OUTSOURCING OUTLOOK

Robust CRO Market Is Driving New Merger and Acquisition Activity



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The blockage in the new product pipeline may be breaking. CROs report increased demand for latestage development services in their latest round of earnings reports. **ublic contract research** organizations (CROs) reported strong quarterly results for the period ended 30 September 2004. Overall, industry revenues were up nearly 9%, but several smaller companies experienced more than 50% top line growth.

The big gains continue to be in early development services, including preclinical services, Phase I research, and clinical trial materials supply. The tightest market conditions appear to be in Phase I testing facilities in the United States, where pharmaceutical companies are in the unusual position of having to book space 3–4 months in advance. A big factor is the effect of the European Union's Clinical Trials Directive, which **PPD** (Wilmington, NC, www.ppdi.com) CEO Fred Eschelman credited for having caused a "mass movement" of Phase I testing from Europe to the United States. The continued high level of activity in generics development is also a factor driving Phase I.

Preclinical testing services showed revenue growth in excess of 20%. Although several providers are bumping up against capacity constraints, capacity seems to be available in the industry overall. **Covance** (Princeton, NJ, www.covance.com) announced plans to expand its Madison, Wisconsin, facility, but CEO Chris Kuebler said he wished the company had more capacity today. **Charles River Laboratories** (Wilmington, MA, www.criver.com), which completed its acquisition of **Inveresk Research Group** in mid-October, reported high use of its preclinical facilities but did not warn of capacity constraints. With the acquisition of Inveresk Research Group, Charles River is now the largest provider of preclinical services.

An increase in backlog (*i.e.*, the value of future projects under contract) raised expectations that Phase II and III outsourcing is on the rebound. PPD reported its Phase II–IV backlog was up 28% for the quarter and CEO Eshelman said in the third quarter his company had won more contracts valued in excess of \$10 million than it had in the first and second quarters combined. Executives at **Icon Plc**, which is heavily focused on Phase II–IV, reported their RFP volume was up 43% in the quarter.

Study delays and cancellations are a continuing source of uncertainty; several CROs reported study cancel rates at an unusually high 25%. The cancellations are blamed on regulatory issues and continual reprioritizing of pipelines at major pharmaceutical companies. Disappointing results in central laboratory services indicated continued problems in patient recruitment for large studies.

Formulation and analytical services are participating in the strong early development market, based on our informal survey of exhibitors at November's AAPS annual meeting. Service providers are keenly aware of how mercurial demand can be; several providers mentioned how quickly the environment changed from 2003, when business was slow, to the hot market of 2004, and know that it could turn again with little warning.

Contractors in the chemical and dose manufacturing segments are still struggling to generate the high growth rates achieved by the preclinical and clinical segments. Major pharmaceutical companies continue to have a lot of internal capacity as a consequence of their weak pipelines, so outsourcing often is not the preferred route for sourcing drugs for clinical trials or commercial distribution.

Merger and acquisition activity

An increased level of merger and acquisition activity is one consequence of the robust industry environment. Current industry participants want to add to their capacity or scope, whereas outsiders are looking to buy their way in. Several acquisitions of note were announced in October and November:

- WIL Research Laboratories (Ashland, OH, www.wilresearch.com), a preclinical toxicology services provider, was acquired from Great Lakes Chemical Corporation by a financial investor, Behrman Capital (New York, www.behrmancap. com). Behrman paid \$105 million for WIL, which has 390 employees. WIL's revenues weren't disclosed, but PharmSource estimates them to be in the \$50–75 million range.
- Laureate Pharma (Princeton, NJ, www.laureate pharma.com) was acquired by Safeguard Scientifics (Wayne, PA, www.safeguard.com) for \$29.5

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million in cash. Laureate provides contract biomanufacturing services as well as microsphere formulations for injectable products; in 2003 it had 70 employees and revenues of \$8 million. Safeguard is a holding company that acquires companies in the information technology and life sciences industries.

PharmaNet (Princeton, NJ, www. ٠ pharmanet.com) is being acquired by SFBC International (Miami, FL, www. sfbci.com) for \$245 million in cash. PharmaNet is a respected, privately held clinical CRO with revenues of nearly \$125 million, primarily from Phase II-IV research. SFBC has been the wunderkind of the CRO industry in recent years, growing itself from a clinical site to a fullservice clinical research services firm through an aggressive acquisition program. SFBC is expected to have revenues of nearly \$150 million in 2004 (before the PharmaNet acquisition), up from just \$8 million in 1999. PT

Table I: 2004 third quarter financial results (in USD millions unless noted).

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| Company | Segment | Revenues | Revenue growth |
| Sigma-Aldrich* | chemical | 64.4 | -2% |
| DSM Pharmaceuticals | chemical | 458.0 | -2% |
| Cambrex** | chemical | 65.4 | 0% |
| Albany Molecular Research | chemical/discovery | 28.7 | -13% |
| Evotec OAI [†] | chemical/discovery | 42.0 | -5% |
| Omnicare CRO | clinical | 28.4 | -6% |
| Parexel International | clinical | 131.5 | 0% |
| Kendle International | clinical | 42.9 | 6% |
| Phase Forward | clinical | 11.7 | 8% |
| Icon Clinical Research | clinical | 78.3 | 14% |
| Bio-Imaging Technologies | clinical | 6.5 | 18% |
| SFBC International | clinical | 40.4 | 39% |
| eResearchTechnology | clinical | 28.0 | 60% |
| PPD | clinical/CMC | 195.5 | 17% |
| Quintiles Product Development | clinical/CMC | 283.0 | 15% |
| aai Development Services | clinical/CMC | 23.1 | 3% |
| Patheon | CMC | 116.8 | 3% |
| Cardinal Health PTS | CMC | 705.0 | 9% |
| Draxis Health | CMC | 12.0 | 69% |
| Hospira | CMC | 46.0 | 21% |
| LAB International [†] | preclinical | ^{††} 7.2 | 60% |
| MDS Pharma Services | preclinical/clinical | ^{††} 134.0 | 7% |
| GeneLogic | preclinical/clinical | 5.1 | 6% |
| Covance | preclinical/clinical | 256.3 | 10% |
| Life Science Research | preclinical/clinical | 40.9 | 25% |
| Charles River Labs [†] | preclinical/discovery | 64.2 | 23% |
| * Fine chemicals only; ** Includes human health and biopharmaceutical businesses; [†] Denotes development services; ^{††} Denotes Canadian dollars. | | | |

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