OUTSOURCING OUTLOOK

Searching for a Viable Business Model

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Drugs development is inherently a low-probability proposition, so pharmaceutical companies instinctively avoid anything that further compounds the risk and uncertainty. That risk aversion helps explain why pharma has tended to lag other industries in adopting business practices such as outsourcing.

The recent news regarding several high-profile providers of contract manufacturing and development (CMC) services certainly has done nothing to bolster the confidence of pharma in outsourcing those activities. Financial issues at Cardinal Health, aaiPharma, and Albany Molecular Research, and the withdrawal from the market of Yamanouchi Pharma Technologies, rekindle client concerns about the dependability of their outsourcing relationships and the security of development projects they have entrusted to their contractors. Memories of the Oread bankruptcy several years ago have not faded at many companies, and clients remain wary.

The problems at the four companies and the underlying causes were specific to each:

- Cardinal Health (Dublin, OH, www.cardinal.com) took a $19 million charge to cover layoffs in its contract services business. The contract business has delivered disappointing operating performance, due in large part to problems in its sterile manufacturing operations. Cardinal Health executives are also dealing with questions raised about accounting practices in their drug wholesaling business and the reduced profitability of the wholesaling business as it transitions to a fee-for-service distribution business.

- aaiPharma (Wilmington, NC, www.aaipharm.com) faced a serious financial crisis as a result of accounting and operational problems in its proprietary products business, which it has emphasized more than its contract services business in recent years (see Outsourcing Outlook, May 2004). aaiPharma is effectively under the control of its creditors, and has brought in new senior management.

- Albany Molecular Research (Albany, NY, www.albemolecular.com) is addressing problems in its strategy to push upstream into discovery services and downstream into commercial API manufacturing. The company has had to write off much of its investment in compound libraries and close several research sites because of changes in the drug discovery marketplace, including intense Asian competition. At the same time, its commercial manufacturing business has been hit by reduced and delayed deliveries to key clients.

- Yamanouchi Pharma Technologies (YPT) was shut down by its parent, Yamanouchi Pharmaceutical Company (Tokyo, www.yamanouchi.com). YPT offered proprietary drug delivery technologies such as its WOWTAB fast-dissolving tablet technology, and contract manufacturing at its Norman, Oklahoma facility. The decision to discontinue YPT probably is related to changes in corporate strategy in the wake of Yamanouchi’s acquisition of Fujisawa Pharmaceuticals, a deal that will close in April 2005.

Various circumstances surround the developments at each of these companies, and concerns about financial viability of the company are serious in only one case. But these companies share at least one characteristic: they have all struggled to find a workable, long-term CMC business model delivering large size, rapid growth, and consistent profitability. Cardinal Health and Albany Molecular Research made major strategic commitments to CMC services through acquisitions and investments, but are having trouble making those strategies pay off. aaiPharma and Yamanouchi, by contrast, made the decision that they could get a better return on their drug development and manufacturing expertise by applying it to proprietary products rather than contract services.

In their search for a viable and successful business model, CMC service providers must face several critical realities of their market-place. First, the CMC business is capital-intensive and overhead-intensive, especially contract manufacturing. Service providers must invest in capacity that takes two-to-four years to come on-line, and can take five years to fill. GMP compliance for that capacity cannot be scaled to use, so it represents an expensive fixed cost of operations. Growing the bottom line, while incurring the fixed depreciation and compliance costs, is a formidable challenge.
The revenue model makes rapid growth difficult. New manufacturing contracts do not generate significant, sustainable revenues until two or three years after signing. Projects for laboratory-based services and clinical-scale manufacturing are often priced at less than $100,000 and seldom more than a few hundred thousand dollars; rapid growth requires a new project stream larger than most CROs can handle.

Going global is difficult for CMC services. GMP regulations differ between North America and Europe, and CMC buying decisions are more localized than they are for clinical research. CMC companies must maintain duplicate regulatory and business development infrastructures for their North American and European operations.

The clinical CRO business does not face these same challenges. As a result, contract clinical research is maturing into a stable and profitable industry. Six publicly-traded companies have more than $500 million in annual revenues, and an equal number generated at least $100 million a year. The clinical CRO business is consolidating as the largest CROs gain market share, acquire smaller competitors, and implement global business strategies. It will probably be some years yet before the CMC services business reaches the same level of maturity.

aaiPharma turns to CRO veteran

aaiPharma, parent of AAI Development Services, named Ludo Reynders, PhD, as president and CEO. Reynders replaces Frederick Sancilio, aaiPharma’s founder. In addition to the CEO spot, Sancilio also relinquished his roles as chairman of the board and chief scientific officer. He will remain on the board of directors until his term ends in 2006.

Until 2003, Reynders was a senior executive at Quintiles Transnational Corp., where he served as CEO of its development services businesses and managing director of its PharmaBio Development venture capital group. He was highly-respected by industry analysts and colleagues while at Quintiles; one former colleague described him as “an extremely intelligent man, very much a visionary and deal maker.”

It appears that aaiPharma’s creditors are effectively in control of the company after the company missed a $10 million interest payment due 1 October to holders of its senior subordinated notes. The company said it would hold discussions with the note holders, presumably about restructuring the debt. The company also warned it was likely to be in default of some covenants under its senior credit facility, and would be seeking waivers from its senior creditors.

It seems likely Reynders took the CEO/president position only after securing prior agreement from the creditors for time to restructure the company. In June, Sancilio indicated that the company’s strategy going forward would be to continue to build its specialty pharmaceuticals business, with a focus on pain management. Reynders is a veteran contract services executive, however, and could take the company back in that direction.