Eriona Gjinukaj, Chief Operating Officer – Dompé

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Dompé's Chief Operating Officer, Eriona Gjinukaj, responsible for creating the Italian mid-cap's US affiliate, reveals the challenges and rewards of that experience and explains how she saw the company go from a primary care-focused Italian company to an internatonal biotech with an EMA and FDA-approved breakthrough therapy.

Could you start by outlining your slightly unconventional career path and how you came to be COO of one of Italy's leading pharma mid-caps?

I have a long experience in management consulting, having worked for Bain and Company for almost 15 years. During that time I specialised in consultancy work with pharma companies, including Dompé. As a consultant, looking from the outside in, there were aspects of all companies that you liked more and less. However, I remember thinking that Dompé was a company that I could actually end up working for. What struck me was the commitment of its people, which was much deeper than elsewhere. For someone like me, who needs to feel passionate about what I do, that was very attractive.

In 2018, while I was consulting Dompé on the future launch of its recombinant human Nerve Growth Factor (rhNGF) [a biotechnological molecule for the treatment of neurotrophic keratitis, a rare neurodegenerative eye disease – Ed.], the former CEO, Eugenio Aringhieri, unexpectedly passed away. This was a critical moment for the company as Eugenio was a driving force for the team and the company was launching its very first biotech product in the US and rolling out a

commercial strategy in the world’s biggest market for rare diseases.

Sergio Dompé, who is Dompé’s shareholder and a visionary Executive President, asked me to join the company with the first big goal of creating the US affiliate from scratch in four months. It was a challenging moment and by far the most exciting in my career. The launch was extremely successful and the best is that we did it “our own way” – making unconventional choices and working very hard.

What lessons did you learn from this experience that other European companies looking towards the US might benefit from?

Every launch is different and depends on so many factors like the therapeutic area, the company, the expectations set. Data show that 80 percent of product launch results differ from expectations by over 50 percent – both upsides and downsides. Knowing that, we decided not do things just because others before had done it that way, but instead we made what we thought were the best decisions for our very specific situation. This became one of our main operating principles: “act on need rather then precedent”. We also decided we wanted to remain agile enough to invest quickly where we saw additional opportunities with quick and lean decision making. Agility and adaptability are therefore crucial and will continue to be so for Dompé’s future launches.

How challenging was it to bring the right talent profiles on board for a firm like Dompé out in California?

Every European company fears this when they enter the US market. Our solution was not to hire people that had done the job before; these profiles would probably not have come to us. Instead, we gave opportunities to ambitious and talented people in who we saw the potential to step-up in their career and become a sales manager, marketing manager, or country manager for the first time. I am just one example of this; Sergio Dompé believed in me and my commitment to the project.

How has Dompé’s business evolved in recent years? Is its CDMO offering still significant?

Most of the traditional Italian pharma companies, including Dompé, have their heritage as family-owned and primary-care focused. Dompé shares the same legacy, but was one of the first to move into biotech back in 1988 when the field was relatively unknown in Italy. We must give credit to Sergio Dompé for seeing the opportunity, investing in it, and navigating the challenges of a new and very competitive sector. When I joined in 2018 the company hadn't shared dividends for several years, re-investing profits in research. We had a major asset: a shareholder who believed in science and was willing to invest all of the company's profits into R&D. I was lucky to have a front row seat in the transformation of what was a small, primary care-focused Italian company into an internatonal biotech.

Large scale CDMO work is not a key part of our business. Our main focus is to manufacture our own drugs and develop strong manufacturing competencies as a competitive advantage. This was a key factor enabling us to successfully bring a recombinant NGF product to market – something no other company has done.

With one FDA approval in the bag for a breakthrough therapy, how much can the technology behind NGF development be applied moving forward?

NGF was discovered in the 1950s by an Italian Professor, Rita Levi Montalcini, who was the only Italian woman to win the Nobel Prize in Medicine. She used to say that NGF is like a sunken iceberg; only the tip is visible but there is so much more beneath the surface. We are therefore studying and actively looking for areas where NGF can have a greater potential.

The eye – the most innervated organ in the human body – was a natural starting point, and the first indication we worked on was *neurotrophic keratitis*, but there are more and highly promising applications we are looking at. Most notably dry eye related to Sjögren's syndrome, and indications within CNS. Although these will require more time and investment, they have the potential to be life-changing products for patients high unmet medical needs.

How significant a contributor is NGF to the firm's global revenues and how healthy are the company's recent financials overall?

rhNGF is our main product and has been the main source of growth for our company in the last 4 years. While this side of the portfolio is performing very well, COVID hit some of our primary care portfolio, especially in respiratory care, quite hard. However, overall, the company is growing. Our

Company is financially very healthy, we have no debt, something unique, we have a healthy P&L, and we continue to invest 15 percent of our revenues in R&D.

As a private company, we can allow ourselves to think long-term. We can ride out a rocky quarter if it is necessary to invest on the longer run. This is a privilege that private healthy companies like us have.

After gaining EMA and FDA approval for rhNGF, China's National Medical Products Administration (NMPA) granted authorisation in 2020. How important is the China market for Dompé today and will you continue attempting to develop there?

China is not yet as attractive for rare diseases as it is in other areas. We believe it will become extremely attractive in the coming decades. Launching in China during the worst of the COVID pandemic was, of course, not ideal, but we think of the country as an investment for the future. Currently, we have a very lean structure there, serving the patients that we are able to, while accepting that there is a lack of significant investments in market access, especially in rare diseases today.

