

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:

- 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 Seni