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TJ Deng, GM China and BioDuro Discovery; and Ian Wisenberg, CFO of BioDuro, share the strategic rationale behind Advent International's 2019 investment into the company; the focus of BioDuro 4.0 on growth, particularly in the US and Chinese markets; the differentiated and value-added services BioDuro can offer clients; and their core focus on offering integrated drug discovery and development solutions to the global industry.

TJ and Ian, to start with the most recent milestone of Advent International's strategic investment in BioDuro in January 2019, how does this contribute to the company's strategy?

TJ Deng (TJ): We are calling this BioDuro 4.0. To provide a little context, BioDuro 1.0 was established as a start-up CRO service provider in China by entrepreneurs Masood Tayebi and John Oyler, where it experienced rapid growth. In 2009, it was acquired by global CRO, PPD, where it saw a slower pace of growth under a different strategic direction.

BioDuro 3.0 followed BioDuro's reacquisition by Bridgewest Investment Group in 2015, whereupon we laid out a five-year plan for BioDuro's growth based on the market potential and BioDuro's core strengths. In mid-2018 however, we ran into a problem: we had realized our five-year plan in just three years! BioDuro 3.0 experienced extremely rapid growth, for instance, 40 percent growth in

2018. In one sense, it was mission accomplished. The company was growing extremely well. In another sense, we started to think, what is our next destination?

This is when we started to receive interest from several international partners that wanted to work with us. We selected Advent not only because they were one of the best PE funds globally with a track record of successful healthcare investments but also in terms of the knowledge and experience that they could bring to support BioDuro's growth. For instance, the current chairman of Advent International is David Preston, who established Sanofi's China affiliate and recently retired as the president of Boehringer Ingelheim China.

BioDuro 4.0 is really about explosive growth. Tangibly, in three years, we are looking to double our current size in both China and the US in order to grow our footprint. In China specifically, we are looking to add a third site to our existing network in Beijing and Shanghai, which will be able to accommodate over 1,000 scientists and researchers. In terms of inorganic growth, we are also on the lookout for M&A opportunities – both in China and globally – in line with our strategic growth priorities to add capabilities in API manufacturing from IND enabling to Phase II stages, and also in biologics.

BioDuro 4.0 is taking us to the next level, or even the next two levels. We want to build on our solid foundations to grow into a much bigger and more international CRO.

Ian Wisenberg (IW): That said, we are not looking to be the biggest necessarily but certainly to be the best. The CRO industry is extremely competitive so we are acutely aware that we have to move away from offering commoditized services to offering very differentiated solutions. This is why BioDuro is focused on being an integrated drug discovery and development service provider, serving clients by helping them bring their discoveries into Phase II. We focus on offering this early-stage, one-stop-shop solution offerings.

BioDuro currently has a strong presence in both the US and China. What have been driving this strong growth for BioDuro in both markets?

TJ: BioDuro has always had a good foundation of Big Pharma clients and we continue to retain these strong relationships. In the past two years, however, we have seen the Chinese and the US biotech industries as the major driving forces of our growth.

What we have seen, probably globally but certainly within the US is that the role of large pharmaceutical companies in innovative R&D has changed significantly. The main driver of innovation in the US is now biotech companies, and pharma companies now focus more on so-called external research, in-licensing or acquiring assets developed by biotech companies. There have been studies conducted by various consultancies like McKinsey looking at the numbers of different ongoing clinical programs globally, and there is a clear trend that more and more early-stage clinical trials are now being sponsored by biotech companies.

IW: There are two major implications of this trend. Firstly, these biotech companies are far less likely to invest in significant research or clinical infrastructure. It is simply not cost-effective for them all to build their own laboratories and purchase expensive equipment. Secondly, pharma companies are now increasingly looking to outsource a significant portion of their early-stage discovery and development to companies like BioDuro. As a result, while globally the industry's R&D spend is growing at a more sluggish pace, the outsourcing component within that R&D spend is growing fast.

