Interview: Dr. Terry McWade – CEO, Valitacell, Ireland

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Dr. Terry McWade, CEO of Valitacell, discusses the founding of his company, the ground-breaking technology they are producing, and how this technology can help to bring new biologic medications to market faster and more cost-effectively.

Having just won the Seedcorn Competition as well as being placed on the list of top Irish companies to watch, can you provide us with the vision behind the founding of Valitacell and your current work?

Valitacell was started in May of 2015, so we are a very young company, but the technology that underpins the company goes back further, around eight years, and was originally developed by my partner in the business Dr. Jerry Clifford when he was commercial director of another Irish life science company called Technopath. He, along with scientists from the University of Sheffield, is the inventor of the technology. The research benefited from funding from Enterprise Ireland, and was also the subject of EU funded research. As such, quite a lot of money had been invested in the early research. Our goal in establishing the company was to bring the technology to market. We launched our first product, ValitaTITER, a high throughput assay for measuring IgG, in March of 2016 at an international meeting in Munich. IgG is the most common type of monoclonal antibody, and so what this test does is measure the amount of IgG produced by cells in cell line development and in so doing assists companies to select which cells should be brought forward to product manufacturing. ValitaTITER performs this test faster and at lower cost than existing alternatives. In addition, it is also simpler and requires less specialized training for the staff to perform the assay.

ValitaTITER is our first product on the market, and we have been delighted with its success to date. We have already signed GE and MedImmune, which is part of the AstraZeneca Group, as customers and we have a number of evaluations that are taking place at the moment as well. We have about another four or five lined up for this month, and we are continuing to grow the sales pipeline. The response has been very positive, and the reason why it is successful is because of the benefits it brings. It is very simple compared to what is out there, and it is lower in cost from both a capital point and recurring point of view.

Even more exciting is our next wave of products that are coming down the line, which we hope to launch later this year. These products are based on a platform which we call ChemStress, and it really goes to the core of how biologics are manufactured. Biologics are manufactured on living cells, as opposed to synthetic drugs, which are manufactured through chemical analysis. One of the challenges with biologics is that not every cell will express the protein in enough quality and quantity to make it viable. Companies are faced with the challenge or screening up to 2,000 clones in order to find a clone which will produce enough drug in terms of quantity, and in terms of quality, to be commercially successful. What our technology does is essentially speeds up that selection process. It is based on the premise that up until this point, most selection has been done purely on the amount of protein being produced, and that current selection processes do not really take place in an environment that replicates the stress that the cell will face in the bioreactor. What we have basically done is try to replicate on a 96-well plate, the stresses that the cells will face in the bioreactor. The way we do that is by coating the plate, each well with a different chemical, having chosen the chemical based on their ability to simulate bioreactor stresses such as oxygen deprivation, nutrient challenges, pH changes, etc. A useful analogy to this is when NASA is selecting astronauts for space, it replicates the environment that the astronauts will face by immersing them in a gravity-free zone and examining how they preform in this environment as a predictor of how they will perform in space.

This technology platform has many applications. It allows you to predict which cells are more likely to produce the antibody at the necessary quantity, and predict that at a much earlier stage and also more accurately. Secondly, it allows you to actually predict which cells will remain stable in the manufacturing environment. We do this through exposing the cells to the chemicals, and then measuring how the chemical exposure has impacted on the growth of the cell, and on the protein protection. This gives us an unique profile of the cell according to how it responds to different chemicals, and we call it the ChemStress fingerprint. What we can do is examine when if that fingerprint changes over generations. With our technology, we can predict whether a cell is stable based on the ChemStress fingerprint much earlier than is currently possible.

This unique fingerprint also allows you to identify whether the cell that you are working with is the cell that you think it is. One of the challenges facing cell line development is that it is difficult to confirm that the cell that you are taking from the cell bank is the same cell and that it has not changed. The ChemStress fingerprint works here like a barcode to confirm that the cell is the cell you believe it to be. These applications are the subject of the grant that we have with Horizon 2020, and we have a number of companies who have volunteered to trial the technology. We are now setting up those evaluations in a number of sites including the West Coast of the United States, the United Kingdom, as well as 3 or 4 sites in Europe as well. Its early days, but we are very excited with the progress to date.

