

Intellect Neurosciences is the Quiet Force Behind the Next Generation of Alzheimer's disease Therapies



**Healthcare
 Biopharmaceutical
 (ILNS OTCQX)**



Dr. Daniel G. Chain Ph.D.
Chairman and CEO

BIO:

Dr. Chain formed Intellect in April 2005 and has served as Chairman and Chief Executive Officer since October 2005. Dr. Chain was previously the President and CEO of Mindset BioPharmaceuticals, a private company he founded in 1999.

Dr. Chain is the inventor of the Company's ANTISENILIN® technology for the treatment and prevention of Alzheimer's disease, which underlies products in Phase 2 and Phase 3 clinical trials by major pharmaceutical companies that have purchased licenses from Intellect Neurosciences for the commercialization of those products. Patents in relation to Dr. Chain's invention have been granted in Europe, Japan and recently received a Notice of Allowance by the USPTO. Dr. Chain is also the inventor of a patent concerning the use of insulin sensitizers for the prevention and treatment of memory loss and dementia and recently filed two new patents that underlie the newest technology platforms at Intellect Neuroscience.

Dr. Chain has spent more than a decade devoted to developing innovative approaches aimed at slowing, arresting or preventing Alzheimer's disease. Collectively, these different approaches drive Intellect Neuroscience's internal drug pipeline that is backed by intellectual property assets across diversified technologies. Dr. Chain has authored numerous scientific research publications in peer-reviewed journals and his broad expertise is increasingly drawing positive attention in the media featuring in articles and radio interviews to discuss new developments in the Alzheimer's field and the progress being made by Intellect Neurosciences. Dr. Chain is a member of the Royal Society of Medicine and the Society for Neuroscience. Dr. Chain obtained his B.Sc., with honors, in Biochemistry from the Institute of Biology in London and obtained his Ph.D. in Biochemistry from the Weizmann Institute of Science in Israel. He trained as a

post-doctoral research fellow at the Center for Neurobiology and Behavior at Columbia University College of Physicians and Surgeons in New York where he collaborated with Nobel Laureate, Professor Eric Kandel.

Company Profile:

Intellect Neurosciences, Inc. develops innovative approaches aimed at arresting or preventing Alzheimer's disease, and other neurodegenerative diseases, focusing especially on proteinopathies. Intellect's pipeline includes therapeutic vaccines, antibodies and neuroprotective antibody drug conjugates.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Chain, what was the impetus behind Intellect Neurosciences?

Dr. Chain: I have a long interest in Alzheimer's disease dating back to the mid-1990's. There was then and remains today a tremendous need for therapies that can slow down or arrest disease progression. In the late 1990's I came up with a potential therapeutic approach for Alzheimer's disease and that was really the technology that was the impetus to for starting my first company whose assets were ultimately transferred to Intellect Neurosciences in 2005.

CEOCFO: What have you developed thus far?

Dr. Chain: We have a very rich patent and technology portfolio. We have patents that date back to the original invention back in 1997. Today, we have 3 products in advanced clinical trials of major pharmaceutical com-

panies. They are developing product independently of Intellect, based on the technology. They have taken licenses from the company, so we would anticipate receiving royalties when those drugs eventually reach the market. The most advanced drug is in Phase III clinical trials and may be on the market by 2014 if Phase III data is positive. The core competence of the company is based on using various different antibody based approaches. This includes vaccines against targets that are important in Alzheimer's disease, such as beta amyloid and tau proteins, as well as antibody drug conjugates, where we take an antibody against these targets and combine them with a small molecule that has neuroprotective function. We have several programs and platforms at various different stages of development.

