

By Conjugating Existing, Clinically Tested Drugs to their XTEN Platform to generate Improved Versions of Products or Biosuperiors, Amunix, Inc. is focused on becoming the Premier Solution for Biopharmaceuticals that require a Long Half-Life

**Healthcare
Drug Development
Biotech**

**Amunix, Inc.
500 Ellis Street
Mountain View, CA 94043
650-428-1800
www.amunix.com**



**Volker Schellenberger, Ph.D.
President, Co-Founder**

BIO:

Volker co-founded Amunix with Willem 'Pim' Stemmer in 2006, where he originally served as CSO and is currently president. Volker has 19 years of biotechnology industry experience. He previously headed Genencor's Protein Engineering department, where he invented combinatorial consensus mutagenesis, novel selection methods, and mutator technology. In addition, he initiated and led a collaboration with Seattle Genetics that focused on antibody-enzyme fusion proteins. Prior to his work on bio-

therapeutics, Volker led projects optimizing enzymes for industrial applications as well as microbes for metabolic pathway engineering. Volker received his Ph.D. from Leipzig University in 1986 for studies on protease-catalyzed peptide synthesis. After postdoctoral studies at the Institute for Protein Research in Pushchino (Russia), he moved to the University of Göttingen, where he developed a novel method for the production of peptides from recombinant peptide-multimers. After postdoctoral work with Bill Rutter at the University of California, San Francisco, he joined Genencor in 1994. Volker is the author of over 40 scientific papers and inventor of more than 70 issued or pending patent applications. He is also the recipient of the Karl Lohman award from the German Society of Biochemists.

About Amunix, Inc.:

Amunix was founded in 2006 by Willem 'Pim' Stemmer and Volker Schellenberger. The company now has 30 employees, a dedicated in-house patent attorney, and over 12,000 square feet of research labs. Our primary focus continues to be the design and preclinical development of protein pharmaceuticals with extended serum half-lives. Our central platform is XTEN, a hydrophilic, unstructured polypeptide that imparts a number of favorable properties to the molecules to which it has been attached. By conjugating existing, clinically tested drugs to XTEN through a process called XTENylation, we are able to generate improved versions of these products, or "biosuperiors". Besides the advantages of a lower

dosing frequency, XTENylation stabilizes plasma drug concentrations, minimizing toxicity and improving efficacy.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine**

CEOCFO: Dr. Schellenberger, would you tell us the concept for Amunix?

Dr. Schellenberger: Our company is based on the generation of biopharmaceuticals with extended half-life. We developed a polymer, which we call XTEN, which is added to other biopharmaceuticals to prolong their activities in the body circulation. This is geared for injectable pharmaceuticals. Of course, patients do not appreciate frequent injections. Products with long serum half-life is very critical for achieving patient compliance and providing convenience, and in many cases, even just for reaching sufficient drug exposure.

CEOCFO: Is what you have developed a totally new concept? Is it something that is better? How does it differ from what might have already been available?

Dr. Schellenberger: XTEN was certainly inspired by existing technology. People used to conjugate a chemical polymer called polyethylene glycol (PEG) to pharmaceuticals that have been very successful, and many resulting products are on the market. But polyethylene glycol (PEG) has many disadvantages. It is a non-biodegradable, chemical polymer, and there are significant safety concerns related to its use. Amunix has developed a recombinant protein that mim-

ics the properties of polyethylene glycol (PEG) but is biodegradable and has a precisely controlled chemical structure.

CEO CFO: Where are you in the process of development, commercialization, partnering; what is happening now?

Dr. Schellenberger: We have out-licensed two of our products, which our partners have taken successfully into clinical trials. The products are based on our technology, and the Phase 1 trials have been published and were very successful. In addition to those, we have a number of collaborations, mostly with leading, top-tier pharmaceutical companies, ongoing for application of our technology to their internal products.

CEO CFO: What are the differences between the two products that you have out-licensed? What were you able to do with the platform you have developed?

Dr. Schellenberger: These are two different pharmaceuticals. One is human growth hormone, also known as VRS-317, which is normally injected daily. After applying our XTEN technology to that product, it will now be administered monthly. The other is VRS-859, a product for type 2 diabetes. Again, the product we are replacing currently requires injection twice daily, whereas the product we are working on will have a significantly longer half-life—it is going to be somewhere between weekly and monthly dosing intervals.

