

NEOPROBE CORP
Form POS AM
December 29, 2009

As filed with the Securities and Exchange Commission on December 29, 2009

Registration No. 333-156810

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

Post-effective Amendment No. 2

to

FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

NEOPROBE CORPORATION
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2835
(Primary standard industrial
classification code number)

31-1080091
(IRS employer
identification number)

425 Metro Place North, Suite 300
Dublin, Ohio 43017-1367
(614) 793-7500

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Brent L. Larson, Vice President, Finance and
Chief Financial Officer
Neoprobe Corporation
425 Metro Place North, Suite 300
Dublin, Ohio 43017-1367
(614) 793-7500

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

SUBJECT TO COMPLETION, DATED DECEMBER 29, 2009.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

NEOPROBE CORPORATION

11,500,000 Shares of Common Stock

This prospectus relates to the sale of up to 11,500,000 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 December 28, 2009, the last reported sale price for our common stock as reported on the OTC Bulletin Board was \$1.05 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 5 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 December __, 2009.]

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Unless otherwise specified, the information in this prospectus is set forth as of December 29, 2009, and we anticipate that changes in our affairs will occur after such date. We have not authorized any person to give any information or to make any representations, other than as contained in this prospectus, in connection with the offer contained in this prospectus. If any person gives you any information or makes representations in connection with this offer, do not rely on it as information we have authorized. This prospectus is not an offer to sell our common stock in any state or other jurisdiction to any person to whom it is unlawful to make such offer.

PROSPECTUS SUMMARY

The following summary highlights selected information from this prospectus and may not contain all the information that is important to you. To understand our business and this offering fully, you should read this entire prospectus carefully, including the financial statements and the related notes beginning on page F-1. When we refer in this prospectus to the “company,” “we,” “us,” and “our,” we mean Neoprobe Corporation, a Delaware corporation, together with our 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 oncology products that enhance patient care and improve patient outcome. 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. In 1998, U.S. and European regulatory agencies completed an evaluation of the status of the regulatory pathway for our RIGS products, which coupled with our limited financial resources at the time, caused us to suspend our radiopharmaceutical development activities and refocus our operating strategy on our medical device business. After achieving profitability in the fourth quarter of 1999 following this retrenchment, we expanded our medical device offerings in 2002 through the acquisition of an Israeli company that was developing a line of blood flow measurement devices.

Although we had expanded our strategic focus with the addition of medical devices outside the oncology field, we continued to look for other avenues to reinvigorate our radiopharmaceutical development portfolio. In 2004, our efforts resulted in a number of positive events that caused us to take steps to re-activate our radiopharmaceutical and therapeutic initiatives. As a result of our efforts since 2004, we now have submitted data from a Phase 3 clinical trial of one of our radiopharmaceutical products, Lymphoseek®, to the U.S. Food and Drug Administration (FDA) for review and we are enrolling patients in a second Phase 3 clinical trial intended to further support and expand our proposed product labeling for Lymphoseek. Interest in, and activity related to, our second radiopharmaceutical product, RIGScan® CR, has also increased significantly in recent years as we sought, and subsequently received, formal scientific advice in 2008 from the European Medicinal Evaluation Agency (EMA) regarding our regulatory and clinical development plans for RIGScan CR. We have taken steps during the fourth quarter of 2009 to obtain similar feedback from FDA through the submission of a pre-Phase 3 meeting request and Special Protocol Assessment (SPA) request. Our subsidiary, Cira Biosciences, Inc. (Cira Bio) is evaluating the market opportunities for yet another technology platform, activated cellular therapy (ACT). The success we have been experiencing in recent years related to our drug development activities caused us, during 2009, to re-evaluate our product initiatives and strategies. As a result of this evaluation, we made the decision during the third quarter of 2009 to discontinue the operations of our blood flow measurement device product line and to attempt to divest our Cardiosonix Ltd. subsidiary. We believe this decision will allow us to better focus on our oncology-related development platforms as we approach several key milestones in the coming twelve to eighteen months.

We believe that our virtual business model is unique within our industry as we combine revenue generation from medical devices covering our public company overhead while we devote capital raised through financing efforts to the development of products such as Lymphoseek which possess even greater potential for shareholder return. In addition, we have sought to maintain a development pipeline with additional longer-term return potential such as RIGScan CR and ACT that provide the opportunity for incremental return on the achievement of key development

and funding milestones.

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The Offering

Fusion Capital, the selling stockholder under this prospectus, is offering for sale up to 11,500,000 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, to sell \$6,000,000 of our common stock to Fusion Capital over a 24-month period which ended on November 21, 2008. Through November 21, 2008, we sold to Fusion Capital 7,568,671 shares for proceeds of \$1,949,999.27 under the agreement. We have not sold any shares under the agreement since November 13, 2007. None of the 7,568,671 shares are part of the offering pursuant to this prospectus. On December 24, 2008, we entered into the first amendment to the common stock purchase agreement which gave us a right to sell to Fusion Capital before March 1, 2011, an additional \$6,000,000 of our common stock along with the \$4,050,000.73 of the unsold balance of the \$6,000,000 we originally had the right to sell to Fusion Capital under the agreement prior to the first amendment. After giving effect to the first amendment the remaining aggregate amount of our common stock we can now sell to Fusion Capital is \$10,050,000.73. In respect of sales to Fusion Capital that we may make in the future under the agreement as amended, we have authorized a total of 10,654,000 shares of our common stock. All 10,654,000 shares are part of the offering pursuant to this prospectus.

On December 1, 2006, we issued to Fusion Capital 720,000 shares of our common stock as a commitment fee upon execution of the agreement. In connection with sales of our common stock, we have issued an additional 234,000 shares of our common stock to Fusion Capital as an additional commitment fee. None of the 720,000 shares or the 234,000 shares are part of the offering pursuant to this prospectus. We issued an additional 360,000 shares in consideration for Fusion Capital's agreement to enter into the amendment. Also, under the agreement, as an additional commitment fee we have agreed to issue to Fusion Capital pro rata an additional 486,000 shares of our common stock as we sell the first \$4,050,000.73 of our common stock to Fusion Capital under the agreement as amended. \$4,050,000.73 represents the unsold balance of the \$6,000,000 we originally had the right to sell to Fusion Capital under the agreement prior to the first amendment. All 360,000 shares and 486,000 shares are part of the offering pursuant to this prospectus.

As of December 15, 2009, there were 80,889,561 shares of our common stock outstanding (78,166,072 shares held by non-affiliates) including the 360,000 shares we issued to Fusion Capital in consideration for Fusion Capital's entering into the first amendment, but excluding the 10,654,000 shares which have not yet been issued and purchased by Fusion Capital and the remaining 486,000 additional commitment fee shares which have not yet been issued to Fusion Capital as we sell the first \$4,050,000.73 of our common stock to Fusion Capital under the agreement as amended. If all 11,500,000 shares offered hereby were issued and outstanding as of the date hereof, the 11,500,000 shares would represent 12.5% of the total common stock outstanding or 13.6% of the non-affiliate shares outstanding as of the date hereof.

In summary, this prospectus covers: (i) 360,000 shares of our common stock issued to Fusion Capital in consideration for its agreement to enter into the amendment to the common stock purchase agreement; (ii) 486,000 commitment fee shares to be issued pro rata as we sell the first \$4,050,000.73 of our common stock to Fusion Capital; and (iii) 10,654,000 shares of our common stock which we may sell to Fusion Capital pursuant to the terms of the common stock purchase agreement as amended. Under the agreement, we have the right but not the obligation to sell more than the 10,654,000 shares to Fusion Capital. As of the date hereof, we do not currently have any plans or intent to sell to Fusion Capital any shares beyond the 10,654,000 shares. However, if we elect to sell more than the 10,654,000 shares, we must first register under the Securities Act any additional shares we may elect to sell to Fusion Capital before we can sell such additional shares. 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. After the Securities & Exchange Commission has declared effective such registration statement, generally we have the right but not the obligation from time to time but prior to March 1, 2011, 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 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. There are no negative covenants, restrictions on future fundings, penalties or liquidated damages in the agreement. The 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 5.

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 \$192 million and had an overall deficit in stockholders' equity as of September 30, 2009. Although we were profitable in 2000 and 2001, we incurred substantial losses in the years prior to that, and again in subsequent years. 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 our device product lines. 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, we believe expansion of SLNB to other indications such as head and neck, 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 eventually 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.

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 may 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 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.

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We believe that we have access to sufficient financial resources with which to fund our operations or those of our subsidiaries for the foreseeable future. We expect to raise additional capital during 2009 through existing financing facilities already available to us in order to continue executing on our current business plan. The continuation of the current worldwide financial crisis and depressed stock market valuations may adversely affect our ability to raise additional capital, either under facilities in place or from new sources of capital. If we are unsuccessful in raising additional capital, closing on financing under already agreed to terms, 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, an Illinois limited liability company, to sell \$6.0 million of our common stock over a 24-month period which ended on November 21, 2008. Through November 21, 2008, we sold Fusion Capital under the agreement 7,568,671 shares for proceeds of \$1.9 million. In December 2008, we entered into an amendment to the agreement which gave us a right to sell an additional \$6.0 million of our common stock to Fusion Capital before March 1, 2011, along with the \$4.1 million of the unsold balance of the \$6.0 million we originally had the right to sell to Fusion Capital under the original agreement. After giving effect to this amendment, the remaining aggregate amount of our common stock we can sell to Fusion Capital is \$10.1 million, and we have reserved a total of 10,654,000 shares of our common stock for sale under the amended agreement. Our right to make sales under the agreement is limited to \$50,000 every two business days, unless our stock price equals or exceeds \$0.30 per share, in which case we can sell greater amounts to Fusion Capital as the price of our common stock increases. Fusion Capital does not have the right or any obligation to purchase any shares on any business day that the market price of our common stock is less than \$0.20 per share. Assuming all 10,654,000 shares are sold, the selling price per share would have to average approximately \$0.94 for us to receive the full \$10.1 million remaining proceeds under the agreement as amended. Assuming we sell to Fusion Capital all 10,654,000 shares at a sale price of \$1.05 per share (the closing sale price of the common stock on December 28, 2009), we would receive the full remaining \$10.1 million under the agreement. Under the agreement, we have the right but not the obligation to sell more than the 10,654,000 shares to Fusion Capital. As of the date hereof, we do not currently have any plans or intent to sell to Fusion Capital any shares beyond the 10,654,000 shares. However, if we elect to sell more than the 10,654,000 shares, we must first register any additional shares we may elect to sell to Fusion Capital under the Securities Act before we can sell such additional shares.