TJ: Looking at China, in the past few years, a whole new innovative biotech industry has emerged. This is certainly one of the largest growth drivers for us. Many of these biotechs are led by highly experienced executives with extensive backgrounds in pharma MNCs – but as you can imagine, these are not the people running research programs in the labs. A very significant portion of their research is already being outsourced to CROs, for a very simple reason: as a new biotech, having raised some money and hiring top talent, which is already very expensive, they will not invest a lot in research infrastructure, especially if they have only a few products. The utilization rate will be very poor. Therefore, the core leadership team will oversee the critical components of their technology platforms or other projects while outsourcing other elements, from biology to chemistry to pharmacology and Drug Metabolism and Pharmacokinetics (DMPK) to CROs like us for the heavy lifting.

This is especially relevant to China because the innovative biopharmaceutical environment is so new. China used to be dominated by generics companies but today, all these new biotechs want to focus on innovative research. The existing pre-clinical infrastructure and capabilities are still being developed. This is another reason CROs like BioDuro are so important: we support the growth and maturation of the entire industry.

Furthermore, as the biotech industry in China continues to evolve to become more innovative, moving away from ‘me too’ and ‘me better’ products to focus on new targets and new mechanisms of action, they will need the support of companies like BioDuro even more, to provide world-class solutions and value-added services in drug discovery and development. We know how to turn their ideas into drugs.

IW: Indeed, while there are a lot of CROs within the industry, what BioDuro is offering is more than an extra pair of hands. We do not merely execute our clients’ instructions, but we actually actively work with them to provide innovative solutions to their problems and challenges. They approach us to solve their problems. This has always been the differentiation and the value that we offer.

With this focus on offering value-added integrated solutions for drug discovery and development up to Phase II, how does BioDuro optimize your project management capabilities across your three sites in San Diego, Beijing and Shanghai?

TJ: When we talk about integrated R&D, the integration can be vertical, from discovery to development; or horizontal, across the different capabilities from chemistry, biology, pharmacology, DMPK and so on.

BioDuro focuses on both horizontal and vertical integration. I like to use the analogy of cooking: you may have the right ingredients, but it does not mean you can put them together into the perfect meal. You need to have the experience with and knowledge of drug discovery and development. The right kind of project management expertise is critical.

I call this one of our secret sauces. This is why we have projects where our project manager is embedded within the client’s site. This ensures that she can interface smoothly with our client as well as within BioDuro across all our departments and sites globally. Certainly, when we look for project managers, we select not only those people with significant drug discovery expertise but also an excellent sense of communication as well as operational excellence.

At BioDuro, our value creation plan is based on understanding what our client really wants. As an example, one of our niche offerings is in solubility solutions. Through our DMPK capabilities in Shanghai and our formulations capabilities in San Diego, we have created what we call a ‘solution engine’, where we use different screening technologies to choose the best formulations for our clients’ needs at a very early stage. Within the same week, we run DMPK tests in animals to

produce the bioavailability data, which we send to our formulations team in San Diego. This links both the formulations piece, usually found in CDMOs, and the DMPK piece. The result is that we hugely accelerate the typical six-month process it takes to choose the right solubility, reducing it by half to three months, and we also conduct the screening process way earlier in the process so that our clients do not have to invest a lot of money into a particular formulation before realizing that it does not work.

As a result of our capabilities in these areas, we can offer clients the ability to decide on the best solubility solutions and enhancements at a far earlier stage, which has proven incredibly valuable on many projects.

IW: If I can supplement some context here as well, over the years, we have really built BioDuro with this commitment to offer integrated drug discovery and development solutions in mind. In 2010, I was part of this company, Molecular Response, then established by Bridgewest Group and Biotech Investment Group, which BioDuro acquired in 2018.

