

**Janet Downie – CEO, Roslin CT, UK**

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*A spinout from the Roslin Institute that created Dolly the Sheep, Roslin CT is a cell and gene therapy CDMO, with a unique positioning in the field today. Its CEO, Janet Downie, presents the company's expansion plans and talks about new areas worth pursuing as well as the advantages of being a Scottish-bred company.*

### **Janet, can you please introduce Roslin CT to our international readership?**

Roslin CT is a cell and gene therapy CDMO, founded as a spinout from the Roslin Institute in 2006. We define ourselves by the quality of the service we provide, our strong scientific base and our dedication to a very collaborative approach. We take a pride in every client project we undertake. We are service driven, have a clear approach to IP and are all about delivering safe, quality products for our clients' clinical trials.

Today we work with a range of clients across the UK, Europe and the US, each representing about a third of our business. Roslin CT employs 50 people but is looking to double that effective within the next few years as we are pursuing an ambitious expansion plan and want to significantly increase our capacity. It is important we adapt our capacity to the fast-growing demand as we are almost at capacity.

For now, our facility is based within the Scottish Centre for Regenerative Medicine in Edinburgh from where we do all our manufacturing. Our expansion would also be geographically situated within the Edinburgh area.

Roslin CT is also a development partner and we can accompany a client from the initial process development through to manufacturing. We are skilled at effective technology transfer, understanding that the devil is in the detail when it comes to success and excellent communication is key.

This approach will remain at the heart of the business as we expand our manufacturing capacity and gear up for commercial supply.

### **What alleys are you pursuing in the context of above mentioned expansion plans?**

We are looking to expand our service offering as we want to be a truly global player in the cell and gene CDMO space. Today, we are one of the only CDMOs in this space in the UK. Most competition comes from the US and the rest of Europe.

The field of cell and gene therapy is one that is rapidly growing. News of developments in the field can be read every day, and the market demands for manufacturing will need to be met. The US promise to be a huge market, and of course our initial expansion will lead on to us to having a

manufacturing foothold on the other side of the Atlantic, it is an obvious step. One development we will be dedicating capacity to in the future is the area of CAR-T therapies.

Because of the rapid growth in cell and gene therapies, there will be a shortage of manufacturing capabilities, and we are gearing up to be ready to meet the demand as the market grows.

To us, the focus should remain on a great client service offering but also on working with a cost-effective high-quality manufacturing approach. We know that we deliver life changing therapies for patients, and we cannot risk any compromise on our products' safety and high standards. We do consider cell and gene therapy manufacturing as being somewhat different than the field of more traditional pharmaceuticals, and we want to ensure our clients can always fully trust in us.

### **Are there any challenges you foresee?**

There is the consideration of Brexit, or rather, the uncertainty surrounding it. We identify it as a barrier at the moment, but we work closely with the government and policy makers to ensure that we are ready to meet any challenges that may transpire. We are confident that as soon as the uncertainties will have cleared, we will be able to move forward on a positive note.

### **What makes Scotland into a great environment to foster the development of cell and gene therapies?**

The UK in general, offers a great environment for businesses in our space. From a regulatory perspective the MHRA is internationally valued and recognised. Roslin CT was an integral part of the advanced therapy taskforce that led to the UK Life Sciences Industrial Strategy. In the UK, there is an incredibly strong expertise in the field, and that competency is very important.

What we might add to this in Scotland is a true culture of service and hospitality, something we value very highly at Roslin CT and that we combine with our development and manufacturing services to ensure we have the best offering possible for our clients.

What is more, we can in Scotland, rely on a very solid scientific base. Edinburgh hosts one the largest global hubs for stem cell research, doubled with the recent development of a centre for tissue repair and the new medicines manufacture innovation centre, all of which is expertise that we can tap into.

### **Scotland has its own Life Sciences Strategy, a main focus being to help businesses scale up. What do you still require in achieving your goals?**

From our perspective it comes down to expanding our capacity, because we already have pretty much everything else at our disposal. Key to success is the quality of our people. We require them to have a well-rounded skillset of not only technical skills but an ability to engage with clients. Therefore, we conduct many inhouse training sessions and continually develop our team. We also offer undergraduate placements at Roslin CT, invite schools to visit so that students get to know the industry. We are also looking to take on recruits from the Advanced Therapies Apprenticeship that is just being developed (in conjunction with Skills development Scotland)

In Scotland we have a basic skillset readily available, and because Edinburgh is such a great place

to live and work in, we remain attractive for talented people from everywhere. Scottish Enterprise is one channel that has time and again supported us in our quest to reach the next stage. I very recently completed a leadership training programme around women-lead Scottish businesses actively scaling up, called Principally Women.

In cell and gene therapy, since we cannot tap into a long list of successful manufacturing companies with a history in the field to acquire talent from, we have to be creative and set everything up ourselves. In Scotland, we have been excelling at leading the way in this for years. Roslin CT itself was set up to plug in a gap in the supply chain of cell and gene therapy, as there were no companies providing high quality stem cells. Out of a niche, we made a success story, and we will continue to build from this early entry to the cell and gene therapy market.

### **What are the immediate next steps for Roslin CT's development aside from the upcoming expansion of capacity?**

As a business we are already profitable and growing, and while we are not looking to raise investment straight away, we will start a funding round this coming year. We are today in a good place with an exciting business. In the field of cell and gene therapy, financing the construction of GMP Manufacturing facilities are considerable, so many young and start-up businesses who are fast expanding will require companies like Roslin CT to support their ambitions with cutting edge manufacturing services.

We are continuously developing our brand and range of business services. I think businesses never do enough in building their brand and we continue to put Roslin CT's name out there (after a successful rebranding exercise last year). We know the players in our field and there are really not that many direct competitors for now, however this will no doubt change, which highlights the importance of ensuring networking and branding is a very sustainable exercise.

### **When we come back for our next edition on the UK, where will we find Roslin CT?**

I think we will be a sector leading player in the manufacturing space for cell and gene therapy, a global business, and a large employer. My goal is that Roslin CT will be recognised as being synonymous with high quality manufacturing. As a spinout from the Roslin Institute, our past is animal-based, after all, Dolly the Sheep was created at the Roslin Institute. Today, we want to reinvent our image, adding a high-quality manufacturing dimension to the scientifically acclaimed named of Roslin.

In general, it can be noted that Scotland has this capacity to break down silos between animal and human health for instance. Probably because of our size, everything is accessible, and you can easily see how our excellent hospitals can draw from the multitude of clinical trials conducted here. Scotland is responsible for over 50% of Europe's Biosafety testing, which is a fantastic resource for a cell and gene therapy manufacturer such as RoslinCT.

A final area we might look to pursue within the coming years which is more of a personal interest is diversify our offering to animal cell and gene therapies. Once more, Scotland could be a pioneer. In fact, all things considered, there are a series of medical and scientific inventions that can be traced back to Scotland, although these often remain under the radar.

Watch this space!

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