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Nile Therapeutics' Targeted Strategy Of Participating In Pre-Clinical And Clinical Development, And Not In Discovery Or Commercialization, Is Allowing It To Focus On Creating Shareholder Value In The Cardiovascular Therapeutics Market

Nile Therapeutics

Healthcare
Biotechnology
(SPDU-OTC: BB

Nile Therapeutics, Inc.

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Peter M. Strumph
Chief Executive Officer

BIO:
Mr. Strumph serves as the CEO and as a director of Nile. Prior to joining Nile, from 1997 to 2007 Mr. Strumph worked for CV Therapeutics, Inc., or CVT, which discovers, develops, commercializes and sells cardiovascular therapeutic products. His latest postion at CVT was Senior Vice President of Operations. At CVT, at various times, Mr. Strumph had responsibility for several functions including, pharmaceutical development and manufacturing, marketing, quality assurance/control, clinical trial operations, project management and alliance management. Additionally, Mr. Strumph was a member of the CEO Executive Staff, was the Project Team Leader for RanexaTM and served as the Chair of the Product Development Committee. Prior to joining CVT in 1997, Mr. Strumph served as Manager, Operations Planning and Development at Biogen, Inc. where he played an active role in Biogen's transition from a research based company to a fully integrated profitable biotechnology company. Mr. Strumph received his M.B.A. in Finance and Healthcare Management from The Wharton School at the University of Pennsylvania and his B.S. in Systems Science and Engineering from The University of Pennsylvania. He also served as a Lieutenant in the United States Navy.

Daron Evans
Chief Financial Officer

BIO:
Mr. Evans serves as CFO of Nile. Mr. Evans has over 10 years of professional experience in drug development financial analysis and fiscal control. Prior to joining Nile, from 2006 to 2007, Mr. Evans served as Director of Business Assessment at Vistakon, a Johnson & Johnson company, where he led efforts to improve R&D efficiency and speed to market. Prior to that, from 2004 to 2006, he was a Director of Portfolio & Business Analytics for Scios R&D, a Johnson & Johnson company, where he was responsible for financial controls and reporting for portfolio of six clinical stage programs and five preclinical stage programs. While at Scios, Mr. Evans also served as Project Manager for the European Registration Trial of nesiritide. Mr. Evans also has experience as co-founder of a biotechnology diagnostic company, and has worked as a Management Consultant in the pharmaceutical industry with Booz Allen Hamilton. Mr. Evans received his M.B.A. from The Fuqua School of Business at Duke University, his M.S. in Biomedical Engineering from Southwestern Medical School & University of Texas at Arlington and his B.S. in Chemical Engineering from Rice University.

Company Profile:
Nile Therapeutics, Inc. is a clinical-stage biopharmaceutical company that is developing innovative products for the treatment of cardiovascular disease. Nile is initially focusing its efforts on developing its lead compound, CD-NP, a novel chimeric peptide in Phase I studies for the treatment of heart failure and 2NTX-99, a small molecule, pre-clinical, anti-atherothrombotic agent with nitric oxide (NO) donating properties.

CD-NP, a novel chimeric natriuretic peptide currently in Phase I clinical studies for the treatment of heart failure, is a selective NPRB agonist which, in vivo, has been shown to have potent renal enhancement and cardiac unloading properties but with minimal hypotensive effects compared with competitive products. CD-NP is a rationally-designed synthetic peptide designed to incorporate favorable properties of naturally occurring natriuretic peptides. Data from Nile's recently completed Phase Ia study in healthy volunteers confirmed several pre-clinical findings, including that CD-NP activated

its target receptor in humans, preserved renal function and caused increases in natriuresis and diuresis at doses associated with a minimal effect on mean arterial pressure. Nile believes that CD-NP could provide a valuable new treatment option for heart failure patients.

2NTX-99 is a novel small molecule that has been shown in vivo and in vitro to inhibit the synthesis and action of thromboxane (TXA2), enhance the production of endothelial prostacyclin (PGI2) and supply a pharmacological amount of nitric oxide (NO) to the vasculature. Nile believes that the unique activity profile of 2NTX-99 has potential utility in a range of atherosclerotic, thrombotic and microvascular diseases.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Mr. Evans and Mr. Strumph, what attracted each of you to Nile Therapeutics?
Mr. Evans: "I joined in January of this year (2007). What attracted me was really the lead molecule. I came from Scios (Johnson & Johnson), who have a natriuretic peptide being marketed for acute heart failure, and it had benefits and drawbacks. The preclinical data for Nile Therapeutics' CD-NP molecule suggested that it could solve a lot of the negatives while maintaining most of the positives. The data suggested that it would be a great thing for patients and I wanted to be part of it."