CEO CFO: That will really go quite far; certainly with the treatment of diabetes! How do you pick what you would like to work on first, or is it what your partners are asking for?

Dr. Schellenberger: Our partners are a driving force because Amunix is a relatively small company. We have about thirty people focused on our core technology. We selected and kept a few applications that are suitable for us. Most applications of XTEN are driven by a partner with more experience in any of the specific therapeutic areas.

CEO CFO: You have out-licensed, so you are working in different manners with companies. Is it strictly opportunistic? Is there a particular plan you have for how you partner?

Dr. Schellenberger: Yes, we have two fundamentally different formats as part of our business model. We are generating pharmaceuticals that are called “biosuperiors”. You take existing drugs that are already approved by the FDA for therapeutic use, add XTEN to them, and therefore improve them. In this case, actually, the biology is already very well understood. Our first two products, VRS-859 and VRS-317, were in that category. Amunix developed these molecules and then started spinout companies, Versartis and Diartis, to take them forward. The other category of product we are pursuing is much more partner-driven. We have participated in many industry conferences where we demonstrated our XTEN technology. Such meetings helped to identify opportunities that will allow us to combine the partner’s knowledge of biol-

“We envision XTEN to become the premier solution for biopharmaceuticals that require a long half-life.”

- Volker Schellenberger, Ph.D.

ogy with Amunix’s knowledge of our XTEN platform to together develop a new product.

CEO CFO: What is in the pipeline that is not being worked on front and center today?

Dr. Schellenberger: We actually have a very exciting direction we are taking for oncology. We are applying XTEN to specifically deliver cancer drugs into tumor cells. In this platform, we take advantage of the fact that the chemical structure of XTEN can be better controlled than with existing technologies.

CEO CFO: What is it that makes it more controllable?

Dr. Schellenberger: It is our unique manufacturing process. We produce XTEN in bacterial cells with very high precision. All the alternative platforms I know are based on chemical polymers, which are produced by random polymerization and result in mixtures,

or they are based on antibodies, which are produced in cell culture and have to be further modified, also resulting in product mixtures.

CEO CFO: Is there much research to your knowledge in the general area you are working in; any competitive ideas that you think are interesting?

Dr. Schellenberger: This area is very competitive. There is undoubtedly a great need out there for making better biopharmaceuticals, and many of them can benefit from longer half-life. There are clearly a number of competing technologies. There is not a one-size-fits-all solution, but we feel that the XTEN platform really offers a unique combination of benefits that positions it for capturing a large slice of that market. We actually have the best combination of properties.

CEO CFO: Are you in a financial position to continue the way you would like, or will you be seeking funding at some point?

Dr. Schellenberger: Amunix is actually very unusual. It was financed by the two founders, and from the beginning we were able to generate enough revenue from partnering deals and government grants that we never needed to seek outside funding. Amunix is now seven years old, employs thirty people, and has never received venture capital. As you probably know, a company of our size typically would spend millions of dollars a year of someone else’s money.

CEO CFO: You have a long history in the industry. What have you learned that is most helpful at Amunix?

Dr. Schellenberger: I headed the protein engineering department at Genencor International, which gave me great exposure to applying protein engineering technologies to a wide range of different biological problems. Then, I was fortunate enough to help Genencor start an initiative into oncology indications. We set up the collaboration with Seattle Genetics, and I got exposure to their targeted cancer drug programs. These experiences enabled me to come up with the concept of XTEN and ultimately start

Amunix together with Pim Stemmer, the co-founder.

CEO CFO: What is ahead?

Dr. Schellenberger: We envision XTEN to become the premier solution for biopharmaceuticals that require a long half-life. There are over fifty molecules in clinical trials based on polyethylene glycol (PEG), the old

technology, and we would like to replace most of them with XTEN.

CEO CFO: We speak with many drug development companies. Why should investors and people in business and healthcare communities be paying attention to Amunix?

Dr. Schellenberger: What sets us apart is that we have a product platform that enables very, very rapid

discovery of biopharmaceuticals. That is normally a very expensive process. Although we are a small company, we have two pharmaceuticals in trials, and are working with a very large number of top-tier biologic manufacturers and applying our technology to their pipelines. As far as a company of our size, I would certainly call us unique.



Amunix, Inc.

**500 Ellis Street
Mountain View, CA 94043
650-428-1800
www.amunix.com**