

NEOPROBE CORP  
Form 424B3  
October 05, 2007

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Registration No. 333-121673

**SECOND AMENDED  
PROSPECTUS  
NEOPROBE CORPORATION  
32,350,000 Shares of Common Stock**

This prospectus relates to the sale of up to 32,350,000 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 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.

Each selling stockholder may be considered 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**<sup>®</sup>) 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**<sup>®</sup> 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**<sup>®</sup> 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**

During April 2003, we completed a bridge loan agreement with our President and CEO, David C. 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 our common stock at an exercise price of \$0.13 per share, expiring in April 2008. The note bore interest at 8.5% per annum, payable monthly, and 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,

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expiring in March 2009. On December 13, 2004, we repaid the balance of the note to Mr. Bupp. The shares covered by this prospectus include the 375,000 shares of common stock issuable pursuant to the warrants granted to Mr. Bupp in March 2004.

In December 2004, we completed a private placement of four-year convertible promissory notes in an aggregate principal amount of \$8.1 million with Biomedical Value Fund, L.P., Biomedical Offshore Value Fund, Ltd. and David C. Bupp (our President and CEO). Biomedical Value Fund, L.P. and Biomedical Offshore Value Fund, Ltd. are funds managed by Great Point Partners, LLC. We modified the convertible notes on November 30, 2006, to eliminate the revenue and cash covenants, modify the repayment schedule of the notes, eliminate certain anti-dilution rights, and avoid potential future violations of the debt covenants. The notes originally bore interest at 8% per annum and were originally due on December 13, 2008. In connection with the November 30, 2006 amendment, we cancelled the original notes and issued to the noteholders replacement notes which bear interest at 12% per annum. Instead of the notes being due on December 13, 2008 per the original agreement, due dates of the principal payments were revised as follows: \$500,000 due January 8, 2007; \$1,250,000 due July 9, 2007; \$1,750,000 due January 7, 2008; \$2,000,000 due July 7, 2008; and the remaining \$2,600,000 due January 7, 2009. Additionally, as part of the amendment we agreed to 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 any such sales to the repayment of the principal on the notes, and to apply at least 50% of the proceeds of any permitted asset disposition or any permitted licensing, distribution or similar strategic alliance agreement to the repayment of principal on the notes. The notes are freely convertible into shares of our common stock at a price of \$0.40 per share. Neoprobe may force conversion of the notes prior to their stated maturity under certain circumstances. As part of the original transaction, we issued the investors 10,125,000 Series T warrants to purchase our common stock at an exercise price of \$0.46 per share, expiring in December 2009. The shares covered by this prospectus include 20,250,000 shares of common stock issuable upon conversion of the notes, and the 10,125,000 shares of our common stock issuable upon the exercise of the Series T warrants.

During 2004 we engaged the services of two investment banking firms to assist us in raising capital, Roth Capital Partners, LLC (Roth) and Laidlaw & Co. (Laidlaw). In exchange for the services of Roth, we agreed to pay \$320,000 in cash, plus warrants to purchase 800,000 shares of our common stock. The warrants have an exercise price of \$0.46 per share. This prospectus covers the resale of the shares of common stock issuable upon the exercise of these warrants.

In exchange for the services of Laidlaw, we agreed to pay \$320,000 in cash, plus warrants to purchase 800,000 shares of our common stock. The warrants have an exercise price of \$0.46 per share. This prospectus covers the resale of the shares of common stock issuable upon the exercise of warrants by the underwriters which received warrants to purchase shares of our common stock as a result of their participation in the offering on behalf of Laidlaw.

With the exception of the warrants granted to Mr. Bupp in March 2004, all warrants issued in connection with this transaction expire in December 2009. This prospectus covers the resale of shares of common stock issuable upon conversion of the convertible promissory notes, warrants issued to Mr. Bupp in exchange for extending the due date of the note executed in his favor in connection with the April 2003 bridge loan agreement, and the shares of common stock issuable pursuant to the warrants granted to the parties to the Securities Purchase Agreement and the placement agents and their assignees.

