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## **NanoBio, With Glaxo as Big Partner, Sees Market in Treating and (Maybe) Preventing Cold Sores**

By Luke Timmerman

[NanoBio](#) has spent a decade of R&D working on nanotech formulations that might help drugs and vaccines be better absorbed, more effective, or more convenient. Now the Ann Arbor, MI-based company is plowing ahead with its first big application—for the treatment and possibly the prevention of cold sores.

This story has been unfolding for some time, but [NanoBio](#) gained some additional cash and [credibility](#) for the idea last December when it formed a partnership with GlaxoSmithKline. London-based Glaxo, the world's [fourth-biggest](#) pharma company by revenue, makes the only FDA-approved topical over-the-counter treatment for cold sores, docosanol ([Abreva](#)). The deal provided NanoBio with \$14.5 million in upfront cash, plus milestone payments worth as much as \$40 million, and a single digit royalty on sales if the new drug reaches the marketplace.

There's both business strategy, and some cool science, to explain how the startup and the drug giant came together. For one thing, Glaxo's patent expires on its existing drug in 2014. If things break right in the development plan for NanoBio's [NB-001](#), then Glaxo could be in position to sell a "new and improved" treatment for cold sores a year earlier, in 2013, says NanoBio chief operating officer [David Peralta](#). Having cold sores isn't a life-threatening condition that puts people in the hospital, and Abreva doesn't generate enough sales to show up on Glaxo's quarterly earnings [reports](#). Still, an [estimated](#) 136 million people in the U.S are said to get herpes simplex virus-1 infections (cold sores). The Abreva pump sells on [drugstore.com](#) for \$16.99, so even if Glaxo only captures a small slice of the market, there's real money to be made.

But besides the business, there's some interesting science at work here. For starters, NanoBio is led by CEO [James Baker Jr.](#), the prolific inventor and director of the Michigan Nanotechnology Institute for Medicine and Biological Sciences at the University of Michigan. Baker's team wondered if it could come up with a localized, dab-on lotion for cold sores that would work better than traditional oral pills that circulate through the entire bloodstream. Topicals often haven't worked well in the past, because older formulations didn't penetrate deep enough into the nerve where the herpes simplex virus resides, Peralta says. The nanotech formulation that

NanoBio developed is designed to penetrate deeper, and kill the pathogen before it can replicate and cause the fever blister that's the visible symptom of a cold sore, he says.

It took a long time to get the particle size right, so it's not too big or too small to do the job, Peralta says. What NanoBio has settled on, after a battery of animal tests and a pair of controlled, mid-stage clinical trials, is a lotion that can be dabbed onto the spot of infection as many as five times a day for 10 days, or until the sore is healed, Peralta says.

The NanoBio drug "definitely accelerates healing" when compared with a placebo, based on the clinical trial results thus far, Peralta says. A less definitive, but intriguing result, suggested that the [NanoBio](#) treatment could do more than just heal the sore, but actually prevent it from forming in a subgroup of patients. No company has ever been able to claim that a drug can prevent cold sores.

"They licensed our product to be the new improved Abreva when it comes off patent 2014," Peralta says. "There's an opportunity for us there."

What happens next in development of NB-001 is the big story for NanoBio, but that's really only part of what the 21-person venture has on its plate these days. The company has raised about \$60 million in equity, and another \$40 million in various grants, plus the roughly \$15 million from Glaxo so far. Taken together, that gives the company about two years worth of operating cash in the bank, Peralta says.

That financial cushion has allowed NanoBio to pursue a broader strategy of treatments for the skin, and for which you want a potent, locally delivered drug, that doesn't circulate through the bloodstream and potentially cause unwanted side effects. A potent drug for killing tough-to-treat nail fungus (onychomycosis), called NB-002, falls into this category. That drug has passed an interim analysis of a 443-patient clinical trial, demonstrating safety and effectiveness compared to a placebo, Peralta says.

NanoBio is preparing its [game plan](#) for a Phase III clinical trial required to get the drug approved for sale by the FDA, and it is in conversations with potential development partners, Peralta says. There is no competitor on the market today with an effective topical, and an [estimated](#) 6 to 8 percent of the adult population has this kind of nail fungus infection, usually in the toes.

There was a whole range of other things Peralta wanted to mention when we spoke a few weeks back, including an inhalable antibiotic for nasty lung infections found in cystic fibrosis patients. NanoBio also envisions creating new formulations of vaccines, particularly so they can be given via nasal sprays for people who want to avoid needles. Much of that stuff is still in its very early days, so I figured such things would be better to cover when more evidence of their effects emerges. But I took it as a good sign that Peralta was willing to talk about so much in the pipeline, not just one lead asset.

"We think we really have some positive news flow to come," Peralta says.

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