We also developed a small molecule that was outside of the core focus of the company, but it was a very interesting technology that we acquired from New York University many years ago. It had the potential for treating several different neurodegenerative conditions. We as a company took this product through preclinical and Phase I clinical trials. Just recently, we partnered with Viro Pharma Incorporated, which is a company in Philadelphia that is focused on the Orphan drug space. They will develop this compound, OX1, for Fredrich's ataxia, which is a rare indication. It is a neurodegenerative condition that is fatal and manifests itself in childhood. This is a very promising compound and it was a very substantial deal for Intellect that we consummated towards the end of 2011. We received \$6.5 million upfront payment from Viro-Pharma. There are \$120 million in milestone payments related to regulatory milestones and then a two-tiered royalty that goes on several years. Therefore, we really developed quite a broad based platform, diversified to mitigate risk for our investors. It really gives us multiple shots on goal in terms of having therapeutic agents

that attack important unmet medical needs in different disease areas.

CEO CFO: Regarding Alzheimer's, would you explain what is different about the way you are approaching the disease and where in the cycle of Alzheimer's are you targeting?

Dr. Chain: There was a lot of debate in the 1990's, at least about two proteins that are implicated in Alzheimer's disease as being very toxic. One of these is called beta amyloid. This protein accumulates in the fluids around the brain and eventually starts to deposit and form insoluble plaques on the surface of cells. This is the hallmark feature of Alzheimer's

Intellect is really an extraordinary company with a portfolio that is much more diverse than other companies in the field are and that really mitigates the risk for investors. It gives us multiple shots on goal. We have really shown now that we tend to pick technologies that find favor with major pharmaceutical companies. We have entered into four agreements with large companies, royalty bearing with significant milestones and we expect that we will have several additional partnering opportunities related to these earlier stage platforms as well. Therefore, we are really unique within the Alzheimer's space; a small company with licensed products in Phase II and III clinical trials. We are addressing the major unmet medical need of Alzheimer's disease.

- Dr. Daniel G. Chain Ph.D.

disease classically, if you look post mortem at the brain on these plaques on the surface of cells. There is a second protein that forms inside the cells and it forms neurofibrillary tangles, which are a second hallmark feature of the disease. This is a protein that is responsible for the holding together the architecture of the cell. There was a lot of debate as to whether it was beta amyloid or whether it was tau; what happens first and what happens second. Today that whole argument really has been put to rest, because the realization today is that both of those proteins are very important and act together to produce the irreversible damage to nerve cells. First it is beta amyloid, but very soon after that, it switches on these abnormal forms

of tau protein that cause death of neurons. Therefore, our approach is to target both of these. We have antibodies that exclusively target beta amyloid, but we also have an active vaccine program that we are very excited about that targets both the beta amyloid and the tau protein or an abnormal form of the tau protein, at the same time.

The whole idea of using antibodies for treating Alzheimer's disease was completely novel in 1997, when we filed our original patents. It was really a couple of years later that other companies and people started publishing reports of how vaccination can improve the pathology originally in animal models of Alzheimer's disease and then taking products into the clinic. We were really the first company to focus on an antibody based approach for the treatment of Alzheimer's disease, so we really have pioneered the field originally. Today, fifteen years on, we are in a position that we are introducing what we believe will be the next generation of improved therapeutics. We are taking that original idea, but improving it a great deal through both the vaccine approach and using antibody drug conjugates. This is where we combine the properties of an antibody with those of a

small molecule.

CEO CFO: Would you tell us about your RECALL-VAX™?

Dr. Chain: RECALL-VAX is a platform for generating antibodies, where an antibody is administered externally as a drug. Here the idea is more like a flu shot, with the idea of being able to immunize patients even before disease starts with an antigen that will promote production of antibodies in the bloodstream that eventually get to the brain. This will allow patients to develop their own immune response against these toxic proteins. We have three candidates from RECALL-VAX that are currently being tested in pre-clinical studies. One of them targets the beta amyloid protein, and the sec-

and one an abnormal tau protein. The third candidate is a combination of those two. Our hope is that the method of vaccination will be safe enough to be administered to anybody who is susceptible. It could be somebody who has reached a certain age that is close to the onset of Alzheimer's disease in the general population, or it could be individuals who carry a particular gene defect or mutations that make them susceptible to develop Alzheimer's disease.

CEO CFO: Intellect Neurosciences has added some people to the team recently; what are they bringing to the table?

