CEOCFO Interviews & News!

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The Acquisition Of CellGate Has Enabled Progen To Leverage Skills And Capabilities In The United States As Well As Australia

Healthcare
Biotechnology
(PGLA-NASDAQ, PGL-ASX)

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T. Justus Homburg
Chief Executive Officer

BIO:
Justus Homburg has an international career working in the pharmaceutical and life sciences industries in the US, Australia, Europe and Asia. His experience ranges from the multi-national biotechnology giant Monsanto Company through to start up organisations such as Chirogen. Justus spent more than a decade at Monsanto Company (1990-2001). During his senior management time with Monsanto he focused on new technology and new business commercialization, technology in and out-licensing, mergers and acquisitions, joint ventures, capital raisings, and the development of international markets. His roles included Regional Business Management (Monsanto Chemicals), Division Management (Growth Enterprises), and Strategic Planning (Monsanto Agricultural Products). In the pharmaceutical sector, his roles in the New Business Development included the creation of NSC Technologies and the Pharmaceutical Services Division. Most recently, Justus was the Managing Director and CEO of Chirogen Pty Ltd (2002-2006), an Australian start-up company established in 2000 to develop chiral chemical manufacturing technology for applications in the pharmaceutical and specialty chemicals industries. Justus has strong analytical and managerial skills, and a leadership style driven by customer focus, innovation, and a strong collaborative approach that fosters the development of top-performing organizations. Justus holds an MBA from the University of Washington. Prior to his business career, Justus held a faculty position at The University of Michigan and was a Fulbright Scholar. He holds degrees from Iowa State University, Southern Illinois University, and The University of Utrecht.

Company Profile:
Progen Pharmaceuticals Limited (NASDAQ:PGLA; ASX: PGL) is a globally focused biotechnology company committed to improving patient outcomes through discovery and development of small molecule-based cancer therapeutics.

Progen targets the multiple mechanisms of cancer across its three technology platforms, angiogenesis, epigenetics and cell proliferation.

Angiogenesis
The company's researchers and collaborators have a deep understanding of the role of heparan sulfate, a complex sugar, in cancer disease processes in particular, angiogenesis. PI-88, which is currently in Phase 3 clinical trials, is our first product from this research focus. A second product, PG545, shows promising preclinical anti-tumor activity and is currently being developed. At an early stage of discovery, Progen has a program to design small molecule inhibitors of heparanase which is the enzyme which is responsible for breaking down heparan sulfate in the body. This enzyme plays an important role in angiogenesis and its inhibition is important to the halting of cancer progression.

Cell Proliferation
Progen has brought into its clinical development pipeline a novel phase 1 clinical candidate. PG11047 is a polyamine analogue that competes with natural polyamines. Polyamine metabolism is dysregulated in cancers. Treatment with PG11047 results in alterations to the natural cascade of events involved in cell division and can induce cell death in tumors. This mechanism is unique, although it has been the focus of considerable scientific interest for many years, and if PG11047 is successful it has the potential to provide a first-in-class oncology product

To date, PG11047 has been shown to have anti-tumor activity in animal models, combined with a good safety profile. Progen is taking PG11047 through early clinical development in parallel to con-

ducting additional translational studies to determine the most promising indications for PG11047.

Epigenetics

Progen has brought together an outstanding platform of new epigenetics assets in preclinical and discovery stages of development. Epigenetics is a new area of gene expression research focused on the modulation of the expression of genes, and in particular those associated with cancer. This process is mediated by enzymes such as Histones Deacethylases (HDACs) and Lysine Specific Demethylase (LSD1). Many of Progen's polyamine platform products have demonstrated that they can inhibit HDAC and LSD1, leading to re-expression of 'silenced' tumor suppressor genes. This in turn has been demonstrated to lead to inhibition of tumor growth in a number of pre-clinical studies. Progen is working actively to determine which of these product series has the best commercial profile for further development and is moving these assets towards clinical development.

