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## Survival Tactics for Small CROs

How to rebound from a recession year

By Michael Schlosser

After spiraling downward for almost a year, the economy has stabilized and is projected to trend upward in 4Q09 and early 2010. Despite the near-term economic rebound, the recession will continue to affect the Pharma industry for years to come as it continues to adjust to the changing economic and political landscape.

All but one of the seven major publicly traded CROs trailed the S&P 500 index for the past year. They all trailed the AMEX Pharmaceutical Index, which lists the CROs' biggest clients. Although most of the CROs outpaced both indexes for a five-year period, that is small comfort to investors worried about this year's prospects.

Until demand returns to 2008 levels, small CROs may want to consider various partnership strategies to improve stability and profitability—or face liquidation. Examining current industry, economic and political trends will help CROs determine the best strategies to survive and even thrive in the months ahead.

### R&D Spending Declines, A New Business Strategy Rises

Limited FDA approvals of NDAs caused many pharma companies, particularly small ones, to focus on their latest stage drug candidates, shelve early-stage projects and minimize R&D spending in 2009.

These smaller pharma companies have moved their focus from preclinical development to clinical projects closer to completion. In past years, these projects would have been outsourced mostly to small CROs.

R&D spending growth among the top 20 U.S. pharma companies slowed to just 5% year-over-year in 3Q08, and to 1% year-over-year in 1Q09. Although the economy is improving, CROs are still reporting increases in contract cancellations and decreased demand for early-stage research. Slack R&D spending is speculated to hold until early 2010.

As a consequence of fewer INDs, NDAs, and lowered R&D spending, smaller CROs — those offering preclinical and early-stage clinical research services such as toxicology, process development and small-scale manufacturing of active pharmaceutical ingredients — have not grown as in previous years. In rough economic times, smaller CROs are more exposed to financial risk because they have less diversified service offerings and less ability to leverage price discounts to weather the storm than their larger counterparts.

In response to these pressures, one popular option gaining momentum for small and mid-sized CROs is to follow what their bigger CRO cousins are starting to do: engage in preferred partnerships and strategic alliances.

### Benefits of Preferred Partnerships and Strategic Alliances



Preferred partnerships develop when pharmaceutical companies agree to outsource research or development services to select CROs for a predetermined amount of time. These agreements, which are becoming more sophisticated in scope and depth, allow pharmaceutical companies to limit the number of CROs used in return for discounts for more work.

Big pharma companies are especially drawn to preferred CRO partnerships because they gain competitive advantage with access to exclusive technology, know-how, guaranteed delivery timelines and preferential pricing. CROs are guaranteed work volume over an assured amount of time, giving them the stability they crave and the efficiencies their sponsors want.

These types of partnerships have formed across the globe. For example, large and small pharma companies have established relationships with CROs in India and China, particularly for early stage discovery and chemical synthesis projects.

One example is the recent three-year collaboration between Pfizer and WuXi PharmaTech for Absorption, Distribution, Metabolism and Excretion (ADME) services. In addition, spurred by the recent development of India's regulatory processes and government support, clinical trial organizations in India are being used by many Pharma companies for their high quality staff, infrastructure and low cost.

In the future, more preclinical CROs likely will vertically integrate into larger sponsor companies. To enhance attractiveness for these contracts, CROs may need to partner with specialty CROs to offer a wider range of in depth services to support early and late stage development research. For example, WIL Research Laboratories has acquired smaller, focused CROs such as Biotechnics (pathology specialist), QS Pharma (formulation specialists), and Midwest BioResearch (immunoanalytical and cell culture experts) to increase its depth of pharmaceutical research offerings. To expand its global presence, WIL acquired NoTox BV, a full-service preclinical CRO located in The Netherlands. This strategy allows a single CRO to offer integrated expert services to Pharma sponsors in many key areas of drug discovery and development.

### **Benefits of Short-Term Mergers**

Pharma/CRO "short-term" or "alternative" mergers not only provide benefits of preferred provider relationships, but also result in evolutionary jumps in costs savings for pharma companies. In a short-term merger, CROs can take over their sponsor companies' facilities and make their research processes more efficient because they have a specific focus in this area. Pharma can then concentrate their resources and talent on their core competencies. In this way, short-term mergers are gaining popularity within large CROs and pharmaceutical companies. Small CROs are looking to gain these advantages as well.

As with Covance's purchase and takeover of Lilly's development facilities in Greenfield, Indiana, a similar deal involving Pharmaceutical Product Development (PPD) and Merck occurred earlier this year. Under their five-year agreement, PPD purchased Merck's 130,000-sq.-ft. facility in Wayne, PA as well as 80 contract employees. In return, PPD will provide Merck with a range of assay development and immunogenicity testing services as well as traditional central laboratory and sample storage services over the next five years to primarily support Merck's vaccine pipeline.

