Drug Development & Delivery

May 2024 Vol 24 No 4 www.drug-dev.com

Next-Generation Injections

The Science & Business of Pharmaceutical and Biological Drug Development

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CEO

TOM SELLIG

Drug Development
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Tom Sellig

CEO

Adare Pharma Solutions

ADARE®
PHARMA SOLUTIONS

Expanding Capabilities to Exceed Customer Expectations

It's been more than two years since Tom Sellig took the reins as CEO of Adare Pharma Solutions. When we spoke with him shortly after he began his tenure, he shared his goals of positioning Adare in a competitive market to address complex formulation and development challenges and expand the company's customer relationships. We recently sat down with Mr. Sellig again to find how he has realized these achievements, and to learn more about the company's focus on addressing special needs in the market, its global expansion, and where he expects to take the company in the future.

Q: What are some of the challenges you're witnessing in the CDMO space?

A: The broader CDMO market includes drug substance, drug product, small molecule, and large molecule segments. There are regional players and global players in each segment, and each of those segments faces slightly different challenges.

When I think about small-molecule drug product – which is primarily where Adare's interests lie – one of the main issues continues to be supply chain challenges regarding API, especially controlled substance API. The DEA has changed the methodology for how it allocates quotas, and this is creating several issues for 2024, such as impacting how manufacturers like Adare produce products. There are mandated quotas for the API providers, and of course we can't manufacture products until we have the API, so scheduling of controlled substance manufacturing has gotten challenging. Luckily, we have a great logistics team that works closely with the DEA, with API providers, and with our customers to help minimize delays.

Q: We've talked about the challenges of the current marketplace. What are some of the opportunities available for CDMOs, and how is Adare taking advantage of them?

A: The CDMO landscape is one of rapid advancements, so companies that invest wisely and stay adaptable will always find opportunities to stay ahead of the curve and seize arising market opportunities. I continue to be really excited about the opportunities in the marketplace. Q1 2024 was very significant in terms of biotech funding, which means more companies can fund more development. That means more innovation and more opportunities for CDMOs, specifically Adare.

I also think companies that have great technology solutions are going to be in significant demand, and an unparalleled emphasis on technology is one way that Adare differentiates its offering. We're always evaluating new technologies to see if they can improve the development and manufacturing journey for our customers. The evaluation process requires time and resources that not every CDMO wants to commit, but at Adare we think it's worth the effort to discover technologies that power innovation for our customers.

Finally, there is a sense that many companies are looking to bring work back to the US that was previously outsourced or is being executed in other countries, which will be a boom for US-based companies.

Add all that up and it's really driving some great growth for the industry at large, and specifically for Adare. Our development pipeline is full of new opportunities. We have had record proposal volume in Q1 and we're seeing significant new opportunities. We are also looking at some growth from existing products. I came to this company two-and-a-half years ago believing firmly that there's significant opportunity for sustainable growth and we're seeing that growth today.

Q: You mentioned technology as a differentiator. What new technologies do you think have the potential to benefit the CDMO industry?

A: Two technologies come to mind immediately, technologies that might not just help grow the industry but even disrupt it in exciting ways. These are AI and 3D printing, both of which have already shown incredible boosts in efficiency and quality when implemented thoughtfully.

Adare has deployed AI very recently for advanced scanning capabilities, allowing us to look at a molecule in a very different way than we could previously. We are also using AI to predict how formulations and molecules will perform in the clinic. This is a really exciting breakthrough because it allows us to zero in on a formulation much faster and give us a higher probability that a particular formula will be successful in clinical studies, saving the sponsor time and money.

We recently installed a development-scale 3D printing capability in one of our Italian sites. This allows us to produce products in a very different way, and we think this will be great for several products in the global pipeline today.

We will be making more announcements about both of these technologies later in the year, so stay tuned.

Q: The continued growth of highly potent products is another major story in the pharmaceutical industry at the moment. How can CDMOs take advantage of this growth?

A: High potency has become an increasingly important part of pharmaceutical development. In fact, about half the drugs in development are highly potent compounds. The main driver is the oncology sector's domination of new drug development. I've seen estimates that 40%-50% of drugs in development are cancer drugs. And of those, 75% are high potency.

