EXPERT INTERVIEW

ADARE PHARMA SOLUTIONS

EXECUTIVE INTERVIEW WITH VICE PRESIDENT OF PHARMACEUTICAL DEVELOPMENT ON GROWTH AND STRATEGY

When Adare Pharma Solutions was acquired in September of 2020 by two private equity firms known for activating growth and innovation, the company sent a signal to organizations that depend on contract development and manufacturing services to bring their pharma solutions to the healthcare market: if you need a trusted partner, now more than ever, Adare is a winning choice.

We asked Giovanni Ortenzi, a 24-year veteran of Adare Pharma Solutions, to explain the company's strategy for becoming a global leader in CDMO services. Before taking the reins as vice president in 2019, Ortenzi split his career evenly between quality and industrial operations, where he gained an appreciation for the entire cycle of developing and manufacturing new pharma products.

Here, Ortenzi describes how pharma companies can leverage Adare's unique CDMO capabilities and proprietary technologies.

You recently announced the acquisition of Adare Pharma Solutions by Thomas H. Lee Partners and Frazier Healthcare Partners. What significance does that have for Adare's customers?

Ortenzi: New ownership puts Adare in an excellent position to help pharma companies bring lifesaving, transformative drugs to patients. Adare is powered by a technology-driven culture, a proven track record of manufacturing and product development, and resources to support growth and expansion of future CDMO activities on behalf of our customers.

Adare's leadership team believes this is good for Adare and good for our customers. They [the new owners] have an excellent record of investing in and growing their healthcare companies' portfolios. As an example, they were able to significantly grow PCI Pharma to several times the initial value. Our target is to become a global leader among CDMOs by widening our technology portfolio and our capacity.

What experience does Adare have that pharma companies would value in a CDMO supplier?

Ortenzi: Adare brings a wide range of consolidated technologies and experience from our history of developing and manufacturing products. Our customers trust this expertise to help develop their formulations and target their needs. In Adare, they'll find a company with expertise in formulation, regulatory support and manufacturing — a turnkey service that is valuable for pharma companies of all sizes. They'll deal with a single company rather than numerous contractors for every stage of development and commercialization of their products.
We are totally focused on providing turnkey CDMO services, including initial prototype development, building intellectual property around formulations, achieving final registration and manufacturing products. Our manufacturing sites and facilities are known for quality, and we're accustomed to working with the world's major health authorities. We have manufactured more than 40 products in 100 countries globally, including branded,

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specialty, OTC and veterinary products. Adare's regulatory expertise is such that we can support registration in several countries.

Adare is known for achieving difficult formulation targets. Can you provide examples?

Ortenzi: We developed Inderal® LA and InnoPran XL®, two products with a special type of release that complements circadian patterns for cardiovascular drug products. The formulation is designed to reduce a patient's vulnerability to cardiovascular events when the blood pressure rises. The traditional extended-release formulations that were on the market delivered a constant drug concentration in the blood without addressing chronotherapy needs. We've also developed taste-masked formulations for a stable pediatric suspension of Tenofovir, using our unique taste-masking, microencapsulation technology.

Adare Pharma Solutions describes itself as a technology-driven company. Aren't all CDMOs technology driven?

Ortenzi: It's true that many CDMOs offer technology as part of their portfolio. In our case, the differentiator is that we have such a wide pool of technologies that other similarly sized CDMOs do not have.

- Optimμm® technology allows us to produce very tiny, regularly distributed lipid beads of 200 to 250 microns. These may be taste-masked, modified-release (delayed/extended-release) and time-release beads. We can deliver these beads in modified-release formulations as capsules, sachets, tablets or suspensions.
- Stratμm™ technology opens a new door for our customers in sterile formulations. This offers the possibility of developing long-acting injectables, formulated in a matrix of polylactic and glycolic acid, PLGA. The product releases very slowly in the body, and it can have a time or pulsatile release, depending on the formulation's matrix and composition, as well as structure of the beads.
- Adare makes oral disintegrating tablets (ODT) using its technology called AdvaTab®, an oral product that, in combination with our Microcaps® technology, masks bitter compounds and quickly disintegrates in the mouth in less than 30 seconds without water and with a pleasant mouth-feel.
- Adare's MMTS™ Multi Mini Tablet System is an interesting multi-particulate solution for customers who want to develop modified-release products with a high drug load and a highly reproducible particle size; they can be formulated into capsules, sachets/stick packs, or combined with our Parvulet® technology to be administered to patients with swallowing problems.
- Similarly, one of our recent technologies, Parvulet®, improves compliance in pediatric, geriatric and dysphagia patients who have swallowing difficulties by converting a tablet or granules into a soft, food-like texture in the presence of water.
- We are also working in the emerging postbiotic microbiome area with our LBiome™ technology. This highly stable microbial composition for digestive health is produced through a proprietary fermentation process by our Adare Biome division in a GMP drug fermentation facility.

These advantages allow us to solve specific problems and target very precise release profiles. They're part of what makes us a technology-driven company, uniquely positioned to serve customers.

Where are your facilities located?

Ortenzi: Adare Pharma Solutions has four pharmaceutical drug facilities. Two are located in Italy and two are located in the United States. Our site in Vandalia, Ohio is also our primary R&D Center, while our Lenexa, Kansas location is specialized in early-stage development activities for the lipid microbead technology, Optimμm®, and the injectable technology, Stratμm™. Our site in France is dedicated to manufacturing our LBiome™ technology.

