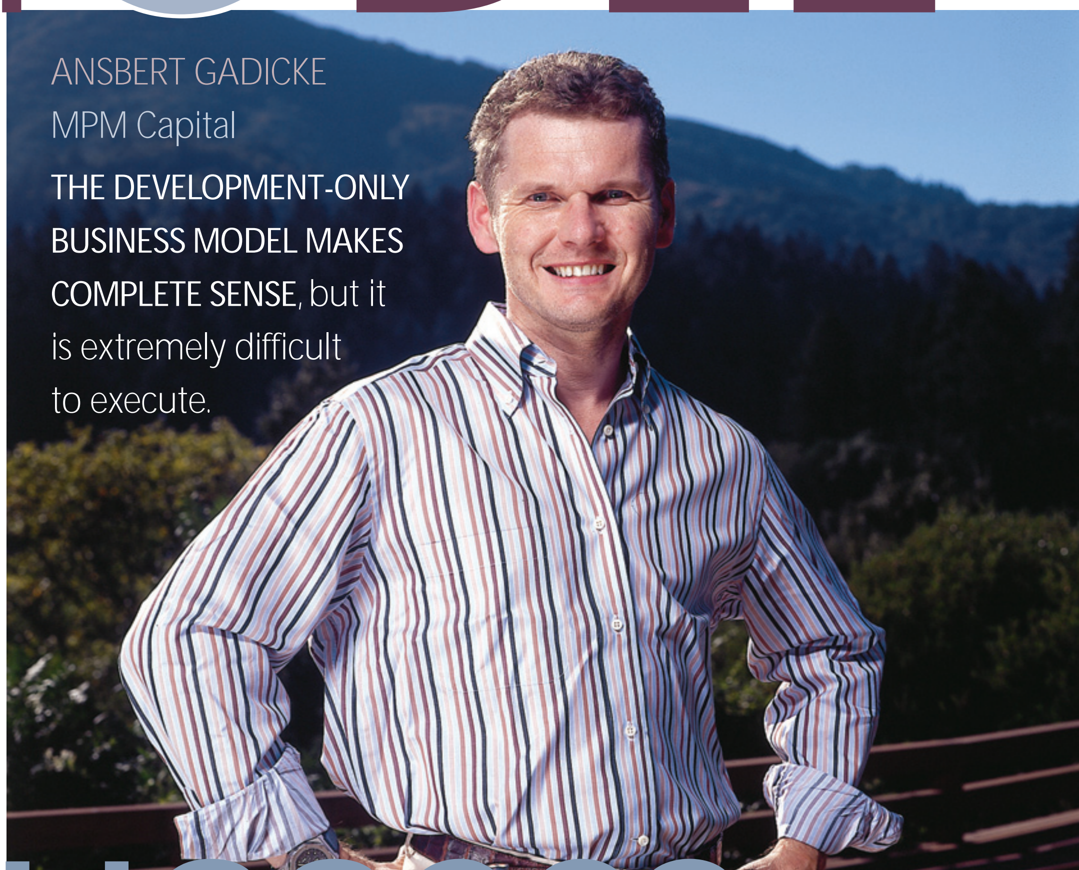
BY DENISE MYSHKO

A MODEL FOR Success



ALTERNATIVES TO THE INTEGRATED PHARMACEUTICAL COMPANY BUSINESS MODEL ARE TAKING HOLD AS SMALLER PLAYERS CONTRIBUTE TO THE INDUSTRY'S VALUE CHAIN.

Some of these newer players are focusing on specific areas, such as development, while others are creating hybrid models.

The usual suspects — rising R&D costs, the introduction of genomics and proteomics, increased regulatory compliance standards, the maturing of clinical outsourcing, and technology advances — are forcing many companies, especially emerging ones, to find alternatives to the traditional integrated pharmaceutical company business model.

Industry experts say these factors are changing the value chain for the industry and providing opportunities for smaller companies. One change is toward a business model whereby a company positions itself in one section of the chain, such as development and clinical research, and partners with other companies along the chain to bring a drug through the discovery, development, and commercialization process. This was a finding of a report by consulting firm Arthur D. Little titled Unraveling the Pharmaceutical Industry.

"Most of the products pharma companies sell today — between 40% and 70% — were not discovered internally," says Jacques Mulder, a principal at Deloitte Consulting. "I've started to refer to pharmaceutical companies as search-and-develop companies instead of research, discovery, and development companies."

According to Rob Franco, Ph.D., lead director of the life-sciences business group at PRTM Management Consultants, this type of business model will become more prevalent.

The Development of a New Model

- The value chain for the pharmaceutical industry is changing, and this is providing opportunities for smaller companies.
- Smaller and emerging companies are looking for alternatives to the fully integrated pharmaceutical and biotech business model.
- Some companies are focusing on development only or are creating hybrid business models.
- These companies are often focused on a single therapeutic area or on products that may not be attractive to larger companies.
- The development-only model is difficult to execute and requires the right people and the right products with the right financing.

