

Phoreus Biotech – Revolutionizing Drug Delivery with Their Technology That Uses Protein Nanoparticles to Encapsulate or Carry Drugs to Into Tissues and Hard to Reach Places



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CEO CFO: *Mr. Schaefer, looking at the Phoreus Biotech website, the first thing I see is "Bringing Precision and Equity to Pharmaceuticals." What is your vision?*

Mr. Schaefer: We have the technology that helps take drugs to places that are hard to get to and deliver them without a needle. Simple speaking, we take these protein nanoparticles and they can either carry the drugs or encapsulate the drugs. Because of the nature of the particles they can get into tissues and places that are hard to get. A good example would be they can get through the

mucous layer of the lung which is hard to get medicines through and it gets to the underlying tissues which is very important for people with Cystic Fibrosis.

Another examples is we can encapsulate drugs that are normally injected by needle or infusion like insulin or GLPs. GLPs are a class of drugs developed for diabetes and now used in weight-loss. We can deliver them in a pill, nasally, inhaled, or transdermal. Basically, they are small enough to transit right through the tissues. That also means that medicines that are hard to distribute because they may need refrigeration, special transport, or injected, can be a provided much easier. That can be a big deal if you have trouble doing the injections, affording the medicine, or even getting it to places that do not have good refrigeration. That is how it all fits together.

CEO CFO: *What makes an area hard to get to and how do you break through the barrier?*

Mr. Schaefer: They have had different types of drug delivery technologies over the years. You are familiar with transdermal patches and things like that. Generally you come up with chemistries or compounds that are either synthesized or foreign to the body and the body has the senses for that, or you come up with stuff that is found in the body, but the delivery method is not as natural. That has been the challenge, so you are trying to find stuff that is biocompatible. We are using a small peptide that is found in the heart muscle, and because of that the body sees that it is friendly and lets it in. We take those small peptides and assemble these little nanoparticles, so it's able to get to places the other stuff cannot.

CEO CFO: *Where are you today in the development process of the technology?*

Mr. Schaefer: The technology was discovered at CalTech, and then further developed at Kansas State University. That took about 15 years and then they spun that technology out to be commercialized. At that point you are trying to test the

technology with different targets. We have worked on vaccines, Cystic Fibrosis, genetic therapies, cancer drugs, peptides (Insulin and GLPs), and many different compounds and many different applications.

To date, we have done proof of principal in several of these areas, and we are now collaborating with university and pharmaceutical investigators to go to the next step, which would be to do the thorough animal and toxicology testing that needs to occur before they can be tested in humans.

CEO CFO: *Have you decided what seems the most promising yet or are you still in the stage where everything looks potentially good?*

Mr. Schaefer: That is a very good question. Many people use the phrase, "Platform Technology," which means that you can do lots of different things. For example, the other day we had someone approach us and said they were looking for an application for the Army, where they would try to encapsulate antibiotics and give that in the lung. We have a lot of these possibilities, which makes your question very relevant.

We have two focus areas, and they are mostly to demonstrate the capabilities, but also the commercial potential. The first is Cystic Fibrosis and COPD, because it is proving the carriers can get to places that others cannot. We are unique in our ability to transit the mucus layer in the lung where other carriers 'get stuck.' Our goal is to enable a gene therapy technology that would then cure Cystic Fibrosis, which is a big deal.

The second area we are focused on is peptides, such as Insulin and GLPs, which are very similar types of peptides. The challenge right now for Insulin is delivering it to patients in a way that is easy to manage. Many diabetes patients have complications and ongoing health issues because they cannot keep their blood glucose under control, and we believe that having a simple administered oral product would make that easier. Getting rid of needles is great for patient comfort, but it is really a game changer when it comes to patient adherence.

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CEO CFO: *Does the fact that GLPs, with an injector pen using small needles is somewhat easy to use, lessen your interest in pursuing that arena?*

Mr. Schaefer: For one thing, there are patients that still have a lot of problems doing those injections, even with the injector pens. There are also children that have been doing injections for other medicines from the time they were babies. With larger doses, they are putting pockets of stuff into their sides, not the small volumes that you are seeing. There are many different variables, but part of it is the fact that if you have to do a needle and injection like that, there is a great deal of shipping, storage, and additional materials and costs associated as well.

They do have some oral GLPs, but they have to use 400 times as much drug to get the amount into the patient's blood stream, which makes that medicine very expensive and also hard to take. Many of the drugs that are injected on infused, are done that way because you have to in order to keep the body from digesting them. We have created this little protective carrier so that it can be delivered more easily.

Refrigeration is also a big thing. When you think about access, we are in a first world country with lots of supply chain and refrigeration and things can be delivered right to the patient's door. However, that is not true everywhere and especially not true for Insulin.

