CEO CFO

Sangart

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With Two Products now in the Clinic for Underserved Large Markets in MP4CO and Sickle Cell Anemia, Sangart is Well Positioned for Future Growth

Healthcare
Biopharmaceutical
(Private)

Sangart

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Brian O'Callaghan
President and CEO

BIO:
Mr. O'Callaghan joined Sangart as President and Chief Executive Officer in June 2008. Mr. O'Callaghan brings a breadth of experience to Sangart, having held senior positions with a number of pharmaceutical and biotechnology companies in both Europe and the US. These include senior positions with Pfizer in the UK and Merck Serono in Germany, before becoming President and CEO of BioPartners, a Swiss based biotechnology company. Since relocating to the US, Mr. O'Callaghan has held senior management positions at Novartis, where he served as General Manager of their Transplantation, Immunology and Infectious Disease businesses, as well as at Covance, a clinical research firm, where he served as General Manager of their Cardiac safety and IVRS businesses. Mr. O'Callaghan joins Sangart from NPS Pharmaceuticals, where he served as Chief Commercial Officer. Mr. O'Callaghan brings his extensive general management background in the pharmaceutical, biotechnology and clinical research sectors, as well as his significant international experience, to lead Sangart through regulatory submission and commercial launch of MP4.

Company Profile:
Sangart is a global biopharmaceutical company dedicated to developing and commercializing targeted ischemic rescue therapies for patients in acute crisis. Sangart's therapies are designed to help patients with medical conditions that cause ischemia, such as hemorrhagic shock and sickle cell disease.

Sangart was founded in 1998 in San Diego, California to develop biopharmaceutical products based on a novel understanding of the mechanisms of oxygen transport. Sangart's research effort was initiated by its founder, Dr. Robert Winslow, and its key scientist, Dr. Kim Vandegriff. This extensive research includes over twenty years of publicly-supported studies conducted prior to Sangart's formation at the Letterman Army Institute of Research and University of California, San Diego into the mechanisms of oxygen transport by cell-free hemoglobin solutions. The discoveries arising from this research have been patented and published in numerous scientific articles and form the basis for Sangart's technologies.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. O'Callaghan, what is the focus at Sangart?
Mr. O'Callaghan: The focus of Sangart is to develop innovative and potentially life-saving therapies for areas that currently have unmet medical needs. The two areas that we are focusing on right now are trauma and sickle cell anemia.

CEOCFO: Why have you chosen trauma and sickle cell anemia?
Mr. O'Callaghan: It comes from looking at the properties of the technology platform that we have developed. We developed a technology platform that is called MP4, which stands for pegylated hemoglobin. What this does effectively is transport gasses to targeted areas of the anatomy. With trauma, what we found was that our platform can transport oxygen very effectively in the case of hemorrhagic shock. Therefore, when someone experiences severe blood loss – for example, due to a traumatic event which causes tissues or organs to go into oxygen debt – we found that our compound can take oxygen and transport it very effectively to those areas which are in a very critical and time sensitive situation. With sickle cell anemia, we found that MP4 can transport very effectively minute quantities of carbon monoxide which in the treatment of sickle cell anemia has proven to have an anti-

inflammatory and anti-sickling effect and prevent apoptosis. This again is an area of high unmet medical need, and in fact we have orphan drug status for that program.

CEOCFO: How does your platform work differently than what is currently available today?

Mr. O'Callaghan: There really isn't anything currently available today that does this. In laymen's terms, hemoglobin is used to transport oxygen to tissues and organs in the body. Through our technology, we initiate a chemical reaction process -- mainly the application of polyethylene glycol which is a pegylation of the hemoglobin. We have found that we are able to transport oxygen deep into the capillaries, which avoids premature offloading of the oxygen once it enters the body. It binds very effectively with the oxygen and holds it until it gets deep into the capillaries where the oxygen debt occurs due to the hemorrhagic shock and traumatic event. The same with the carbon monoxide. Again via process of pegylation and other chemical reactions, we are able to bind it very effectively with carbon monoxide, which means that it offloads very effectively where the carbon monoxide is required to hopefully undo a sickle crisis via anti-inflammation and anti-sickling effect. It will then deliver oxygen, because once the MP4 offloads carbon monoxide and passes through the lungs, it becomes oxygenated and becomes MP4OX. Having picked up oxygen in the lungs, it can transport and transfer oxygen to ischemic tissue, which is also very effective in the treatment of a sickle cell crisis.

