

Biovitrum Is Focused On Developing Unique Protein Drugs For Rare Diseases Where There Are Huge, Unmet Medical Needs And Commercial Opportunities



**Healthcare
Specialty Pharma
(BVT-STO)**



**Martin Nicklasson
Chief Executive Officer**

BIO:

Born 1955. Has a degree in Pharmacy, and a Ph.D. in Pharmaceutical Science. Since 1985 he has been an associate professor at the Faculty of Pharmacy at Uppsala University. Martin Nicklasson joined Biovitrum from a position as member of the executive management of AstraZeneca Plc. as Executive Vice President and head of Global Marketing and CEO of AstraZeneca AB. Has previously held a number of leadership positions within AstraZeneca; including President of Astra Pain Control AB and President of Astra Hässle AB, Executive Vice President of the Astra and AstraZeneca Gastrointestinal Franchise in addition to Executive Vice President of Global Drug Development in AstraZeneca. Martin has also held research leadership positions at Kabi Pharmacia.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com**

CEOCFO: What is the focus of Biovitrum today?

Mr. Nicklasson: “The focus for Biovitrum is on rare diseases, where we believe are huge, unmet medical needs and also commercial opportunities. In particular, we are focusing now on developing unique protein drugs for a variety of interesting diseases as well as trying very hard to expand our commercial presence within this particular area in specialty pharmaceuticals.”

CEOCFO: What are protein drugs and what is your focus?

Mr. Nicklasson: “It is important for people to understand that we have a strong heritage in this organization going more than 30 years back in time as being the pioneers developing the first recombinant human growth hormone called Genotropin. It was in a different name and different stage, but this organization was taught in doing so. Then there are some other important discoveries like recombinant protein for hemophilia, which also originates from this organization. What we actually do here is instead of using chemical principals, and chemical synthesis, we are actually use living cells of bacteria to produce a human like protein that is normally in the body and what you need to live a normal life. You could also use an antibody, which actually acts in the body to prevent diseases. When you talk about protein, the difference is you are talking about large molecules being produced in living organisms.”

CEOCFO: What is the general medical climate for this type of protein drug and where do you fit into the grand scheme of things?

Mr. Nicklasson: “We are for example, active on the market in what is called substitution therapy. These are diseases where the human being, due to genetic

heritage, lacks the ability to produce a protein that controls some specific mechanism in the body. Let’s take for instance hemophilia where because you cannot produce a specific protein in the blood clotting cascade, therefore, you stand the risk of bleeding severely in joints and muscles if you just slightly hurt yourself. This is something that you have to live with for the rest of your life. What we do is actually manipulate cells to produce that specific protein that the patient is lacking and give it back to the patient to be able to live a normal life.

Another exciting program that we are running clinical trials in relatively late stages is to help preterm babies to absorb the fat necessary to grow the brain and nervous system. Nature has been kind in enabling mothers to produce a specific enzyme to break down the non-absorbable fat in to fatty acids, so the babies can normally then digest it. However, these fragile individuals who are born premature and weigh only about a kilo, they lack the ability to be breast fed and hence you have to feed the baby with a tube into the stomach 24/7 with mother’s breast milk or with a milk formula enriched with fat, but there is no enzyme present. What we do is actually restore the normal life by producing exactly that enzyme that the mother is producing for the baby in normal circumstances. We add that to the breast milk or to the milk formula hoping to improve fat absorption, and hence, development of the brain and cognitive functions that are so vital in the early stage of life.”

CEOCFO: How have you decided where to focus, because it seems that you could address many different types of problems?

Mr. Nicklasson: “We have said that our new strategy is focusing number one, on

recombinant proteins when it relates to our in house efforts. This is where we have proven a track record of being successful with a heritage that I mentioned to you initially. We are in areas where we produce and develop proteins that are no longer present in healthy subjects. We believe that if you have a genetic disease and are unable to produce that protein, we can produce it for that specific subject. We have a disease areas strategy in focus where we have said that we want to be strong in blood diseases where hemophilia is an example, in malnutrition or malabsorption, as well as in rare diseases of inflammatory origin for, which protein drugs seems to have a high likelihood of success. For oncology, cardiovascular, or diabetes, we leave that for the big gorillas to fight about, because a small company needs to find it's unique, profitable and successful niche. Therefore, we believe we should focus on these kinds of rare diseases for which there is a great need in society for new intervention, and there is a willingness to adopt new therapies because there are very few available today and the patient is suffering incredibly from their disease."