The extent to which we rely on Fusion Capital 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. To the extent that we are unable to make sales to Fusion Capital 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 \$10.1 million potentially remaining under the agreement with Fusion Capital, 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. During 2009, we successfully completed a Phase 3 clinical trial in patients with breast cancer or melanoma for our most advanced radiopharmaceutical product candidate, Lymphoseek. We are in the process of completing a second Phase 3 trial for this product in patients with head and neck squamous cell carcinoma. In late 2008, we obtained approval from EMEA

for a Phase 3 clinical protocol for our next radiopharmaceutical candidate, RIGScan CR, and are preparing to approach FDA to obtain similar clearance. 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, FDA or EMEA might delay or halt any clinical trials for our product candidates for various reasons, including:

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

While we have achieved some level of success in our recent Phase 2 and Phase 3 clinical trials for Lymphoseek, the results of these clinical trials, as well as pending and future trials, are subject to review and interpretation by various regulatory bodies during the regulatory review process and may ultimately 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 have an agreement in place with Cardinal Health 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 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 devices, who may not be successful in selling our products.

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

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, to control the escalation of healthcare expenditures within the economy and to 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 Capital, we have authorized the sale of up to 18,222,671 shares of our common stock and the issuance of 1,800,000 shares in commitment fees, and we have filed a registration statement with the SEC for the sale to the public of 11,500,000 shares issuable to Fusion Capital pursuant to the agreement. Through December 28, 2009, we have sold Fusion Capital 7,568,671 shares of common stock and issued 1,314,000 shares of stock as commitment fees to Fusion Capital. The number of shares ultimately offered for sale to the public will be dependent upon the number of shares purchased by Fusion Capital under the agreement. It is anticipated that these shares will be sold over a period of up to 26 months from the date of the December 24, 2008 amendment to 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 Capital 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 Capital, 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 Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

The sale of the shares of common stock acquired in private placements could cause the price of our common stock to decline.

Over the past few years, we completed various financings in which we issued common stock, convertible notes, warrants and other securities convertible into common stock to certain private investors. The terms of these transactions require that we file registration statements with the Securities and Exchange Commission 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. Further, some or all of the common stock sold in these transactions may become eligible for resale without registration under the provisions of Rule 144, upon satisfaction of the holding period and other requirements of the Rule.

As required by our financing arrangements with Fusion Capital, we have filed a registration statement registering for resale a total of 11,500,000 common shares, consisting of (i) 10,654,000 shares which we may sell to Fusion Capital pursuant to the amended common stock purchase agreement, (ii) 360,000 shares issued to Fusion Capital in consideration for its agreement to the amendment; and (iii) 486,000 commitment fee shares to be issued pro rata as we sell the first \$4.1 million of common stock under the amended agreement. The number of shares ultimately sold under the registration statement will be dependent upon the number of shares purchased by Fusion Capital under the amended agreement. It is anticipated that these shares will be sold from time to time over a period ending on March 1, 2011, at prices that will fluctuate based on changes in the market price of our common stock over that period. We have the right to control the timing and amount of any sales of our shares to Fusion Capital and the agreement may be terminated by us at any time at our discretion without any cost to us.

On December 26, 2007, we entered into a Securities Purchase Agreement (“SPA”) with Platinum-Montaur Life Sciences, LLC (“Montaur”), pursuant to which we issued Montaur a 10% Series A Convertible Senior Secured Promissory Note in the principal amount of \$7,000,000, due December 26, 2011 (the “Series A Note”) and a five-year Series W warrant to purchase 6,000,000 shares of our common stock at an exercise price of \$0.32 per share. On April 16, 2008, following receipt by the Company of clearance by the FDA to commence a Phase 3 clinical trial for Lymphoseek in patients with breast cancer or melanoma, we amended the SPA and issued Montaur a 10% Series B Convertible Senior Secured Promissory Note in the principal amount of \$3,000,000, also due December 26, 2011 (the “Series B Note,” and hereinafter referred to collectively with the Series A Note as the “Montaur Notes”), and a five-year Series X warrant to purchase 8,333,333 shares of our common stock at an exercise price of \$0.46 per share. On December 5, 2008, after the Company had obtained 135 vital blue dye lymph nodes from patients who had completed surgery and the injection of the drug in the Phase 3 clinical trial of Lymphoseek in patients with breast cancer or melanoma, we issued Montaur 3,000 shares of our 8% Series A Cumulative Convertible Preferred Stock (the “Preferred Stock”) and a five-year Series Y warrant (hereinafter referred to collectively with the Series W warrant and Series X warrant as the “Montaur Warrants”) to purchase 6,000,000 shares of our common stock, at an exercise price of \$0.575 per share, also for an aggregate purchase price of \$3,000,000. On July 24, 2009, we entered into a Securities Amendment and Exchange Agreement (“Amendment Agreement”) with Montaur, pursuant to which Montaur agreed to the amendment and restatement of the terms of the Montaur Notes, the Montaur Warrants and the Preferred Stock, to remove price-based anti-dilution adjustment provisions that had created a significant non-cash derivative liability on the Company’s balance sheet, and upon the surrender of the Montaur Notes and the Montaur warrants we issued Montaur an Amended and Restated 10% Series A Convertible Senior Secured Promissory Note in the principal amount of \$7,000,000, due December 26, 2011 (the “Amended Series A Note”), an Amended and Restated 10% Series B Convertible Senior Secured Promissory Note in the principal amount of \$3,000,000, due December 26, 2011 (the “Amended Series B Note,” and together with the Amended Series A Note the “Amended Montaur Notes”), an Amended and Restated Series W Warrant (the “Amended Series W Warrant”), an Amended and Restated Series X Warrant (the Amended Series X Warrant), an Amended and Restated Series Y Warrant (the “Amended Series Y Warrant”), and in consideration for the agreement of Montaur to enter into the Amendment Agreement, a Series AA Warrant to purchase 2,400,000 shares of our common stock at an exercise price of \$0.97 per share (the “Series AA Warrant,” and together with the Amended Series W Warrant, Amended Series X Warrant and Amended Series Y Warrant, the

“Amended Montaur Warrants”).

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The Amended Series A Note bears interest at a rate per annum equal to 10%, and Montaur may convert the full \$7,000,000 principal amount of the Amended Series A Note into shares of Common Stock in two tranches. Montaur may convert the first tranche of up to \$3,500,000 of the outstanding principal balance of the Amended Series A Note at the conversion price of \$0.26 per share, and a second tranche of the remaining \$3,500,000 of the outstanding principal balance of the Amended Series A Note at the conversion price of \$0.9722 per share. The Amended Series B Note also bears interest at a rate per annum equal to 10%, and is convertible into shares of common stock at the conversion price of \$0.36 per share. Pursuant to the provisions of the Certificate of Designations, Voting Powers, Preferences, Limitations, Restrictions, and Relative Rights of Series A 8% Cumulative Convertible Preferred Stock, Montaur may convert all or any portion of the shares of the Preferred Stock into an aggregate 6,000,000 shares of our common stock, subject to adjustment as described in the Certificate of Designations.

Pursuant to registration rights of Montaur in connection with the SPA, we have filed a registration statement covering the sale by Montaur of up to up to: (i) 3,600,000 shares issuable upon the conversion of the Amended Series A Note; (ii) 6,000,000 shares of Common Stock issuable upon exercise of the Amended Series Y Warrant; (iii) 3,500,000 shares of Common Stock issuable as interest or dividends on the Amended Montaur Notes and the Preferred Stock; and (iv) 2,400,000 shares issuable upon exercise of the Series AA Warrant, for a total of 15,500,000 shares. Additionally, we agreed that within thirty-five days of receipt from Montaur of written request therefor, we would prepare and file an additional “resale” registration statement providing for the resale of: (i) the remaining shares of Common Stock issuable upon the conversion of the Amended Series A Note; (ii) the shares of Common Stock issuable upon the exercise of the Amended Series W Warrant; (iii) the shares of Common Stock issuable upon the conversion of the Amended Series B Note; (iv) the shares of Common Stock issuable upon the exercise of the Amended Series X Warrant; and (v) the shares of Common Stock issuable upon conversion of the Preferred Stock

The selling stockholders 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 these shares. Depending upon market liquidity at the time, a sale of these shares 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, 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.

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.

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 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 difficulty attracting and retaining qualified personnel and our business may suffer if we do not.

Our business has experienced a number of successes and faced several challenges in recent 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. 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 biotechnology 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 have been pledged as collateral for the \$10 million in principal amount of our Series A and Series B Convertible Notes issued to Montaur, and a \$1 million in principal amount Series B Convertible Note issued to our CEO and members of his family dated July 3, 2007, as amended December 26, 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 by December 26, 2011;
- we use the proceeds from the sale of the Notes only for permitted purposes, such as Lymphoseek development and general corporate purposes;
- 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; and
- we indemnify the purchasers of the Notes against certain liabilities.

