

Early Phase Outsourcing is on the Rise

The number of early phase pharmaceutical intermediate projects being outsourced by the pharma industry is increasing, thanks in part to a surge of investment about two years ago in the U.S. biotechnology sector, says Guy Villax, head of privately owned contract manufacturing organization (CMO) Hovione (Lisbon). A number of companies exhibiting at the CPhI 2005 expo, held recently in Madrid, also highlighted an increase in the number of early phase projects they are undertaking. The outlook for the pharma intermediates sector remains mixed overall, however, with no clear signs of market growth in bulk pharma manufacturing, Villax says.

Hovione has seen "an explosion" of growth in its number of early phase projects, and it is currently working on 30, Villax says. Hovione installed a technology transfer center focusing on early phase projects three years ago at East Windsor, NJ. The center doubled its sales, to \$3.5 million in the first half of 2005. The

company says it is close to optimum capacity utilization at the facility. Projects that proceed to commercial scale are transferred to Hovione's facilities at Lisbon or Hong Kong.



Villax: Spreading the risk.

The increase in the number of small projects is "a welcome boost," but such projects represent relatively small pieces of business, Hovione says. Nor do they compensate for a market that in general is being negatively affected by problems associated with the pharma industry, including the low number of new drugs that pharma companies are introducing as well as increased competition from generics, Hovione says.

The custom pharma sector could potentially be helped by major cost-cutting initiatives that are being announced by leading drug companies, some industry experts say. Merck & Co and Pfizer have each recently announced major cost-cutting programs with multiple plant closures (*CW*, Nov. 30/Dec. 7, p. 16). However, the emphasis on reducing costs will likely lead to continued price pressure on

pharma companies' suppliers, and cause big pharma companies to seek supply deals with low-cost CMOs in India and China rather than increase outsourcing to Western CMOs, Peter Young, president of life sciences and chemicals investment banking firm Young and Partners (Y&P; New York), tells *CW*. All major pharma companies are under severe pressure, and more companies will announce big cost reduction programs, Young says.

Hovione nevertheless reports growth in the commercial active pharma ingredients (API) market. The company says it has been involved in developing three of the 19 new drugs approved by the FDA for launch in the North American market during the next 12 months. Hovione increased sales 8%, to \$82 million in 2004, and predicts that 2005 sales will increase 8%-10%. "Compared with our six main competitors in Europe, whose sales volume in fine chemicals declined 14% on average, we worked very well," Villax says. Hovione generates 60% of its sales from generic projects, and 40% from ethical APIs. "It is very important to keep a balance, to spread the risk," he says. —ALEX SCOTT

Halocarbon Unveils Novel Desflurane Technology

Fluorine chemistry specialist Halocarbon (River Edge, NJ) says it has patented a greener low-cost, and catalytic process for manufacturing the anaesthetic desflurane. The system avoids the use of toxic antimony halide catalysts, which generate by-products and make purification of desflurane "difficult," Halocarbon says.

The process uses a chromium-based catalyst in a fixed-bed reactor. "It gives high yield and almost no by-product," says Barry Jones, technical director at Halocarbon.

Halocarbon has not started shipping product derived from the new process because it has yet to forge a deal with a distributor, CEO Peter Murin recently told *CW*. Halocarbon may consider marketing desflurane derived from the process through the company's own distribution channels. The desflurane market is worth "tens of millions of dollars," Murin says.

Halocarbon is operating the process at a semi-commercial scale plant. Proof of concept has been confirmed. —AS

COMPANIES

Excelsyn's Sales Growth Accelerates

Excelsyn (Holywell, U.K.) says its sales increased by about 60%, to \$20 million in the fiscal year ended May 31, 2005, and that it expects sales to increase at the same rate in the current fiscal year. Excelsyn, headed by industry veteran Ian Shott, is a custom fine and specialty chemicals producer as well as a consulting and engineering start-up.

"The ambition is to at least double sales each year for the next three years," says Gareth Jenkins, business development manager at Excelsyn. The company is profitable after less than two years of trading, Jenkins says.

A key reason for Excelsyn's early success is its achievement in turning around the money-losing fine and specialty chemicals site at Holywell that it acquired in 2004 from Great Lakes (*CW*, June 16, p. 25). Excelsyn has gone out to the market, offering itself as a long-term partner for custom manufactur-

ing, Jenkins says. The Holywell site prior to its acquisition by Excelsyn "had been up for sale for three years, so there was a level of uncertainty and not much new business coming in," he says. The site today features a number of recently built laboratories predominantly for early phase custom pharma intermediate and fine chemical projects. The site is delivering 60% sales growth, he adds. "The market is growing, but we are also taking market share."

The number of projects handled by the Holywell site has "significantly increased," and the number of clients has doubled in the past year, Jenkins says. Excelsyn says it is attracting more projects with biotech companies. The site employs 12 chemists, and there are plans to double that. The bulk of Excelsyn's activities at Holywell are for pharma intermediate projects in the pre-clinical to phase II stages. —AS