DR. LAURENT FISCHER
Ocera Therapeutics

A DEVELOPMENT-ONLY STRATEGY IS SYNERGISTIC WITH THE PHARMACEUTICAL COMPANY MODEL. These companies can add value around products that have been overlooked by exploring areas that big pharma would not necessarily investigate.

"In the past, fully integrated biotech and biopharmaceutical companies did all of the work: discovery and research all the way through late development, commercialization, and life-cycle management," he says. "Now there is a 'dis-aggregation' of that value chain. We're going to see the chain break apart into smaller pieces; companies will focus on just one, two, or three aspects of that development chain."

The market for good Phase III compounds is competitive, and there aren't many of them available for licensing, Mr. Mulder says.

"If a company is willing to take a compound earlier, conceptually this could be an incredibly good business model," he says. "Companies can create a significant amount of value by taking that scientific risk."

The assessment to determine the value for a development compound usually comes to the fore in Phase II clinical studies, says Ansbert K. Gadicke, founder and general partner of MPM Capital.

"In a Phase II clinical study, companies primarily show that a drug works, that it is efficacious, and safe in a particular dose," he says. "At this point, pharmaceutical companies are highly interested and willing to pay hundreds of millions of dollars for companies that have such drugs available."

Today, the big companies no longer hold all the cards, and a shift in power is happening, Dr. Franco says.

"The large pharma companies that had the resources and finances used to call the shots," he says. "Now companies that have the innovation, the technologies, and new products are much more in the driver's seat. In this scenario, major pharmaceutical and biotech companies want to be viewed as the partner of choice. They are competing as never before for deal flows and deal structures with many of the smaller players."

CRAIG COLLARD
Cornerstone BioPharma

HISTORY HAS SHOWN THAT THE SPECIALTY PHARMA OF OLD IS A MODEL FOR THE SHORT TERM. It works, but there are longer-term issues.

Many smaller companies are attempting more radical departures from the types of models followed by larger pharma companies, according to a 2003 report by Mercer Management Consulting. An analysis done by Mercer consultants found that a key theme is the unbundling of the value chain as players stake out their own chosen areas of focus.

The first wave of this strategy was the proliferation of drug-discovery-focused biotech companies throughout the 1990s.

According to Mercer, the large amounts of capital that have been sunk into these companies — almost as much as the combined R&D spending of the top 10 big pharma companies over the last few years — means that a bigger and more liquid market for new compounds is

DR. WILLIAM CLAYPOOL
Phoenix Data Systems

DR. ROB FRANCO
PRTM Management Consultants

TECHNOLOGY CAN MAKE A VIRTUAL ORGANIZATION MORE PALATABLE to investors and potential partners.

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beginning to develop. Some companies have positioned themselves as "compound traders," making money by in-licensing undervalued compounds and out-licensing them later at a higher price.

Dr. Franco says for some companies the development-only model could be a long-term strategy.

"I think this is where the real sea change is occurring," he says. "The CEOs of these companies now realize they can have a long-term sustainable advantage by focusing on a particular area, and they are partnering judiciously either with vendors or other pharmaceutical or biotech companies."

Virtual Organizations

In the 1990s and early 2000s, the industry was focused on strengthening the sales and marketing side of the business, says Barry Brand, CEO of CeNeRx BioPharma Inc.

"But along the way, we somehow stumbled on the development side, and the industry is now correcting itself," he says. "This has created explosive opportunities for virtual companies."

CeNeRx is one company that has adopted the development-only business model. It is a start-up biopharmaceutical company focused on identifying and developing therapeutics to treat diseases related to neurotransmitters. Therapeutic priorities include anxiety, bipolar disorder, dementia, depression, epilepsy, neuropathic pain, schizophrenia, Parkinson's disease, and Alzheimer's disease.

"We brought in an experienced management team that knows the right vendors and how to put the right development teams together so that we can take a product through some of the riskier phases of development," Mr. Brand says. "Then we look to hand off the product to big pharma partners."

From a big pharma company perspective, in-licensed products have become more attractive because of the declining productivity of self-developed products, according to analysts at Bain & Co. These industry observers even predict that big pharmaceutical companies could make the switch from a fully integrated pharma model to using partnerships to manage risk and return.

Technology makes a virtual organization more palatable, says William Claypool, M.D., CEO and chairman of Phoenix Data Systems Inc.

"Companies that are staffed leanly can be efficient," he says. "For instance, a big issue for some companies is information sharing. For those using a paper-based process, information sharing can be a very laborious experience. In an electronic data capture world, information sharing is as easy as giving people access to a company's Website."