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What attracts small to medium pharma companies to work with Adare for CDMO services?

Ortenzi: We recently expanded our development capacity by about 30 percent by building a non-GMP laboratory, where we can quickly manufacture initial prototypes using a limited amount of drug substance. This is absolutely necessary for small and midsize companies, where there may be limited availability of APIs for initial studies. We can handle OEB 3 class substances, and we want to expand our offerings up to the OEB 4 class of products in the future.

We offer pre-formulation, formulation expertise, analytical development, material characterization, physical characterization and stability testing. Our customers gain access to modeling and simulation expertise that's necessary during the development of their formulations, along with regulatory support throughout the process.

The reliability of our group to support all activities, from the initial development through final registration and commercial production, is a great value to all customers, especially those who seek exclusivity in the market.

How can Adare solve formulation and life cycle management problems for its customers?

Ortenzi: Adare continues to invest in new technologies to complement our existing technology platforms. The recent acquisition of Orbis expanded our technology offering, not just in the oral space with the Optimμm® technology, but also in the injectable space. Stratμm™ allows us to develop long-acting injectables and produce very tiny (around 20 microns), tightly distributed, polylactic co-glycolic acid as extended-release beads.
We are talking about beads that constantly release the drug substance in the body for six to 12 months. The advantage of this technology is the very uniform particle distribution and small size. It offers better control of drug release and allows the use of smaller needles for the injections, both of which are advantageous for patients and doctors.

Our portfolio expanded in 2019 with Parvulet® technology. Parvulet® allows us to develop sachets or tablets that contain multi-particulate intermediate products and offers easy-to-swallow, taste-masked or modified-release formulations.

Within 30 seconds, tablets or granules convert into a soft, food-like texture with the presence of just a few milliliters of water. The final dosage form is ideal for pediatric and geriatric patients, as well as patients affected by dysphagia.

Our technologies work with prescription drugs as well as OTC products for customers that need taste-masked formulations, oral disintegrating tablets, suspensions, sachets, stick packs and/or sprinkle capsules. We strive to create patient compliant formulations that are ideal for the pediatric and geriatric populations.

How would you contrast Adare Pharma Solutions with other CDMOs in the market?

Ortenzi: I came to Adare from a pharma company that produced standard formulations. Adare has a completely different culture because we work in a niche area. Very few companies are doing the same kind of work.

Adare is not a large bureaucratic organization, so we can offer flexibility, fast response time and better customer service than giant CDMOs. Our ability to be nimble is beneficial for small startups and midsize companies, as well as large pharma companies because we can reduce the time to market for our customers.

We can work with small amounts of APIs, quickly develop initial prototypes, test our technologies and assess what's best for developing a customer's formulation targets. We develop commercial agreements and start experimental activities quite rapidly. Initial prototypes can be delivered within a couple of weeks, depending on the formulation and type of technology we are utilizing.

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Giovanni leads our global pharmaceutical development, technical services and operational excellence teams. He was previously Vice President, Quality at Adare, leading quality assurance, quality control, clinical quality assurance and compliance teams. Prior to that, he led the quality teams at Aptalis Pharmaceutical Technologies. Giovanni held leading positions at Eurand, including Industrial Operations Director–Europe. He also formerly held quality and manufacturing positions with Bristol-Myers Squibb.

Giovanni holds degrees in Pharmaceutical Chemistry and Pharmacy from the University La Sapienza in Rome, Italy.

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Adare Pharma Solutions is a global technology-driven CDMO providing turnkey product development through commercial manufacturing expertise focused on oral dosage forms for the Pharmaceutical, Animal Health and OTC markets. Adare's specialized technology platforms provide taste masking, ODTs, and customized drug release solutions. With a proven history in drug delivery, Adare has developed and manufactured more than 40 products sold by customers in more than 100 countries globally.

Can you share an example of how Adare serves companies that plan to develop an NCE or a 505(b)(2)?

Ortenzi: We are currently working on projects with NCEs for development of taste-masked, immediate-release pediatric formulations, as well as extended-release products for adults. An example is a flexible formulation that can be administered through gastric tube feeding, in addition to suspension, reconstitution and feeding. Adare has achieved important formulation targets for a very complex API.

We have developed and filed several 505(b)(2) formulations for internal development activities as well as for our customers. That includes converting standard- and modified-release formulations into more patient-compliant formulations.

Adare develops the intellectual property on behalf of our customers, and then provides them with additional market exclusivity and protection. One example is a recently-launched amphetamine with an immediate-release, taste-masked ODT formulation that was listed in the FDA Orange Book.

Describe Adare's capability with technology transfers.

Ortenzi: In addition to the pharmaceutical development team that works globally for the entire group, we have technical services teams located in the U.S. and in Europe. Those teams are dedicated to scale-up and commercial validation activities in our facilities.

This year, we completed a very challenging scale-up and tech transfer of a complex generic formulation in our Italian facility. Due to the COVID-19 travel restrictions, we were not able to have our pharmaceutical development team travel to Italy to follow scale-up activities.

All the scale-up activities were organized virtually, with the U.S. team connected to the Italian technical services team 24 hours a day by chat and video for a continuous exchange of information. We were able to successfully scale up and validate well ahead of the forecasted timelines. This opens the door for new ways of working in the future.