CEO CFO

LAUREATE BIOPHARMA

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With Over 30 Years Experience and a Leader in Biopharmaceutical Contract Development and Manufacturing, Laureate Biopharma Scientists are Experts in Process Development and the Production of Therapeutic Proteins

Healthcare
Biopharma

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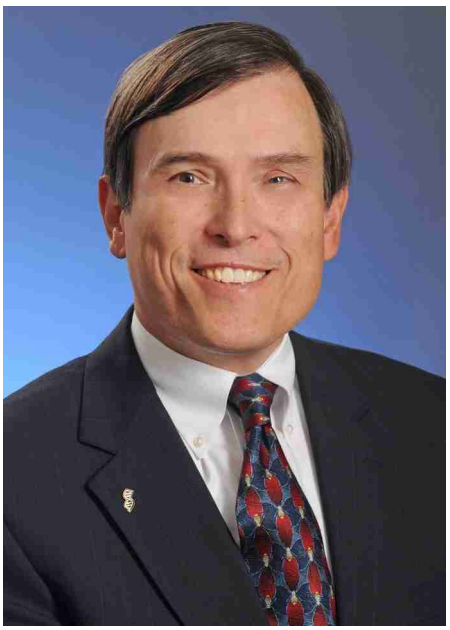

Michiel Ultee
CSO

BIO:
Michiel E. Ultee, Ph.D., has more than 25 years of experience in the biopharmaceutical industry and has worked with antibodies since 1975. He serves as Laureate Biopharma's scientific head and is the leader behind Laureate's Scientific Series, which spotlights the organization's strategies and methods in working together with our clients' scientists to overcome challenges in biopharmaceutical development and manufacturing their biopharmaceutical products.

Dr. Ultee has been a crucial member of Laureate's biopharmaceutical operations team since 1987 holding positions including Vice President of Process Sciences, and Director of Manufacturing & Technical Operations.

Dr. Ultee began his career in Research and Development, where he was part of the team that developed two licensed biopharmaceuticals. He holds four U.S. patents and has published numerous scientific articles. Prior experience includes postdoctoral research in immunology at NYU Medical School. He is a frequent speaker at biopharmaceutical conferences, and he serves on the editorial advisory boards of Bioprocess International and Biopharm International. Dr. Ultee earned his graduate and undergraduate biochemistry degrees from Northwestern University and Dartmouth College, respectively.

About Laureate Biopharma:
Laureate Biopharma is a leader in biopharmaceutical contract development and manufacturing. Our scientists are expert in process development and cGMP production of therapeutic proteins, including monoclonal antibodies and Fc-fusion proteins. In addition, our portfolio of services includes aseptic filling, cell line development, analytical and stability testing, and regulatory support. Laureate has served a global client base from its Princeton, New Jersey facility since 1981. Laureate is a portfolio company of Saints Capital, LLC.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Ultee, would you describe Laureate Biopharma today? What is your main mission?
Dr. Ultee: We are a contract development and manufacturing organization that helps our customers get from a discovery stage to product stage.

CEOCFO: Are there any particular types of drugs that you work with or particular types of projects that you prefer?
Dr. Ultee: We work with more complex glycoproteins. These are produced by mammalian cells in a recombinant fashion. These are typically larger proteins such as antibodies, fusion proteins, enzymes and similar types of molecules.

CEOCFO: What are the specific challenges of working in that area?
Dr. Ultee: Some of the proteins express poorly. That means that the cells do not really produce them well, particularly fusion proteins, which are artificial constructs. They are a construct that is designed by a molecular biologist to put together a piece of one protein with a piece of another protein. As such, these molecules have not had the benefit of evolution to select for good expressing proteins and stable molecules. Therefore, when we work with a fusion protein we know we will have a challenge ahead of us. We have done four of them here and know that we can handle that kind of work.

CEOCFO: How is Laureate equipped to work with those challenges?

