

BIO BUSINESS

The Profits of Nonprofit

The surprising results when drug development and altruism collide

In the beginning, they called her a fool. When pharmaceutical chemist Victoria Hale told friends and colleagues that she wanted to start a nonprofit pharma company, they laughed at her, said it was career suicide, that it couldn't be done. "About 90 percent said that in strong or gentle words," recalls Hale, who had previously worked at the US Food and Drug Administration and Genentech. "But I knew I wanted to try."

And so she did. In 1998, Hale wrote a business plan, gathered seed money, and submitted an application for nonprofit status to the IRS. It was denied. Pharmaceuticals are a profitable industry, the IRS replied, so what's the need for a nonprofit? Frustrated, Hale defended her philosophy for what felt like the hundredth time: Big Pharma makes drugs for Westerners. She, on the other hand, wanted to make drugs for all of humanity—drugs that don't necessarily pull a profit.

In 2001, the argument finally worked, and the Institute for OneWorld Health became the first nonprofit pharmaceutical company in the United States. Since its inception, iOWH has received more than \$200 million from the Bill & Melinda Gates Foundation as well as funds from other philanthropic donors. The socially conscious company has even tugged at the heartstrings of several for-profit pharmaceutical companies, who have agreed to make and distribute drugs developed by iOWH on a no profit, no loss basis. With that backing, the company has already brought to market a drug to treat visceral leishmaniasis—the world's second-largest parasitic killer after malaria—and developed a pipeline of others designed for scourges of the developing world: malaria, diarrheal diseases, and parasitic worm infections.

iOWH is unusual, but it is not alone. With philanthropists funneling billions of dollars into biomedical research and



Victoria Hale, founder of the Institute of OneWorld Health, the first nonprofit pharmaceutical company in the US

traditional drug discovery efforts producing fewer and fewer therapies, the line between for-profit and nonprofit life science companies is beginning to blur as both sides of the divide look for new options. More and more for-profit enterprises are experimenting with nonprofit models, while nonprofit organizations look to incorporate for-profit business practices to stay afloat.

"At one time, people in the nonprofit world had a disdain for business, and business people thought nonprofits were without discipline," says Jack Faris, CEO of the Pacific Northwest Diabetes Research Institute, a nonprofit research center in Seattle, Washington. "People have matured a substantial amount beyond that...There's much more appreciation of the role that each plays and a readiness to work together."

The profits of partnering

Visceral leishmaniasis is a severe disease, transmitted by the bite of an infected sand

fly, that is almost always fatal without treatment. India accounts for half of all cases recorded worldwide each year, and there, current treatments for the disease cost up to \$300. Because such a price would bankrupt the majority of Indians, forcing many to turn to money lenders and put their children in debt, iOWH's first project was to develop an affordable treatment for the disease, says CEO Richard Chin. But to do that required some drastic changes to the traditional drug development paradigm. "To have affordable drugs, we have to have affordable drug development," says Chin.

In 2002, the company identified a promising off-patent antibiotic once cast aside by a large pharmaceutical company for its lack of profitability. Since the drug had been previously approved and marketed in the late 1950s as a broad-spectrum antibiotic, iOWH was able to skip directly to a phase III clinical trial to test the drug as a treatment for visceral leishmaniasis. The trial commenced in 2003,



BDA Foundation ecopreneurs work in tandem with PharmAfrica to grow and market medicinal plant products.

and just three years later—record time in the drug development world—paromomycin was approved for sale in India.

iOWH, however, did not have funds for manufacturing facilities to make and distribute the product. So to get the drug to those who needed it, iOWH partnered with a for-profit company in India, Gland Pharmaceuticals, which has agreed to take on those roles for no profit, no loss. With Gland's help, paromomycin is now available in India and costs \$10-15 for the whole 21-injection course of therapy. "It's a family-run company, and they really care a lot about diseases of the poor," says Chin. "They've been fantastic."

iOWH has also partnered with other for-profit companies, such as Sanofi-Aventis, to produce an affordable anti-malaria drug. Artemisinin-based therapies are currently the most effective treatments for malaria

in areas where other treatments have succumbed to drug resistance. The supply of artemisinin, however, is contingent on the labor- and time-intensive process of harvesting and processing wormwood in Asia and Africa. iOWH's semisynthetic version of the antimalaria drug has entered the commercial scale-up process and is on schedule to be manufactured by Sanofi-Aventis for no profit, no loss, by 2012.

"This [type of partnership] is very new," says Henri Farret, past director of the artemisinin project at Sanofi-Aventis. "This is the first time we've worked in such a way with a nonprofit pharmaceutical company, but we do it to cure big diseases in developing countries."

Other nonprofits have also taken to collaborating with for-profit companies, often very closely, to achieve their goals. The Montreal-based Biotechnology for Sustainable Development in Africa Foundation, for example, works in tandem with its for-profit sister company PharmAfrica to build an industry for medicinal-plant

products in Africa. The nonprofit foundation teaches medicinal-plant farmers in Africa to build and launch businesses, while the for-profit arm develops and commercializes products from the region.