CEOCFO: Are there any potential side-effects that you have seen so far?

Mr. O'Callaghan: As with all effective compounds, it has adverse event profile. With ours, nothing has caused any concern for the patient profiles we are looking at, which are very high-risk patients. Our patients usually present with trauma, where risk of death is imminent, and in the case of sickle cell anemia, patients tend to die young. The adverse event profiles we have seen has not caused any concerns to the drug safety monitoring boards. We have seen little or none of the vasoconstriction of previous compounds that were developed. That was the big adverse event that was seen with previous compounds. Ours doesn't seem to demonstrate that at all. Therefore, there is a relatively low-risk profile in the patient populations that we are looking at.

CEOCFO: Where are you in the development process?

Mr. O'Callaghan: With the trauma program, we are actually very well advanced. We are coming to the end of a Phase IIb study which is a three hundred and sixty patient study. This study will either lead us into Phase III, where we will be running two Phase III studies as is normal. Or if the data is powerful enough out of the Phase IIb study, we may only have to run one Phase III study. Therefore, we are approaching the last stage of clinical development with the trauma program that is MP40X. With sickle cell anemia as an earlier stage study, we are in Phase I with a Phase Ib study. We are about half way through that study also. However, that study morphs seamlessly into a Phase IIb study. Therefore, this program is going to progress much faster than the trauma program and has orphan drug status, so obviously receives a lot of support from the regulatory authorities. Both programs are in the clinic and in patients. It is in Phase IIb in the case of trauma and Phase Ib in the case of sickle cell.

Four years ago when I came on board we were a single product, single formulation, single-indication company. Now we have two products that are seen as separate by the regulatory authorities both in the clinic and both looking at unserved markets with follow-on products coming through. The MP4CO market, or the sickle cell anemia market, is somewhere around a billion dollar market, making it a very attractive market. - Brian O'Callaghan

CEOCFO: You recently added to your management team. Why the need now?

Mr. O'Callaghan: We had been about a year without a head of regulatory. We had gone through our Phase IIa study, our head of regulatory had moved on, and we decided to go about a year without a head of regulatory. We had a second in command who was able to carry us through in terms of regulatory needs. We were about to enter the Phase IIb program which meant that we really wanted to re-engage with regulatory authorities. Therefore, we hired Carmen Betancourt, who was our new head of regulatory as she started at the beginning of this year. With the trauma program there is some unchartered regulatory pathways that are going to have to be navigated. We needed some blue-chip regulatory experience brought into the company to help us. Carmen is somebody very experienced who we felt had very relevant experience to what we need. At the same time our chief medical officer, who was based on the east coast, had decided that he wanted to work for an east coast based company. His work was done basically in terms of setting us on a strategic path which he had done very effectively. Therefore, he was replaced by his number-two, Dr. Frank Booth, therefore, we had a seamless succession plan in place, Dr. Booth just stepped up in his place and the company didn't miss a beat. We moved very efficiently from Phase IIa to Phase IIb. The third position you are referring to is literally new leadership. This is where we were moving from running relatively small studies like Phase I and II into very large pivotal programs. The Phase IIb and Phase III, which are large multinational pivotal programs where currently, for example, in the Phase IIb, we are in fifteen countries in about fifty sites. Clinical operations needed to become a core competency within the company and not just part of the clinical departments where they handle this as well as the clinical strategy and study designs. We therefore spun clinical operations out of clinical and it became a department of its own. It needed blue chip experienced leadership. Therefore, we brought in Mary Rose Keller who has a vast amount of

experience in running large sophisticated multinational clinical trials. Those are the three areas of new leadership in the company in the background siege area. As a result we now again have a full executive team which in the area we are in I believe is world-class and are operating very effectively.

CEOCFO: Sangart has done a recent funding when funding is very hard to come by. How have you managed to do that?