Dr. Ultee: We have been doing this type of work for about 30 years. We have a lot of expertise with different types of proteins. People come to us with their challenging proteins because we have a reputation for successfully tackling such proteins. We hire scientists who are particularly adept at this kind of work. We work closely together with our clients' scientists as well.

CEOCFO: Was it a deliberate plan to work in that arena or was it opportunistic?

Dr. Ultee: I think the biopharmaceutical industry has been gradually moving in the direction of seeking opportunities with specialized molecules that have multiple capabilities, such as fusion proteins. This invariably comes with complexity and challenges. One of the challenges in particular is that these proteins tend to be often less soluble than natural proteins. This means that they tend to aggregate and precipitate. Another challenge is that sometimes the properties of one portion of the protein interfere with the portion of the other attached protein. We have had a number of examples of that, and we have found ways to address it.

CEOCFO: Your website indicates that there have been some changes in Laureate; it is recapitalized and revitalized. What has been happening in that arena?

Dr. Ultee: We have been investing in our capabilities. We have been growing the company. We brought on a new CEO, Michael A. Griffith, three years ago. At that time we were about eighty people. Today we are one hundred and twenty five. That is a 50% increase in staffing. We have invested in new analytical equipment. We invested a million dollars in new analytics just in the last year, alone. That is because biomolecules are very complex. You need some high-powered analytical tools to deal with them. We have also been modernizing our facility; adding additional bioreactors, both with the small-scale and the larger scale. We have been adding newer purification equipment and changing the layout of our facility as well.

CEOCFO: Are you about done in that area or do you see some additional changes?

Dr. Ultee: We see some additional changes. We plan to add a second 2,000-liter bioreactor, which is our largest bioreactor. We also are looking at a five-step plan for continuing to modernize our facility.

CEOCFO: How do you reach potential clients?

Dr. Ultee: We have a number of routes. Often new clients will come to us because of our scientific reputation, which they are made aware of, in part, by our publications and presentations at conferences. Secondly, we also have an active business development team. They are all scientists by training, and they go out in the field. I often travel with them as does our Chief Commercial Officer, Dr. Robert Broeze. Sometimes our CEO attends as well. We go out to meet with potential customers, at their location and at trade shows. Our BD Team has extensive reach, covering North America, Europe, and Asia.

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- Michiel E. Ultee, Ph.D.

CEOCFO: What do you do day to day as Chief Scientific Officer?

Dr. Ultee: I am an advisor to all of our projects. I get involved with a project's scientific and technical aspects. We have weekly and bi-weekly project team meetings with our customers that I often attend, contributing to the scientific discussion and problem solving. This is especially true in the early stages when the project is taking form and it is in the development labs. Once it is mature and has transitioned to the manufacturing phase of development, then my role is reduced, unless there is a specific scientific issue or problem. Many of the molecules that we produce as protein therapeutics are what are called "first in human". That means that they have never been used as a drug before and in some cases have never even been made before. Therefore, there are always some new challenges that arise with such a molecule, and I am often part of the process in dealing with those challenges.

CEOCFO: What are some of the steps that you provide when you are working on a project? What is involved with developing for you?

Dr. Ultee: Starting from the beginning of a project; most of the projects are in a development stage. The initial process may have produced the protein of interest but perhaps in low-yield or in very limited quantities, and often with a research process that is not really suitable for biopharmaceutical production or purity. Therefore, our development team gets to work to improve the process. We begin with a "kick off" meeting between our scientists and the client company's scientists. We conduct a "deep dive" into everything that they know about the protein. We can share our experiences with related proteins, and they talk about the protein and its properties that they have learned in working with it. Then we move forward, starting at cell-line development. Sometimes we are creating a new cell line and other times the client already has a cell line. This is the host cell that is producing the protein of interest. That protein is produced at a certain level. One of our key objectives up front is to get the cells to produce as much product as they can. That can be done by having each cell produce more or by having the cells grow to a higher population density. The product of those two factors gives the "titer" or concentration of protein in a batch. We work with both factors to get more protein product produced. This translates into

