

Spotlight on Business Risk

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Recent events in the pharmaceutical outsourcing industry highlight the importance of ongoing attention to contractors' financial situations and their strategic intent.

Pharmaceutical companies routinely send armies of quality assurance and technical staff members to contract manufacturers and laboratories to audit their compliance with good manufacturing practices regulations and to second-guess their operations. Yet, companies remain remarkably naive, and at times, blissfully ignorant, about the business factors surrounding their outsourcing relationships.

In particular, clients usually overlook the fact that adverse business developments affecting contractors are more likely to have catastrophic consequences than are compliance or technical problems. In a positive example, even when **DSM Pharmaceuticals** (Greenville, NC) was working its way out from under an FDA warning letter and 18-point 483 report during 2000–2002, the company continued to manufacture and ship products to its clients. However, when the CRO **Oread Laboratories** filed for bankruptcy and shut its doors in 2001, clients scrambled to rescue ongoing stability studies and other development work. Companies incurred significant costs to replace the terminated programs.

Recent events in the pharmaceutical outsourcing industry once again highlight the critical importance of ongoing due diligence regarding the contractor's financial well-being and strategic intent. Since the start of 2004, several events have occurred that have disrupted, or have the potential to disrupt, outsourced development programs.

- **Excell Biotech** (Livingstone, Scotland), a provider of clinical-scale biomanufacturing and product development services, suddenly closed its doors in February after its corporate

parent **Qbiogene, Inc.** (Carlsbad, CA) reportedly refused to provide additional working capital.

- **BlisTech** (Fairfield, NJ), a clinical packager, told its clients in January that it would be shutting down operations in April. BlisTech's parent company informed clients in October that it planned to sell the company, but in light of tepid interest in the operation, it decided it would be easier and cheaper to close down.
- **aaiPharma** (Wilmington, NC), the parent of **AAI Development Services**, announced in early March that its Board of Directors was investigating irregularities in sales of its proprietary products which might require changing its reported financial results. The extent and severity of the problems were not known at press time. Similar developments in 2000 at **Akorn Inc.** (Buffalo Grove, IL) precipitated a financial crisis that disrupted Akorn's contract manufacturing business and forced clients to find alternate manufacturers.

Disruptive events similar to these often result from a combination of external environmental conditions and internal financial and strategic considerations. For instance, the closure of BlisTech resulted from a corporate decision to divest smaller business units, but the soft conditions in the clinical packaging market made it difficult to find a buyer for the business. **Excell Biotech** was a start-up company that struggled in recent years as early-stage biopharmaceutical companies cut back their R&D spending while attempting to raise money. And many pharmaceutical companies are nervously watching their active pharmaceutical ingredients and intermediate manufacturers as the pharmaceutical chemical industry responds to reduced outsourcing and overcapacity.

Pharmaceutical companies with millions of dollars or euros at stake in outsourced development and manufacturing programs must continually monitor and assess their contractors' business prospects. This risk assessment should include a thorough review of the mar-

Outsourcing Outlook

ket in which the contractors operate, the strategies of their owners, and their contractor's financial condition. However, a 2003 survey conducted by **PharmSource Information Services** (Springfield, VA) and *Pharmaceutical Technology* found that only 17% of pharmaceutical companies review their contractors' financial statements annually.

Without a small investment in con-

tinuous due diligence, companies that depend on outsourcing are taking on an inordinate amount of financial risk.

New biomanufacturing capacity

New cell culture manufacturing capabilities are good news for biopharmaceutical companies that have restarted the R&D activities that halted during the biotechnology financial slump. However, not all of the new capacity may make it into the

contract manufacturing pool.

Sandoz (Kundl, Austria) has opened a new \$50-million cell culture manufacturing facility in Shaftenau, Austria. The facility houses 13,000- and 3000-L bioreactors with associated downstream isolation and purification equipment. It also has a 100-L bioreactor for manufacturing clinical trial materials.

New US capacity is coming onto the market with the announcement that **Biogen/Idex** (Boston, MA) is selling its cell culture manufacturing facility in La Jolla, California. The operation has been rendered redundant following the merger of Biogen and Idec last year. The 76,708-ft² facility has dual 2750-ft² bioreactors and is FDA- and EMEA-licensed. The facility is likely to be attractive to both contractors and bio-

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pharmaceutical companies, but contract manufacturers are probably in a better position than most sponsors to make the investment thanks to their cash positions and business models. The bioreactor scale and operating history make it suitable for both clinical and commercial products, and the San Diego location is attractive for serving the West Coast market.

Avecia (Manchester, UK) has dedicated a new, \$1-million clinical-scale oligonucleotides manufacturing plant at its Grangemouth, Scotland, facility. With the capacity to produce batch sizes as large as 40 g, the first stage of the investment program has been completed. The second stage, which will produce batches as large 100 g, will be completed in spring 2004. Avecia has similar capabilities at its facility in Milford, Massachusetts. **PT**