How did you identify this as the niche that you wanted your company to address?

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I come from a clinical background, and we were aware that molecular medicine is leading to enormous breakthroughs in research, creating a lot more drug targets, and creating a lot of new drugs and biologics in particular. As patient populations are getting older, demand for these medications is increasing. Furthermore, more of these new drugs are personalized medicines, and treatments for rare diseases. However, from a system point of view, the costs of providing these new treatments is getting higher and higher. It wasn't immediately obvious to us how companies could reduce the core discovery costs in the short term, therefore we believed that the major pressure point with the industry being faced with reduced revenues was going to be manufacturing costs. We validated this with the industry and they confirmed that these divisions of the companies were very much on the critical path and needed significant cost reductions. We felt we could help these companies lower their manufacturing costs and this may result ultimately in lower and so would allow more patients to access the treatments, and for governments to buy more treatments for their populations. Additionally, we believe that we can help companies to get these products onto the market quicker, allowing their innovative drugs a longer life before facing biosimilar competition.

During the life of the company, what have been some of the main challenges you have faced, and how have you overcome them?

As a new company, we thought that trying to introduce ourselves to major biopharmaceutical companies would be a challenge. However, one thing that has excited us is how certain large innovative companies are willing to help smaller companies, provided they see some robust proof of concept laboratory data. Mike Jenns and the team at MedImmune & Ann Lovgren and her team

at GE Healthcare have been fantastic to a small company like ours. What they and others have been convinced by is the data that we had assembled demonstrating the benefits of the technology, and the fact that we had gathered this data onsite with biopharmaceutical companies. In addition, the strength of our research team and the pipeline of products convinced them that it was worthwhile engaging with us as we could assist them deal with the issues that they are facing.

How are the main ways that you differentiate yourselves from your potential competitors?

Our products are all IP protected, and I believe that companies get a lot of comfort knowing that the technology is unique and the fact that the patents are so strong. Additionally, the background of the team is also very strong. My background is in clinical medicine, and then I worked in the pharmaceutical industry for Servier, and then with the Boston Consulting Group for almost 7 years in healthcare consulting. Dr. Jerry Clifford, my partner and inventor of our technology, has worked in academic research in laboratories in Australia, France and Ireland. And the third important player on the team is Professor David James, who is professor of bioprocess engineering at the University of Sheffield, and considered to be a thought leader in the field. That pedigree is very valuable for a young start-up company.

You have a goal of raising two million Euros this year, how do you plan on accomplishing this?

We are talking to a number of investors. This funding will allow us to accelerate the growth of the company, strengthening the team in both sales and in research. We have a laboratory here in NIBRT, and we will be undertaking more of our research here in the future. This will also enable us to develop applications of our technology for other areas such as stem cell and gene therapy. We will also increase our participation at international meetings.

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How have you found your experience to be as a founder of a start-up here in Ireland?

It has been great! Ireland has a very strong start-up culture. There is a very supportive environment, with agencies such as Enterprise Ireland and Intertrade Ireland providing a number of supports to early stage companies including equity investment.

Additionally, the IDA which brings in the foreign direct investment (FDI), links with Enterprise Ireland to try to ensure that indigenous Irish companies can access the international biopharmaceutical companies who are based in Ireland. On the academic side, there are research

programs which facilitate academic and industry partners to work together.

Looking forward three to five years, where do you hope to lead Valitacell?

We hope to see ourselves becoming a major player in the analytical market. For us, while it is excellent to be based in the Irish ecosystem, our customers are international rather than local and we will be investing in our ability to reach international customers.

On a more personal note, what motivates you each morning?

I am excited by the opportunity to mentor people and to make an impact with our technology. I have been working in the life sciences space for quite a while, initially on the clinical side, then the pharmaceutical side, the more recently on the education consulting side. It is great to be able to bring these experiences together to bring something from the laboratory and see it make a difference to in terms of assisting patients access new treatments. It is also great to have talented, younger people coming into the company and being able to provide them with a little bit of perspective and mentoring, and supporting them in their development.

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