The Pacific Northwest Diabetes Research Institute in Seattle, Washington, one of many nonprofit research centers in the Northwest, uses a slightly different strategy, hosting innovative for-profit companies in their own headquarters, and providing workspace, access to equipment, and encouraging interaction between scientists at the for-profit companies and the nonprofit researchers.

"These days, we're interested in building on our internal assets in a whole array of partnerships," says Faris, CEO of the institute. "We're looking for ways to collaborate with for-profit and nonprofit enterprises to do more creative and powerful things."

Going pharma free

Though the idea of a nonprofit pharmaceutical company is still new, nonprofit

foundations and institutes have long been a staple in biomedical research funding in the United States. But they too are breaching the barriers between profit and nonprofit, adopting best practices from the for-profit business world.

The Acumen Fund, a nonprofit venture fund that seeks solutions for global poverty, invests philanthropic funds in for-profit businesses that have a social impact in the developing world, such as Botanical Extracts EPZ Limited, a private Kenyan company that works with local farmers to produce artemisinin. Any returns on investments are funneled into new investments, maintaining the company's nonprofit mission to alleviate global poverty. "We want to recycle the [money], because we think it's a more efficient use of philanthropic capital," says Yasmina Zaidman, director of communications for the Acumen Fund.

Similarly, Scott Johnson, a businessman with no medical background, uses the business savvy he accrued from decades of working as a serial entrepreneur to run a nonprofit foundation as a business. "It struck me that by applying some business principles, you could speed up all elements of the [drug discovery] process," he says.

In 2003, Johnson, who has had multiple sclerosis for 34 years, founded the Myelin Repair Foundation in Saratoga, California. He put together a "dream team" of PIs studying myelination and set up a board of industry professionals to help them identify and prioritize targets that come out of the lab. The company was formed as a nonprofit partly to attract the PIs, who didn't want to be associated with a for-profit company, but also for research freedom. In contrast to for-profit biotechs, which are typically "encouraged" by funders to tackle just one or two promising targets, Johnson says, "we, as a nonprofit, can move dozens of targets forward with a variety of corporate partners," offering the best chance at a real therapy rather than a real profit.

"It's a wonderful entity," says Brian Popko, a neurologist at the University of Chicago and a PI with the foundation who has been developing a new animal

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—Yasmina Zaidman, Acumen Fund

model for demyelination. "The infrastructure is there to move discoveries that occur in our basic science labs forward to therapeutic uses."

The model has already proven its worth: in the last five years, the company has produced 19 new myelin-repair drug targets, 18 patentable inventions, and more than 50 papers; and over 60 research organizations have expressed interest in the model, according to Johnson. The advantages of the structure are real, says Popko. "I think it will catch on."

But embracing for-profit's best practices may pose a serious threat to the mission of nonprofits, warns Bill Landsberg, an attorney for AspenPointe, a large conglomeration of nonprofit mental health companies in Colorado Springs, Colorado. In 2004, Landsberg warned that his own organization's mission was at stake when he witnessed a shift toward business priorities, including an influx of MBAs with no clinical background into

the organization's top ranks and a shift in focus from the companies' patients to financial issues.

In response, the CEO of AspenPointe, formerly called Pikes Peak Mental Health, made an effort to keep the mission in the forefront of all dealings, says Landsberg. Today, mental health clients routinely visit board meetings to share their recovery stories, and posters of clients dot the boardroom. "They're right there, staring us in the face," says Landsberg. The CEO "never lets it get out of our minds," he adds.

Victoria Hale has also made a move toward borrowing business strategies, this time not only to enable nonprofits to develop drugs, but to make and market them without Big Pharma's help. In 2008, she left iOWH to found a "second-generation" nonprofit pharmaceutical company called Medicines360. With a focus on women and children's health, Medicines360 aims to become self-sustaining over time, using revenue from sales of its products at a premium price in the West to subsidize the same products for those who can't afford them in developing countries. The company is currently developing an intrauterine device (IUD) for contraception.

"We're learning that the definitions of for-profit and nonprofit are less useful than they were," says Acumen Fund's Zaidman. "It's a brave new world of creative structures and financing mechanisms." ■

HYBRID HAVEN?

"Technology is way advanced, and it's the business models that are lagging way behind, limiting what social entrepreneurs are able to accomplish," says Victoria Hale, founder of two nonprofit pharmaceutical companies. Yet today, a few emerging hybrid business models may allow companies to combine their altruistic and business interests in a single company. In 2006, the United Kingdom passed legislation creating community interest companies (CICs), allowing proprietors to run a for-profit business for the benefit of the community. The model has readily caught on—close to 4,400 CICs have been registered across the UK.

In the United States, L³Cs, low-profit, limited-liability companies, now bridge that gap. Eight states have passed legislation that permits the creation of L³Cs—defined as socially beneficial for-profit ventures. Many companies have adopted the status, including alternative-energy companies, newspapers, and food companies, but no pharmaceutical or biotech company has yet attempted the model, according to L³C experts. That's not to say they won't, however.

—M.S.