CEO CFO

CYNAPSUS

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A Global Opportunity with a Large Untapped Parkinson's Market

Healthcare
Pharmaceutical
(CTH-TSXV)

Cynapsus Therapeutics Inc.

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Anthony Giovinazzo, M.B.A.
C.Dir., A.C.C.
President and CEO

BIO:
Is an experienced Biotech CEO with more than 18 years of experience in international pharmaceutical drug development, private and public financings, and M&A transactions. Prior to this he spent 16 combined years in international corporate tax management, investment banking and private equity. Mr. Giovinazzo has successfully managed Pre-IND, IND/CTA, end of Phase 1-2, CTD/NDA submissions and negotiations with FDA, EMEA/CPMP. He has identified, licensed, and overseen the development of eight (8) biotech drug development candidates, pre-clinical to Phase 3, for the treatment of Parkinson's, Alzheimer's, anxiety, neuropathic pain, and nausea. Mr. Giovinazzo led the sale of Nova Molecular Diagnostics to Variagenics Inc. through the public listing of Variagenics that resulted in significant above-average returns to investors. As CEO, he also led the acquisition of Cita Neuropharmaceuticals by Vernalis Plc., which resulted in a substantial multiple return to venture investors. He is a faculty member of The Director's College. He is also a business advisory board member of the National Research Council of Canada's Genomics funding program and is on the Board and is Chair of the Audit Committee of Majescor Resources Inc (TSX-V: MJX). He is one of the inventors of the original APL-130277 intellectual property that was acquired by Cynapsus.

Trilingual in English, Italian and French. MBA (IMD); Chartered Director and Audit Committee Certified, designations from. (McMaster & The Directors College); Leadership and Strategy in Pharmaceutical & Biotech Companies (Harvard Business School).

Company Profile:
Cynapsus Therapeutics Inc. is a specialty pharmaceutical company which has the only oral (sublingual) delivery of the only rescue therapy for Parkinson's patients, who experience daily "OFF", or freezing episodes. The potential market could grow to well beyond one billion per year. The Company's plan is to de-risk the project over the next two years, after which a New Drug Application can be submitted, and execute an exit transaction with a large pharmaceutical company.

Cynapsus' lead drug candidate, APL-130277, is an easy-to-administer, fast-acting and oral reformulation of an existing approved drug (Apomorphine). Apomorphine is currently only available as an injection, which is an especially painful method often associated with injection site irritation, inflammation, infection risk and scar nodules. This new formulation is a sublingual thin-film strip of the approved drug which results in a more convenient solid dosage form vs. syringe injection with fast dissolution, fast absorption and a similar PK profile.

Parkinson's disease is a chronic and progressive neurodegenerative disease that impacts motor activity, and its prevalence is increasing with the aging of the population.

The new oral reformulation could be used by 35-50% Parkinson's disease patients, creating an $890 million market worldwide, in the mid-term, to as much as $ 1.6 billion. Three market surveys have been conducted by an independent, experienced, medical survey company in the US and internationally confirming that an FDA approved sublingual formulation of this drug would be widely used and useful in the treatment of PD and would be readily accepted by payers.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Giovinazzo, what are the two or three biggest milestones since you have taken over as CEO of Cynapsus?
Mr. Giovinazzo: I have been in the position for a little more than two years. I was brought in to lead a turnaround and repositioning of the company. There are four critical milestones that have been achieved. The

first, is the inlicensing and now acquisition of the underlying project technology that relates to our single project, which is a reformulation of an approved drug for what is called freezing or off-episodes in Parkinson's disease. The second, is that we were able to create a number of prototypes and optimize them to what is now the clinical product which is a sublingual thin film strip or a Listerine type strip, which is convenient, individually packaged and easy to administer under the tongue. The third, would be the validation of strip in both appropriate animal models and more recently in a human pilot study or Phase I type study. The human study was done to determine if the strip could deliver the right amount of drug and in the right period of time, quite similar to the only other alternative formulation of the drug, which is an injection that is very inconvenient and actually painful as well. The fourth milestone was that we have been able to go out through an American consulting firm and conduct a survey of 500 neurologists in various countries, including the US, Europe and several other countries in the world. These are actual doctors and neurologists who treat patients for these symptoms or what is known as off-episodes or freezing episodes. They have been able to feed back to us the fact that there is a substantial unmet medical need in that many patients do not use the injection, but could and would if there was a more convenient form of the drug. Therefore, we have been able to corroborate the existence of a much larger need for this drug in the form of sublingual thin film strip.