How have these regulatory approvals affected Dompé's operating model?

We always try to be agile and innovative in everything we do. The company will continue to invest in research, which will lead to further growth and hopefully deliver new products in areas of high unmet medical need. However, we perceive innovation as going beyond drug R&D and encompassing everything from finance, to legal, to HR. A key part of our operating model is to find our own ways of doing things. This has helped the firm to remain lean and focused despite tripling revenues, with less than 1,000 employees worldwide. While we are growing our headcount in the US, the agile and innovative DNA of Dompé remains intact.

Are out-licensing or commercial partnerships on Dompé's priority list currently?

Out-licensing is not a priority for us at this moment. We are, however, always looking at innovative ways in which our drugs can be brought to patients across the world. For example, we have a named patient program in partnership with Tanner Pharma Group in many countries.

We are, however, actively looking of in-licensing opportunities, especially in the US in Italy, where we do have distinctive competences that we could exploit. We hope to be able to grow not only organically but also through M&A soon in our future.

Dompé's Exscalate AI and supercomputing platform is designed to accelerate the drug development process and marks a significant incursion into the artificial intelligence (AI) space for a mid-cap Italian pharma company. Can you outline how the firm is currently utilising this platform?

Exscalate is a great example of Dompé finding its own way of doing things. Almost all big pharma companies are looking at utilising AI in drug discovery, and there are a host of service providers looking to partner up with them. However, Exscalate is fully embedded within Dompé, a pharma company that knows what is needed from the molecules that come out of drug discovery to have success in further development stages. The R&D knowhow that comes from having this platform in-house makes Exscalate a very compelling proposition.

Additionally, Dompé is supporting start-ups with a wide range of services around the entire drug discovery and development process, giving them R&D support, financial investment, and taking a stake in those companies so that their success is our success; it's a win-win model having "skin in the game".

There are two good recent examples of this. Firstly, in 2020 Exscalate rapidly identified a lead compound for a new target in a dry eye indication, enabling a Harvard Medical School,spin-off, Aramis Biosciences, to go from zero to phase 2 investigational new drug (IND) approval of a new molecular entity (NME) in as little as 14 months.

Secondly, in 2021, Dompé struck a multi-program deal with University College London spin-off, Engitix, leveraging Exscalate to develop selective molecules for Engitix-discovered targets in fibrosis and solid tumours. This is a fee-for-success model; if we succeed and deliver molecules which are able to enter into clinical development, then a payment back to Dompé is triggered.

How will Exscalate dovetail with Dompé's other areas of focus moving forward? Are there plans to eventually spin it off to provide equity for core businesses?

This is an opportunity we keep thinking about. At present, Exscalate supports both external innovation as well as our internal pipeline. But you are right, a spin-off is possible and could be a way to expand the use of the platform. No decision has been made yet.

As we hopefully emerge from the most difficult moments of the COVID period, what plans have been put in place for the next five years at Dompé?

We are thinking big! Our ambition is to keep transforming and double in size once again in the next 5 years.

As a mid-sized company, we are unable to attract the same talent as bigger companies, but we are also no longer a small local outfit. We are somewhere in-between, and at times it’s a challenging position.

At present we have a great pipeline that we think will deliver results in the near future. We look at therapeutic areas a bit differently and have decided to follow the science rather than given therapeutic areas. For example, we are working with assets like NGF to find applications to several different areas, even those where many other companies have failed, like CNS disorders.

Growth will come from both organic and inorganic sources, and we are leveraging our recent successes to consider acquisitions, mergers, and partnerships. Dompé is a 130-year-old company and we want it to be here for many more decades with great success.

What kinds of acquisition targets are on Dompé’s radar? Are you geographically agnostic?

Our focus is less on geography than on science; the main objective is to acquire companies which have strong science. Dompé is not a huge company and would be challenged to play in highly competitive markets where thousands-strong field forces are needed. Instead, our focus needs to be on areas of high unmet medical need, even niche areas, where we can focus and make the difference. Therefore, we are trying to find assets, both commercial and clinical, that have a good science behind them, and which are probably not on the radar of large companies. Additionally, top science today is global by definition, leading us to look at, for example, US biotechs as well as academic projects in Italy.

As a foreigner in Italy and the representative of an emblematic Italian company, what would you say that the country has to offer to global life sciences?

Italians tend to focus on the negatives of their country, but I always see its positives: most importantly its people and their competencies. Having worked across the world as a consultant, I can say that Italians' passion for their work is unrivalled, and their competences are incredible. Italian academia is very strong, with top scientists and its long tradition in Life Sciences s one of the country's most valuable assets

And what are the challenges of being based in Italy?

I would not say our challenges are country-specific. The market access hurdles that exist here, especially for innovative rare disease drugs, are also present in other European countries such as France and the UK.

Italy's long tradition in science and medical research is its big asset but a greater entrepreneurial culture could be hugely beneficial. Scientists here come up with fantastic research from which – if they were based in the US – multiple companies would have sprung up. This is where companies like Dompé can and should work to support and bring these ideas to life.

Do you have a final message for PharmaBoardroom's international audience on behalf of Dompé?

I hope that the culture and mindset we have at Dompé shines through in this interview. If your readers have good ideas and want to collaborate with a company that puts passion into everything it does, then Dompé should be on their list!

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