



Outsourcing Outlook

Jim Miller

The five largest clinical CROs — **Quintiles Transnational Corp.**; **PPD, Inc.**; **Parexel International Corp.**; **Covance, Inc.**; and **Kendle International, Inc.** — have formed the Association of Clinical Research Organizations (ACRO) to ensure that they have a seat at the table in the upcoming congressional debate about human research subject protection. Based in Washington, DC, the industry group has chosen Quintiles chairman Dennis Gillings to chair ACRO this year and PPD's CEO, Fred Eshelman, as chairman-elect for 2003.

Congressional efforts to strengthen human research subject protections provided the impetus to establish ACRO. Efforts are underway in both the House and Senate to pass new protection legislation. The proposed measures include greater regulatory oversight of clinical research and extension of the "common rule" (i.e., the regulations governing federally funded research) to all clinical research activity.

"The CRO industry didn't exist 25 years ago when the common rule was promulgated," noted Doug Peddicord, PhD, legislative director of ACRO. Today, "CROs are central to the drug development process," he said. "As regulators and legislators look at the potential for oversight of research, they are interested in understanding the role of all the players, including CROs." ACRO presented written testimony before a Senate subcommittee hearing on 23 April 2002.

Beyond the immediate legislative activities, Peddicord expects ACRO to play a role in advancing the contract research

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industry. He observed that "there is great variability in the size and capabilities of CROs" and anticipates that the group will help ensure and promote the quality of CRO services. ACRO plans to issue eligibility guidelines for new members by the end of June.

CRO consolidation

The contract clinical research segment of the pharmaceutical outsourcing industry seems to be going through a period of consolidation. Companies are being bought and sold as big players pursue corporate strategies and marginal players seek long-term survival. Here's a quick rundown of some major deals to date.

- **PPD, Inc.** (Wilmington, NC) has made two major acquisitions thus far. It has acquired **Medical Research Laboratories International**, a central laboratory service with labs in Kentucky and Belgium, and **Piedmont Research Center**, a pre-clinical CRO with facilities near Research Triangle Park, North Carolina. Unquestionably the most profitable clinical CRO during the past three years, PPD is putting its retained earnings to work building its laboratory services business.
- **Celeris Corp.** (Nashville, TN), a small, publicly traded clinical CRO, announced a nonbinding letter of intent to sell its clinical monitoring and data management assets to privately held **StatProbe Inc.** (Ann Arbor, MI). Celeris had revenues below \$10 million and has been chronically unprofitable.
- **SFBC International** (Miami, FL) acquired **Anapharm Inc.** (Quebec City, Canada), a provider of Phase I and II clinical research services. Publicly traded SFBC has been an active acquirer in the past year.
- **Kendle International** (Cincinnati, OH) acquired **Clinical and Pharmacologic LLC Research, Inc.** (Morgantown, WV), a Phase I facility specializing in bio-equivalence studies for generic drugs.

The clinical research arena presents many opportunities for consolidation, with hundreds of companies offering monitoring, data management, patient recruitment, and laboratory services. Laboratory services, because of its capital investment requirements and operating leverage, is particularly attractive to large CROs because of more competitive barriers to entry.

Inveresk IPO

Inveresk Research Group, Inc. (Cary, NC), a CRO that remade itself through a major acquisition, has announced plans for an initial public offering. The company developed a significant preclinical research business in the 1990s. It then changed its profile in April 2001 when it acquired **ClinTrials Research Inc.**, the publicly traded clinical CRO that struggled in the late 1990s. Inveresk generated total revenues of \$156 million in 2001, of which 60% was from the preclinical research business and 40% was from clinical research services. Of the total revenues, 54% was generated in Europe and 46% in North America.

Reducing a burdensome debt load is a major drive behind the proposed public offering. The current primary shareholder of Inveresk, **Candover Investments PLC** (London, UK), acquired the company in a management buyout in 1999 for \$78.8 million. That transaction and the subsequent acquisition of ClinTrials for \$115.1 million were financed through bank debt and debt securities totaling \$205.8 million. Debt service is now eating up cash flow, and Inveresk plans to use the IPO proceeds to repay a large portion of the debt. The price and timing of the offering had not been announced at press time.

It has not been a good year for pharmaceutical and biopharmaceutical companies seeking to raise equity. Yet the value of CRO stocks has risen significantly, which improves Inveresk's chances. **PT**