CEOCFO: Would you briefly explain the freezing episodes?

Mr. Giovinazzo: Approximately one third to one half of Parkinson's patients take a drug called Levodopa, which for the past 50 or so years has been the gold standard in treating Parkinson's. In combination with certain other drugs it is one of the best drugs for helping patients remain active and being able to voluntarily move throughout various points in the day. Unfortunately, the combination of the cells that die in the brain that attributes to Parkinson's and the use of this Levodopa drug, actually causes what is called, "freezing episodes" or "off episodes". This is where there is a wearing off of that Levodopa drug or a slow time to on. This leaves these patients with a gap of anywhere from a couple hours to several hours a day, where they are not able to move at will. They are fairly rigid and must remain where they are sitting down or laying down, because they just cannot move easily. This is what we call off episodes or freezing.

CEOCFO: How does the drug work in general and how does it work specifically sublingually as opposed to an injection?

Mr. Giovinazzo: The drug itself is the only drug that is approved for what we call the acute fast rescue of patients that are going into or are in this freezing episode scenario. What it does is it provides for a very rapid conversion to dopamine, which is a neurotransmitter in the brain that is used to be able to signal to other cells and ultimately nerves in various parts of the body to move and do things. Its mechanism of action is what it is called a dopamine agonist. It is the only dopamine agonist that has these rescue properties, because the mechanism kicks in very quickly and is able to for a poorer choice of words, get patients unstuck very quickly. Therefore, it has a very short half-life of approximately an hour. It allows patients to be more mobile while they wait for their levodopa dose to take its time to work.

CEOCFO: Cynapsus is working with 500 neurologists worldwide; what is the market oppotunity?

Mr. Giovinazzo: Approximately one-third to 50% of Parkinson's patients are the target market. They are primarily divided up into mild to moderate to severe patients. The moderate and severe groups are the more advanced type patients. Currently, the injection is used in primarily in a small portion of the severe category. What these neurologists have told us is that there is a much larger group of patients that experience these off episodes or freezing episodes at least once a day. They would benefit from the acute (fast) rescue that this drug provides, but are not likely to use the injection, because of the two aspects. One is that it is inconvenient. Therefore, they would not want to be seen doing it at a party, in front of their grandkids, at lunchtime or driving. Secondly, and more importantly, it actually has in most instances what we call injection-site reactions. It causes scarring, noduling, inflammation and pain that can last several days to several months in some cases. That requires you to move the injection around the body, so there is a large number of patients that do not do anything or will take more of their Levodopa drug in the hope of trying to bridge these gaps of inability. That becomes the market opportunity. When we translate that into numbers of patients, we do it on a model basis that looks at how many Parkinson's patients are diagnosed and treated. For example in the United States a number of public sources indicate there are close to a million maybe slightly more than a million diagnosed and treated Parkinson's patients. When we did our calculations, we actually started from 410,000 Parkinson's patients, which is a very conservative estimate of the population in the United States. There would be a subset of that, which would qualify and then within that subset, we have indicated you will never get all those patients. We have also indicated that some patients require the drug once a day, while others will require the drug two to three times a day. Therefore, you have to be able to separate those subgroups. What this translates into in a few years time after launch, is a potential market of somewhere between $800 million and $1.6 billion a year of peak annual sales. That is because there is also a much larger baby boomer generation that is ageing rapidly over the next several years and it is contributing to a larger number of Parkinson's patients in the world. The World Health Organization has indicated that there are approximately 4 to 6 million diagnosed and treated Parkinson's patients around the world today. They have estimated that in the next eight years, by 2020 that number is expected to be well beyond 10 million. Therefore, there will be a large increase of patients as well that drives those market numbers.

CEOCFO: Are you able to use your drug repeatedly, and is there any immune effect that would build up over time?

Mr. Giovinazzo: The answer is no, there is no wearing off effect. That is the beauty of this particular drug and its purpose, which is that fast rescue. It can be taken up to several times a day chronically for a number of years and it does not wear off in terms of its ability to actually function.

