Interview: Patsy Carney – co-founder and CEO of EirGen Pharma, Ireland

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Patsy Carney, co-founder and CEO of EirGen Pharma, tells us the strategy behind their 2015 acquisition by US-based OPKO Health, the highlights of their current transformation from an Irish CDMO business to a center of excellence in R&D and supply chain for the Group, the new sterile, oral solid dose and dry powder inhalation capabilities their new R&D center in Waterford will have, and his priorities for the next few years.

Patsy, what have been the highlights of the past year, since EirGen Pharma was acquired by the US-based OPKO Health in May 2015?

We are here in Waterford, the original starting point for EirGen Pharma, which was founded in 2005. For ten years, this has been our site for R&D, manufacturing and supply chain activities, and for a number of years leading up to 2015, we had been positioning EirGen Pharma for an acquisition to advance onto the next phase of development.

The May 2015 acquisition by OPKO was therefore very timely. OPKO's Chairman and CEO, Dr. Phillip Frost, has stated from the very outset that the ambition is to position EirGen as the Group's center of excellence for R&D and supply chain. Most notably, this has seen the establishment of a new, 25,000 sq ft R&D center nearby in the Advanced Technology Building (ATB), acquired from the Irish Development Agency (IDA). We expect to take possession in the upcoming weeks, with planning permission expected before Christmas 2016. The operations team will mobilize just after

Christmas and contractors should be working on the site by February 2017.

For the past 17 months then, EirGen has been in a state of transformation. Our core business prior to the acquisition would have been as a classic CDMO with exports to 45 countries of our out-licensed products. This means an extensive customer base – whose existing commitments we continue to fulfill – and robust project pipelines; we have around 23 projects in R&D at last count, for instance. We are now transitioning to incorporate OPKO's own pipeline, itself very strong, into our operations. To illustrate, from a business development perspective, in November, we would typically be focusing on acquiring several new projects to drive our business for next year. This year, however, we are instead focused on consolidating our existing commitments and fulfilling our obligations to our existing customer base.

What made EirGen and OPKO Health a good fit?

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EirGen's DNA is in R&D and supply chain – that is what we have always done, with excellent results. Being a CDMO is much more difficult if all you do is bring external products in for manufacture, because the focus then is on the cost base and keeping very tight margins. Our view – and the value that we bring – has always been in maintaining complete responsibility and control over the product's entire development and commercialization life cycle.

OPKO Health has a very strong pipeline, with many in the early and middle stages of the product development life cycle, so it was the right time for a company like EirGen to come in to support their development and commercialization. We are bringing that expertise in terms of completing the R&D, preparing the requisite regulatory filings for international markets and managing the supply chain networks to the Group. Whether it is an OPKO product or a stock-keeping unit (SKU) for existing clients, the same processes are required, so EirGen's competences have dovetailed very neatly with OPKO Health's needs.

On the flip side, EirGen would benefit from OPKO Health's size and financial resources. For instance, in the new R&D center, we will also be adding dry powder inhalation (DPI) product capabilities. The technology already exists within the OPKO Group. Many DPIs are driven off hard capsules, which are pierced to release the active ingredient. If you remove the medical device, it is essentially just an oral solid dose product, so we can also leverage on our oral solid dose expertise. This is an area in which we had previously considered and were interested in, but the barrier cost to entry for inhalation products is eye-watering. The clinical programs are quite challenging, constantly developing and very expensive, so it was not feasible for EirGen to move into that

space. Being part of OPKO enables us to nurse this ambition. I would really characterize this as a win-win partnership!

How will this new R&D center complement EirGen's existing facility?

We will be moving all of our existing R&D activities into the new site, so this existing facility will be dedicated exclusively to manufacture and supply chain operations. This facility has functioned as both our R&D and supply chain hub for the past decade, with around 150 employees. We plan to hire around 70 to 80 new employees next year, so the new capacity will be very welcome.

