

MARIA FLYNN, ADARE PHARMACEUTICALS



As President and Chief Executive Officer of Orbis Biosciences, Maria Flynn led a company that provides innovative technology that improves the delivery, efficacy, and safety of pharmaceuticals. Under her leadership, the Convention on Pharmaceutical Ingredients awarded Orbis the Excellence in Formulation Award and, in 2020, Adare Pharmaceuticals acquired the company. Previously, Ms Flynn was a Director at Cerner Corporation (North Kansas City, MO, US) and, before that, an engineer with Camp Dresser & McKee (now CDM Smith, Boston, MA, US).

Ms Flynn has been named in *Entrepreneur Magazine's* "Entrepreneurial Women to Watch", *Kansas City Business Journal's* "Women Who Mean Business", and *Ingram's Business Magazine's* 40 Under 40", and she received the Central Exchange's "STEMMY Award for Enterprising Innovator". She serves on the Board of Directors of BioNexus KC (DBA Kansas City Area Life Sciences Institute), and she is a member of Pipeline Entrepreneurs, the region's premier entrepreneurial leadership organisation.

Ms Flynn holds an MBA from the University of Chicago Booth School of Business, where she was a Herman Family Fellow for Women in Entrepreneurship, an MS in engineering from Stanford University, and a BS in engineering from Kansas State University.

In this exclusive interview, Maria Flynn talks with ONdrugDelivery about trends in the oral drug development and delivery space, completing the Orbis acquisition during a global pandemic, and how the excellent technology portfolio and strategic fit between Orbis and Adare form part of the combined organisation's unique story.

Q We're picking up an increase in activity, innovation, energy and optimism around the oral drug delivery segment at present. What do you think are the causes/drivers?

A With our clients – pharma and OTC companies that invest behind innovation – we have seen increased attention on product lifecycle management. For example, we see pharmaceutical companies applying innovative technologies and creating difficult-to-replicate formulations, within their product portfolios. In addition, there is a marked increase in attention to medication compliance.

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This has to be done very cost-effectively, in part due to the pricing pressures that pharma companies face. That is where many

of Adare's solutions are well-positioned – technologies that can be scaled and offer a rapid speed to market.

Q How is Adare Pharmaceuticals positioned to capitalise on this upswing in activity?

A Flexible manufacturing solutions are another key industry requirement. As a technology-driven specialty CDMO, Adare provides exactly those turnkey CDMO solutions. Indeed, a top driver for Orbis to integrate into Adare was to be able to provide our customers with that turnkey flow from development all the way to commercial production (see Figure 1).

In terms of technology offering, we have a number of solutions that address the increased industry focus on specific patient populations with particular needs.

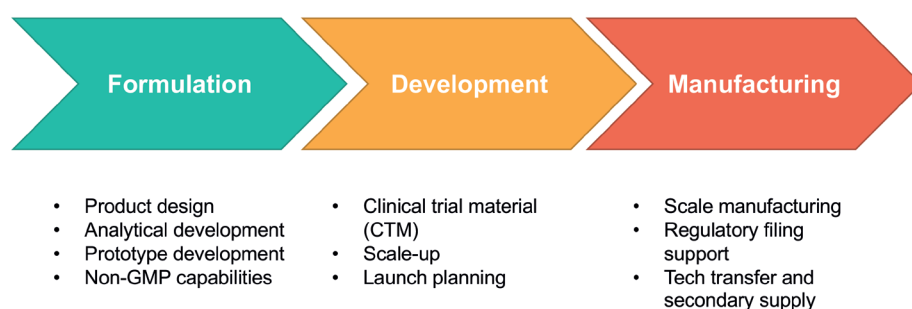


Figure 1: Adare's turnkey CDMO solutions, from development through to commercialisation.



Figure 2: Selection of Adare's key technology brands.

Orbis provides innovative taste masking and controlled release solutions for oral and injectable pharmaceutical products

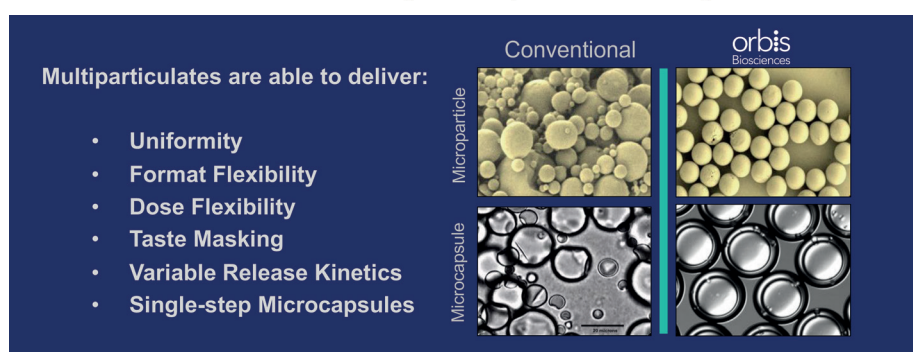


Figure 3: Superior particle uniformity from the Precision Particle Fabrication technology.

They include taste-masking, novel dosage formats, easy-to-titrate formats, and easy-to-swallow solutions. These technologies, combined with our expertise and intellectual property, provide our customers with protectable products, including next-generation treatments.