The acquisition of Molecular Response really added a whole new dimension to BioDuro. Oncology has always been a major therapeutic area of focus for BioDuro. But the acquisition of Molecular Response, which possessed the world's largest living tumour bank, allowed us to position our oncology business as a separate business unit offering highly differentiated technology. For instance, using our unique tumour microenvironment (TME) screening technology, the need to use mice models is obviated, allowing for a much quicker readout and lowering the costs significantly. We are extremely excited about how we can grow our oncology business further by leveraging on these capabilities and technologies.

The same principle was behind our 2015 merger with Formex during our re-acquisition of BioDuro from PPD. Formex was also established by Bridgewest Group and I was a member of the founding team. When we merged Formex and BioDuro, we thought very seriously about how we could best leverage both entities to create the extremely successful BioDuro company that we see today, and the main rationale was to combine BioDuro's drug discovery capabilities with Formex's formulations and cGMP manufacturing capabilities.

With such a great track record and bold ambitions for the future, what are some of the headwinds you foresee for BioDuro?

TJ: The top challenge is talent. Since we focus on providing value-added services, we really need extremely talented people. This is a challenge for the entire industry with competition for talent being very fierce, from both the sponsor side and supplier side. Working for a CRO, especially a highly differentiated one like BioDuro, does offer researchers and scientists a very different training ground with opportunities to access different innovative technologies and to work on different novel projects. This is why in addition to hiring experienced people, we also look at identifying high-potential researchers that we can offer valuable training experience to take them to the next level as well. In this way, we can see recruiting talent as both a challenge and as an opportunity to train the next generation of industry leaders.

IW: From a financial perspective as well, talent is certainly the biggest component of our cost. How to protect our margins within a highly competitive industry where our clients are increasingly cost-conscious is a question for us. Certainly, within China, both our clients and local CROs are very price-driven. Local companies sometimes feel that they might not need the 'brain' component of our services, which I would argue is a misconception.

As China becomes an increasingly large part of our business – China now represents nearly 15 percent of our global revenues from the five percent it was previously – we are focusing on how to communicate the value of our service offerings to clients here.

On a more personal note, in different respects, both of you have grown and developed with BioDuro. How has your leadership philosophy defined and been defined by BioDuro?

TJ: When we reacquired BioDuro from PPD, the senior management team actually walked along the Bund in Shanghai for two hours to define the kind of company we wanted to build. We came up with five words that we wanted to become the core values of the new BioDuro: Accountability, Respect/Responsibility, Tenacity, Result, and Integrity – ARTRI.

ARTRI defines our company culture and reflects the core values we want to embody at BioDuro. As leaders of this organization, we have to inculcate this within our teams.

For me personally, the first priority is to build a team. For any company, not just a CRO, having a capable, stable team that shares the same mission and goals is very important. I do not worry so much about market fluctuations and trends. If you have the right product, the good service

mentality and you can make your clients happy, business will come. But to achieve the first three, you must have a great team that believes in your objectives and are willing to grow with the company. This is the direction that the new BioDuro 4.0 together with Advent International is going.

IW: As part of this focus on our employees growing with the company, we have our BioDuro Learning Institute where we provide ongoing education for our employees, from both internal and external experts, to share new trends, perspectives and technologies across many different areas.

For me personally as well, through Bridgewest, Molecular Response, Formex and of course, the BioDuro now, I have been involved with this company in many different ways. I met the original founders, Masood Tayebi and John Oyler in San Diego in 2004 when they were thinking about establishing BioDuro. Through the past 15 years working with our Masood, one theme really rings true: family. This is something we are very committed to. The core of BioDuro has always been a family culture. Our core values, ARTRI, are not just an acronym. They are embedded in the way we run our company. No matter how the industry develops or how BioDuro evolves, the glue that holds everything together is this sense of family, culture, understanding and empathy that pervades the company internally and also extends to the way we treat and work with clients. While we are financially driven, we do not lose sight of the personal side of the business.

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