To fulfill our role as the Group's global center of excellence in R&D and supply chain for OPKO means that we will need to have the expertise and capacity for a number of platforms. EirGen's niche has always been high-containment, high-potency products in the oral solid dose area, but OPKO's product portfolio is more diverse. The new R&D facility will be a sterile facility, adding the capacity to manufacture sterile injectables. We also expect to be supporting both the R&D and supply chain requirements of a number of proprietary OPKO oral solid dose products that are not necessarily high-containment.

What are some of the exciting products in the pipeline for EirGen at the moment?

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Just an hour before this interview, in fact, we received the final set of data for RAYALDEE®, which is one of the most exciting products in our pipeline at the moment. It is an OPKO product that we will be launching in November, and we will be entirely responsible for the supply chain. It is intended for the treatment of patients with stage 3 or stage 4 chronic kidney disease suffering from secondary hyperparathyroidism (SHPT). The clinical results have been very promising. We have really only brought it to the market's attention just last week at an American Society of Nephrology (ASN) in Chicago but the market feedback has been very positive. An agreement has been signed with Vifor, who will market the product internationally outside of the US; our focus now is on the global registration and commercialization of RAYALDEE® in partnership with Vifor. What is even more promising is that we are also already exploring the use of RAYALDEE® for other indications and presentations, so this may turn out to be quite a dominant product for OPKO and EirGen.

We also have a number of other in-house products in the sterile area, including Factor VIIa, for the treatment of hemophilia, as well as some promising candidates from recent OPKO acquisitions, which we have found to be good matches with our competences here in Waterford. All in all, we are currently working on around five to six products from OPKO's portfolio for next year, and we see

huge potential in them, not least because they are innovative products, not generics.

Given the international scope of EirGen's activities, how challenging is it to manage the diversity of regulatory regimes that exist globally?

As I mentioned, we are a fully export-driven business and we actually have no products servicing the Irish market at the moment. It is true that international supply chain and distribution logistics are extremely complex, but we would have cut our teeth on some of the biggest, most challenging markets out there since our inception, so we have a pretty solid background in terms of what is needed.

The facility here is state-of-the-art and licensed by all the main regulatory bodies: HPRA, EMA, FDA, PMDA, the Saudi FDA, etc. Since day one, we have invested as much as possible into our facility – and in fact, our facility here has tripled in size since the beginning, so we are working from a very solid foundation.

We do see potential challenges ahead. Serialization is a key one and the industry is in a bit of a holding pattern at the moment; not everyone is investing in this yet but we are up against hard deadlines for its implementation: November 2017 for the US and early 2018 for Europe. This will complicate things quite significant for the industry and bring a significant level of complexity to the packaging aspect of our business. That said, we simply need to build relevant areas of expertise into our business and get on with it. After all, if our job was easy, everybody would be doing it!

EirGen is definitely in a very exciting phase of transformation at the moment. Looking forward, what would you like to achieve for EirGen in the next few years?

EirGen is a tremendously exciting company to work for. There is a palpable sense of excitement within our company because there is direct alignment of every employee working for EirGen, from the product and technical teams up to management. When a product is about to be launched – as RAYALDEE® was, for instance – our employees are able to relate their personal work very strongly to the press release on that product launch, for instance. This creates the buzz – people feel that they are positively influencing the direction of the organization to which they belong, which is very motivating.

Now that we are part of OPKO Health, I am very happy to see this close alignment continue. Senior management in Miami provide constant validation regarding the importance of EirGen to the overall organization.

For me on a personal note, I am very reassured by the fact that the people leading the company themselves have come from an industry background. You do not always see this in the industry anymore, but I believe that the vision and direction of a pharma company needs to come from those with technical competence in the industry.

In terms of concrete objectives, I expect that we will have firmly established the R&D center in a few years' time, and perhaps even have further expanded that facility to add more commercial sterile capabilities. By that time, the focus for EirGen would also be completely on internal in-house projects rather than an external customer base. We would be in a very strong position to support the R&D and supply chain requirements of the OPKO portfolio across a number of platforms: oral solid dose, dry power inhalation and sterile products. Ultimately, with Dr. Frost, you can never be sure where the road will take you, but it will definitely be bigger and better!

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