CEOCFO: Where is Cynapsus today in the development process?

Mr. Giovinazzo: As I indicated, we have optimized the clinical product. We have tested it in vitro, in animal and more recently and appropriately, in a volunteer group of healthy humans. We have demonstrated that we can obtain the right amount of drug in the right period of time into the bloodstream. What we are doing in 2012 is we are going to submit to the US FDA, an Initial New Drug application, in the summer. Then we plan to run a larger healthy volunteer bio equivalent study, which will should be finished by the November timeframe. That is a clear and important de-risking event, because that is a trial that the data of which would be presented to the FDA after completion. Then if the data is acceptable, we would be running in 2013 the pivotal or last trial, which is called the safety study. In the safety study we would be required to treat Parkinson's patients, approximately 150 or so, and determine if our delivery method is as safe or safer than the injection. Remember, this drug is approved in the United States and a number of countries around the world. Therefore, its efficacy, safety and tolerability are already known. What we are doing is delivering the same drug in a different way. We have to prove that we can deliver it in the first study (bio equivalence) by the end of 2012, within a set of parameters, which measure the time as well as the appropriate amount of drug in the bloodstream in comparison to the injection. If we meet those parameters, which we have already in our pilot Phase 1 study, then we would be continuing with the safety study in 2013. Therefore, 2012 is a critical pivotal year. We think it is a breakout year for us, because the successful completion of that study substantially de-risks the project quite significantly and allows us then to move to the last study in 2013.

CEOCFO: Will cost be a factor for potential users?

Mr. Giovinazzo: We have not been able to get definitive numbers, but based on what we know, we think the cost of the injection's average wholesale price in the US, per dose, is approximately $9-$10 US. Patients will take this injection anywhere from one to three and in some cases four or five times a day, so it can add up because it is on a daily basis. The sublingual thin filmstrip from what we can tell, based on our conservative projections, will have an all-in cost of approximately $1.60 per dose. That is the manufacturing and packaging cost. What we believe is that we will not be the sellers of this final product. It will be the large pharmaceutical companies who will also have marketing education and various other costs that they have to add onto that. They will likely sell it for something around $7.00 a dose, which is a fairly significant drop from the injection. What it also provides is that in not all instances, but in many instances, patients would be able to self administer, compared to today, because it is an injection, they may have their spouse or a caregiver, someone in an institution if that is where they are, providing that service. The caregiver person usually has a cost to the system associated with it. So there could be additional savings to the system in addition to a lower price per dose.

CEOCFO: Cynapsus Therapeutics recently announced a financing; how far will that take you?

Mr. Giovinazzo: It was really an interim short-term financing. It was a little more than a $1million and it really is quite short-term. It helps us to complete some work that we are currently doing to prepare for the bio equivalence study. However, we do plan to raise additional capital in the not-too-distant future, to allow us the additional time to prepare for and begin to execute on the bio equivalent study.

CEOCFO: Has the investment community been paying attention?

Mr. Giovinazzo: Not as much as we would have liked. The reason we think is that we ourselves admit that we have only begun an investor awareness program in the last two and a half months. Our understanding is that it does take some time for people to read materials, then investigate the company and its proposition. Where we have been somewhat lucky in that recently at the end of February (2012), an independent Canadian investment bank research analyst with whom we do not have a financial relationship, issued a very detailed positive research report. They did their own due diligence to identify risks and rewards. The financial community is now beginning to see that report, read it and respond accordingly. Therefore, we are starting to see some reaction from that point of view.

CEOCFO: Why should investors pay attention to Cynapsus Therapeutics today?

Mr. Giovinazzo: We are substantially undervalued, we have a short timeline to an approvable drug candidate, which is of lower risk as a new way to deliver an already approved drug, which if approved would enter a potentially very large market opportunity, with no direct competition. Our business model as a single project focused company is to motivate a substantial exit transaction in 2 years time, in the several hundreds of millions of dollars total value. The analyst in her research report on page ten, indicated that her very conservative estimate of enterprise value before any transaction premiums, two years from now, is $200 million. Our current market cap is approximately $8-9 million, so there is a significant difference.

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