Through August 31, 2007, we have repaid the noteholders, excluding Mr. Bupp, a total of \$2.0 million through both scheduled principal repayments and mandatory principal repayments. This has decreased the total shares of common stock issuable upon conversion of the notes from 20,250,000 to 15,000,000.

**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 willing or allowed to purchase it or may demand steep discounts. Sufficient additional financing may not

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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 6.8 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;

discovery of unacceptable toxicities or side effects;

development of disease resistance or other physiological factors;

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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 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.

***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



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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'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 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;

- civil or criminal penalties;

- finances;

- 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

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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), a Johnson & Johnson company, 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.

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

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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.



**Table of Contents*****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, \$1,000,000 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;

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

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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 report 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, negative net worth and uncertainty of future profitability;

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 report.

In addition, in this report, we use words such as anticipate, believe, plan, expect, future, intend, 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 report. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report 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.

**Table of Contents****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.

|  | <i>High</i> | <i>Low</i> | <i>Close</i> |
|--|-------------|------------|--------------|
| <i>Fiscal Year 2007:</i>                 |             |            |              |
| 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         |
| <i>Fiscal Year 2006:</i>                 |             |            |              |
| 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         |
| <i>Fiscal Year 2005:</i>                 |             |            |              |
| 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.

Table of Contents**DESCRIPTION OF BUSINESS****Development of the Business**

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**<sup>®</sup>) 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**<sup>®</sup> 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**<sup>®</sup> 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.

**Our Technology***Gamma Detection Devices*

Through the second quarter of 2007, 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 markets.

Our patented gamma detection device systems consist of hand-held detector probes and a control unit. The critical detection component is a highly radiosensitive crystal contained in the tip of the probe 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**<sup>®</sup> 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 four major software upgrades for customer units designed to improve the utility of the system and/or offer the users additional

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features, including our most recent release that enables our entire installed base of **neo2000** users to use our Bluetooth® wireless gamma detection probes which were commercially launched in late 2006. Generally, these software upgrades have been included in new units offered for sale but have also been offered for sale separately. Surgeons are using our gamma detection devices in a surgical application referred to as sentinel lymph node biopsy (SLNB). SLNB 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. SLNB 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 2,000 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 SLNB 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 SLNB have found that our gamma detection probes are well-suited to the procedure.

Hundreds of articles have been published in recent years in peer-reviewed journals on the topic of SLNB.

Furthermore, a number of thought leaders and cancer treatment institutions have recognized and embraced the technology as standard of care for melanoma and for breast cancer. Our marketing partner continues to see strong sales, especially for use in breast cancer treatment. SLNB in breast cancer has been the subject of national and international clinical trials, including one major study sponsored by the U.S. Department of Defense and the National Cancer Institute (NCI) and one sponsored by the American College of Surgeons. The first of these trials completed accrual approximately two years ago and preliminary results may be available in the next year or two. Accrual on the second trial was halted early, due, we believe, to the overwhelming desire of patients to be treated with SLNB rather than be randomized in a trial whereby they might receive a full axillary dissection. We believe that once data from these trials are published there may be an additional demand for our devices from those surgeons who have not yet adopted the SLNB procedure. We also believe, based on an estimate of the total number of operating rooms in medical centers that are capable of performing the types of procedures in which our gamma detection devices are used, that while we are potentially reaching saturation at the major cancer centers and teaching institutions, a significant portion of the global market for gamma detection devices such as ours remains untapped.

