



Outsourcing Outlook

Jim Miller

Doomsday, in the form of reduced revenues and profits resulting from blockbuster products going off patent, has finally arrived for major pharmaceutical companies. A number of majors, including **Merck**, **Eli Lilly**, **Bristol-Myers Squibb**, and **Schering-Plough**, have warned that 2002 results will be flat or down relative to 2001 as a result of new generic competition. Compounding that problem is the increasing downward pressure on drug prices from state governments, buying groups, and third-party payers, which are forcing drug companies to offer large discounts and rebates.

The profit squeeze will have several implications for the outsourcing industry. CROs are counting on sponsors to maintain or increase their product development efforts to fill the revenue gaps and maintain historic growth rates. This was an explicit assumption in the recent revenue forecasts of several publicly traded CROs, and sponsor behavior seems to be bearing this out. Bristol-Myers Squibb, for instance, announced that its R&D budget would grow by at least 10% in 2002, and Merck projected a 16% increase in its R&D spending, despite both companies' revenue losses.

That commitment to product development spending should bode well for contractors, but there are some caveats. Cost-conscious sponsors will want to make sure that in-house resources are used fully before going to a CRO, so ex-

pect them to look even harder at the justification for each outsourced project contract. Also, sponsors will use their muscle to get the best possible prices from their contractors, so look for more work going to preferred providers as well as tough price negotiations.

One response to lower profits that has a downside for contractors would be another wave of mergers among major pharmaceutical companies. Such mergers in recent years (e.g., Pfizer with Warner-Lambert and Glaxo Wellcome with Smith-Kline Beecham) have meant project cancellations and program delays until the merged entities sorted out organizational and portfolio issues. Those delays and cancellations played havoc with CRO financial performances two years ago, and with Lilly, Bristol-Myers Squibb, **American Home Products**, and **Pharmacia** (among others) still viewed as likely merger candidates, CROs could find themselves re-playing 2000 all over again.

Ultimately, sustained pressure on sponsor revenues and profits could lead to restructuring that could push certain CROs and contract manufacturers into becoming true strategic partners to their clients. Chronic financial performance problems eventually force companies to take drastic measures to fix underlying issues. Even a \$90 billion colossus such as IBM could not absorb losses forever in its personal computer business; it recently signed a \$5 billion deal to outsource much of its PC manufacturing.

High profit margins have allowed Big Pharma to ignore many of the tough resource allocation decisions that companies in other industries have had to face. In a more difficult environment, their management's first reaction will be to keep as much activity as possible in-house to cover fixed costs. In the end, however, corporate executives will focus on seriously reducing those fixed costs to maintain profitability while freeing resources for

new product development. When that happens, outsourcing may get senior management attention as it never has before.

Contractors versus smallpox

Two contract manufacturers scored big in the government's latest award of a smallpox vaccine contract. Both **BioReliance Inc.** (Rockville, MD) and **Chesapeake Biological Laboratories** (CBL, Baltimore, MD), a subsidiary of Cangene Corporation, are subcontractors to **Acambis plc** (Cambridge, UK), which was awarded the \$428 million contract by the Centers for Disease Control and Prevention (CDC). The contract calls for the production of 155 million doses of a smallpox vaccine within 12 months and includes funding of an accelerated clinical development plan. BioReliance will support Acambis with testing and development services for the smallpox vaccine, and CBL will perform the final fill and finish, including lyophilization.

CBL said the contract was the largest in its history, and it recently built a manufacturing suite specifically for handling live-virus vaccines. Capacity that is not used for the CDC contract will be available to the industry.

BioReliance President and CEO Capers McDonald indicated that the company's work with Acambis, on top of preexisting commitments, will use most of BioReliance's available manufacturing and analytical testing capacity through the end of 2002. In a recent interview, McDonald said that BioReliance is moving ahead with plans to expand both its manufacturing and analytical testing capacity. Build-out of the viral manufacturing facility, which will increase manufacturing capacity eight-fold, will be completed in the next three years, while expansion of the cell-culture facility in Stirling, Scotland, is underway. The company will add a 37,000-ft² expansion of its analytical laboratory space. **PT**

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