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

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

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

Our common stock is traded over the counter, which may deprive stockholders of the full value of their shares.

Our common stock is quoted via the OTC Bulletin Board (OTCBB). As such, our common stock may have fewer market makers, lower trading volumes and larger spreads between bid and ask prices than securities listed on an exchange such as the New York Stock Exchange or the NASDAQ Stock Market. These factors may result in higher price volatility and less market liquidity for the common stock.

A low market price may severely limit the potential market for our common stock.

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

The price of our common stock has been highly volatile due to several factors that will continue to affect the price of our stock.

Our common stock traded as low as \$0.35 per share and as high as \$1.48 per share during the 12-month period ended December 28, 2009. 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 December 28, 2009, was approximately 93,000 shares.

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 in the foreseeable future, stockholders will only benefit from owning common stock if it appreciates.

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- general economic and business conditions, both nationally and in our markets;
- our history of losses, 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 prospectus.

In addition, in this prospectus, 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 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.

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 fiscal years, and the current fiscal year through December 28, 2009, 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 2009			
First Quarter	\$ 0.80	\$ 0.42	\$ 0.54
Second Quarter	1.20	0.35	0.95
Third Quarter	1.48	0.91	1.40
Fourth Quarter through December 28, 2009	1.40	0.95	1.05
Fiscal Year 2008			
First Quarter	\$ 0.42	\$ 0.29	\$ 0.35
Second Quarter	0.87	0.34	0.68
Third Quarter	0.75	0.42	0.57
Fourth Quarter	0.68	0.45	0.57
Fiscal Year 2007:			
First Quarter	\$ 0.27	\$ 0.20	\$ 0.24
Second Quarter	0.32	0.19	0.31
Third Quarter	0.50	0.23	0.31
Fourth Quarter	0.35	0.25	0.29

As of December 15, 2009, we had approximately 767 holders of common stock of record. On December 28, 2009, the last reported sale price for our common stock as reported on the OTC Bulletin Board was \$1.05 per share.

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.

DESCRIPTION OF BUSINESS

Development of the Business

Neoprobe Corporation (Neoprobe, the company or we) is a biomedical company that develops and commercializes innovative oncology products that enhance patient care and improve patient outcome. 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. In 1998, U.S. and European regulatory agencies completed an evaluation of the status of the regulatory pathway for our RIGS products, which coupled with our limited financial resources at the time, caused us to suspend our radiopharmaceutical development activities and refocus our operating strategy on our medical device business. After achieving profitability in the fourth quarter of 1999 following this retrenchment, we expanded our medical device offerings in 2002 through the acquisition of an Israeli company that was developing a line of blood flow measurement devices.

Although we had expanded our strategic focus with the addition of medical devices outside the oncology field, we continued to look for other avenues to reinvigorate our radiopharmaceutical development portfolio. In 2004, our efforts resulted in a number of positive events that caused us to take steps to re-activate our radiopharmaceutical and therapeutic initiatives. As a result of our efforts since 2004, we now have submitted data from a Phase 3 clinical trial of one of our radiopharmaceutical products, Lymphoseek®, to the U.S. Food and Drug Administration (FDA) for review and we are enrolling patients in a second Phase 3 clinical trial intended to further support and expand our proposed product labeling for Lymphoseek. Interest in, and activity related to, our second radiopharmaceutical product, RIGScan® CR, has also increased significantly in recent years as we sought, and subsequently received, formal scientific advice in 1998 from the European Medicinal Evaluation Agency (EMA) regarding our regulatory and clinical development plans for RIGScan CR. We have taken steps during the fourth quarter of 2009 to obtain similar feedback from FDA through the submission of a pre-Phase 3 meeting request and Special Protocol Assessment (SPA) request. Our subsidiary, Cira Biosciences, Inc. (Cira Bio), is evaluating the market opportunities for yet another technology platform, activated cellular therapy (ACT). The success we have been experiencing in recent years related to our drug development activities caused us, during 2009, to re-evaluate our product initiatives and strategies. As a result of this evaluation, we made the decision during the third quarter of 2009 to discontinue the operations of our blood flow measurement device product line and to look for opportunities to divest our Cardiosonix Ltd. subsidiary. We believe this decision will allow us to better focus on our oncology-related development platforms as we approach several key milestones in the coming twelve to eighteen months.

We believe that our virtual business model is unique within our industry as we combine revenue generation from medical devices covering our public company overhead while we devote capital raised through financing efforts to the development of products such as Lymphoseek which possess even greater potential for shareholder return. In addition, we have sought to maintain a development pipeline with additional longer-term return potential such as RIGScan CR and ACT that provide the opportunity for incremental return on the achievement of key development and funding milestones.

Our Technology

Gamma Detection Devices

Through 2009, our line of gamma radiation detection devices has generated substantially all of our revenue. Our gamma detection systems are 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 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 mounted 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 pen flashlight. The neoprobe® GDS gamma detection system, originally released in 1998 under the name neo2000®, is the fourth generation of our gamma detection products. The neoprobe GDS is designed as a platform for future growth of our instrument business. The neoprobe GDS is software upgradeable and is designed to support future surgical targeting probes without the necessity of costly remanufacture. Our most recent software release that enables our entire installed base of neoprobe GDS and neo2000 users to use our wireless gamma detection probes based on Bluetooth® wireless technology that have been commercially launched over the last few years. During 2009, we introduced a new gamma detection probe capable of detecting higher energy isotopes such as Fludeoxyglucose F18 (FDG or F18) that are frequently used in connection with Positive Emission Tomography (PET) scans.

Surgeons are using our gamma detection devices in a surgical application referred to as sentinel lymph node biopsy (SLNB) or intraoperative lymphatic mapping (ILM or lymphatic mapping). SLNB helps trace the lymphatic drainage 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 have 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.

The application of SLNB to solid tumor cancer treatment has been most widely developed in the breast cancer and melanoma indications. Numerous clinical studies, involving a total of nearly 2,000 patients and published in peer-reviewed medical journals as far back 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 four years ago. While we are not aware of the exact timing of publication or presentation of

results from these trials, it is possible that such data may be available sometime in 2010. Accrual on the second trial was halted early (in 2007), 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 widely 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. We also believe we are beginning to see the development of a replacement device market in the gamma detection device sector, aided in part by new offerings such as our wireless probes, as devices purchased over ten years ago during the early years of lymphatic mapping begin to be retired.

Although lymphatic mapping has found its greatest acceptance thus far in breast cancer and melanoma, we believe that Lymphoseek may be instrumental in extending SLNB into other solid tumor cancers in which surgeons are currently investigating such as prostate, gastric, colon, head and neck, and non-small cell lung cancers. Investigations in these other cancer types have thus far met with mixed levels of success; however, we believe our development of Lymphoseek may positively impact the effectiveness of SLNB in such indications. Surgeons have also been using our devices for other gamma-guided surgery applications, such as evaluating the thyroid function and conducting parathyroid surgery, and in determining the state of disease in patients with vulvar and penile cancers. Expanding the application of SLNB beyond the current primary uses in the treatment of breast cancer and melanoma is a primary focus of our strategy regarding our gamma-guided surgery products and is consistent with our Phase 3 Lymphoseek clinical trial strategy. To support that expansion, we continue to work with our marketing and distribution partners to develop additional enhancements to the neoprobe GDS platform such as the wireless probes that were introduced over the last few years and the new F18 probe we launched at the Society of Surgical Oncology (SSO) 62nd Annual Cancer Symposium held in March of 2009. We believe the market for the intraoperative detection of higher energy isotope detection is just beginning to develop and may not significantly impact our sales for some time.

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 are used. The product we are developing with the greatest near-term potential in this area is Lymphoseek, a proprietary drug compound under exclusive worldwide license from the Regents of the University of California through their UC, San Diego affiliate ("UCSD"). 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 product specifically designed and labeled for the targeting of sentinel lymph nodes.

The initial pre-clinical evaluations of Lymphoseek were completed in 2001. Since that time, Neoprobe, in cooperation with UCSD, has completed or initiated five Phase 1 clinical trials, a multi-center Phase 2 trial and a multi-center Phase 3 involving Lymphoseek. The status of these trials is listed below:

Indication	Phase	Number of Patients	Status
Breast (peritumoral injection)	1	24	Completed
Melanoma	1	24	Completed
Breast (intra-dermal injection, next day surgery)	1	60	Ongoing
Prostate	1	20	Ongoing
Colon	1	20	Ongoing
Breast or Melanoma	2	80	Completed
Breast or Melanoma	3	130	Completed
Head and Neck Squamous Cell Carcinoma ("Sentinel")	3	180*	Ongoing

*estimated number; actual number is dependent on statistical analysis at potential early stoppage points

The Phase 1 studies were or are being supported, including being substantially funded through research grants, by a number of organizations such as the Susan G. Komen Breast Cancer Research Foundation, the American Cancer Society (ACS) and the NCI. Research data from some of these clinical evaluations of Lymphoseek have been presented at meetings of the Society of Nuclear Medicine, the Society of Surgical Oncology and the World Sentinel Node Congress. The ongoing breast, prostate and colon studies are being conducted under Neoprobe's investigational new drug (IND) application that has been cleared with FDA using drug product supplied by Neoprobe.

In November 2003, we met with the Interagency Council on Biomedical Imaging in Oncology, an organization representing FDA, the NCI and the Centers for Medicare and Medicaid Services, to discuss the regulatory approval process and to determine the objectives for the next clinical trial involving Lymphoseek. During 2004, we prepared and submitted an IND application to FDA to support the marketing clearance of Lymphoseek.