Mr. O'Callaghan: Well, we are very lucky. Sangart is backed by a group of investors that in total are about a hundred investors. However, the reality is that one investor has diluted almost everybody else out of the equation and that is a group called Leucadia. They are a New York based diverse holding company with investments in many areas. We are their only life science investments as far as I know. They have been with the company for seven or eight years now. They are very different from the normal life science investors that you tend to come across. First of all, they have been there for seven or eight years. They do not have the typical three to five year exit plan approach. In fact when it comes to "exit plan", they do not usually have a defining of the plan, they more or less leave that evolved through the developing of the company and the recommendation of the management team. They are very strong when it comes to the ability to invest being very cash rich. As a result, they have actually insulated us from much of the global economic implosion that has occurred over the last three to four years that has caused Life Science Investments to dry out. Last year we did a $100 million inside round with Leucadia. The first $50 million was upfront and we got that last year. The second $50 million was to be due on positive interim analysis from the Phase IIb trauma study, which we received last month. Having received that positive interim analysis, we qualified for the second $50 million, which was the second half of that round. Therefore, we received a full $100 million.

CEOCFO: You must have many envious colleagues!

Mr. O'Callaghan: I assure you, we don't take it for granted. I attend a lot of conferences here in New York and I speak at some of them. I have shared the podium very recently with very innovative companies who have great technologies and would be an easier sell to investors than we are, for example, and they struggle to raise money, and we do not. I understand the situation we are in and do not take it for granted at all and say we are blessed to have Leucadia.

CEOCFO: Why should investors pay attention today to Sangart?

Mr. O'Callaghan: The main reason for paying attention to us right now is first and foremost, we are looking at markets that are vast and unserved. The trauma market for example, is a far bigger market than oncology and cardiovascular combined in terms of the amount of people that die and go relatively untreated. We believe that the portion of the trauma market that is relevant to our product, such as those that are in oxygen debt, is about a $6 billion market and that is primarily just Europe and US. Even with conservative estimates of market penetration, we are looking at a blockbuster product here that has a market that could easily achieve $1 to $2 billion peak sales in a relatively short period of time with a total market of $6 billion. The second reason to pay attention to us is that we are the only product of this kind that is close to market. There are no competitors behind us, at least within sight. There is some very early stage stuff going on, but a long way behind us. Therefore, if we do enter the market on time, we will have a dominant position in that market. Another reason to look at us is that we do have follow-on products currently in development. We do have a lot of IP protection surrounding the compounds that I have been describing. However, we already have follow-on compounds coming through. In terms of life cycle management, we are well positioned there also. The second fundamental reason is that we are not just based on one market and one product. We are currently based on two, with the MP4CO product looking at sickle cell anemia. Four years ago when I came on board we were a single product, single formulation, single-indication company. Now we have two products that are seen as separate by the regulatory authorities both in the clinic and both looking at unserved markets with follow-on products coming through. The MP4CO market, or the sickle cell anemia market, is somewhere around a billion dollar market, making it a very attractive market. Other reasons relating to bold markets are the margins are extremely high. Therefore, it is a very profitable market to be in as well. Finally, the fact that we are at such late-stage development, there are not many private biotech companies that have reached Phase IIb, which have generated such positive data in such large quantities, because we have in excess of a thousand patients now in our clinical trials. Additionally, large pharma companies are out there looking to fill their pipelines and some of the vacuums that are emerging within their pipelines and looking for large products with low competition and high margins that are in late-stage developments. We tick all those boxes and on top of that, low or zero competition. Many of these companies are looking for specific therapies that are very selective and have achieved orphan drug status. We have that too. Therefore, there are many reasons to be looking at Sangart right now. Finally, they should be looking at us because we are not a desperate biotech company. We are well funded. We can take ourselves through the clinical development program. Therefore, they know that we are not cutting corners. We are doing the job right. At the stage they would be coming in at, which you would assume the earliest that would be would be next year, they would be looking at positive Phase IIb in the case of MP4OX and Phase Ib in the case of sickle cell. We have gotten through a large part of the risk-associated areas of product development.

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