



All Signs Indicate a Strong 2004 for Contract Services

Jim Miller

Exhibitors at October's AAPS meeting confirmed that the demand for services is robust and believe that the industry's pipeline appears stronger than it has been in the past few years.

The annual meeting of the American Association of Pharmaceutical Scientists (AAPS) is one of the best windows of the state of the contract services industry. This year's meeting in Salt Lake City, Utah, was no exception, and with traffic in the exhibit hall lighter than usual, contractors had more time to talk than they had in previous years.

The mood of most vendors was strongly positive. So far, most small, privately held providers of laboratory and clinical trial material (CTM) services have reported good financial results for 2003, with revenue gains averaging 15% or more. This news was encouraging because some of the large public CROs have reported disappointing results in their laboratory services businesses this year. Small laboratories have a pretty diversified client base, meaning they have had less exposure to Big Pharma mergers and to the financing problems of biopharmaceutical companies (contract laboratories that focus on biopharmaceutical companies reported having an off-year). In addition, small laboratories usually are more flexible in terms of meeting a client's needs than are large CROs. That flexibility has helped them retain business in a slow market.

CRO and contract manufacturing organization (CMO) staffers at AAPS confirmed other market indicators that new-product development activity and spending are improving. Most said they are seeing the upturn in RFP activity that public CROs have been reporting during their quarterly earnings conference calls. One CMO that focuses on finishing APIs reported that it had worked on almost 90 new chemical entities during the year, most of which are in the preclinical phase.

Some service providers have focused on the expansion of CTM formulation manufacturing capacity, especially for sterile products. **DSM Pharmaceuticals** (Greenville, NC) and **Quintiles Transnational Corp.** (Kansas City, MO) both will begin new clinical-scale sterile manufacturing operations in 2004. Just before the AAPS meeting, **Baxter** (Deerfield, IL) announced a strategic alliance between its **Baxter**

Pharmaceutical Solutions unit (Bloomington, IL) and **Althea Technologies** (San Diego, CA) by which Althea will provide Phase I and II CTM services to clients and Baxter Pharmaceutical Solutions will handle Phase III and commercial manufacturing. **Patheon** (Toronto, Canada) is expanding its offerings of development services at its Cincinnati, Ohio, facility that it acquired from Aventis in 2002.

Drug delivery technology was the hot topic at AAPS once again, with many of the scientific presentations and poster sessions dedicated to scientific and technical issues. Approximately 75 exhibitors highlighted their proprietary drug delivery technologies and expertise. Although dosing convenience and product differentiation are important drivers, formulation challenges may be the biggest driver of all. According to some estimates, as much as 50% of all new drug candidates involve poorly soluble APIs.

Strong third-quarter results

Publicly traded contract services providers reported good results for the July–September quarter, but the big news was the strength of its new business activity. After a slow first half, proposal and contract activity has really picked up, and contractors expect 2004 to be an especially strong year.

Overall, revenues for the third quarter were up an average of 15% more than the same quarter in 2002, with profits growing at a slightly higher rate. The strongest results were in Phase I clinical research, where most CROs reported very high utilization rates and preclinical toxicology, especially in Europe. Phase II and III research were slowed by the weak business development activity in the first half of the year and by recruitment problems in the start-up of new studies.

CRO executives were especially optimistic about 2004. All experienced a substantial increase in RFPs during the third quarter, and several experienced record results in new business signings. There was a general sense that Big Pharma is finally getting its pipeline moving and that biopharmaceutical companies are more willing to spend money now that the fi-

Jim Miller is president of PharmSource Information Services, Inc., and publisher of *Bio/Pharmaceutical Outsourcing Report*, tel. 703.914.1203, fax 703.914.1205, jim.miller@pharmsource.com, www.pharmsource.com.

Outsourcing Outlook

nancial markets are more receptive. The strong performance reported by preclinical and Phase I services providers has increased optimism about the future of Phase II and III activity, which accounts for 60% of total R&D spending. Executives at **Charles River Laboratories** (Wilmington, MA) see R&D funding continuing to favor development more than discovery (i.e., target and lead iden-

tification and optimization), which has hurt the company's discovery services business.

Cardinal Health makes more waves

Cardinal Health once again got the industry's attention with an acquisition—this time of UK-based **Intercare plc** (Harrogate, UK). Intercare is a manufacturer and wholesaler of generic

pharmaceuticals in the United Kingdom, as well as a leading contract sterile-products manufacturer. Its sterile-products manufacturing operations include **Federa**, with sites in Brussels, Belgium; Limoges, France; and Martindale, United Kingdom. The company also owns **L.C.O. Sante** (Osny, France), a contract manufacturer of hormone-based therapies. According to George Fotiades, president of Cardinal Health's Pharmaceutical Technologies and Services business unit, Intercare's sterile manufacturing operations are a "strategic platform" for the expansion of Cardinal Health's business in Europe.

The acquisition heats up the rivalry in sterile manufacturing on several fronts. Cardinal Health will now compete directly with Patheon for FDA-compliant sterile manufacturing in Europe. Federa is building a new manufacturing facility in Brussels that is intended to be FDA-compliant, and Patheon has two FDA-compliant sites in Italy. In addition, this acquisition will intensify competition between Cardinal Health and Baxter Pharmaceutical Solutions by increasing Cardinal Health's capabilities in manufacturing pre-filled syringes. Cardinal Health is already installing a 60-million unit syringe manufacturing operation in Puerto Rico, and Federa's new facility will have complementary capabilities.

Cardinal Health is paying \$530 million in cash and assumption of debt for publicly traded Intercare, whose annual sales are approximately \$550 million. The sale is pending approval by Intercare stockholders. There was no word yet about how Cardinal Health would manage Intercare's distribution and generic products businesses. Fotiades said that Cardinal Health has a strategic interest in hospitals, but has yet to decide what it will do with the distribution business, which accounts for just 25% of Intercare's operating profits. **PT**