In early 2005, we announced that FDA had accepted our application to establish a corporate IND for Lymphoseek. With the transfer of the UCSD physician IND to Neoprobe, we assumed full clinical and commercial responsibility for the development of Lymphoseek. Following the establishment of the corporate IND, Neoprobe's clinical and regulatory personnel began discussions with FDA regarding the clinical development program for Lymphoseek.

As a "first in class" drug, Neoprobe was advised that additional non-clinical studies needed to be completed before additional clinical testing of the drug could occur in humans. The additional non-clinical testing was successfully completed in late 2005 and the reports were filed with FDA in December 2005. The seven studies included repeat administrations of Lymphoseek at dosages significantly in excess of the anticipated clinical dosage. None of the non-clinical studies revealed any toxicity issues associated with the drug.

Upon the submission of the IND and draft Phase 2 protocol, FDA advised Neoprobe that commercially produced Lymphoseek would need to be used in the Phase 2 clinical study, as opposed to using drug previously manufactured in laboratories at UCSD. Also, the regulatory agencies raised a number of Chemistry, Manufacturing and Control (CMC) questions regarding the drug compound and characterization. Neoprobe began the transfer of bulk drug manufacturing to Reliable Biopharmaceutical Corporation (Reliable) early in 2005 and engaged OSO BioPharmaceuticals Manufacturing LLC (OSO Bio, formerly Cardinal Health PTS) to develop and validate procedures and assays to establish commercial standards for the formulation, filling and lyophilization of the drug compound. We submitted an initial CMC response to FDA in 2006.

We received clearance from FDA in May 2006 to move forward with patient enrollment for a multi-center Phase 2 clinical study of Lymphoseek. The first of our Phase 2 clinical sites received clearance from its internal clinical review committee, or Institutional Review Board (IRB), in July 2006. The IRB clearance permitted us to finalize arrangements to begin patient screening and enrollment activities for the Phase 2 trial, and we began patient enrollment in September 2006 and completed enrollment of the 80 patients in June 2007. We announced positive preliminary efficacy results from our Phase 2 Lymphoseek trial in June 2007 and final results in December 2007. Localization of Lymphoseek to lymphoid tissue was confirmed by pathology in over 99% of the lymph node tissue samples removed during the Phase 2 trial. We held an end of Phase 2 meeting with FDA during late October 2007 during which the final results were reviewed. The Phase 2 study was conducted at five of the leading cancer centers in the U.S.: John Wayne Cancer Center; University of California, San Francisco; MD Anderson Cancer Center; University Hospital Cleveland (Case Western Reserve); and the University of Louisville.

Based on dialogue with FDA, we proposed to FDA that we conduct two separate Phase 3 studies to support an application for marketing clearance. During 2008, we initiated patient enrollment in the first of the two phase 3 clinical studies to be conducted in patients with either breast cancer or melanoma (NEO3-05). In March 2009, we announced that this first study had reached the accrual of 203 lymph nodes, the study's primary accrual objective. The NEO3-05 Phase 3 clinical trial was designed to provide, and achieved its primary endpoint of, the evaluation of the efficacy of Lymphoseek in anatomically delineating lymph nodes in both breast cancer and melanoma patients that

may be predictive of determining whether cancer has spread into the lymphatic system. Final data from the trial has now been reviewed and audited, and Neoprobe has submitted an end-of-Phase 3 meeting request to the US FDA to discuss the results of the clinical trial as part of our continuing preparation of a New Drug Application (NDA), which we plan to file later in 2010. The NEO3-05 study has also been closed on the national clinical trials website www.clinicaltrials.gov.

The NEO3-05 clinical trial results confirmed the identification of lymphatic tissue in patients with either breast cancer or melanoma as designed, and when used in conjunction with and compared to vital blue dyes, showed a marked improvement in this identification. Pathological assessment of lymphatic tissue removed during surgery provided further prognostic value in determining the disease state. The Phase 3 trial was designed to determine the accuracy of Lymphoseek to identify lymphatic tissue as compared to commonly used vital blue dyes. The primary objective of the Phase 3 was to obtain at least 203 lymph nodes identified with the vital blue dyes and to statistically demonstrate that 94% of those nodes were identified with Lymphoseek. Procedure-compliant patients in the trial contributed 215 vital blue positive nodes and Lymphoseek identified 210 of those nodes for a success rate of over 97%. In addition, Lymphoseek identified 85 lymph nodes that were missed by the vital blue dyes. Of these Lymphoseek positive nodes, over 18% were found by pathology to contain tumor.

A second Phase 3 study is also underway to validate Lymphoseek as a sentinel lymph node targeting agent. This second trial, NEO3-06 or the "Sentinel" trial, is being conducted in patients with head and neck squamous cell carcinoma. The Sentinel study is designed to validate Lymphoseek as a sentinel lymph node targeting agent. Our discussions with FDA and EMEA have also suggested that the Sentinel trial will further support the use of Lymphoseek in sentinel lymph node biopsy procedures. We believe the outcome of the trial will be beneficial to the marketing and commercial adoption of Lymphoseek in the U.S. and European Union (EU). We plan to have approximately 25 – 35 participating institutions in the Sentinel trial. Patient recruitment and enrollment is actively underway at a number of institutions and the trial protocol is currently under review at several. The accrual rate for trials of this nature is highly dependent on the timing of IRB approvals of the NEO3-06 protocol. Our experience in the NEO3-05 trial has shown that this process may be lengthening due to risk management concerns on the part of hospitals participating in clinical trials and other factors.

We plan to use the safety and efficacy results from the Phase 3 clinical evaluations of Lymphoseek, which will include sites in the EU, to support the drug registration application process in the EU as well as in the U.S. However, as noted previously, we have submitted a request for an end of Phase 3 meeting with FDA to review the results of the NEO3-05 trial and to clarify our clinical development and regulatory submission plan. Our goal is to file the new drug application with FDA for Lymphoseek later in 2010. Depending on the timing of patient accrual, and the timing and outcome of FDA regulatory review cycle including FDA feedback on the results of the NEO3-05 trial, we believe that Lymphoseek could be commercialized in mid-2011. We cannot assure you, however, that this product will achieve regulatory approval, or if approved, that it will achieve market acceptance. We expect to incur approximately \$4 million in out-of-pocket development costs in 2009 related to the clinical and regulatory development of Lymphoseek. Depending on the timing and outcome of the FDA regulatory review cycle, we believe that Lymphoseek can be commercialized by mid-2011. We cannot assure you, however, that this product will achieve regulatory approval, or if approved, that it will achieve market acceptance. See Risk Factors.

RIGS

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

RIGScan CR is an intraoperative targeting agent consisting of a radiolabeled murine monoclonal antibody (CC49 MAb). The radiolabel used is ¹²⁵I, a 27 - 35 KeV emitting isotope. The CC49 MAb was developed by the NCI and is licensed to Neoprobe by the National Institutes of Health (NIH). The CC49 MAb is produced from a murine cell line generated by the fusion of splenic lymphocytes from mice immunized with tumor-associated glycoprotein-72 (TAG-72) with non-immunoglobulin secreting P3-NS-1-Ag4 myeloma cells. The CC49 MAb localizes or binds to TAG-72 antigen and shows a strong reactivity with both LS-174T colon cancer extract and to a breast cancer extract.

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

Neoprobe conducted two Phase 3 studies, NEO2-13 and NEO2-14, of RIGScan CR in the mid-1990s in patients with primary and metastatic colorectal cancer, respectively. Both studies were multi-institutional involving cancer treatment institutions in the U.S., Israel, and the EU. The primary endpoint of both studies was to demonstrate that RIGScan CR detected pathology-confirmed disease that had not been detected by traditional preoperative (i.e., CT Scans) or intraoperative (i.e., surgeon's visual observations and palpation) means. That is, the trials were intended to show that the use of RIGScan CR assisted the surgeon in the detection of occult tumor. In 1996, Neoprobe submitted applications to EMEA and FDA for marketing approval of RIGScan CR for the detection of metastatic colorectal cancer.

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

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

Following review of our applications, we received requests for further information from FDA and from the European Committee for Proprietary Medicinal Products on behalf of EMEA. Both FDA and EMEA acknowledged that our studies met the diagnostic endpoint of the Phase 3 clinical study, which was to provide incremental information to the surgeon regarding the location of hidden tumor. However, both agencies wanted to know how the finding of additional tumor provided clinical benefit that altered patient management or outcome for patients with metastatic colorectal cancer. In a series of conversations with FDA, the product claims were narrowed to the intraoperative detection of hepatic and perihepatic disease in patients with advanced colorectal cancer and patients with recurrent colorectal cancer.

FDA determined during its review of the BLA that the clinical studies of RIGScan CR needed to demonstrate clinical utility in addition to identifying additional pathology-confirmed disease. In discussions between Neoprobe and the

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

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

In 2004, we obtained access to survival analyses of patients treated with RIGScan CR which have been prepared by third parties, indicating that RIGScan CR may be predictive of, or actually contribute to, a positive outcome when measuring survival of the patients that participated in our original BLA studies. The data or its possible significance was unknown at the time of the BLA review given the limited maturity of the follow-up experience. The data includes publication by some of the primary investigators involved in the Phase 3 RIGS trials who have independently conducted survival follow-up analyses to their own institution's RIGS trial patients with apparently favorable results relating to the long-term survival prognosis of patients who were treated with RIGS. Based primarily on this survival-related information, we requested a meeting with FDA in 2004 to discuss the possible next steps for evaluating the survival related to our previous Phase 3 clinical trials as well as the possible submission of this data, if acceptable, as a prospective analysis in response to questions originally asked by FDA in response to our original BLA.