higher productivity in the production bioreactors, which means more product per batch and a lower cost of goods. This is the upstream part of process development. There is also a very important subsequent step which is the purification or downstream step. The cells that grow in our bioreactors are producing not only the protein that we have programmed them to make, but they also produce their own proteins. All of these proteins and by-products are secreted into the culture media (that is the substance in which the cells grow). At the end of the process, we filter out or remove those cells, leaving us with a kind of "soup" or media containing the protein of interest, plus a bunch of other proteins, amino acids, nucleic acids and other impurities. We have to purify the desired protein away from all the other components. This has to be done to a very high standard of purity. The products are proteins that are going to be injected into a patient, so the amount of allowed impurities is down to the parts per million level. We use a series of stringent process steps to accomplish this objective. To do that typically takes five or six purification steps. Once the desired protein is purified in bulk, it has to be formulated and filled into individual vials to be administered to patients. We offer that service, too. Some other contract manufacturers do not, but we have always had the "formulation and fill-finish" capability so our customer can have their product filled directly into vials here, rather than have it shipped somewhere else. Finally, there is a lot of analytical testing that takes place of the protein product throughout the process, from the beginnings when it is expressed by the cells through purification to the bulk drug substance and filled product vials. There is also active engagement by our Quality Assurance group throughout the manufacturing process to ensure strict adherence to current Good Manufacturing Practices, or cGMP.

CEOCFO: Do you ever have projects that you have to abandon or that you are just not able to do, or is everything that you decide to take on doable?

Dr. Ultee: We have not had any that has been abandoned from our end. Before taking on a new project, we carefully assess all the technical aspects, and develop a detailed proposal and contract. Some of our customers have abandoned a project, because they have changed their mind about the nature of the concept or think it is not worth the effort. We have been successful in producing all of the molecules that we have taken on. However, some of our customers have, for various reasons, such as having to cut back on their total programs, or "back burner" some of them, abandoned or delayed projects. Other times they come up in their research labs with a better candidate and so they have abandoned the first one. That happens from time to time. However, on our end we have always been able to produce the protein.

CEOCFO: How is business these days?

Dr. Ultee: Business is good! As I mentioned earlier, Laureate has made enormous investments in its business. Thanks to the upgrades in our facility, our enhanced analytics and new staffing, we have been able to attract business from the larger pharmaceutical companies. We now work with six of the top fifteen large pharma companies. They are less dependent the economic circumstances of the larger economy than the small companies.

CEOCFO: Why does Laureate Biopharma stand out for investors and people in the business community? Why should people look at it and say that it is an exceptional company?

Dr. Ultee: I mentioned earlier our scientific expertise. Secondly, the collaborative spirit that our scientists have with the client's scientists; we publish together and we co-present at scientific conferences. We work well as a team. We are very flexible. Our size is such that we can do that. We have and have always had that culture of being flexible. Our clients especially appreciate this because these are new protein molecules, and we expect that they may require changes in the scope of a project going forward. We also have strong a project-management team. We have five of them, who have all come out of our operations or related operations elsewhere and have scientific degrees. Therefore they really understand the processes. Rather than just looking at charts, they understand what is exactly is going on in our labs and plant since they have personally worked with scientists in the lab or manufacturing setting. Finally, we have a thirty-year reputation for doing biopharmaceutical work here. We have been producing FDA-licensed biological products here since 1994 and have been regularly inspected since then. This lets people know that we have good manufacturing practices here at Laureate. People also like the "one-stop shop" that we have here, going from the early creation of a cell line or cell-line development, all the way through the finished vial. Therefore, our clients can avoid having to deal with two or three or more contractors in getting their protein product made, as they can that have everything done here. We are one team, one group of people and one location.

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