

# New year, new success strategies

There are still ways for small CROs to prosper in difficult times, says **Dr Michael Schlosser**, president of **Midwest BioResearch**

**A**fter four straight quarters of decline, it became clear in late 2009 that the global recession is hopefully ending and the economy is beginning to stabilise and even grow. However, a recent survey by *Pharmaceutical Technology* of both pharmaceuticals and CRO respondents reported that outsourced spending growth was slower than total spending for the first time in three years. Moreover, pharma companies are making marked efforts to consolidate the number of contractors they use.<sup>1</sup>

The increasingly competitive market has forced CROs to come up with innovative ways to remain in business. Until demand returns to pre-recession levels, small CROs may want to consider various partnership strategies to improve stability and profitability. Examining current industry, economic and political trends will help them to determine the best strategies to survive and even thrive in the months ahead.

## New CRO strategies needed

Limited FDA approvals of NDAs caused many pharmaceutical companies, particularly small ones, to focus on their late stage drug candidates, shelve early-stage projects and minimise R&D spending in 2009. Meanwhile, smaller pharma companies have moved their focus away from the pre-clinical development they would probably have outsourced to small CROs and on to clinical projects that are closer to completion.

R&D spending growth among the top 20 US pharma companies slowed to just 5% year-over-year in Q3 2008 and to 1% year-over-year in Q1 2009. 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 expected to hold until early 2010.

With fewer INDs and NDAs and reduced R&D spending, smaller CROs - those offering pre-clinical and early-stage clinical research services, such as toxicology, process development and small-scale manufacture of APIs - have not grown as in previous years. In rough economic times like these, smaller CROs are more exposed to financial risk because, compared to their larger counterparts, they have less diversified service offerings and less ability to leverage price discounts to weather the storm.

In response to these pressures, one option gaining popularity among small and mid-sized CROs is to follow what their bigger cousins are starting to do: engage in preferred partnership and strategic alliances.

## Partnerships & alliances

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

Big Pharma is 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 and their prevalence is only likely to increase. Both 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 ADME services. In addition, spurred by the recent development of India's regulatory processes and government support, pharma companies are starting to use clinical trial organisations in India for their high quality staff, infrastructure and low cost.

In the future, more pre-clinical CROs are likely to integrate vertically into larger sponsor companies. To enhance their attractiveness for these contracts, CROs may need to partner with specialised 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 (a pathology specialist), QS Pharma (formulation) and Midwest BioResearch (immunoanalytical and cell culture) to increase its depth of offerings, while also spreading its global presence by acquiring the Dutch full service CRO Notox. This kind of strategy allows a single CRO to offer integrated expert services to sponsors in many key areas of drug discovery and development.

## Short-term mergers

In 'short-term' or 'alternative' mergers, CROs take over their sponsor companies' facilities and make their research processes more efficient because they have a specific focus in this area. This enables the sponsor to concentrate its resources and skills on its own core competencies.

These mergers are gaining popularity within large CROs and pharmaceuticals companies, because they not only provide the benefits of preferred provider relationships but also result in evolutionary jumps in costs savings. Small CROs are looking to gain these advantages as well.

Recent examples include Covance's purchase and takeover of Lilly's development facilities in Greenfield, Indiana, and a five-year deal between PPD and Merck & Co. earlier this year. PPD

purchased Merck's 12,000 m<sup>2</sup> facility in Wayne, Pennsylvania, as well as 80 contract employees. In return, it will provide Merck with a range of assay development and immunogenicity testing services, as well as traditional central laboratory and sample storage services, primarily to support Merck's vaccine pipeline.

### What about smaller CROs?

Because of the recent commoditisation of many CRO services and the large increase in CRO capacity over the years, pharma companies looking to outsource work to CROs have been in something of a buyer's market, depending on what specific services are being sought. Unfortunately, because of their fewer service offerings and inability to discount prices compared with their larger counterparts, smaller specialised CROs may be overlooked when outsourcing partnerships are sought.

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

By specialising in niche services, smaller CROs may also benefit in another way - by becoming attractive acquisition targets to larger CROs looking to gain strategic advantage. For example, Charles River acquired Molecular Imaging Research, in part, for its *in vivo* imaging expertise.

Small US-based CROs may want to take advantage of unique opportunities to align with offshore CROs. In particular, there has been an emerging trend of partnering with Asian CROs (e.g. MPI Research and Shanghai Medicilon), which will only increase as Chinese markets and expertise grow. One smaller CRO with traditional services making inroads into China is Frontage Laboratories, a bioanalytical and analytical laboratory.

Similarly, European and Asian CROs are looking to expand their operations by entering the US market. The recent acquisition of Prevalere Life Sciences of the US by Ireland-based Icon is a case in point.

Not all European CROs, however, are looking to expand geographically. Some small to mid-sized firms are broadening their services in order to be more competitive. For example, CIT, a French CRO, will be adding tissue cross-reactivity services, while another, Biovays, is adding biomarker discovery.

Mega-mergers like Pfizer/Wyeth also provide opportunities for smaller CROs because they force pharmaceuticals 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 sub-divisions within existing organisations 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 to work within a very large organisation. Reorganisation and project expansion will create additional new business opportunities for smaller CROs.

### Obama: Good or bad?

With approximately 60% of CROs based in North America, US politics is bound to have an impact on the global CRO industry and the Obama administration is already enacting policies that will affect the CRO industry. Although Obama's current healthcare plan is meeting opposition, there will probably be some form of long-term expansion in public health care to capture the estimated 15% of the US population who are uninsured, and this would increase future drug revenues.

**Michael Schlosser** (left) in the Midwest lab



However, Obama's approach to the FDA may be even more significant. The FDA was recently approved to receive \$2.35 billion for the 2010 fiscal year, compared with \$2.06 billion in fiscal 2009. This is the largest increase in the regulator's history.

The FDA's budget had shrunk or been held flat since the mid-1990s, and the funds will help it hire more inspectors and scientists and increase the number of drug candidates it sees moving through the approval process. Interestingly, Obama's recent appointment of Margaret Hamburg to head the FDA indicates that the administration's priority will be safety and not necessarily speeding through drug approvals.

Meanwhile, the National Institutes of Health (NIH) budget and funding for basic research, which includes translational medicine grants, are both expected to double over the next ten years. This funding will be good for CROs working with the emerging biotech spawned from universities.

For example, there has already been a tremendous increase in grants to universities working on therapeutic targets. As monies to academic institutions increase, technology transfer and commercialisation 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 the 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.

### Conclusion

Despite the drop in early-stage research, recent reports foresee a growth in the CRO market. A new report conducted by Business Insights states that the global CRO market is expected to grow by 14%/year during the next three years, making contract research a \$35 billion industry by 2013. A recent Frost & Sullivan report predicts the European CRO market will almost double from \$7.1 billion in to \$13.5 billion by 2015.

However, this market growth comes in the face of increasing consolidation of pharma and biopharma companies and increased rates of contract cancellation. Now more than ever, CROs are competing for fewer customers.

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 of failure.

### Reference:

1. Jim Miller, 'Industry Outlook: Down But Not Out', *Pharmaceutical Technology* 1 August 2009

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