The April 2004 meeting with FDA was an important event in the re-activation of the RIGS program. The meeting was very helpful from a number of aspects: we confirmed that the RIGS BLA remains active and open. We believe this will improve both the cost effectiveness and timeliness of future regulatory submissions for RIGScan CR. Additionally, FDA preliminarily confirmed that the BLA may be applicable to the general colorectal population; and not just the recurrent colorectal market as applied for in 1996. Applicability to a general colorectal population could result in a greater market potential for the product than if applicable to just the recurrent population. During the meeting, FDA also indicated that it would consider possible prognostic indications for RIGScan CR and that survival data from one of our earlier Phase 3 studies could be supportive of a prognostic indication.

Our statistical analyses following the 2004 meeting with FDA indicated a potential trial size which proved cost prohibitive to us and our potential development partners in evaluating continued development for RIGScan CR. However, during 2008 we developed a protocol design which we could believe could support our desired clinical endpoints but in a much smaller patient population. We made the decision to initially approach the EMEA with this trial design under their formal process for seeking scientific advice. After holding a successful pre-submission meeting with EMEA in July 2008, we received positive feedback in October 1998 to the clinical trial design which involved approximately 400 patients in a randomized trial of patients with colorectal cancer. The participants in the trial would be randomized to either a control or RIGS treatment arm. Patients randomized to the RIGS arm would have their disease status evaluated at the end of their cancer surgery to determine the presence or absence of RIGS-positive tissue. Patients in both randomized arms would be followed to determine if patients with RIGS-positive status have a lower overall survival rate and/or a higher occurrence of disease recurrence. The hypothesis for the trial is based upon the data from the earlier NEO2-13 and NEO2-14 trial results.

Our desire has been, and continues to be, to develop a clinical development plan which is harmonized between the U.S. and the EU. To that end, during December 2009 we submitted an investigational new drug (IND) amendment to the United States FDA which includes the design of a proposed Phase 3 clinical trial of RIGScan CR. The IND amendment includes a Special Protocol Assessment (SPA) in accordance with the Prescription Drug User Fee Act of 1992 (PDUFA) and current regulatory guidelines, and will be registered on the clinicaltrials.gov website following discussions with FDA regarding the SPA.

The Phase 3 clinical study as currently designed would be a randomized clinical study that would evaluate the ability of RIGScan CR to identify tumor-associated tissue in a group of patients as compared to a group of patients provided with traditional surgical care. Based on our current statistical analysis, we now believe the sample size for the proposed Phase 3 clinical study may be as few as 250 patients including both the RIGScan CR and traditional

treatment groups. In addition to assessing the ability of RIGScan CR to identify tumor-associated tissue, the survival rate of the RIGScan CR treated patients will be compared to the patients treated with conventional treatment modalities.

It should also be noted that the RIGScan CR biologic drug has not been produced for several years. We would have to perform some additional work related to ensuring the drug cell line is still viable and submit this data to EMEA and possibly FDA for their evaluation in connection with preparations to restart pivotal clinical trials. During the third quarter of 2009, we announced that we had executed a Biopharmaceutical Development and Supply Agreement with Laureate Pharma. This agreement will support the initial evaluation of the viability of the CC49 master working cell bank as well as the initial steps in re-validating the commercial production process for the biologic agent used in RIGScan CR. In addition, we will need to re-establish radiolabeling capabilities for the CC49 antibody in order to meet the regulatory needs for the RIGScan CR product. We have also begun discussions with parties capable of supporting such activities.

We continue to believe it will be necessary for us to identify a development partner or an alternative funding source in order to prepare for and fund the pivotal clinical testing that will be necessary to gain marketing clearance for RIGScan CR. In the past, we have engaged in discussions with various parties regarding such a partnership. We believe the recently clarified regulatory pathway approved by EMEA is very valuable, but we believe clarifying the regulatory pathway in the U.S. is important for us and our potential partners is assessing the full potential for RIGScan CR. However, even if we are able to make such arrangements on satisfactory terms, we believe that the time required for continued development, regulatory approval and commercialization of a RIGS product would likely be a minimum of five years before we receive any significant product-related royalties or revenues. We cannot assure you that we will be able to complete definitive agreements with a development partner or obtain financing to fund development of the RIGS technology and do not know if such arrangements could be obtained on a timely basis on terms acceptable to us, or at all. We also cannot assure you that FDA or EMEA will clear our RIGS products for marketing or that any such products will be successfully introduced or achieve market acceptance. See Risk Factors.

Activated Cellular Therapy

Through various research collaborations, we performed early-stage research during the late 1990's on another technology platform, ACT, based on work originally done in conjunction with the RIGS technology. ACT is intended to boost the patient's own immune system by removing lymph nodes identified during surgery and then, in a cell processing technique, activating and expanding "helper" T-cells found in the nodes. Within 10 to 14 days, the patient's own immune cells, activated and numbering more than 20 billion, are infused into the patient in an attempt to trigger a more effective immune response to the cancer.

In the course of our research into ACT performed with RIGS, we learned that these lymph node lymphocytes containing helper T-cells could be activated and expanded to treat patients afflicted with viral and autoimmune disease as well as oncology patients. We have seen promising efficacy of this technology demonstrated from six Phase 1 clinical trials covering the oncology, viral and autoimmune applications.

In 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 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 exclusive 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 exclusive licenses to several pending patent applications.

In 2006, Cira Bio engaged the Battelle Memorial Institute to complete a technology and manufacturing process assessment of the cellular therapy approach. Cira Bio has attempted over the past few years to raise the necessary capital to move this technology platform forward. In August 2007 we entered into a Stock and Technology Option Agreement whereby Neoprobe gained the option to purchase the remaining 10% of Cira Bio from Cira LLC for \$250,000; however, this option expired in 2008. The prospects for the ACT technology have been buoyed in during the fourth quarter of 2009 as a result of the publication of the discovery of a retrovirus linked to chronic fatigue syndrome, an autoimmune dysfunction the treatment of which showed promise the early clinical trials for ACT. Based on this disclosure, we are renewing our investigation the technology applications and prospects. We do not know if our assessment of the technology's prospects will ultimately yield positive results or if we will be successful in obtaining funding on terms acceptable to us, or at all. In the event we fail to obtain financing for Cira Bio, 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. See Risk Factors.

Market Overviews

The medical device marketplace is a fast growing market. Medical Device & Diagnostic Industry magazine reported in 2008 an annual medical device and diagnostic market of as much as \$75 billion in the U.S. and \$169 billion internationally.

Cancer Market Overview

Cancer is the second leading cause of death in the U.S. and Western Europe and has been estimated to be responsible for over 565,000 deaths annually in 2008 in the U.S. alone. The NIH has estimated the overall annual costs for cancer (the primary focus of our gamma detection and pharmaceutical products) for the U.S. for 2007 at \$219.2 billion: \$89.0 billion for direct medical costs, \$18.2 billion for indirect morbidity, and \$112.0 billion for indirect mortality. Our line of gamma detection systems is currently used primarily in the application of SLNB in breast cancer and melanoma which, according to the ACS, have been estimated to account for 13% and 4%, respectively, of new cancer cases which occurred in the U.S. in 2008.

The NIH has estimated that breast cancer will annually affect half a million women in North America, Western Europe, and other major economic markets. Breast cancer is the second leading cause of death from cancer among all women in the U.S. The incidence of breast cancer, while starting to show minor declines in the past year or so, generally increases with age, rising from about 100 cases per 100,000 women at age 40 to about 400 cases per 100,000 women at age 65. While the incidence rate for breast cancer appears to be decreasing, the overall number of new cases of breast cancer is still increasing. According to the ACS, over 182,000 new cases of invasive breast cancer are expected to be diagnosed and approximately 41,000 women are estimated to have died from the disease during 2008 in the U.S. alone. Thus, we believe that the significant aging of the population, combined with improved education and awareness of breast cancer and diagnostic methods, will continue to lead to an increased number of breast cancer surgical diagnostic procedures.

Approximately 80% of the patients diagnosed with breast cancer undergo a lymph node dissection (either ALND or SLNB) to determine if the disease has spread. While many breast cancer patients are treated in large cancer centers or university hospitals, regional and/or community hospitals continue to treat the majority of breast cancer patients. Over 10,000 hospitals are located in the markets targeted for our gamma detection SLNB products. We believe a significant portion of the potential market for gamma detection devices remains unpenetrated and that a replacement market is beginning to develop as units placed in the early years of SLNB begin to exceed over ten years of use. In addition, if the potential of Lymphoseek as a radioactive tracing agent is ultimately realized, it has the potential to address not only the current breast and melanoma markets on a procedural basis, but also to assist in the clinical evaluation and staging of solid tumor cancers and expanding SLNB to additional indications, such as gastric,

non-small cell lung and other solid tumor cancers.

We estimate the total market potential for Lymphoseek, if ultimately approved for all of these indications, could exceed \$250 million. However, we cannot assure you that Lymphoseek will be cleared to market, or if cleared to market, that it will achieve the prices or sales we have estimated.

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The ACS has also estimated that nearly 148,000 new incidences of colon and rectal cancers were expected to occur in the U.S. in 2008. Based on an assumed recurrence rate of 40%, this would translate into total potential surgical procedures of over 200,000 annually in the U.S. alone. We believe the number of procedures in other markets of the world to be approximately two times the estimated U.S. market. As a result, we believe the total potential global market for RIGScan CR could be in excess of \$2 billion annually, depending on the level of reimbursement allowed. However, we cannot assure you that RIGScan CR will be cleared to market, or if cleared to market, that it will receive the reimbursement or achieve the level of sales we have currently estimated.

