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Therapeutics and Travel Medicine for Tropical Diseases Such as Dengue Fever and Malaria

Geoff Dow
CEO

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- Geoff Dow

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CEOCFO: ***Mr. Dow, what is the concept behind 60 Degrees Pharmaceuticals?***
Mr. Dow: We have a dual mission, to provide therapeutics where there is an unmet medical need for tropical diseases, which is a therapeutic area that has been underserved for a long time. Our dual mission is to accomplish that while providing an effective return on investment for our shareholders, and delivering products that have value for patients.

CEOCFO: ***Tropical diseases certainly are prevalent. Why are they underserved?***
Mr. Dow: Drug development is still primarily a market driven phenomenon. Unless your commercial market size approaches a minimum level, (people debate what that is but it is probably four or five hundred million dollars), it is very hard to attract the sustained investments from big pharma. That means all development projects for tropical diseases are insufficiently invested in terms of capital, and that means schedules are long. The flip side of that is that patients in tropical countries who might be affected by tropical diseases have much less capacity to pay, either as governments or individuals, than diseases of equivalent significance in developed countries.

CEOCFO: ***Why are you addressing the situation and taking the challenge, when over and above finding the drugs there is the whole dollars and social side to it?***
Mr. Dow: Maybe it is my personal background. My family spent a long time in Indonesia when I grew up. You see a lot of extreme poverty that you would not see if you grew up in a developed country. That has never sat right with me. My scientific training is in tropical diseases. I have spent most of my professional life working on malaria treatments. For me personally, there was an opportunity to apply that scientific and professional knowledge to a social problem that has bugged me for a long time.

CEOCFO: ***Would you tell us a little bit about what you are working on specifically and where you are in the process?***
Mr. Dow: We have two programs. The first is dengue fever. Dengue is a viral disease that causes flu like illness, but can also lead to a severe form that causes shock and bleeding. There are vaccines in development, but vaccines are only partially preventative. Therefore, it will not really eliminate the disease. They are also not very useful for treating the disease. In fact, they have no value for that purpose. Currently, with treatment of dengue patients it is really just fluids and painkillers. There is not really much available. Therefore, we see an opportunity to reduce the direction of illness and also to reduce the risk or progression to severe forms of the disease. Our strategy has been to take several molecules that have been in clinical trials for other diseases, so there is a good safety profile and reposition it for dengue fever.

CEOCFO: ***Would you tell us about dengue fever?***
Mr. Dow: There are about four hundred million infections every year in tropical countries. One hundred million of those are symptomatic. Then there is something around two million hospitalizations every year for the severe form of the disease, which can cause hemorrhage and shock, requiring treatment with intensive care and fluids. Anyone who has had dengue never ever wants to get it again! It is a really nasty disease and experience for a patient. Even though sometimes public health authorities give it less significance than malaria or HIV because it does not cause as much mortality, the individual patient experience is quite memorable and hits you in a bad way.

CEOCFO: ***What else is on the plate for you?***
Mr. Dow: We also have a malaria program. We are commercializing an anti-malaria drug called tafenoquine, which is a much more convenient drug to administer than some of the other drugs that are available for prevention of malaria. Our plan is to commercialize it over the next two to three years for the travel medicine market. Eventually, with some additional clinical data, we think it could be quite valuable as an addition to malaria control assets in endemic countries.

CEOCFO: ***What does your formulation do scientifically? What is happening inside the body that does not happen now?***
Mr. Dow: It has a very long half-life. That means the levels in the blood persist for several weeks. That is the first major advantage. That means you can administer the drug once a week. For many people that is an easier regimen to remember and comply with. The other thing that makes the drug a bit different from other antimalarials is that it targets all stages of the malaria parasites and it prevents the relapsing form of the disease, which can come back months or weeks later. When you get

back from a trip the number of doses you have to take after travel is much less than for the available conventional drugs.

CEOCFO: ***You worked on that with the Department of Army? What is the relationship there?***
Mr. Dow: I worked on the molecule professionally as a scientist when I worked at Walter Reed Army Institute of Research. About two years ago, once I had left, the Army competitively bid the project out to several potential partners, one of which was my company. After that process we signed a commercial development agreement last year.

CEOCFO: ***What is happening day-to-day as you are working on these? I know it is a slow progression, but what is happening today? What will be in three months or six months? What is the time table as you move forward?***
Mr. Dow: We recently received approval for some funding from the Singapore government for our dengue clinical trials. Right now our job is to find matching funding from the private sector to support our half of that program. The next technical step is manufacturing in preparation for the trial. We are also doing a lot of outreach to folks in the community to lock in some additional funding as well for support.

CEOCFO: ***Are you finding interest from investors today? Is this area becoming more important, perhaps with something like the Ebola crisis stirring more attention?***
Mr. Dow: I think that probably in terms of hot topics in this space the focus and investor interest is really around the priority review voucher. That is basically a voucher granted by the FDA if you succeed in getting regulatory approval for a drug for a tropical disease. Those vouchers can be sold to another company that allows fast track review at the FDA of an unrelated therapeutic. They are freely salable on the open market. The most recent sale was for three hundred and fifty million by United Therapeutics to Abbvie. Three out of four of our products are eligible for the PRV and it is a financial incentive independent of your actual development program or the therapeutic you are moving forward. Therefore, that definitely has interest for individual investors, but also big pharma who have an interest in molecules that happen to be in your portfolio.

CEOCFO: ***As you have been doing the research and working on development what has changed? What have you learned that has changed your original concept or do you feel that you are on track with what you suspected all along?***
Mr. Dow: Probably what has changed is my understanding of how the market works; the idea that investors are willing to invest in programs that have a social mission and take a lower return on investment because they are directed towards a social mission. That is a theory that we had about the market before we really got the company going. I guess what has changed for me is that I have really seen the dichotomy in folks interests'. There really is sort of a tendency towards either wanting to invest in programs or companies that are truly philanthropic and not expecting a return, or to invest in companies or programs that are fully commercial and there is not any diminution in the expectation of return. We started doing a number of discovery projects that were early in development. We thought there might be an interest in that because it was a brand new disease area and there were very few other companies involved in that space. However, it is very hard to generate private sector

interest in discovery programs in a disease with a relatively small market. I guess the other thing we changed is moving towards developing projects that have much lower risk.

CEOCFO: ***Is there much competitive research today?***
Mr. Dow: There has definitely been a change in the last eighteen months. There have been two or three new corporate entrants into the disease space, which we see as actually helpful. I think that is a reflection of the recognition that there is a medical need there. In terms of whether that is a competitive threat or not; I think that our program is certainly as advanced as anyone else's in terms of where we are in clinical development. There is plenty of room for different approaches and other drugs, because we really do not know what works yet. Therefore, I think that all of the things that have been tried will help the field.

CEOCFO: ***Why does 60 Degrees Pharmaceuticals standout?***
Mr. Dow: We are one of the very few small companies that are willing to take genuine risks in an underserved disease area. As it relates to dengue we have two therapeutics which are the most clinically advanced in the field, and we are well positioned to deliver in the next two years a new therapy for a brand new disease area.

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

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