

Q&A with Sam Huttenbauer, Jr., CEO of Agragen, LLC using Engineered Camelina to produce Bioactive Lipids for Manufacturing Biosimilar Fish Oil and a Biosimilar Anti-Inflammatory Therapeutic



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CEOCFO: *Mr. Huttenbauer, would you tell us the idea behind Agragen?*

Mr. Huttenbauer: The idea behind Agragen is to use biotechnology to engineer camelina to make bioactive lipids, such as fish oil, and biopharmaceuticals in a sustainable manner and at a lower cost point than traditional routes of production.

CEOCFO: *What is camelina?*

Mr. Huttenbauer: Camelina is an ancient plant that is thought to have been cultivated in the Roman Empire as an oil seed crop to produce oil for human use and use as a lamp oil with the meal used in livestock. It was referred to as gold-of-pleasure or as false flax. It was first cultivated in N. America in the mid-1800's. Camelina is now considered an re-emerging group because of its value as a feedstock for biofuels. However, we think Camelina's true potential lie in its flexibility to produce a large range of molecules using a biotechnology approach that adds a sustainability component with a plant that does not outcross well with other plants as it is a self-pollinating plant.

CEOCFO: *What has happened since the purchase?*

Mr. Huttenbauer: One of the things we expanded our effort with was our lead compound, AGR-131. AGR-131 is a biosimilar to a commonly used therapeutic protein. Our objective was to manufacture something in a more reasonable manner than what was currently being accomplished in the pharmaceutical marketplace. In some initial pre-clinical studies, AGR-131 demonstrated at least equivalence to one the major biologics in the marketplace. AGR-131 is designed to limit inflammation associated with rheumatoid arthritis, psoriasis and inflammatory bowel disease. We have also continued with our program in bioactive lipids, focusing on making biosimilar fish oil in Camelina. Earlier this year we announced an agreement with DuPont Pioneer to acquire the genes required to make fish oil and other bioactive lipids in Camelina.

CEOCFO: *You announced last week a significant step forward. What has changed?*

Mr. Huttenbauer: We had examined the ability of AGR-131 to bind its target molecule, TNFalpha, at a high affinity and functional work to limit changes in TNFalpha in cell culture models of inflammation. The results were quite favorable, but what makes this much more exciting is that the current cost structures of these drugs in the U.S. are quite high and we look to dramatically reduce the cost of this particular biopharmaceutical to make it much more affordable for more people.

CEOCFO: *Would you tell us how it works?*

Mr. Huttenbauer: This is a classic cytokine trap that essentially eliminates a specific molecule that produces inflammation in a number of disease. In this case, the cytokine trapped by the drug is Tumor Necrosis Factor-alpha (TNF-alpha). Our current lead molecule binds TNF-alpha as well as what is the gold standard drug in this drug class.

CEOCFO: *What were the challenges in getting to the point where you are now and what are your next steps?*

Mr. Huttenbauer: The challenges are all related to funding. A lot of money was spent to get to where we find ourselves at the moment. The next steps are to continue preclinical studies and ultimately to go into clinical trials. We have a very efficient patented method for producing and purifying the protein from the plant. This method is far cheaper than the current methodology used to produce similar drugs. This is the major point where cost savings are realized.

CEOCFO: *Are the medical and pharmaceutical communities aware of camelina?*

Mr. Huttenbauer: In prior years there has been skepticism about using plants to make biological-based pharmaceuticals. A number of challenges that resulted in this skepticism were valid a few years ago and still are for many in the field, but our patented technology overcomes most of those challenges.

CEOCFO: *What have been the stumbling blocks and has the industry overcome them?*

Mr. Huttenbauer: I think the industry has pretty well overcome some of the major stumbling blocks. Our CSO is a medical professor as well and he understands fully the hurdles that we have to cross but we are now better prepared to do that than in the past because of science that has been done. These advancements have alleviated most of the pitfalls of using plants to produce biological-based pharmaceuticals.

CEOCFO: *Is camelina relatively easy to grow?*

Mr. Huttenbauer: We have extensive experience in the agronomics and challenges to growing Camelina. We have grown about 150 thousand acres of it through one of our other companies. It is easier to grow than canola and similar to wheat. It grows well in marginal land, requires limited inputs with regards to fertilization, and grows with limited moisture. It is a short season crop and is quite adaptable to colder climates.

CEOCFO: *Is this a hardy plant?*

Mr. Huttenbauer: All plants are susceptible to certain things. We from time to time have rust occur with a plant. Camelina's origin is as a weed and it has survived as a weed. The varieties that we have are rather

hardy. If it uses any pesticide at all, it is very limited because the plant naturally produces compounds that limit other pest.

CEOCFO: *What is your strategy for funding?*

Mr. Huttenbauer: We are envisioning partnering with a larger partner with the capacity to move products through the clinical trials and through the approval process. Large pharmaceutical companies do that very, very well. I think that is our basic strategy. If I may add at this point that Agragen is not a one-trick pony. We have done a great many things with this plant. For example we have engineered the plant to make lauric acid, essentially producing a plant that makes medium chain triglycerides that also contain essential fatty acids. We currently are involved in transforming the plant so it makes a synthetic fish oil that has the same fatty acids as fish oil coming out of the ocean. We envision having the same amounts of docosahexaenoic (DHA) acid in that plant that you would find in a fish, as well as eicosapentaenoic (EPA) acid. We also have done work on that plant to produce other industrial chemicals so we are looking for someone who is interested in a company who can make a number of diverse molecules with the plant using our biotechnology experience.

CEOCFO: *How do you get a foot in the door to tell your story?*

Mr. Huttenbauer: I call upon the people that I know. I am an older entrepreneur in all areas of agribusiness. I have people who like what I am doing. Does that translate automatically to money? No. We need the help of people like you who get to people who are decision-makers interested in Agragen and our technology. Once they have heard our story, we anticipate that people will get very interested, but a key point is to get our story out there. We have a strong potential anti-inflammatory biosimilar that has already been shown to work in preclinical studies. With the fish oil, we will leverage co-existing technology to make this product and the proof of principle has been done by an academic entity in England, so we know it will work. We just need to get our story out there.

CEOCFO: *Why are you confident that your vision will take hold?*

Mr. Huttenbauer: I think the timing is correct to reduce the cost of medicines in the United States. Anybody that reads their hometown tabloids knows that there are many pharma products that are out of financial reach for a lot of people because these products are too costly. In short, we want to provide an effective, but significantly lower cost alternative.

CEOCFO: *Why pay attention to Agragen now?*

Mr. Huttenbauer: Agragen has some very interesting things to take into the marketplace that are all very cogent needs in the current in the marketplace. We are working on low cost biosimilar therapeutic proteins that are in high demand, but economically unsustainable in our current health care system. As a nation, we must find less expensive routes for production of these critically important drugs. In the case of our fish oil, it is addressing something that is drastically needed as marine sources of omega-3 oils are now stretched to the breaking point. Aquaculture needs sustainable sources of these fatty acids. In short, at Agragen we are working on things that are just simply needed.