Marketing and Distribution

Gamma Detection Devices

We began marketing the neo2000 gamma detection system in October 1998. Since October of 1999, our gamma detection systems have been marketed and distributed throughout most of the world through Ethicon Endo-Surgery, Inc. (EES), a Johnson & Johnson company. In Japan, however, we market our products through a pre-existing relationship with Century Medical, Inc.

The heart of our gamma detection product line, the neoprobe GDS, is a control unit that is software-upgradeable, permitting product enhancements without costly remanufacturing. Since the original launch of the GDS' predecessor platform, the neo2000 (in 1998), we have also introduced a number of enhanced radiation detection probes optimized for lymphatic mapping procedures, including three wireless probes, as well as a new probe optimized for the detection of high energy radioisotopes. We have also developed four major software upgrades for the system that have been made available for sale to customers. We intend to continue developing additional SLNB-related probes and instrument products in cooperation with EES to maintain our leadership position in the gamma detection field.

Physician training is critical to the use and adoption of SLNB products by surgeons and other medical professionals. Our company and our marketing partners have established relationships with leaders in the SLNB surgical community and have established and supported training courses internationally for lymphatic mapping. We intend to continue to work with our partners to expand the number of SLNB training courses available to surgeons.

We entered into a distribution agreement with EES effective October 1, 1999 for an initial five-year term with options to extend for two successive two-year terms. In March 2004, EES exercised its first two-year extension option, and in March 2006 EES exercised its option for the second and final two-year term extension, thus extending the term of our the agreement through the end of 2008. In December 2007, Neoprobe and EES executed an amendment to the distribution agreement which extended the agreement through the end of 2013. Under this agreement, we manufacture and sell our SLNB products almost exclusively to EES, who distributes the products globally (except for Japan). EES has no ongoing purchase or reimbursement commitments to us other than the rolling four-month binding purchase commitment for gamma detection devices and certain annual minimum sales levels in order to maintain their exclusivity in distribution in most global markets. In addition, the economic terms of the revenue sharing from the end customer sale of our gamma detection devices increased commencing in January 2009. Our agreement with EES also contains certain termination provisions and licenses to our intellectual property that take effect only in the event we fail to supply product, or for other reasons such as a change of control. See Risk Factors.

Gamma Detection Radiopharmaceuticals

During the fourth quarter of 2007, we executed an agreement with Cardinal Health, Inc.'s radiopharmaceutical distribution division (Cardinal Health) for the exclusive distribution of Lymphoseek in the United States. The agreement is for a term of five years from the date of marketing clearance of a NDA from FDA. Under the terms of our agreement with Cardinal Health, Neoprobe will receive a share of each patient dose sold. In addition, Neoprobe will receive up to \$3 million in payments upon the achievement of certain sales milestones by Cardinal Health. 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 securing collaborative partners for other global markets or radiopharmaceutical products, or that we will be able to negotiate acceptable terms for such arrangements. We believe the most preferable and likely distribution partners for Lymphoseek would be entities with established radiopharmaceutical distribution channels, although it is possible that other entities with more traditional oncology pharmaceutical portfolios may also have interest.

With respect to RIGScan CR, we believe there are development milestones that can be achieved prior to the need for significant capital investment in RIGScan CR, such as harmonizing the regulatory requirements in the US and EU for the planned Phase 3 trial. We continue to believe it will be necessary for us to identify a development partner or an alternative funding source in order to prepare for and to fund the pivotal clinical testing that will be necessary to gain marketing clearance for RIGScan CR. At the present time, while we have parties who have indicated an interest in entering into a development relationship, we do not believe these efforts will result in a definitive partnership at least until a regulatory and development pathway is obtained. We anticipate continuing discussions for RIGScan CR as we move forward with the clinical development of the product; however, we cannot assure you that we will be able to secure marketing and distribution partners for the product, or if secured, that such arrangements will result in significant sales of RIGScan CR.

Manufacturing

Medical Devices

We rely on independent contract manufacturers, some of which are single-source suppliers, for the manufacture of the principal components of our current line of gamma detection system products. See Risk Factors. We have devoted significant resources to develop production capability of our gamma detection systems at qualified contract manufacturers. Production of the neoprobe GDS control unit, the 14mm probe, the 11mm laparoscopic probe, and the wireless probes involve the manufacture of components by a combination of subcontractors, including but not limited to, eV Microelectronics, a division of Endicott Interconnect Technologies, Inc. (eV), and TriVirix International, Inc. (TriVirix). We also purchase certain accessories for our line of gamma detection systems from other qualified manufacturers.

We have purchased certain solid-state crystals and associated electronics used in the manufacture of our proprietary line of hand-held gamma detection probes from eV. We do not currently have a supply agreement with eV, however we currently purchase from them under extended blanket purchase orders. The number of potential suppliers of such solid-state crystals is limited. In the event we are unable to secure a viable alternative source of supply should we become unable to obtain crystals from eV, any prolonged interruption of this source could restrict the availability of our probe products, which would adversely affect our operating results.

In February 2004, we executed a Product Supply Agreement with TriVirix for the manufacture and/or final assembly of our gamma detection products, including probes and control units. The original term of this agreement expired in February 2007 but has been extended under the automatic renewal terms of the agreement through February 2010. The Agreement will continue to be automatically extended for successive one-year periods unless six months notice is provided by either party.

We cannot assure you that we will be able to maintain agreements or other purchasing arrangements with our subcontractors on terms acceptable to us, or that our subcontractors will be able to meet our production requirements on a timely basis, at the required levels of performance and quality. In the event that any of our subcontractors is unable or unwilling to meet our production requirements, we cannot assure you that an alternate source of supply could be established without significant interruption in product supply or without significant adverse impact to product availability or cost. Any significant supply interruption or yield problems that we or our subcontractors experience would have a material adverse effect on our ability to manufacture our products and, therefore, a material adverse effect on our business, financial condition, and results of operations until a new source of supply is qualified. See Risk Factors.

Gamma Detection Radiopharmaceuticals

In preparation for the commencement of a multi-center clinical evaluation of Lymphoseek, Neoprobe engaged drug manufacturing organizations to produce the drug that was used in the Phase 2 trial and is expected to be used in the pivotal (i.e., Phase 3) clinical trials. Reliable has produced the active chemical compound and OSO Bio has performed final product manufacturing including final drug formulation, lyophilization (i.e., freeze-drying) and packaging processes. Once packaged, the vialled drug can then be shipped to a hospital or regional commercial radiopharmacy where it can be made radioactive (i.e., radiolabeled) with Tc99m to become Lymphoseek. The commercial manufacturing processes at Reliable and OSO Bio are being validated and both organizations have assisted Neoprobe in the preparation of the chemistry, manufacturing and control sections of our submissions to FDA and EMEA. Both Reliable and OSO Bio are registered manufacturers with FDA and/or EMEA. At this point, drug product produced by Reliable and OSO Bio has been produced under clinical development agreements. Commercial supply and distribution agreements are being negotiated with both Reliable and OSO Bio. We cannot assure you that we will be successful in reaching such agreements with Reliable or OSO Bio on terms satisfactory to us or at all.

During the third quarter of 2009, we announced that we had executed a Biopharmaceutical Development and Supply Agreement with Laureate Pharma. This agreement will support the initial evaluation of the viability of the CC49 master working cell bank as well as the initial steps in re-validating the commercial production process for the biologic agent used in RIGScan CR. In addition, we will need to re-establish radiolabeling capabilities for the CC49 antibody in order to meet the regulatory needs for the RIGScan CR product. We have also begun discussions with parties capable of supporting such activities.

We cannot assure you that we will be successful in securing and/or maintaining the necessary biologic, product and/or radiolabeling capabilities. See Risk Factors.

Competition

We face competition from medical product and biotechnology companies, as well as from universities and other non-profit research organizations in the field of cancer diagnostics and treatment. Many emerging medical product companies have corporate partnership arrangements with large, established companies to support the research, development, and commercialization of products that may be competitive with our products. In addition, a number of large established companies are developing proprietary technologies or have enhanced their capabilities by entering into arrangements with or acquiring companies with technologies applicable to the detection or treatment of cancer. Many of our existing or potential competitors have substantially greater financial, research and development, regulatory, marketing, and production resources than we have. Other companies may develop and introduce products and processes competitive with or superior to those of ours. See Risk Factors.

For our products, an important factor in competition is the timing of market introduction of our products or those of our competitors' products. Accordingly, the relative speed with which we can develop products, complete the regulatory clearance processes and supply commercial quantities of the products to the market is an important competitive factor. We expect that competition among products cleared for marketing will be based on, among other things, product efficacy, safety, reliability, availability, price, and patent position.

Gamma Detection Devices

With the continued emergence of SLNB, a number of companies have begun to market gamma radiation detection instruments. Most of the competitive products have been designed from an industrial or nuclear medicine perspective rather than being developed initially for surgical use. We compete with products produced and/or marketed by Care Wise Medical Products Corporation, Intra-Medical Imaging LLC, RMD Instruments LLC (a subsidiary of Dynasil Corporation), SenoRx, Eurorad S.A and other companies.

