THE WALL STREET TRANSCRIPT
Connecting Market Leaders with Investors

NeuroVive Pharmaceutical AB (OTCMKTS:NEVPF, Nasdaq Stockholm:NVP.ST)

ERIK KINNMAN, MBA, M.D., PH.D., is Chief Executive Officer of NeuroVive Pharmaceutical AB. Dr. Kinnman is a seasoned life science executive with broad experience in and understanding of the industry. He has held a number of senior leadership positions in biopharmaceutical companies such as AstraZeneca and Sobi. His expertise and experience includes clinical development, business strategy, business development and investor relations. Dr. Kinnman also has experience in the financial sector. Dr. Kinnman holds an Executive MBA from the Stockholm School of Economics and has comprehensive scientific qualifications from the Karolinska Institutet, where he earned his Ph.D. and taught as an associate professor. Dr. Kinnman is board-certified in neurology and pain management. He has been at NeuroVive since 2016.

SECTOR — PHARMACEUTICALS

TWST: Briefly, what is NeuroVive Pharmaceutical?

Dr. Kinnman: NeuroVive Pharmaceutical is a Swedish pharmaceutical research and development company that is focused primarily on mitochondrial medicine. This is our scientific base and also the origin of the company. We work very closely with Lund University in Sweden and have an R&D portfolio that contains two clinical and several research projects. These are in fields such as traumatic brain injury, genetic mitochondrial disorders as well as NASH and liver cancer.

TWST: Tell us about the core mitochondrial medicine technology.

Dr. Kinnman: I assume you know that mitochondria are the powerhouse of cells and that basically all cells in the body have mitochondria, with the only exception being red blood cells. They make up 10% of the body weight, a significant percentage. We work on taking new drug concepts that enhance and protect the mitochondrial function.

The core technology is cyclophilin-inhibiting compounds. We have a number of molecules in this field that we are developing. The cyclophilin inhibitor that we develop for traumatic brain injury is actually a new formulation of cyclosporine, NeuroSTAT, that we have orphan drug designation for as well, which has shown powerful neuroprotectant properties in a high-profile translatable experimental model. We are doing further clinical development for NeuroSTAT in traumatic brain injury.

Then, we have other cyclophilin inhibitors, such as NV556, which is a drug we are developing for nonalcoholic steatohepatitis, or NASH. We are further working on other molecules in this field and other chemical entities that are actually affecting various parts of the mitochondria and, by doing that, safeguarding or enhancing the energy producing function of mitochondria. I can tell you more about that as we talk about the projects, but basically, our focus is around the function of mitochondria. We have patented chemistry around the mechanisms involved and are developing new compounds as well. The basis is the science around mitochondrial medicine and diseases in which the mitochondria are involved.

TWST: Do you own the IP, or do you license it from Lund University?

Dr. Kinnman: We own the IP. In Sweden, researchers own their own inventions. The people at Lund University that we collaborate with are actually part-time employees of the company. The ownership of the inventions are ours. The same goes for the chemical molecules that we have developed. Those are actually not developed by us, but we have a very close partnership with a British company called Isomerase. We work closely with the management there, and we own 10% of their company. The actual molecules that are in our various drug projects are proprietary.

TWST: The NeuroSTAT, which you mentioned, is in Phase II for traumatic brain injury. Just so we are clear, is this a new way of addressing this injury in the brain, or is it similar to anything else that is being used?

Dr. Kinnman: There's nothing on the market that actually protects the brain after an acute traumatic brain injury. The current standard of care is to remove pressure to the brain due to swelling or bleeding, regulate blood pressure and reduce inflammation. Other than that, there is no specific treatment, and there is hardly any competition in this area in terms of finding something that will protect against the secondary loss of neurons after the acute injury.

Our concept is to administer NeuroSTAT over the course of five consecutive days after the acute injury in patients with moderate to severe

traumatic brain injury. The active ingredient of NeuroSTAT, cyclosporine, has shown powerful protective effects on brain damage in preclinical work, and in our own studies and the recent study done in collaboration with the University of Pennsylvania and the Children's Hospital of Philadelphia, we have shown that in an experimental model, it actually protects on a group level 35% more than otherwise seen. In our first clinical study that was recently successfully completed, we have shown cyclosporine to be safe and that it can reach the brain in a dose-dependent manner in human patients suffering from traumatic brain injury.

TWST: Given where it stands in development, give us a sense of what is being revealed on a scientific level and how it connects with the mitochondrial technology.

Dr. Kinnman: We took cyclosporine, which is an existing compound, and changed it into a new formulation. Cyclosporine is a so-called cyclophilin inhibitor, and more specifically, we want to target the cyclophilin enzyme in the mitochondria, cyclophilin D. By inhibiting cyclophilin D, cyclosporine blocks the so-called membrane permeability transition pore of the mitochondria. By doing that, it stabilizes the mitochondria of the healthy neurons not destroyed in the acute situation and helps these neurons at risk to survive throughout the injury cascade that starts after the acute injury. By doing that, the goal is to limit the actual secondary damage and the future disability of the patients.

