

# Executive Summary

**Roger L. Hawley**  
CEO, Zogenix



## Zogenix: New Specialty Pharma Dives Right Into Competitive Migraine Market

By: Cindy H. Dubin, Editor-In-Chief

When the news was announced in late summer that Aradigm Corp. would focus on pulmonary delivery, and that it sold its Intraject® subcutaneous delivery technology and related assets to Zogenix Inc., a newly formed privately held Specialty Pharma company was born. Zogenix plans to complete development and commercialize the sumatriptan Intraject product for migraine, and may seek to commercialize other products based on the Intraject technology. Under the agreement, Aradigm received an upfront payment of \$4 million.

Zogenix is by no means an insignificant company, having raised \$60 million in a Series A private venture financing. Proceeds from the financing will go toward acquiring and commercializing products based on the Intraject technology in the migraine field and other CNS applications and seeking technology license agreements in other therapeutic areas.

Roger L. Hawley, CEO of Zogenix, told *Specialty Pharma* that the company's initial focus on the global development and commercialization of Intraject sumatriptan — a needle free, single-use, disposable, subcutaneous delivery system — will put Zogenix in the middle of a competitive \$2.7-billion triptan segment of the migraine market.

**Q:** *Can you please provide a brief explanation of how Zogenix came to be?*

**A:** Founded in August 2006, Zogenix was a marriage of a start-up Specialty Pharmaceutical company focused on CNS and pain, with a spin-out of the novel Intraject drug delivery technology platform from Aradigm Corp. Our management team is also a melding of talent from these two worlds: we have the technical expertise and leadership of Stephen Farr, our President and COO, and the talented people he has brought with him from Aradigm; and we have my business and commercial experience supported by a team I am in the process of assembling. Add in the vast experience of Cam Garner, one of our six founders and non-executive chairman, along with the depth of our investors, and we have a really strong team building Zogenix. We are all now focused on a single goal — bringing our first product, sumatriptan Intraject, to market.

**Q:** *You have a pretty impressive founding management team. How did such a group assemble?*

**A:** The founders of Zogenix were pulled together from two great teams. The Aradigm team was established, with a track record of success developing the Intraject technology, led by Steve Farr. The operational experience of John Turanin and the business development leadership of Jonathan Rigby completed the package. I was working with Cam Garner when we started looking at Intraject. Cam had introduced me to Bret Megargel, and he has significant venture experience to lead us through the business development and the VC funding process. Recently, we added our commercial lead, J.D. Haldeman, to help us in preparing for launch, and I know from direct experience she is a terrific marketer. And, of course, Cam has vast experience in building successful Specialty Pharmaceutical companies. I had experience with the commercialization of three of the seven triptans, including Imitrex® (sumatriptan), the market leader at GSK. It just really all fits together. Zogenix has a strong foundation, and the team has the passion to make it all work.

**Q:** *What is the connection now between Zogenix and Aradigm?*

**A:** Ultimately, this was a simple product acquisition deal that brought with it key talent. Zogenix acquired the assets from Aradigm, and the deal went very smoothly. Aradigm had a change of strategic direction, and that created the opportunity. The key was also attracting the experienced talent from Aradigm, and we are very fortunate to have solid technology and great people.

**Q: *What makes Zogenix unique?***

**A:** Perhaps our tag line says it best — Where Medicine Meets Technology. We are a Specialty Pharmaceutical company first. Additionally, we have a very unique asset in our Intraject technology, a needle-free, single-use, disposable, subcutaneous delivery system. It has 10 years of development behind it, and it works! This has enabled us to become a Specialty Pharmaceutical company providing very unique product offerings with a state-of-the-art technology and the opportunity to gain approval of new products quickly using the 505(b)(2) regulatory path.

