CEO CFO

G1 THERAPEUTICS

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G1 Therapeutics, Inc. is well positioned to move their Chemoprotectant Compounds through IND-Enabling Studies and into the Clinic for Protecting Bone Marrow and other Organs including the Kidney and Lung from Toxic Insult

Healthcare
Biotechnology

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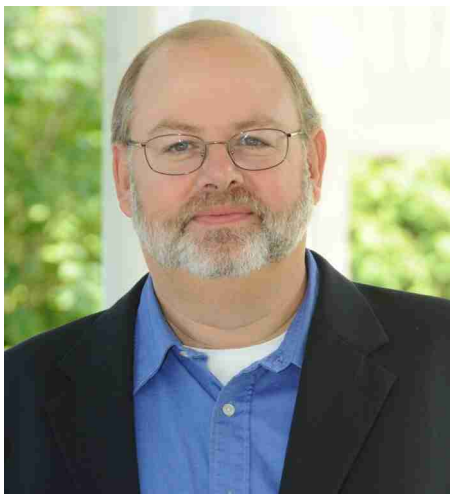

Jay Strum
President

BIO:
Dr. Jay Strum brings more than 17 years of drug discovery experience to G1 Therapeutics. While at GlaxoSmithkline, Dr. Strum led early drug discovery programs in Cancer and Metabolic Diseases, and incorporated the use of human adipose-derived stem cells into the drug discovery process under his leadership. He also played a key role in establishing and driving genomics research at GSK through the creation and management of a transnational gene expression department including a Human tissue repository. Dr. Strum obtained his PhD in Biochemistry from Wake Forest University and received postdoctoral training with Dr. Bob Bell in Molecular Cancer Biology at Duke University and in Molecular Cell Biology at GlaxoWellcome. Dr. Strum has a wide multidisciplinary expertise and has authored over 40 scientific papers, 3 book chapters and is an inventor on 4 patents.

About G1 Therapeutics, Inc.
G1 Therapeutics, Inc. is a privately held pharmaceutical company based in Chapel Hill, NC, that focuses on the discovery and development of novel small molecules for use in cancer therapy and biodefense applications. These molecules are being developed for targeting specific proteins associated with cell proliferation and growth. Such therapies may be useful to protect the bone marrow and other organs, including the kidney and lung from toxic insult.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Strum, what is the basic concept at G1?
Mr. Strum: We were formed out of discoveries at UNC Lineberger Comprehensive Cancer Center where we were studying bone marrow and regeneration of blood cells following damage by chemotherapeutic agents and ionizing radiation. The discovery was based upon the understanding that the enzymes CDK4 and CDK6 control the proliferation of hematopoietic stem and progenitor cells. They are unique compared to most cells in the body in being dependent upon these enzymes for proliferation. What we found was that we could use small molecule inhibitors of these enzymes to transiently arrest these cells in the G1 phase of the cell cycle and during that time it would prevent direct DNA damage to these cells as well as allow cells the opportunity to repair any damage to the DNA before they re-entered the cell cycle and continued proliferating. We termed this Pharmacological Quiescence or "PQ", for short.

CEOCFO: How does PQ prevent what is happening now?
Mr. Strum: When people receive chemotherapeutic agents or they are exposed to ionizing radiation, the dose limiting toxicity is called hematologic toxicity. It is basically these hematopoietic stem and progenitor cells that are really sensitive to DNA damage by radiation and chemotherapeutic agents. What we do, simply, is to protect those cells from DNA damage. By doing so it allows those cells to survive and quickly replenish the blood cells in your body.

CEOCFO: What have you figured out that is able to protect the cells?
Mr. Strum: When you arrest the cells in the G1 phase of the cell cycle, the cells are quiescent and the DNA is in a protected state. The most effective chemotherapeutic agents we have actually work during the S phase of the cell cycle. If the cells are not in the S phase of the cell cycle then those DNA damaging agents do not work on G1 arrested cells. We think that with ionizing radiation there is probably some damage that occurs, but we believe that being in G1 allows

cells time to repair the DNA and then enter back into the cell cycle without DNA damage.

CEOCFO: Where are you in the development process?

