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ACORDA THERAPEUTICS

Acorda's CEO on failure, perseverance and the profound risks of drug development

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Dr. Ron Cohen isn't easily deterred. The physician-turned-executive has spent decades in the biotech industry and weathered a number of setbacks – he learned in his early years at the now-defunct Advanced Tissue Sciences that to succeed, he needed resilience.

"I learned that it took hundreds of millions of dollars if not billions to develop a single drug successfully. I learned that the odds of success were approximately 10%. I learned that even if you were successful it probably was going to take you, on average, between 10 and 15 years," he told ***Drug Delivery Business News.*** "And I thought that was great."

The discouraging statistics on drug development didn't dissuade Cohen in part because he saw it as a chance to try to bring cutting-edge science out of the laboratory and make it work for patients.

"As a physician, that sang to me," he told us.

Years later, Cohen now oversees roughly 460 employees as CEO of Acorda Therapeutics (NSDQ:ACOR). He leads a team that's developing drugs to tackle debilitating neurological conditions, including multiple sclerosis and dementia.

"The thing I find most poignant and terrible about these diseases like Parkinson's and Alzheimer's and MS is that they slowly rob you of who you are," Cohen said. "We are particularly interested in restoring functionality in these diseases."

Acorda's product to treat people with Parkinson's disease, which is under review at the FDA, makes use of a formulation technology first developed by Bob Langer's laboratory at the Mass. Institute of Technology.

Langer and his team figured out how to load more drug into an inhaled dry powder without weighing the powder down. Cohen's team at Acorda used that drug-delivery technology to develop a self-administered, inhaled formulation of levodopa for people experiencing a re-emergence of Parkinson's symptoms.

Levodopa, also known as L-dopa, is traditionally administered to Parkinson's disease patients via a pill.

Cohen

"It turns out that this molecule is not particularly well absorbed by the gut. It also turns out that it's even worse for people with Parkinson's disease because Parkinson's affects their gut motility as well," Cohen said.

As the disease progresses, people with Parkinson's disease begin experiencing unpredictable "off" periods – their symptoms re-emerge, despite taking their prescribed regimen of oral L-dopa.

"It's totally disruptive. It's like someone put a ray gun on you and just sort of paralyzes you. It's not quite paralysis. It's like someone loading you up with lead bars and you just can't do anything," he explained. "There's a crying need in this area for something that is easily administered, well tolerated, that can get people out of their 'off' periods rapidly without screwing up their oral schedule so that they can live a near normal day day-to-day."

Acorda's inhaled product, Inbrija, has succeeded in late-stage Phase III safety and efficacy trials, helping to improve motor function in people with Parkinson's disease.

But the company faced a major regulatory setback with its Inbrija product last year. Acorda shares plummeted nearly -30% after the FDA issued a 'refuse to file' letter to the company, signaling that it would not review Acorda's Inbrija application.

"It always rocks you back on your heels because you have really good people, you put together the NDA which is a very complicated document, you've dotted your i's, crossed your t's, and you have external consultants look at it," Cohen said. "You have to go to the company. You have to make sure that people are continuing to be focused, that

they understand that it's another bump in the road. You work through it and you move ahead."

The Acorda team resubmitted its Inbrija application and the FDA formally accepted the NDA in February this year. The U.S. regulatory agency is slated to make a decision by Oct. 5.

"The people who are in this industry, they get what it's about. They understand that developing a new drug successfully is one of the hardest things that a group of human beings can do," Cohen said. "It is so incredibly complex and there are so many ways to get stalled out or have setbacks."

It is among this rigorous and sometimes defeating process that Cohen finds himself frustrated by the criticism levied at the pharmaceutical and biotech industries regarding drug prices.

"I don't think people appreciate by and large what really goes into this and what it means when we say that 90% of drug programs fail," he said. "Think about it – most of the industry is composed of little companies with just one product in development. If you extend that, that essentially means that nine of ten companies are going to fail. Now, it's not that bad because companies usually have a pipeline, but it becomes an existential issue for many, many companies that are trying to bring advanced therapies to patients.

"I don't believe that there is much appreciation at all of the reality of the lives we lead here and the fact that the successes are vanishingly few. The failures are daily. If you didn't have people who were willing to put up with that, we would have no progress. We would be using today's drugs for our kids and grandkids and beyond that," Cohen added.

Of the nine products that have reached human trials since Cohen founded Acorda in 1995, all have failed except two.

"That means there are seven that we invested a lot of tears and blood and sweat and time and money – and they're not here," he said.

For young biotech entrepreneurs, Cohen extended a piece of advice – harvest perseverance, because you're going to need it.

"The number one quality that you need and that everyone in your company needs is perseverance. If you don't have that, then you should just go back and do something else for a living because you cannot do this type of work if you don't have a thick skull and a thick hide and the ability to get off the mat again and again and again," he said. "Even now, 30 years into my career I'm frequently reminded that I didn't dot enough i's, that I didn't double-check, that I didn't get enough people looking at it. The stuff we do is so complex that you just always have to be thinking what did I miss? What could I have missed?"