

**Clinical Trial Materials Development and Manufacture for the Pharmaceutical Industry**

**Healthcare  
Pharma**

**Agere Pharmaceuticals**  
62925 NE 18th Street  
Bend, OR 97701  
541.318.7115  
[www.agerepharma.com](http://www.agerepharma.com)



**Dr. Marshall D. Crew**  
CEO

**BIO:** Marshall has 17 years of experience improving oral bioavailability with solubilization technologies. Throughout his career, he has focused on developing technologies for the delivery of poorly soluble drugs, and then managing their implementation to achieve client success. Marshall has over 28 patents and patent applications to his name on various drug delivery platforms including controlled release, nanotechnology and solid dispersions. His scientific expertise includes formulation design and development, solid-state characterization of drug substance and product, and computational modeling (predicting shelf-life and pharmacokinetic and bioavailability for oral, devices and

parenteral delivery). He is expert at in vivo study design and interpretation, and the design of API physical properties to optimize efficacy and overcome PK and delivery constraints. Marshall holds a PhD in Physical Chemistry from Oregon State University, and is a member of Agere's Board of Directors.

**About Agere Pharmaceuticals:**

Agere is a leading contract development and manufacturing organization (CDMO) providing pre-clinical formulation development through clinical-stage cGMP manufacturing services for drug products. We specialize in improving the oral bioavailability of BCS II – IV compounds through fundamental science, solubilization expertise, and proprietary solubilization technologies. Agere's formulation services leverage our proprietary Quadrant 2<sup>TM</sup> design platform, which encapsulates fundamental science, extensive expertise and best practices to achieve a faster path to bioavailability enhancement.

**Interview conducted by:  
Lynn Fosse, Senior Editor  
CEOCFO Magazine**

**CEOCFO:** Dr. Crew, what is the concept at Agere? What do you do?

**Dr. Crew:** Agere is a contract development and manufacturing organization for the pharmaceutical industry. We develop and manufacture clinical trials materials primarily in the solubilization space.

**CEOCFO:** What are the particular segments of the industry that are of focus?

**Dr. Crew:** We provide services to large and small pharmaceutical companies, with the majority of our busi-

ness supporting companies from virtual pharma and biotech companies on the order of 250 to 500 employees.

**CEOCFO:** Was that by design or opportunistic?

**Dr. Crew:** Actually a combination of both. On the formulation design side, we are a small company that is very science focused, and we are expert at developing formulation solutions customized for each API solubilization challenge. We tend to find a more receptive audience in the smaller pharmaceutical companies where they simply don't have the resource and the expertise that we can provide.

**CEOCFO:** There are many companies in your space. What do you understand at Agere that perhaps others do not?

**Dr. Crew:** There are a couple of key aspects that differentiate Agere. One, as I mentioned earlier, we are highly science focused, and our methodology for developing formulations and process is very physical chemistry-based. In other words, we approach problems from a mechanistic, molecular level. We think about each compound's structure and how it interacts with its environment, and then extrapolate that to bulk properties that can be measured in the lab. It is our belief that this approach sets us apart from our competition.

Second is that we are a very customer focused company, so excellent service is very important to us. What I mean by that is that we take the approach that we are on the client's team. We work collaboratively and we recognize that making our clients successful or helping them advance their products into say, a clinical stage, is the number one priority. We make every effort to make that a smooth and worry-free process.

**CEO CFO:** How does your formulation approach differ from the standard method?

**Dr. Crew:** In many ways. For example, formulation development is typically based on prior experience with a degree of empiricism to arrive at a final formulation composition. This approach starts with a number of formulations and seeing what works best, a trial-and-error methodology. In that case, it is possible that success might never be achieved, but you wouldn't know that until significant time and resource had been expended. Agere's process is very different. We start with the molecule and ask what must be done to achieve success. Then we focus resource on the high-probability path, and more quickly arrive at an answer.

**CEO CFO:** Do many of your clients take advantage of the full range of services that you can provide?

**Dr. Crew:** Yes, the vast majority start with Agere for formulation and continue through clinical trials materials manufacturing. We are continually adding capabilities as clients request additional services.

**CEO CFO:** Would that be something you have added because a client asked you to do it and that has been able to add to the mix?

**Dr. Crew:** One of the major services we have added in response to clients' requests was GMP manufacturing and analytical capability. That is of course a big addition, but done to support virtually all of our clients, as the majority were asking Agere to support CTM manufacturing. The reason our clients requested the cGMP services was that it was just too costly and time-consuming to have us do early development without being able to take them into the clinic.

**CEO CFO:** Your website indicates Agere is committed to effective client communication. What does that mean in practice?