TWST: Given it all goes well, when might be the earliest that it could be commercialized?

Dr. Kinnman: We anticipate 2025.

TWST: What would be the U.S. patient population?

Dr. Kinnman: If you look at the moderate to severe TBI, it is fewer than 200,000 patients a year. If you look at TBI overall, it is something close to 1.5 million patients per year. We are actually targeting the more severe cases, and because of that, we also have an orphan drug designation for our project, which is helpful in the continued clinical development process.

TWST: What does it mean that you have assets in development for NASH and liver cancer for out-licensing?

Dr. Kinnman: Yes, that is a good question. We have a two-part company strategy. One is to take the rare diseases or orphan diseases all the way to the market with the vision to actually build a sales and distribution organization, especially for the genetic mitochondrial medicines, while at the same time being very much involved in mitochondrial medicine, which also involves metabolic diseases, such as NASH, diabetes, and neurological diseases, such as Parkinson's disease and Alzheimer's disease. These are very big diseases that some of the largest pharma companies are collaborating on, rather than trying to develop drugs themselves, because these involve big trials with big investments.

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TWST: It sounds like it is similar to stroke therapy, which is time-sensitive in terms of administration. Is it very important to get this medicine into somebody quickly after what is viewed as the injury onset?

Dr. Kinnman: Yes, there is that challenge. We don't know yet how long that time window is, but we believe that it is considerably longer than in stroke. On the other hand, we don't have the same challenge as stroke patients, where typically patients actually get their stroke in the middle of the night and while in bed, and people are found in their bed later in the morning after some time has already passed.

We are targeting moderate to severe TBI, which is what would typically occur after a traffic accident or a bicycle-car accident. These patients who have a moderate to severe damage will be unconscious. There are usually ambulances, trauma care and then intensive care involved, and that means that the time to getting into the appropriate care is very short. The possible time window will not, we anticipate, be a problem for our compound, which is supported by preclinical studies.

TWST: This could also be used in wartime situations I would imagine?

Dr. Kinnman: Absolutely. There is a very considerable interest from the Department of Defense in this area. We have had various types of meetings together with the Department of Defense, and interestingly, it is not only an interest of the Department of Defense in the U.S. but also in China. We have an agreement with a Chinese company for this project.

Rather than putting such opportunities aside, our approach is to develop them to the preclinical stage, which carries considerably lower investment involved for validation. There is a clear interest now that big companies are reducing their early-stage activity. Research organizations are looking to smaller companies and academia for innovation. We believe that a project like ours in NASH, which is unique in its mechanism of action, is something that is very attractive to bigger players.

TWST: When you say it has a unique mechanism of action, what does that mean, because I do know that there are many other companies that are trying to address this patient population?

Dr. Kinnman: Yes, there are a huge number of projects going on, and some of them are in fairly late-stage clinical development. Nobody knows what will actually work. Most likely, there will be more than one therapy. This is, as I am sure you know, a disease that develops over a long period of time, and initially, it is silent.

As you move from it being a metabolic disease with fat accumulation, it goes into inflammation, fibrosis development, cirrhosis and then hepatocellular cancer, with different mechanisms of action coming into play. The most mature project that we have, NV556, addresses the fibrosis development by actually inhibiting the fibrosis collagen development, and as the mechanism of action acts through cyclophilin inhibition, it is actually unique. There is no other such project — that we are aware of at least — although there are numerous other NASH projects. In that sense, it is unique.

TWST: I know it's early, but is your thought that this mechanism of action would allow it to arrest the disease at that stage?

Dr. Kinnman: Yes, we believe that it will block further fibrosis development, and because the liver has a regenerative ability, it will enable a very high regenerative ability as well. We think the liver has the possibility to actually self-heal and for the stress to the liver cells to reduce and the fibrosis development to be blocked.

TWST: Now, I know a new project was added to your portfolio within the last year called NVP025. Did you want to comment on that?

Dr. Kinnman: Absolutely. It is a perfect fit with what we are doing otherwise in the genetic mitochondrial disease area. The most advanced project is KL1333 in genetic mitochondrial diseases. This will be a general treatment for these types of diseases and a disease modifier. Then, we have NVP015, which is developed to treat acute energy crises in these patients. The nice thing here is that NVP025, based on cyclophilin inhibition, is our third project in the same field. The model compound is now tested in an experimental model with genetically modified cells that mimic the patient's situation, and if that one turns out positive, then we will select amongst our molecules a lead candidate.

TWST: Outside of out-licensing partners, which I am assuming you are actively seeking, are there other partnerships or agreements you would want to enact? And if so, what might they be and for what purpose?

Dr. Kinnman: Well, we just recently in-licensed a compound from a South Korean biotech company now merged with a Korean pharma company — Yungjin Pharm — KL1333. We have the global rights with the exception of South Korea and Japan to develop and commercialize that project. A very important collaboration for our chemistry development is with the British company Isomerase, as I told you. It is a long-standing partnership.