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

CEOCFO: Mr. Homburg, how has Progen changed under your direction?

Mr. Homburg: "I joined Progen about two-and-a-half years ago in early 2006. We focused on creating an infrastructure around strong and accelerated critical path projects planning approaches to new compounds and actually the compounds that we already had in development. The other aspect that we really wanted to accomplish was an expansion of our portfolio technologies. Those were two key things that we set out to accomplish and we are pleased to say that we have accomplished both of these in the past couple of years. We have expanded our portfolio of compounds dramatically through the acquisition of a private US based oncology company, Cellgate and we have changed our company culture to embrace critical path project planning so that we can ensure we take the right compounds forward for the right reasons."

CEOCFO: You are working on oncology; what is the common thread of the technologies and projects you are working on?

Mr. Homburg: "No doubt the common thread would have to be our commercial mindset combined with an extraordinary group of capabilities through the people that we have in our team. Something that is quite unique about Progen in the sense that we started life as a biopharmaceutical manufacturing operation contract manufacturing organization. We know manufacturing well; it is a core capability and it is one that we had for a long time. This commercial backbone to the Company has been instrumental in us being able to very effectively and efficiently move our lead compound PI-88 from preclinical through to Phase III clinical development. In the last seven-eight years, we have also developed core capabilities in clinical results, with a team of staff. We are unusual in the sense that not only do we have discovery group, and medicinal chemistry; we have pre-clinical development capabilities, clinical development capabilities and manufacturing. In terms of having core capabilities that help you to drive products forward it is pretty remarkable to have all of these capabilities in an organization that is small with fifty people."

CEOCFO: Are the challenges of manufacturing something that most development companies do not think of? What are the unique problems that you are able to address early on?

Mr. Homburg: "Manufacturability is always going to be an issue. In my previous work I spent a lot of time thinking of manufacturing issues, and having high-speed chemistry capabilities that are linked-up with scale-up manufacturing skills is extremely important. One of the reasons that Seril was able to take a compound like Celebrex from first-lead compound identification to commercialization in a record 39 months is the ability to understand all of the elements that are relevant to getting a product into the market place from the very start, so issues of manufacturability, issues of clinical developments at late stages, regulatory affairs, market positioning were all addressed at the time that the first lead compound had been identified. There is the ability to think about where we are going to make this, how we are going to make this, is it something that we can get through the registration process, what are the implications in terms of delivery. These are all very critical issues. The last thing you want to end up in is the situation where you are getting ready to go in the Phase II and say, 'Alright we now need ten kilos of material; where and how are we going to get it made?' Then someone says that it is a 40 step chemical synthesis and then you realize that it is going to take a year and a half get it made and it is going to cost us millions of dollars, and all of a sudden your entire program is falling apart because you hadn't thought about issues of manufacturability at the stage of development where these things can be changed. I use manufacturability as an example and not as a always-critical element in everything that you do in any compound development because there are many issues, there are issues of registration, issues of competitive environments, ethics in clinical developments, there are a whole range of issues all of which need to be considered very early on. We use critical path project planning to ensure that we understand what the issues are and address them at the appropriate time."

CEOCFO: Please, tell us about your lead compounds, and what is different about them?

Mr. Homburg: "Progen has three core technology platforms, and each one of those core platforms has categories within which there are different groups of compounds that have different applications. We call our first platform our angiogenesis platform and the lead compound in this platform is in Phase III development at the moment and that is all based on the principle of interacting with two processes in cancer that are very important and one is new blood vessel formation (angiogenesis) and the other is metastasis or the spread of cancer. It is interesting that one compound should have both of those particular characteristics, that there is a common element that cancer cells use to trigger new blood vessels to form so that tumors can grow and get access to the nutrition and grow, and the process of metastasis. There is an enzyme that is common to both of those processes and our lead compound, PI-88 as well as some other technologies in that overall

chemical category have an impact on and that enzyme is called heparanase.

