

With a New Name to Reflect the Strategy of Bringing Novel Technology and Products to Market, Navidea Biopharmaceuticals is Now Focused on the Precision Diagnostic Space

**Healthcare
Precision Diagnostic
(NYSE Amex: NAVB)**

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**Dr. Mark Jerome Pykett V.M.D.,
Ph.D., M.B.A.
President and CEO**

BIO:

Dr. Pykett, 47, has served as President and Chief Executive Officer since April 2011. He served as Vice President and Chief Development Officer of Neoprobe from November 2010 to April 2011. Prior to joining Neoprobe, Dr. Pykett served as Founding CEO of Talaris Advisors LLC, a strategic drug-development company serving the biotech industry, from 2009 to November 2010. Prior to Talaris, Dr. Pykett was President and Chief Operating Officer of Alseres Pharmaceuticals, Inc., President and

a Director of CyGenics, President of Cordlife, and President and Chief Executive Officer and a Director of Cytomatrix. Dr. Pykett has also served as a Director of several private and not-for-profit organizations. Dr. Pykett was an adjunct lecturer in cancer biology at Harvard University's School of Public Health and served on Northeastern University's Center for Enterprise Growth Corporate Advisory Board. Dr. Pykett graduated Phi Beta Kappa, summa cum laude from Amherst College, earned a V.M.D., Phi Zeta, summa cum laude, and a Ph.D. in molecular biology from the University of Pennsylvania and holds an M.B.A., Beta Gamma Sigma, from Northeastern University. In addition, Dr. Pykett completed post-doctoral fellowships at the University of Pennsylvania and Harvard University.

Company Profile:

Navidea Biopharmaceuticals, Inc., (NYSE Amex: NAVB) (previously Neoprobe Corporation) is a biopharmaceutical company focused on the development and commercialization of precision diagnostics and radiopharmaceutical agents. Neoprobe is actively developing three radiopharmaceutical agent platforms – Lymphoseek[®], AZD4694 and RIGScan[™] CR – to help identify the presence and status disease and enable better diagnostic accuracy, clinical decision-making and patient care. Neoprobe's strategy is to deliver superior growth and shareholder return by bringing to market novel radiopharmaceutical agents and advancing the Company's pipeline through selective acquisitions, global partnering and commercialization efforts.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOMagazine.com**

CEOCFO: Dr. Pykett, you have been with Neoprobe for about a year, and six months as CEO; what attracted you to the company?

Dr. Pykett: Neoprobe had an outstanding platform in the radiopharmaceutical space. At the time I joined, we had a device business and a radiopharmaceutical agent in development for interoperative lymphatic mapping to aid in the diagnosis of cancer that was in Phase III. We have now completed the Phase III studies. When I joined, I felt that it was just a very pivotal time for the company in which it was poised for tremendous growth that we could really capitalize on and build to have a very strong presence in the precision diagnostic space.

CEOCFO: Would you tell us about the recent changes at Neoprobe?

Dr. Pykett: We have been busy at transforming the company into radiopharmaceutical company focused on precision diagnostics and in that regard we have made quite a lot of progress over the last six to eight months. In August, we sold our device business to our commercial partner, Devicor Medical Products. This transaction provided us with \$30 million in upfront payments and potentially an additional \$20 million in royalties on sales-based milestones. That happened at about the same time that we were filing the New Drug Applications to the FDA for our radiopharmaceutical Lymphoseek, which we think is a Best in Class radiopharmaceutical for interoperative lymphatic mapping.

That filing with the FDA occurred in August and subsequently it was accepted by the FDA in October. We are now looking at a PDUFA date with the Agency of June 10th 2012. We also have made good forward process with our second program known as RIGS, which is an antibody aimed at identifying types of metastatic and occult cancer. This was a program that had made good forward progress with the FDA and the EMA over the past half year to bring the program back to the point where upon completion of some manufacturing activities, we can open a new IND and bring it back into the clinic in the second half of 2012. Lastly just this week we announced that we had in-licensed a very promising diagnostic imaging agent that could aid in the diagnosis of Alzheimer's disease from AstraZeneca. This is a technology that we believe has Best in Class capabilities in being able to detect beta amyloid plaque build-up in the brains of patients with cognitive impairment, to be able to help diagnose Alzheimer's disease and differentiate it from other forms of dementia and cognitive impairment. On top of that, we have continued to grow the organization; in February of this year we became listed on the American Stock Exchange (AMEX) and it has been a very good half year or so of turning this company and putting it in a very strong position to be successful in the diagnostic space.