**Q: *What is your business model?***

**A:** Our business model is three-pronged: first, to successfully commercialize our lead product, sumatriptan Intraject, in the US initially, and then in Europe with a partner. This includes completing a final clinical study, filing the NDA, and preparing and executing the launch, including building a full commercial group and a specialty sales force. Next, we plan to develop and commercialize additional CNS and pain therapeutics that utilize the Intraject technology platform. Finally, we look to establish high-value partnerships around licensing out our Intraject technology for products outside of our therapeutic focus, such as hepatitis C.

**Q: *How did you raise \$60 million in Series A funding? What were investors looking for in Zogenix?***

**A:** That's the \$60-million dollar question, isn't it? Our investors were attracted by several features. First, they were impressed by the management team we had assembled. The background and experience of our team fits the opportunity like a glove. We have the depth and breadth needed for success. They also saw a large market opportunity in our first, very near-term product, which, due to its advanced development, has relatively low technical risk. The acute treatment of migraines is a very large market, over \$2.7 billion in the US alone, and Intraject is a perfect fit for patient use at home. Finally, we all saw in Intraject a truly unique, high-quality technology asset that could be developed with many new drugs, and we have a very long runway with our Intraject patents and manufacturing know-how.

**Q: *What plans do you have for this money?***

**A:** Our path is very clear — use these funds to get our first product on the market. Beyond that, we plan to pursue other products and opportunities to utilize and partner the Intraject technology.

**Q: *You announced that some of the \$60 million was used to purchase sumatriptan Intraject for migraines from Aradigm Corp. How will Zogenix be handling that product from this point?***

**A:** Sumatriptan Intraject is our primary focus now, and is expected to be our first product launch. We have filed our IND, we have started our pivotal trial and we plan to file our 505(b)(2) NDA in mid-2007. We are now scaling up our manufacturing with some additional automation to be prepared for launch. We plan to build our commercial organization in 2008.

**Q: *Will Zogenix be developing other products as well for the CNS market?***

**A:** As we mentioned earlier, yes. We are already looking at a number of other product opportunities in the areas of pain and CNS. Some of these are a natural fit with our Intraject technology. Others make sense due to the therapeutic focus. Marketed products that are already subcutaneous can be brought to market in the Intraject system on a relatively short timeline.

**Q: *Are you interested in in-licensing or partnering at this point?***

**A:** Partnering opportunities will be key to our success in the future — both in- and out-licensing. We have partnered with a respected group of contract manufacturers to bring our first product to market. As we launch sumatriptan Intraject into the specialty market, we may also look to a US co-promotion partner with a sales force having broader primary care reach. We will also look to partner with companies that have products complementary to our own. We want to find a partner for sumatriptan Intraject in Europe. And, of course, we see many partnering opportunities to put other compounds in the Intraject system. We have plenty of partnering work ahead of us, and that is very exciting.

**Q: *Can you envision long-term goals for the company at this point? If so, what are the top three?***

**A:** From the beginning, I have envisioned building a top-tier Specialty Pharmaceutical company focused on CNS and pain. This will mean building a high-quality commercial organization to sell our products. We also hope to create a whole new vision for subcutaneous delivery of pharmaceuticals. Our Intraject system is the vehicle to do this, and it is really a major step forward for patients. After a decade of work, it is now ready to move into the market. Finally, we want to build a company that focuses on attracting and growing the best people in the business. If we do that, we will be successful in whatever we do. From day one, our culture and values were important topics for all of the founders.

**Q: *As a fledgling company in the realm of Specialty Pharma, what is the one mistake you must avoid going forward?***

**A:** We must stay very focused. Nothing is more important than the launch of our first product using Intraject to deliver a great drug, sumatriptan, for the acute treatment of migraine. This will validate our technology and the company. We have so many opportunities in terms of both products and our technology. The key will be to stay focused on the most important tasks and execute on them flawlessly.

**Q: *Are you getting any sleep these days?***

**A:** We are all very busy, but in a good way. Start-ups are hard work; talent is crucial in every position. I keep telling my team how much fun this is, but they already know. We know we will hit bumps along the way, but for now, we are having a great time building this new company, and so far, everything is going just as we planned. ■