CEO CFO: *Does geographic location make a difference?*

Mr. Schaefer: Yes. They can deliver iron orally, but it is a terrible product to take orally because it messes up your insides, so half of the people that get oral iron cannot tolerate it, so they have to go to the hospital and get infusions. However, there are many places in the world where going to the hospital for an infusion is just not an option. Therefore, we are working with some pharmaceutical companies, especially in Latin America and Asia, that are really excited about having a product that would deliver iron, for especially women's health and anemia, without having to use a needle.

CEO CFO: *What have you learned from the early testing that surprised you?*

Mr. Schaefer: With medicine, when they start using it for one thing, they find that it may be useful for something else or it may have side effects. For example, there is a lot of discussion now about what happened with the Covid-19 vaccines because they used a carrier that was made of lipid nanoparticles, which were not meant to be put into the human body, so when you put it into your arm, you are getting an immediate immune response. For some people that was soreness or a rash, and for some people it was a big deal with a lot of complications.

We are developing this carrier now that is being looked at for vaccines because it does not have any of those side effects. It is essentially a natural compound, so the human body is happy with it. In fact, we knew that it was going to be immune friendly because it is a protein. What we didn't realize was that when we started working with certain vaccines, we were not going to get the same effectiveness that the other versions were getting, which was a surprise because we were delivering the same stuff. However, those other delivery methods, because they stimulate the immune system, and ours did not, we realized that was missing. Therefore, realized that if we delivered a vaccine that needs that boost to the immune system, we would have to add an adjuvant, which is basically an enhancer. However, you can pick your adjuvant that will stimulate the immune system in a positive way. That was the surprise.

Another surprise was when they took a mouse's tail, dipped it in the solution and boom, it went into the blood. It felt like a miracle. They do transdermal for things like nicotine, but those are small molecules that are bathing your whole system. However, we are talking about going into the blood stream with something that is a complex molecule.

CEOFCO: *Where are you with funding today?*

Mr. Schaefer: We have done two Seed Round and raised just under \$4 million. We have a very strong group of private and angel investors, so we are at that state where we are trying to raise money for a Series A. In the Biotech world right now that is very hard to find. The venture capital companies have big chunks of cash, but they are not investing in lots of small companies with little investments. What they are doing is fewer investments, just bigger. That means there are thousands of companies out there looking for funding and it is very hard to get their attention and get them to put the time in to analyze what we have.

CEOFCO: *How do you get around that?*

Mr. Schaefer: We do have a short cut, which is that if we have good enough data, we will be able to sit down with pharmaceutical partners and license it to them directly. Instead of raising a lot of money and creating a pharmaceutical company, our plan is to do animal testing and verification, in vitro and in vivo, to prove it is working. Then if we can prove to them, we can deliver these medicines in the way we are talking about, that would be such a big commercial value to them that they would step up and license stuff early.

CEOFCO: *What has been the response from the medical community?*

Mr. Schaefer: We are working with Dr. Matthias A Salathe, and Dr. Michal Kim. over at University of Kansas Medical Center. Their passion is research in Cystic Fibrosis and lung health, and when they saw the first data of particles going through the lung, they were really excited. That is what I use as verification that we are on target, because Dr. Salathe is someone that not only sits in the research world, but he sees patients, so he is not going to spend time with me and our company unless he thinks we have something of potential value.

Another example on the GLPs we are working with, Dr. Matt Hayes, over at the University of Pennsylvania Medical Center and Dr. John Thyfault at University of Kansas Medical Center, who are experts in Insulin and GLPs and especially metabolic diseases and emesis (throwing up). About 20 or 30% of the patients taking GLPs get very nauseous; in fact, they cannot tolerate the medicine. Therefore, Dr. Hayes with working on cutting edge ideas on how to make it more tolerable for that issue,, Working with leading research clinicians like them is very exciting.

CEOFCO: *You have a long history in this arena; what has been most helpful with Phoreus Biotech?*

Mr. Schaefer: Earlier in my career I worked in some exciting areas scientifically that were in very dramatic clinically. I was involved with the first resistance testing for HIV. There are lots of new technologies and people trying to come up with new things, but finding people that have the resources, whether it is investors or companies; people that have and can deploy the resources to get things done. It is about finding people that get it and understand the connection between, developing it, deploying it and how that creates value for patients. There are so many people in research and

science at pharmaceutical companies that have their heads down, working in their labs and on widgets. However, they are disconnected from the patient community.

Years ago, I worked at a Top 10 pharmaceutical company, where I was in corporate planning. I worked in one day and asked the Executive Assistant if she knew what we did there, and she said, "No, not really." I realized this \$10 billion plus company making all these products for patients and they had no idea how that impacted people's lives. Finding people that understand science and how it impacts patient care is a big deal. If you can find those people, they are the ones that will give you the resources to make things happen.