CEOCFO: How do your offerings in the various segments differ from what is currently available?

Dr. Pykett: With all of our technologies, we simply aim to provide better diagnostics that can more accurately diagnose disease. In the case of Lymphoseek, what we have is first receptor targeted compound for being able to detect lymph nodes. You can pinpoint which lymph node to biopsy in order to assess whether cancer has metastasized from the primary cancer site, into the lymphatic system and then to properly stage the cancer. So

by being a receptor targeted agent it has a high degree of accuracy and is differentiated from non-receptor base, non-specific agents that are used in lymphatic mapping today.

CEOCFO: That seems like quite a breakthrough!

Dr. Pykett: It is. We believe it will truly add value to physicians as they try to be as accurate as possible in understanding whether cancer has spread into the lymphatic system to diagnose their patient properly. We think that beyond the technical attributes, it has a series of very tangible, practical benefits in the clinic because of its underlying mechanism of action. One of those benefits is it can be injected anywhere from fifteen minutes to twenty-four hours before the proce-

We have been repositioning the company for a number months to really take on a pure focus on radiopharmaceuticals. Part of that repositioning was facilitated by the sale of our Gamma Detection device business in August. With the sale of the Gamma Detection devices, which are known as the Neoprobe GDS Systems, we had to sell our name as part of that transaction. However, more importantly, we wanted to take on a new name to convey the strategy and new focus of navigating ideas, bringing novel technology and innovation through to useful products that can help physicians and patients. Therefore, we have chosen a Navidea Biopharmaceuticals to represent navigating ideas.

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cedure, and binds to and stays within the first predictive lymph node. It does not move into downstream lymph nodes which are less informative, and that is a key differentiator from some competitive agents as well. This allows for a great degree of scheduling flexibility and efficiency in the clinic, so doctors will be able to reach higher levels of productivity in their clinic when using Lymphoseek® compared to the competition.

CEOCFO: Has the medical profession been looking for something better in that area or is it just something they will be glad to have when they know it is there?

Dr. Pykett: We believe the medical field has been looking for an advance in this area. In today's day and age,

targeted agents provide so much more value and so much more information than non-targeted agents where it is kind of hit or miss and a little bit of an art form. Here what we are doing is providing an agent that is purpose-built and engineered to do what it is intended to do, which is identify the most informative lymph nodes to assay and to biopsy. So in that regard the physicians have in generality, but also in the case of lymphatic mapping, recognized that the more accurate you can be in diagnosing any number of disorders, and in this case cancer, the better off patients will be and the better therapeutic choices physicians will be able to make.

CEOCFO: Would you tell us about some of Neoprobe's technologies and products?

Dr. Pykett: Our second technology is called RIGS (Radio Immuno Guided Surgery). This is a humanized monoclonal antibody that is specific for a tumor antigen, meaning a protein found on tumor cells across a wide range of cancers, mostly solid tumor cancers, such as colorectal cancer, ovarian cancer, breast cancer, lung cancer and prostate cancer. This agent is also radio-labelled, so it is also

a radiopharmaceutical, where we can identify areas of metastatic disease during surgery that may have been missed by the surgeon and provide an opportunity for removal of residual disease that might have been left behind in the patient. We can also use the antibody to potentially be able to image patients so that prior to surgery physicians get an idea of how disseminated the disease is and where the metastatic areas are located, so they can perform their surgery more effectively as well. Therefore, this would be a true breakthrough in surgical oncology by being able to give surgeons the opportunity to pinpoint disease that would have been missed by conventional measures and take it out so that the patient has better

prospects and better survival outcome.

CEOCFO: Where is RIGS in the process?

Dr. Pykett: This agent that has actually been in Phase III previously, but it was a different form of the antibody. By virtue of our dialogue with the FDA and the European regulatory authority, we are completing manufacturing and our plan is to take it back into the clinic in 2012. We do not yet fully know the scope of the studies that we will have to do, because we have to go back to the regulatory authorities and map out the full clinical trial plan, but we believe we will be back in the clinic with this new clinical effort in 2012.

CEOCFO: Do you have some other products as well?