CEO CFO: Where are you in terms of commercialization of your products?

Mr. Nicklasson: "We have 8 commercial brands on the market that we manage. We are in a luxury position being a mid-cap bio-pharma company in Europe. Number one, we have the full value chain in place, namely early research to commercialization and in between manufacturing and we do make money already at this stage. Very many are burning money and they would love to be in our luxury position. I'm not cocky, but I am just making a remark that we are in a nice position being self funded and we don't need to raise money to run our operations. Back to your question, we do have eight commercial brands that we do manage. Originally, we in-licensed co-promotion rights, or direct sales rights for products in the Nordic countries, Sweden, Denmark, Finland, Iceland and Norway, which is a 25 million plus population area. It is not big, but that is where it started. As of December of 2008, we have

brands on the international scene from a deal that we made with Amgen, where we acquired the exclusive rights to three biotech products that are being sold in North America, the entire European Union, and Down Under. We are currently expanding the market access by talking to interested parties in Southeast Asia, China, Japan, and Latin America, to long term grow the value of these proprietary products that we now fully control and own. We are growing those organically but also by strategic acquisitions of specialist products. All of the three were biotech in nature."

CEO CFO: Do partnerships and alliances come into play for you or are you commercializing on your own?

Mr. Nicklasson: "Our core philosophy since two years back, when I entered my new role in the company is that every-

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thing we do is in house. We would love to be part in the full exploitation of the commercial opportunities; however, we have to be careful when we talk about the world. We say that we would like to be the driver and owner of the European commercial area, but would like to see partnerships in other geographies. We do currently work on the establishment in the US, and when we reach the right critical mass, we might have your own operations in the US in the not too distant future. We also have our own collaborations on going. In two very important programs in the next generation of hemophilia products where we are in the frontline of competition, we do collaborate with Biogen Idec in the US, on a 50/50 development partnership and a 50/50 worldwide profit sharing of the commercial success. There we have decided that Biovitrum takes full accountability for the European launch, and Biogen Idec would take full accountability for the US launch, and then we share the

profit in a harmonious way. For the rest of the world, we are currently deciding who would be the right party to run Asia, and Latin America. It's a very nice position to be in and that mid-sized European company can work with a big biotech player in the US on equal grounds."

CEO CFO: So there are lots of opportunities for you?

Mr. Nicklasson: "Absolutely."

CEO CFO: Do you also produce proteins?

Mr. Nicklasson: "We do. We are actually the sole manufacturer of the active protein on behalf of Wyeth for ReFacto AF®. We have done that for a number of years and as we speak, we are currently launching the new version of ReFacto in the Scandinavian market. The new product has been launched in the US already

under the name of Xyntha®. We are the sole manufacturer of the active protein worldwide and we do have the marketing rights in the Nordic countries."

CEO CFO: What do you see for the next 2-3 years down the line for Biovitrum?

Mr. Nicklasson: "I would see a very expansive development of our commercial strengths. I

do anticipate that we would be in the capacity of striking additional, attractive, and commercial deals enabling us to improve our P&L even further, so we can have the luxury of long term investment in new research and development. That is number one. Number two is that we have taken a big step forward in our late stage, clinical programs. In 2-3 years, we could see the launch of one of our first in house, proprietary products on a global scale."

CEO CFO: Is the investment community paying attention?

Mr. Nicklasson: "I think that we are gradually experiencing interest both in the US and Europe. We have had some tough times together with all other players due to the financial crisis, which has more or less cooled off the willingness to take a risk from the investment community. But we have a very strong shareholder position and people are very patient. We have some good progress and

the share price has kicked up by 50% since the start of the year and I think people are appreciating more and more that we do execute on our strategy and not just talk about it.”

CEOCFO: Address potential investors; why pick Biovitrum out of the crowd?

Mr. Nicklasson: “It is a very crowded field, but Biovitrum is a company that actually has a proven track record of being successful in protein drug delivery. We are a profitable company and as we move forward, we would grow the profit and EBIT, because of our commercial activities. We are very close to launching

some significant projects with the peak sales potential of between \$500 million, up to \$1 billion US, on a world wide basis and that should attract a number of investors to invest in Biovitrum; hopefully not too late, because the train is soon leaving the station.”



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