

Revving Start-Up Engines

BY DEBORAH ERICKSON



► Because no one has cracked the solubility problem yet, start-up companies continue entering the fray. Enavail started up in Austin, TX, in the autumn of 2009 to work through solubility issues as a fee-based service for clients. The company is now also developing a new formulation of docetaxel, the now-generic compound that became a blockbuster as Taxotere and remains a key part of many chemotherapy regimens. Enavail's hybrid business model has been difficult for others to make work, president Brian Windsor acknowledges, but he thinks the company's focus is tight enough and the corporate structure lean enough to prevail.

Enavail cannot yet say its particle-engineering technology has been validated by a product reaching market, but it has had preclinical data on some 20 compounds published in more than 50 peer-reviewed journals. Even so, skepticism abounds, Windsor notes. He reckons it stems from the fact that so many companies have tried but failed to improve solubility. "Drugmakers and investors alike say our data is good," he says, "but they want to know: Does it *really* work and can you make something that will ultimately get to market?"

To distinguish itself, Enavail is focusing its approach on cancer drugs, which are not only notoriously insoluble but also cytotoxic. "The easy formulations others can do, and there is a lot more competition. We want

to take the things that are hard to work with," Windsor declares. Enavail's technology entails rapid freezing and controlled precipitation of molecules, which allows functional excipients to be mixed in with the drug before ever making the ice that makes a powder of the drug. Adding a pH-sensitive polymer, for instance, promises to let the drug withstand stomach acid and release once it reaches the neutral pH and larger surface area of the lower intestine. Enavail's process is also gentle enough to handle compounds that cannot be milled without loss of activity, Windsor says.

For now, Windsor says Enavail is building a client base among "smaller pharma companies who are highly motivated to advance the one or two products they may have that have hit a snag." It doesn't hurt that Enavail is funded and managed by Emergent Technologies, he concedes: Credibility and nice office space come with that connection, and allow the start-up to access management functions without adding staff. To further entice clients, Enavail has begun offering manufacturing services pertinent to the niche of cytotoxic cancer drugs. "Hot melt extrusion" is a great tool, he says, explaining that drug extruded like hot plastic, as a rod, can, once cooled, be ground into pellets for capsules or granules for tablets. It can be cut into thin films or wafers or even shapes to fit a device. Hot-melt technology is not proprietary and has been around for years,

so its utility is widely accepted. But there is much art and skill involved in using it well, Windsor notes, and so Enavail is already benefiting from having as an advisor Jim McGinity. The professor at the University of Texas at Austin is a recognized expert in the method.

A U.K. delivery company, founded in 2010, is similarly seeking to leverage the expertise and name recognition of its founder, Howard Stevens. Through him, Glasgow's Drug Delivery International (DDI) is affiliated with the University of Strathclyde, internationally known for its school of pharmacy, and with a "sister" company that Stevens also

founded. Bio-Images Research specializes in using "gamma scintigraphy" to track with radioactive isotopes how a delivery system affects the movement of a drug through the body. DDI helps clients with formulations, while working on its own controlled-release formulations of drugs to be given at night, to treat conditions known to flare in the morning hours. DDI aims to out-license its drug candidates.

Both of these companies exemplify how individual or small-group expertise with a given ODT can anchor a business. Adding on

access to related services that help clients advance drug candidates is a sensible way to boost appeal. Start-ups like this can and do feature photos of their experts

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BRIAN WINDSOR, PRESIDENT, ENAVAIL

on their websites, conveying a sense of attentiveness to clients that is quite distinct from the powerful but impersonal images that larger companies cultivate. ●