We also have a new collaboration with the Children's Hospital of Philadelphia where we are actually testing some of our compounds in an experimental model for genetic mitochondrial disease. At the same site, we have also been doing high-profile experimental work in the traumatic brain injury area in a model also at University of Pennsylvania and the Children's Hospital of Philadelphia. Two of our employees have actually been based in Philadelphia for the last couple of years to be involved in this work.

TWST: What was it that enticed you to in-license that exactly?

Dr. Kinnman: It was a beautiful opportunity to actually complement our portfolio and a very good fit to focus on mitochondrial medicine. It is also a good fit with our business model of taking rare disease projects all the way to the market. The company that licensed this to us has experts in the field and also has experience in running clinical trials and in a very innovative manner, and is a good potential partner in taking the asset further into development.

TWST: I was reading that you had moved research resources from Taiwan. Can you give us some understanding of what that was about?

Dr. Kinnman: Yes. Well, we had, prior to me joining the company, the ambition to very rapidly expand our business in the Asian markets. There was the possibility to do some continued development of our project in Taiwan, more specifically around treatment of stroke and virus infections using cyclophilin inhibition. When we re-evaluated our strategy, we decided that we needed to focus the projects in our current portfolio and also focus in terms of our resources. As a consequence of that, we moved the existing resources in Taiwan back to Sweden and sold off the remaining assets to the Taiwanese owners.

TWST: What are your strategic objectives for the next 12 months?

Dr. Kinnman: The most important milestones ahead of us are further readouts of our first traumatic brain injury study, which will be presented in the fourth quarter of this year, and then the continued progress of that development project. We are now looking to get an IND in the U.S. and the equivalent, the CTA, in Europe, and then start our Phase II efficacy study in the second half of next year. For KL1333, it is completing the first in-human study, now ongoing in Korea, and reporting interim results until we have the finished study at the beginning of next year. The goal is then to start the next clinical study in the second half of next year.

Obviously, since this is a development in the orphan space, we are also seeking orphan drug designation applications, and that would be significant as well. A very important milestone would be if we succeed in the out-licensing efforts of the NASH program — NV556 — and of course the continued progress in the rest of the preclinical and discovery program and delivering new lead candidates for the mitochondrial disease programs. We have a second NASH program, a liver cancer program and the new program for mitochondrial myopathy.

TWST: Do you have the financing you need for the next set of milestones?

Dr. Kinnman: We have the financing until the first quarter of next year. Obviously, we are not making any profits yet. Until we complete an out-licensing deal, we will not have any revenues. Thus, we currently have the task from the board to evaluate different financing alternatives, including capital markets, of course, but we are also applying for major grants to help us support, for instance, a traumatic brain injury trial with nondilutive money.

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TWST: What is the long-term vision for the company? I am assuming it has something to do with being the dominant player in mitochondrial medicine.

Dr. Kinnman: Yes, we are definitely in the forefront from a scientific point of view, but the ambition is obviously to translate the opportunity that we have and innovate medicines that will be provided to patients who need them in areas such as traumatic brain injury and genetic mitochondrial disorders.

TWST: Are you intending to make significant management or operational changes in the next, say, 24 months, and if so, what are they, and why would they be happening?

Dr. Kinnman: Yes. We are a very small organization. We just recently hired a Communications Director and a Vice President for Business Development, so we are not looking to hire people. However, we do need consultants, which is the way for a small company like ours to stay very flexible and agile in the way we have been. It allows us to be very opportunistic in terms of what we prioritize and focus on, and we intend to remain that way. So there are no immediate plans for adding people to management or operations, but rather, we will continue to actually hire people on a consulting basis as they are needed.

TWST: What do you want a potential investor to know today about NeuroVive Pharmaceutical?

Dr. Kinnman: An investor should look at the multitude of milestones coming up in our important and exciting clinical programs: NeuroSTAT for traumatic brain injury program and KL1333 for mitochondrial disease. They should also pay attention to the possibility of us out-licensing the best-in-class cyclophilin inhibitor NV556 for NASH.

TWST: Is there anything else you wanted to mention that we haven't covered?

Dr. Kinnman: Regarding our competition, these would be companies that are also focused on mitochondrial medicine and mitochondrial diseases. An example of that is Reata in the U.S. It has a completely different valuation compared to ours. There are companies in Europe as well, such as Khondrion and Santhera. Santhera is the only company that actually has a drug for one of the syndromes within the group of genetic mitochondrial diseases called LHON, or Leber's hereditary optic neuropathy, and it is approved in Europe just recently and not approved in the U.S. That could be of interest for those who are interested in our company to look at as comparison from a valuation perspective.

TWST: Is your science relatively different, or are you just pursuing different indications from some of the companies that you mentioned?

Dr. Kinnman: The science is definitely different from these companies, but the indications are similar. From that perspective, they are competitors. Because the chemistry around the function of the mitochondria is very complex, there are a multitude of pathways and targets that you can actually affect. Obviously, we are strong believers of the way we are approaching this, but there are obviously other ways as well, and those are being pursued by other companies.

TWST: Thank you. (KJL)

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