While these broad-based partnerships help accelerate drug development programs, drive enhanced productivity and flexibility and provide stability for both companies, there are also downsides to short-term mergers for small CROs.

### **How Smaller CROs Can Compete in a Buyer's Market**

Because of the recent overall decrease in demand for general CRO services, the commoditization of many CRO services, and the large emergence of CRO capacity over the years, pharma companies looking to outsource work at CROs have has a buyer's market (depending on what specific services are being sought). Unfortunately for smaller specialty CROs, they may be overlooked when pharmaceutical companies look to establish outsourcing partnerships because of their fewer service offerings and inability to discount prices compared with their larger counterparts.

Therefore, smaller CROs must distinguish themselves as leaders in their areas of specialty to retain clients while still being sensitive to price. Small CROs in niche areas have advantages as large CROs may be slow to adapt to new technologies until they are fully validated and accepted, which is especially true in early discovery and development. By concentrating services in these unique areas, a smaller CRO can remain profitable in a down market.

By specializing in niche services, smaller CROs may benefit in another way—by becoming attractive acquisition targets to larger CROs looking to gain strategic advantage. For example, Charles River Labs acquired Molecular Imaging Research, in part, for the latter's in vivo imaging expertise.

Small U.S. CROs may want to take advantage of unique opportunities to align with foreign ones. In particular, there has been an emerging trend of partnering with Asian CROs over the last few years (e.g. MPI Research and

Shanghai Medicilon), which will only increase as Chinese markets and expertise grows. An example of a smaller CRO with traditional services making inroads into China is Frontage Laboratories, a bioanalytical/analytical laboratory.

At the same time, European and Asian CROs are looking to enter the U.S. market. The recent acquisition of Prevalere Life Sciences (U.S.) by ICON (Ireland) is a case in point. One caveat of cross-culture partnerships, however, is that a time lag is often incurred before real value is realized for the pharma sponsor.

Mega-mergers like Pfizer/Wyeth also provide opportunities for smaller CROs because they force pharmaceutical companies to reexamine their current CRO agreements. These mergers give smaller CROs with strong service offerings and competitive prices new opportunities to be noticed. Mergers can also create subdivisions within existing organizations that did not exist before. For example, large companies may split by therapeutic areas or by disciplines, which create separate outsourcing groups and thus greater opportunity for smaller CROs for working with a mega-organization. Reorganization and project expansion will create additional new business opportunities for smaller CROs.

### **Obama: Good or Bad for the CRO Business?**

The Obama administration is enacting policies that will affect the CRO industry. Although Obama's current healthcare plan is meeting opposition, there will likely be some form of long-term expansion in public health care to capture the estimated 15% of the population who are uninsured, which would grow future drug revenues.

However, President Obama's approach to the FDA may be even more significant. The FDA was recently approved to receive \$2.35 billion for fiscal year 2010 compared with \$2.06 billion in the previous fiscal year—the largest increase in the regulator's history. The FDA's budget had shrunk or been held flat since the mid-1990's, and the funds will help the agency hire more inspectors, more scientists and increase the number of drug candidates it sees moving through the approval process.

Interestingly, Pres. Obama's recent appointment of Lester Crawford to head the FDA indicates the FDA's priority under the Obama administration will be safety, not necessarily speeding through drug approvals.

Short-term, the NIH budget and funding for basic research, which includes translational medicine grants, are both expected to double during the next 10 years. This funding will be good for CROs working with the emerging biotechs spawned from universities. For example, there has already been a tremendous increase in grants to universities working on therapeutic targets, particularly those involving Homeland Security (e.g., anthrax vaccines) and antiviral agents. As monies to academic institutions increase, Technology Transfer and Commercialization groups within these universities will grow, which will be good for CROs equipped with the capability and expertise to ensure these projects meet their milestones.

On the downside, small CROs should look out for changes in small business legislation—small business taxes and employee health insurance costs may increase under this administration. These increases could adversely affect profitability and thus the success of a small CRO. On the other hand, pro small-business legislation may positively impact small and mid-size CROs. Increases in amount of capital written off have already given many CROs additional equity. The industry is hoping Obama will simplify and make permanent the research tax credit, providing an incentive for businesses to invest in R&D.

Despite the financial crunch and a drop in early-stage research, a new report conducted by Business Insights states that the global CRO market is expected to grow 14% per year during the next three years, making contract research a \$35 billion industry by 2013.

As the world economy emerges from this dark period and as the demand for new medicines continues, pharma should emerge as one of the market's strongest performers. The CROs with strong performance records, solid financing and established specialty capabilities will be the survivors in the coming months. Those too exposed to commodity services and unable to obtain preferred vendor status or strategic alliances due to experience and scale of services may be more at risk for failure.

***Michael Schlosser, Ph.D. is founder and president of Midwest BioResearch, LLC, a WIL Research Company.***