



## Bringing INDEAS

Serodus is developing life-changing products for the treatment of cardiovascular diseases by being the mediator between academic and commercial entities.

Images by Ulrik Eriksen

va Steiness, CEO of Serodus, has 10 years of clinical training in medicine and has also worked in the academic sphere at the University of Copenhagen. This range of experience has given her a holistic understanding of the pharmaceutical sector from both research and commercial perspectives, putting her in good stead to head up Serodus as the company continues developing innovative drugs to treat cardiovascular disease.

Since joining Serodus in 2009, Eva has helped the company gain credibility and strength in the marketplace. "One challenge has been during the early days when we had no money and only one project that we had in-licensed. We had to convince our external partners that a small group of very experienced people are actually able to manage these compounds by outsourcing and managing those research organisations.

"You cannot go to an external provider and say, 'I have a compound; please come back when you've done the first trial'. You need to know what you want to do, how you're going to do it, so you need to manage contractors. So it has been a challenge to convince people that a small group of four people were able to do that, but just recently we had a market cap day where we proved that it is what we can do and we've had fantastic results."

Serodus has shifted its focus towards cardiovascular disease as Eva regards it as a fascinating field worth pursuing. "You get excited about how to solve heart-related problems. You don't do drug development without taking at least a few months of being challenged with some findings—things that don't go according to plan. You have to bear in mind that we have to ensure that we have substance. We have a compound, and then we have to develop products because they are the way

that we administer compounds to patients, and then we have to be sure we have the right patient population, that they are included time-wise as we have promised our board and the shareholders that we would have finalised delivery to patients by that date.

"You actually have to drive that whole process in order to achieve something that would, in the end, create value for the company and for the investors. That is a challenge which is fascinating; you need to be interested in the commercial, you need to be interested in driving the team to see new ideas coming up and see where you can use it and for which disease, because we don't develop compounds as 'me too'; all our compounds are add-ons to those compounds that are already in the market but have failed to create successful outcomes in treatment, which means the patient will still have these compounds, but then we add compounds to the current treatment." >

theceomagazine.com



80. The CEO Magazine - January 2015



Eva is excited about the product pipeline Serodus has in development. "We out-licensed a couple of compounds with the first one of them out on the market now in Europe and on its way in the US, which was out-licensed to Sanofi. Then I was offered to revitalise a Norwegian company and that is Serodus. We have in-licensed a couple of compounds and we have acquired a biotech company from Denmark. Today we have four compounds in development; one has just finalised the Phase IIA study in patients with systolic hypertension and got very impressive results. We are now planning for continuing to Phase IIB, we are in preparation for Phase IIA study for another compound, and the other two compounds are in the pre-clinical phase.

"It is always a pleasure working with Eva on complex and challenging drug development projects. We share the same values of trust and mutual respect, combined with effective and open communication. This is key to our ongoing successful business partnership." - Dr Bernd Raschack, Senior Business Development Manager, Bachem AG "We have just announced the outcomes from the Phase IIA study in systolic hypertension, a condition which is seen more and more often the older you get; it is the way that systolic blood pressure increases with age and the diastolic blood pressure decreases. If you have high systolic blood pressure—around 140 as a mean over 24 hours—then you run the risk of getting stroke, myocardial infarction, and renal failure. The higher the blood pressure, the higher the risk.

"What we know is that our compound SER100 is able to reduce the high blood pressure without harming the low pressure in patients who are not sufficiently treated with available antihypertensive drugs. So the patients should continue that treatment, which is a basic treatment, and then we add our compound as well. And that goes for all our projects where we do not try to compete with well-established compounds; we take

those patients who are not well treated with the compounds that are available today, and then we add our compounds."

Since universities have the

resources and staff to extensively research new products, Serodus works closely with key universities to assist with product development. "I should also say that Serodus is a pharmaceutical company, but we have a new business model. which means we are only four people who don't have any labs. The reason for that is that we strongly believe that universities all over the world are really good at creating new ideas, new findings, but may not be as good at commercialising these ideas. When we need to include new compounds, we will go shopping at universities. So we have no lab, we collaborate with those that can do what we need to do in order to bring a given project or compound further on, reaching new value."

## TOGETHER WE WRITE HISTORY WITH PEPTIDES BACHEM

**PIONEERING PARTNER FOR PEPTIDES** 

BUILDING ON OUR HERITAGE, WE PIONEER INNOVATIONS TO DELIVER THE BEST QUALITY FOR EVERY PEPTIDE NEED.

- MORE THAN 40 YEARS EXPERIENCE IN PEPTIDE CHEMISTRY
- PROCESS DEVELOPMENT AND CUSTOM MANUFACTURING
- COMPREHENSIVE TECHNICAL AND REGULATORY SUPPORT
- A LARGE NUMBER OF GENERIC APIs
- MULTI-KG SCALE cGMP
   MANUFACTURING FACILITIES
   IN USA AND EUROPE



One of the key problems for big pharmaceutical companies and universities collaborating is a lack of understanding from either party. "There aren't that many people from the industry that have also been in the university space after they graduated. I understand how researchers think because I have been one of them for quite some years and I've managed them. And then I turned over to the industry and so I know what the industry needs. When I go into an office where I'm going to negotiate with universities, we are going to have a win-win situation.

"Very often, researchers believe that they will be limited in what they're allowed to do, that they cannot have freedom in their research. That's not true-of course they can do that. When you collaborate with other people, both parties have to come out and find that the collaboration is good. If vou have that attitude and understand what their core business is, being a research university, and you know what the core business for an industry is, then you will be able to bridge the two together, which hasn't been difficult for us."

"Innovation is not just a new idea; it's also how smart we can do this or that, how we can surround a problem that has just shown up. That is also innovation and that is built into our day-to-day work."

- Eva Steiness

As Serodus is a small organisation, Eva observes that this makes internal communication and innovation much easier to facilitate. "We meet frequently, twice a week, and since half of us are in Denmark and the other half are in Norway, we have Skype conferences for a couple of hours and we go through what we've experienced. We get calls from scientists and we discuss what is of interest. In a way, innovation is not just a new idea; it's also how smart we can do this or that, how we can surround a problem that has just shown up. That is also innovation and that is built into our day-today work. I think it has something to do with the way the CEO manages a group of people."

With an exciting pipeline of products, Eva sees a bright future for Serodus. "What we're aiming for is to bring our products through Phase IIB, which means we finalise Phase II where we identify the safety profile, have a proven concept, and then continue Phase IIB where we define the optimal dose for a given patient population or the way a patient should be dosed.

"After Phase IIB, we want to out-license our products to partners who take it through Phase III. It might be that we collaborate with a licensee and say 'we can do this and that' like small studies that have to be done, or it might be that the licensee takes over. Very often, if it's a big pharma company then they take over and do it themselves, but if it's a mid-sized pharma company then they might take on some of the work and we take on the rest.

"So finding partners or completely out-licensing is our goal, or to sell the whole company with its projects when we reach a given stage around the end of 2016 where we will have a basket of three cardiovascular projects all in Phase II. And then, in a 100-per-cent-owned subsidiary, we have an anti-diabetic compound that is very, very interesting, but is a little bit different from the focus on cardiovascular disease. So we are open for individual licensing and agreements of various kinds or selling the whole company. It depends on what is in the best interest of the investors." •

theceomagazine.com

The CEO Magazine - January 2015 83.