Mr. Strumph: "I feel the same way as Daron, I like the technology of Nile Therapeutics' lead compound, and in addition, I like the model of the company where we participate in development but not in discovery and not in commercialization. I like this very focused strategy and feel it will lead to very efficient creation of shareholder value."

CEOCFO: How does this work?
Mr. Evans: "Nile Therapeutics' lead molecule is a peptide whose properties suggest that it would help heart failure patients in the acute setting. The hypothesis is that CD-NP would help them remove fluid and salt from the system, and help them reduce the filling pressure of the heart to relieve congestion. When these patients present to the hospital, they are not feeling well. They are having trouble breathing and they are retaining a lot of fluid. Their bodies are having trouble finding the balance. We hope this drug will relieve the symptoms and help them find the balance."

CEOCFO: Where are you in the process of development?
Mr. Evans: "The CD-NP molecule has completed a Phase I study in healthy volunteers. We are beginning trials in Phase Ib in patients to better characterize the molecule. With our second compound, 2NTX-99, an anti-thrombolytic, we are in the very early stages and performing preclinical toxicology and manufacturing."

CEOCFO: You have recently become a public company; why is this the time and how are you set for financing?

"We have generated clinical safety and clinical biomarker data for our lead product CD-NP. These data are supportive of the hypothesis, which differentiates CD-NP from other approved and development compounds for Heart Failure." - Peter M. Strumph

Mr. Strumph: "We are exactly where we should be. We arrived here rather quickly from a company age standpoint, but we have enough development milestones that we have recently achieved and that we will achieve over the next eighteen months to build value as a public company. In addition, when we were looking at different capital structures, the way in which we went public by merging with a public shell, was very attractive relative to the other financing options. Compared to the option of a more traditional cap structure where we do an A, B and C round of financing with venture capital companies and then go public, this alternative provided us access to capital at a lower cost. The financing went well for us, we raised $20 million from investors who were happy to be investing in a publicly traded company. Being public also provides us with access to a greater variety of investors for our future capital requirements."

CEOCFO: Is there much available to treat heart attack patients and will this be a better way or more of a new way to do the treatments?
Mr. Evans: "One of the problems with heart failure is that no drugs really cure it. They target symptoms. There are a couple different classes of drugs available to these patients that really just give them a tune-up. They do not actually do any repair or remodeling. One of the systemic problems with all of these drugs is with their benefits they have some side effects and some of the side effects are not great. Inotropes are one such class. They help the heart beat harder to get more blood flow and oxygen to the system. It has been proven that, while it may help them feel better and help their heart work better, at the end of the day, it actually reduced lifespan. It is a very serious disease; I am not sure people realize that it is equivalent to cancer from a mortality point of view. All the drugs to date may have benefits that temporarily push off the inevitable, but they also have side-effects that are not as pleasant as they could be. Therefore, we think we are addressing a market with a tremendous unmet need. We don't expect CD-NP to be a magic treatment, but we do hope that it will address the symptoms, reduce the side effects, and improve mortality."

CEOCFO: Are you looking to add new drugs and continue to create more in the pipeline?
Mr. Strumph: "We have the one lead molecule, CD-NP that we have been talking about. This summer we licensed another molecule 2ntx99. We would like to have three or four molecules in development."

CEOCFO: Do you have plans down the line as you get closer, will you be partnering or is it too early to make plans?
Mr. Strumph: "Our strategy is to partner the compounds as they get closer to the later stages of development and commercialization."

CEOCFO: Why should potential investors be interested in Nile?

Mr. Strumph: "An investor should look at the current value of our development pipeline but also look at the value creating milestones expected. We have generated clinical safety and clinical biomarker data for our lead product CD-NP. These data are supportive of the hypothesis, which differentiates CD-NP from other approved and development compounds for Heart Failure. Future value creating milestones include starting and completing Phase 1b studies in Heart Failure patients, staring Phase 2 in Heart failure patients and submitting an IND for our second compound, 2NTX-99."

CEOCFO: Will you tell us about the strength of the management team, and why does that stand out at Nile?

Mr. Strumph: "Our team is our management team; we have a very flat and leveraged model. We work with consultants and other outside resources to accomplish our work. If you look at the management team that we have, Daron, our vice president of development, Jenny Hodge, and, by way of extension, our scientific advisory board, which includes Dr. John Burnett *(Mayo Clinic),* as well as other luminaries in the heart failure space, it is clear that we have a management team who have worked for many years in drug development and more specifically, many years in cardiovascular drug development, space."

CEOCFO: What should people reading this interview take away about Nile?

Mr. Strumph: "We have a product in clinical development on which we are making progress. Listen to what we tell you. We will deliver, and over the course of the next several years, you will see us make great progress in the development of our lead compound CD-NP, as well as our pipeline which at present includes 2NTX-99."

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