It is often difficult to glean accurate competitive information within the lymphatic mapping field, primarily because most of our competitors are either subsidiaries or divisions of larger corporations or privately held corporations, whose sales revenue or volume data is not readily available or determinable. In addition, lymphatic mapping does not currently have a separate reimbursement code in most healthcare systems. As such, determining trends in the actual number of procedures being performed using lymphatic mapping is difficult. We believe, based on our understanding of EES' success rate in competitive bid situations, that our market share has remained relatively constant or increased slightly in light of changes in the competitive landscape over the past few years. As we have discussed, we believe that current sales levels indicate that some prospective customers may be waiting on the results of important international clinical trials prior to adoption of the SLNB procedure and purchasing a gamma detection device. We expect the results from these trials, when announced, will likely have a positive impact on sales volumes. We believe our intellectual property portfolio will be a barrier to competitive products; however, we cannot assure you that competitive products will not be developed, be successful in eroding our market share or affect the prices we receive for our gamma detection devices. See Risk Factors.

Gamma Detection Radiopharmaceuticals

We do not believe there are any directly competitive intraoperative diagnostic radiopharmaceuticals with RIGScan CR that would be used intraoperatively in the colorectal cancer application that RIGScan CR is initially targeted for. There are other radiopharmaceuticals that are used as preoperative imaging agents; however, we are unaware of any that could be used as a real-time diagnostic aid during surgery such as RIGScan CR.

Surgeons who practice the lymphatic mapping procedure for which Lymphoseek is intended currently use other radiopharmaceuticals such as a sulphur-colloid compound in the U.S. and other colloidal compounds in other markets. However, these drugs are being used "off-label" in most major global markets (i.e., they are not specifically indicated for use as a sentinel node targeting agent). As such, we believe that Lymphoseek, if ultimately approved, would be the first drug specifically labeled for use as a sentinel lymph node targeting agent.

Patents and Proprietary Rights

We regard the establishment of a strong intellectual property position in our technology as an integral part of the development process. We attempt to protect our proprietary technologies through patents and intellectual property positions in the United States as well as major foreign markets. Approximately 20 instrument patents issued in the United States as well as major foreign markets protect our gamma detection technology.

Lymphoseek is also the subject of patents and patent applications in the United States and certain major foreign markets. The patents and patent applications are held by The Regents of the University of California and have been licensed exclusively to Neoprobe for lymphatic tissue imaging and intraoperative detection worldwide. The first composition of matter patent covering Lymphoseek was issued in the United States in June 2002. The claims of the composition of matter patent covering Lymphoseek have been allowed in the EU and issued in the majority of EU countries in 2005. The composition of matter patent is being prosecuted in Japan and we have received notice of the allowance of the underlying claims.

We continue to support proprietary protection for the products related to RIGS and ACT in major global markets such as the U.S. and the EU, which although not currently integral to our near-term business plans, may be important to a potential RIGS or ACT development partner. Composition of matter patents have been issued in the U.S. and EU that cover the antibodies used in clinical studies. The most recent of these patents was issued in 2004 and additional patent applications are pending. We have a license to these patents through the NIH; however, our license is subject to ongoing diligence requirements.

The activated cellular therapy technology of Cira Bio is the subject of issued patents in the United States to which Neoprobe has exclusive license rights. European patent statutes do not permit patent coverage for treatment technologies such as Cira Bio's. The oncology applications of Cira Bio's treatment approach are covered by issued patents with expiration dates of 2018 and 2020, unless extended. The autoimmune applications are covered by an issued patent with an expiration date of 2018, unless extended. The viral applications are the subject of patent applications and other aspects of the Cira Bio technology that are in the process of being reviewed by the United States Patent and Trademark Office. Cira Bio has received favorable office action correspondence on both applications.

The patent position of biotechnology and medical device firms, including our company, generally is highly uncertain and may involve complex legal and factual questions. Potential competitors may have filed applications, or may have been issued patents, or may obtain additional patents and proprietary rights relating to products or processes in the same area of technology as that used by our company. The scope and validity of these patents and applications, the extent to which we may be required to obtain licenses thereunder or under other proprietary rights, and the cost and availability of licenses are uncertain. We cannot assure you that our patent applications will result in additional patents being issued or that any of our patents will afford protection against competitors with similar technology; nor can we assure you that any of our patents will not be designed around by others or that others will not obtain patents that we would need to license or design around.

We also rely upon unpatented trade secrets. We cannot assure you that others will not independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets, or disclose such technology, or that we can meaningfully protect our rights to our unpatented trade secrets.

We require our employees, consultants, advisers, and suppliers to execute a confidentiality agreement upon the commencement of an employment, consulting or manufacturing relationship with us. The agreement provides that all confidential information developed by or made known to the individual during the course of the relationship will be kept confidential and not disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual will be the exclusive property of our company. We cannot assure you, however, that these agreements will provide meaningful protection for our trade secrets in the event of an unauthorized use or disclosure of such information. See Risk Factors.

Government Regulation

Most aspects of our business are subject to some degree of government regulation in the countries in which we conduct our operations. As a developer, manufacturer and marketer of medical products, we are subject to extensive regulation by, among other governmental entities, FDA and the corresponding state, local and foreign regulatory bodies in jurisdictions in which our products are sold. These regulations govern the introduction of new products, the observance of certain standards with respect to the manufacture, safety, efficacy and labeling of such products, the maintenance of certain records, the tracking of such products and other matters.

Failure to comply with applicable federal, state, local or foreign laws or regulations could subject us to enforcement action, including product seizures, recalls, withdrawal of marketing clearances, and civil and criminal penalties, any one or more of which could have a material adverse effect on our business. We believe that we are in substantial compliance with such governmental regulations. However, federal, state, local and foreign laws and regulations regarding the manufacture and sale of medical devices are subject to future changes. We cannot assure you that such changes will not have a material adverse effect on our company.

For some products, and in some countries, government regulation is significant and, in general, there is a trend toward more stringent regulation. In recent years, FDA and certain foreign regulatory bodies have pursued a more rigorous enforcement program to ensure that regulated businesses like ours comply with applicable laws and regulations. We devote significant time, effort and expense addressing the extensive governmental regulatory requirements applicable to our business. To date, we have not received any notifications or warning letters from FDA or any other regulatory bodies of alleged deficiencies in our compliance with the relevant requirements, nor have we recalled or issued safety alerts on any of our products. However, we cannot assure you that a warning letter, recall or safety alert, if it occurred, would not have a material adverse effect on our company.

In the early- to mid-1990s, the review time by FDA to clear medical products for commercial release lengthened and the number of marketing clearances decreased. In response to public and congressional concern, FDA Modernization Act of 1997 (the 1997 Act) was adopted with the intent of bringing better definition to the clearance process for new

medical products. While FDA review times have improved since passage of the 1997 Act, we cannot assure you that FDA review process will not continue to delay our company's introduction of new products in the U.S. in the future. In addition, many foreign countries have adopted more stringent regulatory requirements that also have added to the delays and uncertainties associated with the release of new products, as well as the clinical and regulatory costs of supporting such releases. It is possible that delays in receipt of, or failure to receive, any necessary clearance for our new product offerings could have a material adverse effect on our business, financial condition or results of operations.

While we are unable to predict the extent to which our business may be affected by future regulatory developments, we believe that our substantial experience dealing with governmental regulatory requirements and restrictions on our operations throughout the world, and our development of new and improved products, should enable us to compete effectively within this environment.

Gamma Detection Devices

As a manufacturer of medical devices sold in various global markets, we are required by regulatory agency regulations to manufacture the devices under recognized quality standards and controls. Our medical devices are regulated in the United States by FDA in accordance with 21CFR requirements, in the EU according to the Medical Device Directive (93/42/EEC), and in Canada and Japan according to the Medical Devices Regulation. These regulatory requirements for quality systems are prescribed in the international standard ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. To ensure continued compliance in our daily processes, we have established and maintain the Neoprobe Corporate Quality Management System, which is based on the ISO 13485 standard. These requirements can also be extended to drug and biologic products regarding our future product portfolio.

Our first generation gamma detection instrument received 510(k) marketing clearance from FDA in December 1986 with modified versions receiving similar clearances in 1992 through 1997. In March 1998, FDA reclassified "nuclear uptake detectors" as Class 1 and conditionally exempt from 510(k) with full quality controls. We obtained the European CE mark, by "self-declaration," for the neo2000 device in January 1999, with full quality controls. The gamma detection products are Class IIa in the EU. We maintain a "manufacturer's license" in order to import our gamma detection products into Canada, with full quality controls. The gamma detection products are Class II in Canada.

Gamma Detection Radiopharmaceuticals (Lymphoseek and RIGScan)

Our radiolabeled targeting agents and biologic products, if developed, would require a regulatory license to market by FDA and by comparable agencies in foreign countries. The process of obtaining regulatory licenses and approvals is costly and time consuming, and we have encountered significant impediments and delays related to our previously proposed biologic products.

The process of completing pre-clinical and clinical testing, manufacturing validation and submission of a marketing application to the appropriate regulatory bodies usually takes a number of years and requires the expenditure of substantial resources, and we cannot assure you that any approval will be granted on a timely basis, if at all. Additionally, the length of time it takes for the various regulatory bodies to evaluate an application for marketing approval varies considerably, as does the amount of preclinical and clinical data required to demonstrate the safety and efficacy of a specific product. The regulatory bodies may require additional clinical studies that may take several years to perform. The length of the review period may vary widely depending upon the nature and indications of the proposed product and whether the regulatory body has any further questions or requests any additional data. Also, the regulatory bodies will likely require post-marketing reporting and surveillance programs to monitor the side effects of the products. We cannot assure you that any of our potential drug or biologic products will be approved by the regulatory bodies or approved on a timely or accelerated basis, or that any approvals received will not subsequently be revoked or modified.