Dr. Pykett: Yes, there is a very exciting technology that we licensed from Astra-Zeneca, called AZD4694, which is an imaging agent that binds to beta amyloid in the brain, the biomarker that is associated with Alzheimer's disease. This is an agent labeled with an isotope called Fluorine 18 (F18) and it is used with PET imaging to effectively provide a window into the brain that will allow physicians to assess the amount of beta amyloid deposits that may be found in a patient who may be suspected of having Alzheimer's disease. Consistent with our overall business model, this is a way to provide precise information to physicians so that they can have better insight into a patient's symptoms and the underlying disease they could have. In this case, this is an agent that is Phase III ready. It has been in about 75 patients to date, with very strong results in Phase I and II. We are very excited by its potential to be a Best in Class agent that would provide enhanced diagnostic information to physicians so that they would go through their diagnostic process for patients suspected of having Alzheimer's disease.

CEOCFO: Are you looking to add

more to the mix; Neoprobe seems to be working on a number of fronts right now?

Dr. Pykett: We are very pleased with the pipeline that we have and with the lineup of technology that we have. Plus, we believe that this area of radiopharmaceuticals and precision diagnostics is an area of high growth. However, there are a number of very exciting technologies out there that we think could potentially add value. Our value primarily is in development and registration of these agents, because we work with the commercial community partners who are very good at marketing, sales and distribution of these products to bring them to the market. Therefore, from a development standpoint, we are seeing

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quite a number of potential programs that we are excited about and we may want to engage in a very paced and deliberate process to bring on the best assets that we can, on the best terms and at the right time.

CEOCFO: Would you tell us about the name change from Neoprobe to Navidea?

Dr. Pykett: We have been repositioning the company for a number months to really take on a pure focus on radiopharmaceuticals. Part of that repositioning was facilitated by the sale of our Gamma Detection device business in August. With the sale of the Gamma Detection devices, which are known as the Neoprobe GDS Systems, we had to sell our name as part of that transaction. However, more importantly, we wanted to take on a

new name to convey the strategy and new focus of navigating ideas, bringing novel technology and innovation through to useful products that can help physicians and patients. Therefore, we have chosen a Navidea Biopharmaceuticals to represent navigating ideas.

CEOCFO: What is the financial position for Neoprobe today?

Dr. Pykett: We have a very strong balance sheet, part of which comes from the sale of our Gamma Detection Device business over the summer. We have a very promising outlook for revenues beginning in mid-2012, upon the approval of our Lymphoseek product and we are partnered with Cardinal Health in the U.S.

in a very favorable arrangement to be able to bring Lymphoseek to the U.S. market. We are currently exploring opportunities around the world as well, and are in discussions now with partners to bring Lymphoseek to markets outside the United States. So we think that, coupled with some ongoing sales royalties from milestones in our device business, will provide us with a very strong cash position to be able to do the development that we are seeking to do and continue to build the

company.

CEOCFO: Neoprobe participates in many investor presentations; is the market paying attention to Neoprobe and do you feel they are understanding the story?

Dr. Pykett: The market is paying much more attention. We have seen a lot more visibility among analysts, institutions and retail investors. It is a protracted process that one needs to engage in to get the story out there and to take advantage of multiple opportunities including ones such as this. Slowly but surely, people are hearing the Neoprobe story. It is still relatively untold, and there is a lot more below the surface that investors are just now beginning to grasp, including the implications of our growth strategy. As that plays out, more peo-

ple are paying more attention and as we continue to execute at a very high level, people are getting confident that we can fulfill our business model and the Neoprobe value proposition.

CEOCFO: In closing, why should potential investors pay attention to Neoprobe today, and what is the most important thing that people overlook that should be understood?

Dr. Pykett: This is a company that has the expertise to be successful in the area where it has chosen to be strong, the radiopharmaceutical

space, focusing on precision diagnostics. There are not very many companies out there capable of developing these types of precision diagnostics, which are very strong technologies and very good product opportunities. We have a very strong agent in our Lymphoseek lymphatic mapping compound that we expect to bring to market in the United States in 2012. We have a very good second agent in line in our pipeline in RIGS to be able to identify metastatic cancer; and lastly we have a Best in Class Alzheimer's disease imaging candidate in

AZD4694 that we think will really add value in assisting to diagnose potential patients with Alzheimer's disease. What people are missing is perhaps just that they have not in the past paid a lot of attention to Neoprobe, and viewed it as sort of a device-drug hybrid company, perhaps with not a lot in its portfolio or a lot in its pipeline. We are working hard to change that. We think this will continue to create excitement in 2012 and change the outlook of the company and I think investors are starting to take note.



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