Hybrid Models

Other companies are adopting a hybrid business model. One such company is Ocera Therapeutics Inc., a privately held biopharmaceutical company focused on the development of candidates to treat gastrointestinal and liver diseases. The company plans to commercialize its products in the United States and partner for commercialization elsewhere.

"We look at compounds that may not, at first glance, appear attractive to big pharma due to the size of the market," says Laurent Fischer, M.D., president and CEO of Ocera. "We take those compounds to the clinic for a number of indications and will then either commercialize them ourselves in specialty markets or out-license or eventually partner with a pharmaceutical company that has a salesforce in those specialty or primary-care markets."

Dr. Fischer says as a semivirtual organization, the company relies on an internal team of very experienced development people and CRO partners.

"This model works synergistically with the pharmaceutical company model, whereby we can expand opportunities by taking venture capital and adding value around products that have been overlooked or explore areas that big pharma would not necessarily investigate," he says. "In the end, we can generate value by creating new compounds and adding to therapeutic areas that will enhance a company's portfolio."

Tracon Pharma, an emerging biotech company targeting cancer therapies, is another company that is following a hybrid model. The company plans to take a dual approach: partnering with companies or licensing out compounds as well as taking some compounds through to commercialization.

"The development-only business model is just one arm of our hybrid strategy," says Mazen Skaf, Ph.D., chief business officer of Tracon Pharmaceutical Inc. "We do intend to commercialize certain products in our portfolio where we would have a clear advantage or can be on par with the best in the industry to com-

We're moving ours

One of the challenges that comes with growth is change. In this case, a change of address and a change of neighborhood. And, perhaps most significantly, a change in status as an agency. Having grown from three people to 150 in just eight years, RCW is definitely in a new place. It's only logical that we'd get a new office.

And since we're die-hard New Yorkers, we're proud to say that our new home is the Socony-Mobil Building, a landmark on 42nd Street, mere steps from such others as Grand Central Terminal and the Chrysler Building. Of course, we still have a view of the Empire State Building to share with the world via our webcam.

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mercialize those products. The main determinant is the value strategy for each specific therapeutic. For products that can be marketed and sold by targeting a small number of prescribers and key opinion leaders, Tracon will lead the launch and commercialization."

He says companies need to have a robust strategy that will enable them to manage development, regulatory, and commercial risks and carry them through the changes in the industry environment.

"An independent study conducted by SDG, a management consulting firm, and further corroborated by Tracon Pharma's own analysis has shown that, among companies with revenue below $3 billion, there is an advantage for companies that have a development focus on one or two therapeutic areas," he says. "In fact, among companies with annual sales below $3 billion those that focus on one or at most two therapeutic areas have outperformed their peers in the number of NMEs launched."

Dr. Fischer says the narrow focus may be perceived to be a disadvantage, but one product most often can make a company successful.

"We all know companies, especially young companies, whose success is based on one product," he says. "Focusing on three other products to make the pipeline look good can dilute a company's efforts. It is hard enough to find one good product and even harder to find more than one at the same time."

Risky Business and Success Factors

An integrated model makes a company stronger, agrees Craig A. Collard, president and CEO of Cornerstone BioPharma Inc., a company that licenses products for commercialization.

"History has shown that the specialty pharma of old is a model for the short term," he says. "It works, but there are longer-term issues. Development companies run into trouble because, while there is a window of opportunity where they can be profitable and not bleed cash, there is a point when investors want a return on their money. I think the biggest risk these companies run is that they can't get products to market."

This business model can make sense but it is difficult to execute, Mr. Gadicke says.

"One challenge for these companies is to identify, assess, and win the most valuable assets to develop," he says. "Companies or academic institutions that take the product to clinical trials will deal with a number of competing firms that could develop them clinically."

Mr. Gadicke says these companies would need financing in the order of $50 million to $100 million.

EXPERTS AGREE THAT ONE OF THE MORE IMPORTANT FACTORS FOR SUCCESS is recruiting and keeping the right people.

He says the financing environment, though, is positive for such companies.

"We've witnessed over the last few years that the overall amount of capital going into pharmaceutical companies is relatively level," he says. "But financing deals in the order of $50 million are dramatically increasing year to year. What that means is that the best companies are able to attract a lot of capital."

Experts agree that one of the more important factors for success is recruiting and keeping the right people.

Dr. Franco points out oftentimes people are recruiting from large pharma.

"Different skill sets are needed for these emerging business models," he says. "The challenge is to operate effectively in an environment that may not have the infrastructure of a large pharma company. These people have to be good at managing others and collaborating with others to get things done."

Dr. Fischer says it's been his experience that companies pursuing the development-only model or another hybrid model can make incredible progress in a short period of time — if the right management team is in place.

"These are very attractive models," he says. "But they do require the right type of people and expertise around the table to succeed. In our case, we were able to get our first patient in a pivotal trial six months after having signed the license agreement with five people on staff. That is remarkable."✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Experts on this topic

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