# A Research Development Company

**An Interview with Dr. Joan Fallon, Chief Executive Officer and Founder, Curemark**

*Dr. Joan Fallon*

**EDITORS' NOTE** *Having filed her first patent application in 1999, Dr. Joan Fallon has worked to research autism and related disorders, as well as to bring her findings to a platform for commercialization. As a seasoned clinician, she worked as a pediatric chiropractor for 25 years specializing in pediatric development. She taught anatomy, physiology, and developmental biology as an assistant professor of natural science and mathematics at Yeshiva University, in addition to lecturing about pediatric development around the world. Dr. Fallon has recently been appointed as Senior Advisor to the Henry Crown Fellows at the Aspen Institute. She has also been appointed as a Distinguished Fellow at the Athena Institute for Leadership at Barnard College of Columbia University. Her discovery of a potential biomarker for autism and ADHD, and her vast array of intellectual property in the area of gastrointestinal secretory deficiencies, form the basis of Curemark. She was one of the first physicians of any type to enter Romania and to help determine the state of the Romanian orphanages. She served as an advisor to the New York Yankees for disability services for the new Yankee Stadium. She has a B.A. from Franklin and Marshall College where she serves on the Board of Trustees, a D.C. from Palmer University, and completed coursework for the M.Sc. in clinical investigation from Harvard University's joint program with Massachusetts General Hospital.*

**COMPANY BRIEF** *Curemark (curemark.com) is a drug research and development company focused on the treatment of neurological and other diseases, especially those with dysautonomic components, by addressing certain key gastrointestinal/pancreatic secretory deficiencies.*

**Where does the Curemark business stand today and what are your key priorities as you look to the future?**

We've really grown since our initial concept. We were born out of an observation about children with autism, and we developed the company around autism and doing clinical trials for it.

At the same time, we are looking at many other areas in neurology and neurodegeneration that we felt were akin to autism. We now hold 46 worldwide patents on our technology in multiple disease areas, and we're going to start looking more closely at others things.

We consider ourselves to be a research development company. We understand the science and conduct clinical trials with a potential to commercialize or license our technology to other companies who would commercialize it.

**Is that initial focus around autism still at your core?**

Absolutely. We completed our first Phase III looking at what we call biomarker positive children, and the FDA had to ask us to look at all children with autism to see if our drug is beneficial for children we call biomarker negative. It has to do with serotonin and the boost in serotonin that our drug may give to all the children with autism.

We are submitting our new drug application and we have a rolling NDA with the FDA because of our FAST TRACK status. While we're doing that, we're conducting this second trial.

Autism has been our core and will remain so.

**How much progress has been made in the treatment of autism and are you optimistic that this matter is being addressed efficiently?**

There is currently a lot of excitement around genes and gene therapy, and those things are promising but they don't bring treatments to people who need them today. There aren't a lot of treatments being developed for these children, which is sad to me, because autism is a spectrum disorder and we are going to need many drugs to treat various aspects of the condition, and there isn't much being done.

The underlying cause of the condition and the precipitating issues are still unknown, so there isn't a lot of investment money in the area, which also slows down progress on treatment.

**How critical is Curemark's technology platform and is technology playing a major role in these advances?**

I believe so. Our new trial is done electronically so it speeds things up and makes everything more efficient.

In terms of other areas of development, we're going to do a Phase II in cocaine addiction. There is new evidence that a transcription factor in the brain called deltaFosB may play a major role in cocaine addiction. There is a major need for dopamine and the interplay between dopamine and phenylalanine, the amino acid building block of dopamine. Our enzymes are very important in releasing the phenylalanine from ingested food, which is the only source of phenylalanine in the body. These discoveries are new and exciting. We also hope to use functional MRI in some of our clinical trials to look at changes that our enzyme produces in the brain.

It's a critical thing as we continue to explore our existing technology and look at what the future may hold for it.

**You put together a seasoned board of individuals who are leaders in business, and who have innovative mentalities and business vision. How critical has that been in advancing the company and focusing on its growth? In this same regard, would you also touch on the emphasis you put on talent?**

The initial work we did seemed really out of the box, and now science has caught up to us. However, I really needed to surround myself with people who could think a little differently – for example, someone who was a seasoned regulatory person who understood what our mission and our goals were and could take that mission and those goals and fit them into a mainstream regulatory environment that made sense for broad clinical trials.

I think that having a multiplicity of people around who could advise me and help make this a reality is really important because it requires many different kinds of thinking, and an understanding of the science that could push it through.

**As the pipeline has grown, has it been hard to manage that growth?**

Yes. We're at a critical juncture where we're beginning to hire people to help execute our mission. It's a relevant piece because as we get bigger and interact with more people and more people want to look at our drugs for different diseases, it's really important to have the ability that can help execute that. We're currently in the process of hiring that team.

**How do you evaluate success in this area? Is it hard to be patient sometimes and do you celebrate the wins along the way when there is so much more to do?**

As an entrepreneur, I have to celebrate the wins along the way because if I didn't, I would have become fatigued very early on in the process.

We have to look at the milestones and goal achievement as we move forward as victories in and of themselves.

It's optimism coupled with clear vision that allows this to happen.

Entrepreneurship is about making these victories happen. ●