In addition to lymphatic mapping, surgeons are investigating the use of our devices 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 for SLNB in prostate, gastric, colon, head and neck, and non-small cell lung cancers. Expanding the application of SLNB 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 additional software-based enhancements to the **neo2000** platform as well as our new Bluetooth wireless probes introduced in late 2006. To that end, our goals for our gamma detection device business for the remainder of 2007 center around working with our marketing partners to further penetrate the breast care market and identify ways to expand the application of SLNB to other indications beyond breast cancer and melanoma. We also believe that our development of **Lymphoseek** could be an integral step in helping expand the application of SLNB.

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### *Blood Flow Measurement Devices*

Accurate blood flow measurement is essential for a variety of clinical needs, including:

real-time monitoring;

intra-operative quantification;

non-invasive diagnostics; and

evaluation of cardiac function.

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 has developed and is commercializing the **Quantix** line of products that employ a unique and proprietary technology that allows for measurement of blood flow volume, velocity and several other hemodynamic parameters that permit the real-time assessment of conduit hemodynamic status.

The **Quantix** 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 designed to provide blood flow measurement and cardiac output information to physicians in cardiac/vascular surgery and neurosurgery. The technology also has the potential to be applied in other healthcare settings where measurement of blood flow may be beneficial.

**Quantix/OR**<sup>TM</sup> is designed to permit cardiovascular surgeons to obtain intraoperative volume blood flow readings in various targeted blood vessels within seconds. The system consists of an insonation 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 can be very beneficial during anastomotic or other bypass graft procedures to determine adequate blood flow. While measurement is advisable whenever a blood vessel is exposed and manipulated intra-operatively, generally this is not the current practice. Ultimately, in practice, the surgeon generally resorts to using his or her 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, simple and low cost; 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 distention and strong pulse that may mislead the surgeon. Rather than rely on such a subjective clinical practice, which is highly experience-dependent, the **Quantix/OR** is designed to allow the surgeon to rely on more quantifiable and objective information. We believe that **Quantix/OR** represents a measurable 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 non-skeletonized vessel measurements are required. As a result, a majority of surgeons generally resort to finger palpation to qualitatively, rather than quantitatively, measure vessel perfusion.





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The initial physician and distributor evaluation of the flagship product, the **Quantix/OR**, during 2004 indicated a number of design deficiencies that needed to be corrected before further commercial distribution of the product was advisable. The development activities for the **Quantix/OR** over the last year have therefore involved modification of the user interface software functions and a redesign of the **Quantix/OR** probe ergonomics to enhance system performance, improve ease of measurement and expand physician acceptance of the system. The **Quantix/OR** device 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/ND**<sup>TM</sup> is intended to allow neurosurgeons and neurologists, as well as intensive care unit or emergency room physicians, to non-invasively measure the internal carotid artery blood flow in a simple, real-time manner.

**Quantix/ND** consists of a control unit and an 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 may minimize the risk of brain impairment. To date, we have placed the **Quantix/ND** device with only a limited number of thought leaders. While we are unaware of any competitive measurement system on the market today that provides real-time, bedside, non-invasive, continuous, direct and accurate measurements of a complete suite of hemodynamic parameters including blood flow, we also believe that the current market for the **Quantix/ND** may be primarily as a research tool until additional feedback is received from those who are evaluating the device. The **Quantix/ND** device has received CE mark regulatory clearance for marketing in the EU as well as FDA 510(k) clearance for marketing in the United States.

Our strategy related to Cardiosonix products for the remainder 2007 is to work with our marketing and distribution partners 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. We cannot assure you, however, that any of Cardiosonix's products will achieve market acceptance. See 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. The product we are working on with the greatest near-term potential in this area involves a proprietary drug compound under exclusive worldwide license from the University of California, San Diego (UCSD) that we refer to as **Lymphoseek**. The UCSD license grants Neoprobe the commercialization rights to **Lymphoseek** for diagnostic imaging and intraoperative detection applications. If proven effective and cleared for commercial sale, **Lymphoseek** would be the first radiopharmaceutical specifically designed and labeled for the targeting of lymphatic tissue. Neoprobe and UCSD completed the initial pre-clinical ev