Early Development Still Driving CRO Performance

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Early development services continue to be a sweet spot for contract R&D services. The big question is how soon the impact of early-development candidates will be felt in late development and commercialization.

Companies providing early development services (including preclinical and Phase I research, bioanalytical and analytical chemistry, and clinical trial manufacturing and packaging) reported very robust operating results for the second quarter of 2004. Most CROs experienced a revenue increase of 20% or more for early development services, with preclinical, Phase I, and analytical chemistry especially strong. The only weak spot is European Phase I services, because the new clinical trials directive (CTD) seems to have retarded activity somewhat. European Phase I activity was especially strong last year, however, which may indicate that pharmaceutical companies accelerated some programs before the tougher CTD requirements were implemented.

Demand for early development services is driven by (a) Big Pharma's efforts to improve the efficiency of R&D operations by quickly moving more candidates through the pipeline and (b) the improved funding environment for early-stage companies. Some CROs also report that Phase I studies are getting longer and more complex.

Downstream services have yet to feel the favorable impact of strong early-development activity. CROs reported weak gains or actual declines in late-development revenues. Phase III studies—with their large patient populations, global scope, and significant use of central laboratory services—are the real money-makers in late development. The actual billable activity in that area, however, is down. Demand for line-extension studies (so-called Phase III-B studies) and postapproval studies (Phase IV) has been stronger, but usually cost less than studies for new molecular entities.

A major problem for the industry is that Phase II has become a black hole for drug development: new drug candidates can't escape once they enter. In a recent analysis of their own data, the editors of the *Pharmaprojects* database found that the number of candidates in Phase II development grew 7% from May 2003 to May 2004. It is now 50% higher than the number Phase I drugs. The number of candidates in Phase III development was essentially flat from May 2003 to May 2004.

A principal explanation for this situation is that pharmaceutical companies are getting more aggressive in killing candidates before they move into the expensive late-development stages. With increasing frequency, companies have divided the Phase II research stage into Phase II/A (*i.e.,* small proof-of-concept studies) and Phase II/B (*i.e.,* larger efficacy studies). The ideal time to kill a candidate is immediately after Phase II/A, and many companies are doing just that. Industry planners now assume that Phase II survival rates for new drug candidates have fallen below 50%.

SFBC acquires Taylor

The acquisition of **Taylor Technology Inc.** (Princeton, NJ) by **SFBC International, Inc.** (Miami, FL) in late July is a reflection of the hot early-development services market. The acquisition of Taylor, a respected bioanalytical testing laboratory with $11 million in revenues, provides SFBC with an immediate boost to capacity for its rapidly growing bioanalytical testing business. In a further capacity-expansion effort, SFBC also announced it will invest $4 million to build a bioanalytical laboratory at its Toronto Phase I facility.

SFBC paid $20.9 million for Taylor Technology, including $16.9 million in cash and the remainder in stock. The price represented 6.5 times Taylor's earnings before depreciation, interest, and taxes of $3.2 million. Of Taylor's top ten clients (which include Johnson & Johnson), SFBC said that only one company is already a significant bioanalytical customer for SFBC. The Taylor operation will be marketed with SFBC's other US bioanalytical laboratory in Philadelphia, which was acquired by SFBC in 2002.

One challenge SFBC faces after its recent acquisition and investment efforts is that it has

Table I: Second-quarter financial results.

Company	Segment	Revenue (millions)	Revenue growth
Cambrex**	chemical	$75	2%
DSM Pharmaceuticals	chemical	$461	–6%
Sigma-Aldrich Fine Chemicals†	chemical	$65	5%
Lonza Exclusive Synthesis	chemical	€23	–24%
Bio-Imaging Technologies	clinical	$7	20%
eResearchTechnology	clinical	$26	88%
Icon Clinical Research	clinical	$77	30%
Kendle International	clinical	$41	7%
Omnicare CRO	clinical	$29	–17%
Parexel International	clinical	$547	5%
SFBC International	clinical	$36	62%
PPD	clinical/CMC	$185	10%
aai Development Services	clinical/CMC	$25	13%
Patheon	CMC	$123	17%
LAB International	preclinical	*$6	90%
Charles River Laboratories††	preclinical	$67	29%
MDS Pharma Services	preclinical/clinical	*$131	3%
Covance	preclinical/clinical	$251	7%
GeneLogic††	preclinical/clinical	$6	12%
Inveresk Research Group	preclinical/clinical	$79	19%
Life Science Research	preclinical/clinical	$38	17%

* denotes Canadian dollars; ** includes human health and biopharmaceutical businesses
† denotes fine chemicals companies; †† denotes development services

forfeited long-term economies of scale in exchange for a short-term capacity fix. Bioanalytical testing involves running large numbers of samples through expensive liquid chromatography–mass spectrometry instruments using assays that frequently are sophisticated. These operations lend themselves to economies-of-scale in instrument use, compliance overhead, and investments in LIMS systems. In the current market environment, with strong demand and tight capacity, pricing trends may mask the cost disadvantages of having multiple small facilities. And the recent performance of market-leader MDS Pharma Services and heavyweights Covance Inc. and PPD Inc. demonstrate that economies-of-scale are not sufficient to guarantee strong performance. As the industry matures and the market levels off, however, having multiple small facilities could be a disadvantage. **PT**