Mr. Strum: Right now we are in preclinical development. We have a number of small molecule inhibitors that we are progressing for a couple of different indications. One is for chemoprotection; the way that we envision this working is that when patients come in to receive the chemotherapy it is usually by intravenous fluids and they would receive our chemoprotectant just prior to receiving the chemotherapy. That would protect their blood cell counts. Normally, what happens is that they receive the chemotherapy and almost immediately it kills off many of the blood cells and really damages the hematopoietic stem and progenitor cells and prevents the body from being able to recover very quickly from the chemotherapy. Therefore, patients become anemic because they lose their red blood cells and they become susceptible to infections because they lose neutrophils. There is a drug on the market called Neulasta® and that is a growth factor that "whips" the bone marrow to generate neutrophils. That drug works fairly well but it does not protect from DNA damage, so it's really stimulating cells that sometimes harbor DNA damage. We have an advantage over that approach because we first protect the cells from DNA damage and since we protect the hematpoietic stem and progenitor cells, we also are protecting all four lineages of blood cells. The first compound would be for a chemoprotectant. We also have a biodefense application that the government is interested in because they are looking for medical countermeasures against radiological incidences; things like the Fukushima plant in Japan or terrorists getting hold of radioactive material and dispersing that in a dirty bomb in a metropolitan area or on a military base or a battlefield. Therefore, we are developing that compound as a radiomitigant. We have also discovered that the PQ mechanism protects the kidney from damage during ischemia, platinum containing chemotherapy or with contrast used during kidney imaging. We are working to move the compounds from preclinical to IND-enabling studies. We also have a direct antineoplastic compound as well.

CEOCFO: Has the medical community started to pay attention or is it a bit too early?

Mr. Strum: It is still a little too early, although we are working at publishing papers for each of the indications right now. We have some key collaborators that we are working with and once we get the compounds through the IND-enabling studies and start the clinical trials that will be when most of the medical community will really start paying attention.

CEOCFO: Is G1 Therapeutics funded to get through the next steps?

"We have really been able to create value with the proprietary molecules that we have generated. We are well positioned to take those compounds to create even more value as we move them up through IND-enabling studies and into the clinic." - Jay Strum

Mr. Strum: Right now we have an advanced technology Phase II SBIR. We are just starting the fourth year of that grant. That grant was initially for 3.6 million dollars. That has been really helpful. We have also had a number of small grants and awards and a loan from the North Carolina Biotechnology Center last year that really helped to accelerate our chemistry program. We ended up having to develop our own proprietary small molecule kinase inhibitors and that really took quite a bit of time and money. However, the composition of matter patent is one of the most important parts of our intellectual property. We just recently took some private equity financing from Hatteras Venture Partners here in Research Triangle Park. That has really helped to get us to the next step where we believe we are going to be able to take numerous molecules now into IND-enabling studies. Depending upon the funding of our other grants that we have, we believe that within a year or a year and a half, we will probably have to do another round of funding, maybe a Series A round, where we we'll have to pay for the IND-enabling studies. One other possibility is a partnership with pharma. We are in discussions with a couple of large pharma about partnerships and one of those may work out to support one of our indications and one of our compounds. That is where we are in terms of funding right now.

CEOCFO: Drug development is a long process; what do you see as the timetable?

Mr. Strum: Yes, it is very difficult. The best that we could estimate right now is that in less than two years we will have our first molecule in Phase I clinical trials. We may have to take some of the indications and compounds through a Phase II proof of concept before that is passed off to a pharma partner for further development. However, we think that that is probably going to be in the three to four year range from now.

CEOCFO: Do you see partnerships or is it to early to talk about commercialization?

Mr. Strum: I had spent fifteen years at Glaxo and during that time we were very focused on our in house research and development. However, the strategy has sort of changed for them and other large pharmas over the past few years. It is really more about balancing research that is done outside of big pharma and being able to "cherry pick" some of the best opportunities and then develop and commercialize those themselves. I think that given the environment is such that it is going to be much more difficult for a small company like ourselves to be able to take a compound all the way up through product development and commercialization. I think it is more likely that it is going to be passed off to a big pharma partner. They are very good at commercializing products and doing the registration trials that are very expensive, so I suspect it will end up playing out that way.

CEOCFO: We speak with many companies in your industry. Why should G1 stand out?

Mr. Strum: G1 stands out for several reasons. We've been very efficient at creating value up to this point. We are a team of people that have both academic and medical experience as well as pharmaceutical experience. Our co-founders are very well known in the scientific and medical fields. There is Dr. Kwok-kin Wong who is scientific director of the Belfer at the Dana-Farber Cancer Institute. Dr. Ned (Norman) Sharpless is our other co-founder here at UNC Chapel Hill. Both of them are physician scientists, so they still see and treat oncology patients and yet they are much respected in their field for their scientific acumen. The scientific team that's headed up by myself has more than fifty years of pharmaceutical development experience. We have been very successful at doing this in big pharma. We have a number of marketed drugs that we contributed to that are out there treating patients right now. Therefore, over just the past few years, we have really been able to create value with the proprietary molecules that we have generated. We are well positioned to take those compounds to create even more value as we move them up through IND-enabling studies and into the clinic and the indications we're pursuing have very large markets. A couple of the markets are multibillion dollar a year markets. We have some that are smaller like the biodefense applications, but that particular indication would be funded completely by the US government. That increases the value of the company and makes the company more attractive to investors as well because you have a lot of non-diluted financing that will be coming into the company to support some of the infrastructure.

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