In addition to regulations enforced by FDA, the manufacture, distribution, and use of radioactive targeting agents, if developed, are also subject to regulation by the Nuclear Regulatory Commission (NRC), the Department of Transportation and other federal, state, and local government authorities. We, or our manufacturer of the radiolabeled antibodies, must obtain a specific license from the NRC to manufacture and distribute radiolabeled antibodies, as well as comply with all applicable regulations. We must also comply with Department of Transportation regulations on the

labeling and packaging requirements for shipment of radiolabeled antibodies to licensed clinics, and must comply with federal, state, and local governmental laws regarding the disposal of radioactive waste. We cannot assure you that we will be able to obtain all necessary licenses and permits and be able to comply with all applicable laws. The failure to obtain such licenses and permits or to comply with applicable laws would have a materially adverse effect on our business, financial condition, and results of operations.

Research and Development

We spent approximately \$4.3 million and \$2.5 million on research and development activities in the fiscal years ended December 31, 2008, and December 31, 2007, respectively. For the nine-month period ended September 30, 2009, we spent approximately \$3.7 million on research and development activities.

Employees

As of December 29, 2009, we had 25 full-time employees. We consider our relations with our employees to generally be good.

DESCRIPTION OF PROPERTY

We currently lease approximately 11,300 square feet of office space at 425 Metro Place North, Dublin, Ohio, as our principal offices. The current lease term is from June 1, 2007 and ending on January 31, 2013, at a monthly base rent of approximately \$8,200 during 2009. We must also pay a pro-rata portion of the operating expenses and real estate taxes of the building. We believe these facilities are in good condition, but that we may need to expand our leased space related to our radiopharmaceutical activities depending on the level of activities performed internally versus by third parties.

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 Registration Statement on Form S-1, 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 5.

The Company

Neoprobe Corporation is a biomedical technology company that provides innovative surgical and diagnostic oncology products that enhance patient care and improve patient outcome. We currently market a line of medical devices, our neoprobe® GDS gamma detection systems. In addition to our medical device products, we have two radiopharmaceutical products, Lymphoseek® and RIGScan® CR, in 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).

YEARS ENDED DECEMBER 31, 2008 AND 2007

Results of Operations

Revenue for 2008 increased to \$7.6 million from \$6.8 million in the prior year. The increase was primarily due to sales of our neoprobe GDS control units (launched during 2008) and wireless probes, offset by decreases in sales of the legacy versions of our gamma detection systems (i.e., neo2000 control units and corded probes). In addition, we recognized revenue of \$172,000 related to research and development revenue from EES related to the development of a high energy probe recently introduced at a conference of the Society of Surgical Oncology.

Gross margins for 2008 increased to 63% as compared to 57% in 2007. The increase in gross margins was due to a combination of factors including research and development revenue from EES in 2008, a lower proportionate level of demonstration units placed in 2008 compared to 2007, increased unit sales and prices of gamma detection control units and increased unit sales and prices of wireless probes offset by a decrease in the percentage of ASP for wireless probes received by Neoprobe. The price increases we experienced in 2008 were due in part to the current favorable impact on our sales prices to EES of the Euro to U.S. Dollar exchange rate as well as improvement in prices in base currencies.

Results for 2008 also reflect an increase in research and development expenditures of \$1.8 million to \$4.3 million from \$2.5 million in 2007. The increase was primarily due to higher Lymphoseek development expenses related to conducting the Phase 3 clinical trials as well as increased activities related to RIGScan CR. Research and development costs were further increased by additional expenses related to investment in our gamma detection device line related to product line expansion and innovation. Consolidated selling, general and administrative expenses increased to \$3.0 million in 2008 from \$2.4 million in 2007.

Net Sales and Margins. Net sales, comprised primarily of sales of our gamma detection systems, increased \$644,000, or 10%, to \$7.4 million during 2008 from \$6.8 million in 2007. Gross margins on net sales increased to 62% of net sales for 2008 compared to 57% of net sales for 2007.

The wireless innovations we have made to both the probes and control units in our gamma detection device product line over the last two years have positively impacted our sales in 2008. Overall, the increase in net sales was the result of increased gamma detection device sales of \$491,000, increased gamma detection device extended service contract revenue of \$145,000 and increased gamma detection device service-related revenue of \$9,000. Increased unit sales of our control units and wireless probes were partially offset by decreased unit sales of corded probes. Increased unit prices of our control units and corded probes were partially offset by decreased unit prices of our wireless probes due to a decrease in the percentage of ASP received by Neoprobe offsetting an overall increase in ASP for wireless probes.

The increase in gross margins on net product sales was due to a combination of factors including a lower proportionate level of demonstration units placed in 2008 compared to 2007, increased unit sales and prices of gamma detection control units and increased unit sales and prices of wireless probes offset by a decrease in the percentage of ASP for wireless probes received by Neoprobe. The price increases we experienced in 2008 were due in part to the current favorable impact on our sales prices to EES of the Euro to U.S. Dollar exchange rate.

Research and Development Expenses. Research and development expenses increased \$1.8 million, or 71%, to \$4.3 million during 2008 from \$2.5 million in 2007. Research and development expenses in 2008 included approximately \$3.3 million in drug and therapy product development costs and \$948,000 in gamma detection device development costs. This compares to expenses of \$1.8 million and \$680,000 in these segment categories in 2007. The changes in each category were primarily due to (i) increased clinical activities related to Lymphoseek due to costs of conducting the Phase 3 clinical trials in 2008 being higher than costs of conducting the Phase 2 clinical trials in 2007, as well as increased activities related to RIGScan CR and (ii) development of our neoprobe GDS control units and various probes in 2008.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased \$585,000, or 25%, to \$3.0 million during 2008 from \$2.4 million in 2007. The net difference was due primarily to increases in investor relations expenses, professional services and personnel-related expenses.

Other Income (Expenses). Other expenses, net decreased \$1.2 million to \$2.1 million during 2008 from \$3.3 million in 2007. Interest expense, primarily related to the convertible debt agreements we completed in December 2004, July 2007, December 2007 and April 2008, decreased \$539,000 to \$1.7 million during 2008 from \$2.3 million in 2007. Of this interest expense, \$706,000 and \$1.4 million in 2008 and 2007, respectively, was non-cash in nature related to the

amortization of debt issuance costs and discounts resulting from the warrants, beneficial conversion features and derivative liabilities related to the convertible debt. Interest expense in 2007 also included an adjustment to non-cash interest which was recorded in the third quarter of 2007. During the fourth quarter of 2007, we also recorded debt extinguishment charges of \$860,000 related to modification of the terms of a convertible debt agreement with our CEO. In addition, during 2008 and 2007, we recorded \$451,000 and \$248,000, respectively, of increases in derivative liabilities resulting from the accounting treatment for the convertible note agreements we executed in December 2007 and April 2008 and the related warrants to purchase our common stock, which contained certain provisions that resulted in their being treated as derivative instruments.

Discontinued Operations. During the third quarter of 2009, we made the decision to discontinue operations of the blood flow measurement device segment of our business as the segment was no longer considered a strategic initiative to the Company. This determination was based in large part on positive events in our other development initiatives. Total revenues from discontinued operations were \$297,000 and \$351,000 in 2008 and 2007, respectively. The net loss from discontinued operations was \$534,000 and \$748,000 for the years ended December 31, 2008 and 2007, respectively.

THREE AND NINE MONTH PERIODS ENDED SEPTEMBER 30, 2009 AND 2008

Overview

This Overview 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 medical device product lines. We cannot assure you 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 believe that the future prospects for Neoprobe continue to improve as we make progress in all of our key growth areas, especially related to our Lymphoseek initiative. Despite the current global economic conditions, our gamma device line continues to provide a strong revenue base. Due in part to the increased revenue share we receive from EES starting in January 2009, we expect overall revenue for our gamma device line for 2009 to be higher than 2008. Our primary development efforts over the last few years have been focused on our oncology drug development initiatives: Lymphoseek and RIGScan CR. We continue to make progress with both initiatives; however, neither Lymphoseek nor RIGScan CR is anticipated to generate any significant revenue for us during 2009 or 2010.

In August 2009, our Board of Directors decided to discontinue operations of Cardiosonix and to attempt to divest our Cardiosonix subsidiary. This decision was based on the determination that the blood flow measurement device segment was no longer considered a strategic initiative to the Company, due in large part to positive events in our other development initiatives. Until a sale is completed, we expect to continue to generate modest revenues and incur minimal expenses related to our blood flow measurement device business.

Our operating expenses during the first nine months of 2009 were focused primarily on support of Lymphoseek product development. In addition, we continued to modestly invest in our gamma detection device line related to product line expansion and innovation. We expect our drug-related development expenses to increase significantly over the remainder of 2009 as we continue the second multi-center Phase 3 clinical evaluation of Lymphoseek and support the other drug stability and production validation activities related to supporting the potential marketing registration of Lymphoseek. We expect to continue to incur modest development expenses to support our device product lines as well as we work with our marketing partners to expand our product offerings in the gamma device arena.

Our efforts thus far in 2009 have resulted in the following milestone achievements:

- Completed a multi-center Phase 3 clinical trial of Lymphoseek (NEO3-05) in patients with breast cancer or melanoma and announced that the primary efficacy endpoint was exceeded with no drug-related safety events reported.
- Initiated patient enrollment in a second multi-center Phase 3 clinical trial of Lymphoseek (NEO3-06 or the “Sentinel” trial) in patients with head and neck squamous cell carcinoma.
- Initiated drug development activities for RIGScan CR to support a multi-center Phase 3 study.

- Began a new five-year term of our EES gamma detection device distribution agreement.
- Added a high energy (F-18) probe to our gamma detection device product portfolio.
- Completed a debt restructuring agreement allowing reclassification of a majority of the Company's derivative liabilities and resulting in the accelerated exercise of the Series Y Warrants, producing \$3.45 million in cash flow to the Company.