

Drug Development & Delivery

May 2022 Vol 22 No 4

www.drug-dev.com

Self-Injection: the “New Normal”

IN THIS ISSUE



INTERVIEW WITH
ADARE PHARMA
SOLUTIONS'
CEO
TOM SELLIG

DELIVERY & FORMULATION APPROVALS 18

Kurt Sedo
Esay Okutgen, PhD

ARTIFICIAL INTELLIGENCE 24

Updesh Dosanjh, MS

REGENERATIVE MEDICINE 56

Thomas Donner, MD

DEVICE UX DESIGN 64

Aditya Jagannathan

AUTOMATION SOLUTIONS 68

Rich Ellson
John Fuller, PhD

TECHNOLOGY & SERVICES SHOWCASES 71

The Science & Business of Pharmaceutical and Biological Drug Development



Cindy Dubin
PFS & Parenteral
Drug Delivery:
Self-Injection is
Very Much the
“New Normal”



**Paul
Matejtschuck, PhD**
Unravelling the
Complexities of
Freeze-Drying
Pharmaceuticals With
Advanced Microscopy
Techniques



Shawn Cain
PCI Pharma
Services:
Broadening Our
Biologics Footprint,
Together

Drug Development EXECUTIVE



Tom Sellig

CEO

Adare Pharma
Solutions



Adare Pharma Solutions: The Journey to Become a Full-Service Provider

Tom Sellig was excited to take over the role of CEO at Adare Pharma Solutions in January because he saw a unique chance to make a difference, create value, and seek out growth opportunities. He and the leadership team at Adare are confident that the company is now well positioned on its journey to become a world-class, full-service CDMO, thanks to the company's expanded development and manufacturing capabilities, its growing biome-based business, and the Frontida BioPharm acquisition this past December.

Mr. Sellig recently spoke with *Drug Development & Delivery* about his expectations for Adare and how he can leverage his 30-plus years of pharma experience to put Adare in a competitive position to address complex formulation and development challenges. He also addressed how acquiring Frontida, a vertically integrated CDMO focused on oral formulations, will help build and expand Adare's customer relationships.

Q: What mark are you hoping to make as the new CEO of Adare?

A: There are certain segments within our business, offering more opportunity than we realized, and other areas that we are less excited about. You learn to minimize certain areas of the business and maximize other larger growth opportunities. Specifically, I am referring to our technologies and our biome business, the latter residing in a space that is exploding and for which we are well positioned. We are also focused on how we go to market with our customers, our messaging, and taking advantage of the technology, assets, and capabilities that we have not really gone

after in the past. The legacy Adare business offers taste masking, controlled release, and patient-centric dosage forms. When combined with Frontida's capabilities of high potency, comprehensive packaging, and multi-layer tableting, we now can offer a suite of technology services to help customers develop products and address their formulation challenges. Combined, the company now has nearly 100 scientists and experts in product development to create customized solutions for customers worldwide.

Q: Please describe Adare's biome business.

A: Adare Biome™ is our specialized division located in Houdan, France, near Paris, where our team is focused on harnessing the power of the microbiome. Biotic-based products are growing at a significantly faster rate than the rest of the market. We see leading pharma companies, and even growing mid-sized companies, focused on biome-based solutions. Using our proprietary LB (*Lactobacillus fermentum* and *Lactobacillus delbrueckii*) strains and the ECHO™ Process to enrich, concentrate, and heat treat organisms, Adare Biome provides post-biotic solutions in human and animal health. Our own Lactéol® is a proprietary combination of LB and fermented culture medium (neutralized and enriched with metabolites) that safely fights diarrhea, in addition to rehydration and/or dietary measures, in children and adults, using a unique combination of actions to inhibit pathogens and boost natural defenses. We see this biome business as a growth opportunity for our organization and we plan to make additional investments to scale this business.

Q: As you joined Adare right after the Frontida acquisition, do you have your own vision now for how the two companies move forward?

A: Our investors believed there were opportunities that existed between the two organizations. And I am aligned with most of that rationale, as well as the strategic and financial drivers. When it comes to taking those messages and capabilities to customers, we see additional upside opportunities. We are committed to helping our business development teams and customer management teams converse with customers. I have significant experience driving growth and thinking about scaling customer solutions to be more specific around our solutions and

benefits to customers, such as integrated solutions that can mean faster development cycles, creative cost reduction strategies, and overcoming formulation challenges.

Q: How does the Frontida acquisition expand Adare's capabilities, capacity, and expertise and how will you brand this message to pharma clients?

A: The overall response is capacity and scale. We have added three new sites into our overall network, two in Philadelphia and one outside Chicago in Aurora, IL. We have added tremendous development and commercial manufacturing capacity. Additionally, we brought in experts who have both complementary and differing skill sets from our existing Adare team. Finally, we now offer capabilities in high potency, multi-layer tableting, and packaging. The synergy between the two companies gives us full-service capabilities without needing to use third-party providers to provide end-to-end solutions for our customers. Most clients in the industry have worked with either Adare or Frontida in the past. They know Adare as a product-based organization, but now they will know us as a service-based organization.

Q: What is Adare's business model and does the acquisition change that model?

A: At our core, we are a technology-driven CDMO that has end-to-end capabilities, from early-stage development through commercial manufacturing, including packaging capabilities and capacity. We will continue to add capabilities to fill gaps and double down on the breadth of capabilities and capacity we bring to the market. We will expand customer relationships and geographical footprint to build out the vision of developing products and addressing formulation challenges.

Q: How will Adare position itself against other CDMOs going forward?

A: This goes back to our core technology-driven platform and leveraging our broad-based solutions. As I think about the CDMO space today, there are players looking to provide solutions for cell and gene therapy, biologics, and sterile. Then there are some international CDMOs focused on cost. I think

about differentiation through service and technology. These are the areas where we can build a world-class leading CDMO that specializes in small molecule and oral delivery solutions. About 90% of the volume in global pharma is in small molecule. While other segments may be growing, this continues to be an important space. Being able to support those products and looking for better solutions for generics or new NDAs is where we want to create our position in the market.

Q: Are there specific therapeutic areas that interest Adare?

A: We actually went through a formal, comprehensive analysis of the global drug development pipeline and looked at every product in clinicaltrials.gov. We identified where they are in their development cycles and matched that with our capabilities, both in development and commercial manufacturing. What we found was that we are able to cover most therapeutic areas. Some don't fit into our sweet spot, but we can support quite a wide range of products that cover virtually all the therapeutic areas.

Q: What keeps you up at night?

A: The things I don't worry about are our quality, regulatory compliance, operational performance, and delivery – all of which are very strong. I do worry about how to bring our solutions to more customers, how to scale, and how to keep up with the latest technological needs in the industry. I think about the numerous things on our roadmap to become a world-class CDMO and feel confident that we are well on our way. ♦

To view this issue and all back issues online, please visit www.drug-dev.com.

Drug Development[®] & Delivery

Keeping you connected to your target audience is now more important than ever.

For more than 20 years, Drug Development & Delivery has successfully connected technology and service providers with R&D scientists, business development professionals and corporate managers working at pharmaceutical and biotechnology companies.

So, while we work through these challenging times, Drug Development & Delivery keeps you in front of your key audience.

Call us today or visit us at drug-dev.com and let us show you how.

**Print & Digital Editions | Website Marketing
Email Campaigns | Videos
Exclusive Whitepaper & Webinar Marketing
Online Company Profile | eBooks
eNewsletters**

John Kiesewetter: 541-338-0022

jkiesewetter@drug-dev.com

Ralph Vitaro: 973-263-5476

rvitaro@drug-dev.com

drug-dev.com