Some of Adare's key technologies (Figure 2) include: Microcaps for taste-masking via a solvent or aqueous-based coacervation process; Diffucaps, which incorporates release-controlling polymers or protective coatings into drug layer cores, granules, or crystals; and MMTS, the Multi Mini Tablet System, in which functional membranes are applied to one- or two-millimetre cylindrical tablets to control release rates.

Another interesting technology from Adare is Parvulet®, which enables pharmaceutical products to be presented as a solid powder or a tablet that converts into a semi-solid in the presence of water. It has great potential for addressing special swallowing considerations for paediatric, geriatric, and dysphagic populations with applications on both the prescription and OTC side.

To the Adare portfolio, Orbis adds the Precision Particle Fabrication® technology, the only technology on the market that can meet that need for uniform particles, and offer true control over variability in particle size that is so important for oral and injectable drugs (see Figure 3).

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Figure 4: Orbis's Optimum platform for oral delivery is based on its Precision Particle Fabrication technology.

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This technology offers format flexibility, dose flexibility, taste-masking, variable release kinetics, and a single-step microcapsule process, via a flexible, reproducible and scalable technology that accommodates a wide range of APIs.

Our Precision Particle Fabrication technology has given rise to three different platforms: Optimum®, for oral delivery (Figure 4); Stratum™, for injectable delivery; and Unison®, for otic treatments. The Orbis technologies compliment Adare's existing offering and capabilities well (Figure 5), enabling us to offer our customers a broader range of innovative tools and solutions to create new successful products.

Q How has the Covid-19 pandemic affected the company, and did it have an impact on the Adare/Orbis acquisition process?

A In many ways Orbis was very lucky to join Adare during this time. Adare has facilities in Milan, Italy, which was at an epicentre of the pandemic. Seeing how these sites kept working was remarkable. My perception was that the Adare executive leadership team was on the ball and saw the Covid-19 implications coming before most



TECHNOLOGIES EXCLUSIVELY FROM ADARE



Figure 5: The combined Adare / Orbis delivery technology portfolio offers an impressive range of solutions.

people did. They put in place the necessary processes and procedures early, securing PPE, and doing the right things to take care of their people. It was impressive to watch and, once the acquisition was completed, to join the organisation. Orbis incorporated these best practices into our site in Lenexa, Kansas.

Completing the acquisition during a global pandemic was definitely a test of flexibility. Throughout the due diligence, deal, and integration, we were able to keep going by adjusting our processes. Things you might normally do in person, we did virtually. It shows Adare's commitment because it would have been very easy to delay and say, "Let's table this for a better time". However, we completed the deal, and it is a great success story.

Beyond the Orbis integration, the pandemic continues to present challenges, and we continue to overcome them. For example, Adare completes technology transfer from

its Ohio, US site to the Milan, Italy site, and managed to work out how to do this virtually. In business development, we cannot be at conferences, so we find other ways to meet customers virtually as well. Our customers' programmes continue, and there is the same need to get their products to market, so these are very busy times. There is a lot of learning that we would not have had if we were not going through this Covid-19 experience.

Q Adare acquired Orbis in May 2020 and this was a major event for both companies. Could you describe how the acquisition came about, why the two companies represent a good fit?

A We built Orbis with a vision to integrate it into a larger company after making the necessary progress and maturing the technology.

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Figure 6: Adare benefits from a rich drug delivery and development heritage, going back to Eurand in the 1980s.

Adare has a rich drug delivery and development heritage, going right back to Eurand in the 1980s. Orbis has known Adare for about eight years, when what is now Adare was called Aptalis (see Figure 6). Even in those early days, the fit between the companies' missions was clear. Both Orbis and Adare had been able to achieve best-in-class drug delivery technologies in the solutions that they brought to the market.

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In terms of the strategic fit from a technology portfolio perspective, we looked at how we could present our clients with the most robust offering. Across taste masking, extended release, enteric release, and novel formats for oral drugs, the companies saw an opportunity to build on Adare's technology portfolio.

One clear point of differentiation is Orbis's Stratum technology, which is for injectable products. This represents an exciting expansion of Adare's offering beyond oral products and into injectable products for the first time.

What is fascinating about Adare is the mindset and ability to evolve continuously. Rather than remaining the same company for 40 years, it has expanded and grown. The recent innovations such as the Parvulet™ technology and the addition of Orbis's technologies, including the new expansion into injectable products, show how the organisation really understands how to keep continually moving to the next level. That is what characterises our unique and ongoing story.

ABOUT THE COMPANY

Adare Pharmaceuticals is a global technology-driven specialty CDMO providing turnkey product development through commercial manufacturing expertise focused on oral dosage forms for the pharmaceutical, animal health and OTC markets. Adare's

proprietary technology platforms specialise in ODT's, taste masking and customised drug release.

With more than 30 years of proven legacy, Adare has successfully developed and manufactured more than 40 products sold by partners in more than 100 countries globally.

ADARE
PHARMACEUTICALS

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A SPECIALTY CDMO TRANSFORMING ORAL FORMULATION CHALLENGES INTO PRODUCT SOLUTIONS

RIGHT DRUG, RIGHT PATIENT, RIGHT FORM

As a technology driven specialty CDMO, Adare provides extensive expertise and advanced knowledge to guide your project from product development through commercial manufacturing. We specialize in ODTs, taste masking, and customized drug release for the Pharmaceutical, Animal Health, and OTC markets. With over 30 years of proven legacy, Adare has successfully developed and manufactured more than 40 products sold by partners in more than 100 countries globally.

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