**Dr. Crew:** One is making sure that we communicate on a timely basis of any progress on a project, whether good or bad. Many of these projects are early stage, so they naturally run into

a number of challenges as we work through the development process. Ensuring effective communication about what those challenges are and how they could affect timelines and cost is critical. It is an incredibly important feature of our communication because clients need to understand how the formulation development effort might impact their program in a global sense. We recognize that we are only one part of the development process and we make sure that clients have all the information available as soon as it's available, as our work can impact their comprehensive product development process. Knowing how the Agere-part of the overall project is progressing assists clients as they make decisions about their project and how they are going to manage and adjust timeframes, if required.

**"We are leading experts in the delivery of poorly soluble molecules and a major supplier of spray drying services."  
- Dr. Marshall D. Crew**

**CEO CFO:** How do you reach prospective clients?

**Dr. Crew:** Our two most effective methods are word of mouth and technical presentations at conferences.

**CEO CFO:** When you are speaking with a prospective client, is there an "aha" moment when they understand the difference at Agere or does that come when they've actually started working with you?

**Dr. Crew:** That's an interesting question. I think we often observe an "aha" moment, and usually it occurs as we're getting into technical detail with the client team. Frequently as we are meeting with clients to understand and discuss the rationale for the potential solutions, we see the light bulbs go on. This is part of our standard process and it serves us well as we get the information that helps us frame the problem and solution, and clients tell us that they learn a lot from these meetings, as well. This is of great value to Agere, as then we have a more informed client about the aspect of the work we are performing on their behalf.

**CEO CFO:** What is the key to working with a scientist or researcher who is too close to their idea to be objective? How do you navigate those waters?

**Dr. Crew:** For one thing, we believe the business is essentially about delivering value, relationships and building confidence in our capabilities. One key aspect of all of this is to provide rationale. This gets back to collaborating closely with the client so we understand their molecule and business goals, and they understand what we can do. The approach reflects that we try to not just say "this is what you need to do". Instead, we point out some of the challenges that we see, potential approaches to overcoming them, and the reasons why it makes sense to us.

There is usually a back and forth. We know we're dependent on the client to get the full picture, and so gaining perspective from the innovator company is critical to being able to make sound decisions. We really try to engage and work in a collaborative way.

**CEO CFO:** How is business today?

**Dr. Crew:** Business is very good. Agere has been growing at 50% or greater year over year for the last three years. We are looking for continued rapid growth next year.

**CEO CFO:** Are you able to accommodate the growth without additional people or will you be adding to the team?

**Dr. Crew:** We will definitely be adding to the team. As in most service industries, growth is really around people. It takes quality people to manage a project and do the work. We will definitely be adding additional staff.

**CEO CFO:** You have a fair number of patents and patent applications. Is that related to projects that you are doing for your customers? Is that something outside of that and how involved are you personally still?

**Dr. Crew:** The philosophy of our company is to innovate for our clients' success. We typically assign the IP that is related to a client's compound and product to that client. In exchange, we generally want to retain

the more generic IP. Most of our IP however, is know-how and trade secret.

On the technical level, I am still involved in solving problems if we face formulation challenges on which I can provide a unique perspective. But as we've grown our scientific team and added world-class expertise, my technical and scientific involvement is diminishing. I focus on the overall company and on innovations that will support our goal to continue to add to our capabilities. We are initiating an internal research and development program in our company and I'm heavily involved in that.

**CEOCFO:** Do you miss it?

**Dr. Crew:** Yes and no. I really enjoy running the company and it's something that I want to do, but I also enjoy the science. By working as needed with the other Agere scientists and

being involved in IR&D, it's the best of both worlds.

**CEOCFO:** What surprised you at Agere?

**Dr. Crew:** What has surprised me? Well, one pleasant surprise is to see what you think should happen in a business, happen. Of course, that is accomplished through a lot of hard work and a talented and committed team. We are fortunate that we have both here at Agere, making this a truly great and rewarding experience.

**CEOCFO:** Why should investors and people in the business, healthcare and CRO communities pay attention to Agere? Why is Agere exceptional?

**Dr. Crew:** One reason is that we are leading experts in the delivery of poorly soluble molecules and a major supplier of spray drying services. It is well known that this a growing segment of the pharmaceutical industry. More and more compounds with good

pharmacodynamic properties are increasingly insoluble. We are a company focused on that segment of the industry and we have a tremendous amount of experience in that field.

We also are rapidly increasing capabilities to help our customers through the clinical stage as well as the capacity to handle multiple customer compounds. We are a growing company in that space and I think that we are also quite innovative in terms of solving the key technical hurdles that remain in the space. Poorly soluble molecules are very challenging from a physical and chemical perspective and the internal research that that we began here is aimed at solving a lot of the remaining key technical challenges in making this a less novel approach to deliver a poorly soluble molecules.



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