Dr. Chain: Our key recent recruit is Dr. Dan Shochat, as a vice president for non-clinical development. Dan has thirty years of experience in antibody drug development and especially, he has brought three products all the way through FDA approval. He led the first team that had the first approved antibody drug conjugate for cancer, a drug called Mylotarg. He developed two additional products, so he brings an enormous breadth of experience to the program and we expect them to take the lead in directing this program towards the initiation of clinical trials.

CEO CFO: What do you see for the next year or so for Intellect?

Dr. Chain: We have many exciting things coming up. I should just mention that we have just recently achieved a very important milestone for the company with a patent allowance from the USPTO for the key patents that we have licensed to big pharma. In addition, we expect additional patents related to that technology to issue during the course of the year. Then we have the anticipated completion of Phase III clinical trials on a drug, Bapineuzumab, that is based on our ANTISENILIN platform technology. That data will, hopefully, be available towards the end of the year, or maybe the beginning of next year. That Phase III clinical data is very important, first of all, to validate Intellect core immunotherapy approach. It is also obviously of enormous importance to the community at large. It would be the first disease

modifying drug for Alzheimer's disease and the first new drug approved for Alzheimer's disease since 2004. There is now a very large trial ongoing that I have to emphasize is being done independently of Intellect. It uses Intellect platform technology, but it is being independently developed and it is a co-development between Pfizer and Johnson & Johnson.

CEO CFO: What surprised you most as you have been working on Alzheimer's?

Dr. Chain: The whole model in terms of a biotechnology business has changed dramatically since I started in the late 1990's and that time most biotech companies would have, first of all, one key technology. They would take it through some initial proof of concept, partner it with a large company, do an IPO and then all of the original founders and shareholders get out at that point and go start another company. That whole model has really disappeared. Today, there are fewer exits for companies and for shareholders. One tends to stay with the development or is linked to the development of the drug all the way through. That is a very different model than the one that we had envisaged. Also, the time for developing a drug as changed. It was at one point a ten-year development and now it is really a fifteen-year development, especially for Alzheimer's disease. That is really quite challenging if you are starting at ground zero and have to think about that time course before the drug actually makes it through trials. It has been a tremendous learning experience. We have seen the Alzheimer's field evolve tremendously over this time. There is much more understanding about the fundamental mechanisms involved in Alzheimer's disease, and there is a lot of clinical trial experience that is making the design of new trials much easier than previously. There are very good biomarkers that are beginning to play, including imaging biomarkers. When we started, we did not think we would see any surrogate markers approved by the FDA within our lifetime and that has changed. In fact, with the new biomarkers, one still relies on a

cognitive outcome, but we had made a lot of progress in the field in terms of developing biomarkers that could help facilitate clinical trial design and outcomes. Therefore, there have been very important developments over this period of time.

CEO CFO: You mentioned \$6 million coming in; what is the general financial picture for Intellect Neurosciences and how long will the money last?

Dr. Chain: It depends what we want to do. What we would like is progress with the earliest stage programs now that we licensed the IP related to late-stage clinical development. We are focused on these very innovative, but relatively early stage platforms that we believe will generate data to attract additional partnerships over the next year and eighteen months. Therefore, what we would like to do is to raise some additional capital now that will allow us to move forward aggressively with developing those programs.

CEO CFO: Why should investors consider Intellect Neurosciences today?

Dr. Chain: Intellect is really an extraordinary company with a portfolio that is much more diverse than other companies in the field are and that really mitigates the risk for investors. It gives us multiple shots on goal. We have really shown now that we tend to pick technologies that find favor with major pharmaceutical companies. We have entered into four agreements with large companies, royalty bearing with significant milestones and we expect that we will have several additional partnering opportunities related to these earlier stage platforms as well. Therefore, we are really unique within the Alzheimer's space; a small company with licensed products in Phase II and III clinical trials. We are addressing the major unmet medical need of Alzheimer's disease. We also have gone into the Orphan Drug space with the licensing of OX1 for Fredrich's ataxia and we have technologies that could be applied to several different indications and generate new drugs.



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