The second platform that we have is focused on cell proliferation. We have a a polyamine analog that targets hyper-proliferating cells and bind to nucleic acids and other intracellular sites currently in Phase 1 development. Treatment with these compounds results in cessation of the natural cascade of events involved in cell division and can induce cell death..

Our third platform is the one in earliest development but the one that we are probably most excited about, this is epigenetics. We have a new class of compounds that we have found can reactivate genes that normally suppress cancer and are deactivated in cancer-triggering processes. This biological process is called epigenetics. We are now extending these studies to animal cancer models to determine if we can inhibit the growth of tumors.

CEOCFO: Do you see partnerships down the line?
Mr. Homburg: "We definitely see partnerships, absolutely. We now have a portfolio of compounds and technologies that are so large that that it would be remarkable if we could take any significant number of them all the way through. Our focus is very much on how do we develop those core technologies to a point where co-development or straight out-licensing or any kind of combinations are out would make very good sense creating the most value at the appropriate time."

CEOCFO: What is the financial picture like for you today?
Mr. Homburg: "We raised about $99 million Australian over the last eighteen months since December of 2006. Therefore, we are in a strong and sound financial position. We do have a Phase III trial running and they are expensive. However, we have a long standing history of being very cost conscious and always making the notes of what it is we have. We are well-positioned to go and do the things that are real priorities for us, which is to continue on with the Phase III developments of our lead compounds in primarily liver cancer, as well as execute on the Phase I development of that polyamine compound as well as bring forth through pre-clinical development a number of compounds that are in other fields, so key technology platforms."

CEOCFO: Do you see additional acquisitions in the future?
Mr. Homburg: "We will always continue to look at those, absolutely! I think continuing to expand on one's core capabilities and we really see as our core capability and the development of new drugs especially in the oncology area."

CEOCFO: Please tell us about the market opportunity in the areas you are in.
Mr. Homburg: "It is always very difficult to say, especially as one looks at other earlier stage compounds. Obviously, there is a huge need in oncology. As an industry we have made tremendous inroads in treating patients with cancer, and clearly we can do that. It continues to be a very important area in pharmaceuticals to pursue. What is very difficult to assess especially with novel chemistry and novel opportunities that are in the early stages of development is that which particular cancers are most likely to be efficacious and what is competitive environment within which those particular compounds would competes, and what kinds of things you can worry about in terms of clinical development and commercialization. Knowing that something would be efficacious in for example lung cancer or breast cancer or prostate cancer, where there are many, many patients. Those are going to be important commercial opportunities. You also have to look at it from the perspective of where are the areas of need. There are many cancers where we can be involved, but there are other players in the oncology space that are in a position to provide significant benefits to patients. How many patients are there, how long is the treatment, what is the value of the treatment, what is the benefit to patients, all of those things come into play and it is so hard to assess whether or not one is talking about a million-dollar product or a $500 million product. The fact of the matter remains that if you can provide a benefit there is a commercial opportunity there."

CEOCFO: There are many biotech and oncology companies; why should prospective investors pick Progen out of the crowd?
Mr. Homburg: "There are several reasons, and there is a core set of capabilities that underlies what Progen can do and as I have said we have a real strong capability in manufacturing, clinical development and medicinal chemistry. We are no longer a company wrapped around a particular technology that we are trying to drive through any particular process. What we have is several key platforms and within each platform we have a large number of compounds that have different mechanisms of action, each of which will provide an opportunity for solving patient problems and commercialization. So whereas there are many biotechnology companies, most of those end up being really centered around a particular technology that they are pushing forward and generally do so, without me being critical of that I certainly understand that very well and many of these companies will be very successful, but they use a virtual network of outside service providers to drive that compound forward towards the market. We manage a portfolio of new technology with a primary focus on oncology."

CEOCFO: What should people remember most about Progen?
Mr. Homburg: "Through the CellGate acquisition, Progen is well positioned in both Australia as well as the United States and that allows us to leverage

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