed to on a retail basis to end customers. By comparison, we recorded \$45,000 of inventory impairments related to our laparoscopic gamma detection probe and \$13,000 of inventory impairments related to our blood flow product line in 2005.

Results for 2006 also reflect significant expenditures made in the development of **Lymphoseek** and in continuing to innovate our gamma detection device line with the introduction of a Bluetooth wireless probe. Despite these development advances, our research and development costs for 2006 decreased to \$3.8 million compared to \$4.0 million in 2005. Consolidated general and administrative expenses decreased slightly to \$3.1 million in 2006 from \$3.2 million in 2005.

*Net Sales and Margins*. Net sales, primarily of our gamma detection systems, increased \$132,000, or 2%, to \$6.1 million in 2006 from \$5.9 million in 2005. Gross margins on net sales decreased to 57% of net sales for 2006 compared to 60% of net sales for 2005.

The increase in net sales was the result of increased blood flow device sales of \$263,000, offset by a decrease of \$134,000 in sales of gamma detection devices and extended service contracts. The price at which we sell our gamma detection products to EES is based on a percentage of the global average selling price received by EES on sales of Neoprobe products to end customers, subject to a minimum floor price. The base system price at which we sold **neo2000** systems to EES decreased approximately 3% from 2005 to 2006.

The decrease in gross