So, there are a lot of opportunities out there for CDMOs who want to get involved with high potency, but companies need to exercise abundant caution when doing so. Highly potent compounds require containment and infrastructure, and they take investment to support. You need to be vigilant about cross contamination and employee safety.

Because of these concerns, customers are hesitant to work with companies who are new to high potency. They demand CDMOs with deep experience handling highly potent products. That's where a company like Adare comes in. We have a long history of working with high potency, and we have facilities already in place that have been handling highly potent compounds for years.

In 2024 and beyond, we're leveraging that experience to further expand our high potency capabilities at most of the sites in our network. This will allow us to serve a broader range of the market by addressing high potency needs for additional steps in the manufacturing process and at different scales. For example, we will soon be offering wet and dry granulation that can support both clinical and commercial scale. With these expansions we will be able to serve more customers at more stages in their commercialization journey and ultimately help them get important products into the hands of patients faster.

Q: Pediatric formulations are a hot topic in the industry right now. This is one of Adare's specialties, so can you speak to the current landscape and how the company approaches pediatric development?

A: Pediatrics continues to be a growing portion of the market and you're right, there is quite a bit of focus on it at the moment. For example, there was legislation not too long ago that provides additional patent exclusivity for pediatric products. There's a greater awareness in the industry that pediatric products require different formulations for different metabolism in the body. Simply put, pediatric formulations are no longer a "nice to have." Companies must have a dedicated pediatric strategy in place to see their product live up to its full potential.

There are a lot of interesting challenges to overcome in pediatric development. If you've ever tried to get your child to take medicine, you know that it has to be convenient and easy to dose. It can't be hard to swallow, and it can't be bitter. Our formulators and scientific teams are well-versed in the needs of pediatric patients, and we deploy various strategies and technologies to meet those needs. We're the experts at taste masking bitter API via our Microcaps® encapsulation technology, and we provide customized release and other dosing options so that children ideally don't have to take as many doses. We also offer creative dosing formats that make medications easier to take, like powders that can be sprinkled on food and a solid dosage form that turns into an applesauce-like texture when you add a little bit of water to it.

Q: How do your high potency and pediatric offerings position the company in a competitive marketplace serving these special needs?

A: We want to be considered a leader in these spaces. We differentiate ourselves through our advanced technologies and capabilities, and through our focus on oral solid development for small molecules. We have a portfolio of technologies to deploy that can solve complex formulation and manufacturing challenges. We have a very deep toolbox that allows us to create a wide range of solutions to meet the demands of today's pharmaceutical global pipeline.

In summary, Adare is a full-service firm, able to offer solutions from the earliest phases of development and at every step all the way through to commercial manufacturing and beyond, including packaging.

Q: How has Adare adjusted its business model to become this full-service offering?

A: In many ways, we had to go back to basics. We acquired Frontida BioPharm in December 2021, around the time I joined Adare. Our leadership team assessed our priorities and the culture we wanted to build. To do that, we had to think internally about how we operate, how we are structured, and how we go to market.

It starts with having a client-centric mentality across the entire organization. As a company, we are wired to do everything necessary to ensure our clients are successful. Our leadership team personally takes ownership for ensuring the success of client projects, whether it's a smaller client or Big Pharma.

Q: What's Adare's business strategy on the world stage?

A: Adare is a global CDMO, and our business strategy is to constantly make significant investments in new equipment and capabilities for our global network to support more customers around the world. As one example, we recently upgraded our Pessano site in Milan, Italy to include expanded warehousing and a dedicated facility for packaging. In Europe, they prefer blister packs rather than bottles for oral solids, so we are installing blistering equipment to support those clients. The Pessano site is also part of our high potency expansion plan, allowing us to offer those services in Europe and beyond.

Q: We last spoke just over two years ago. Where do you see Adare in the next two years?

A: We want to continue on the successful path that we have started. We are going to see our internal investment projects through to fruition. We will continue to prioritize our customer-focused culture, and find creative ways to be cost-effective, faster, safer, and more efficient for our customer's projects. Most importantly, we will remain committed to our continuous improvement mentality of getting 1% better every day. ◆