

Optimism Taking Over in Pharmaceutical Chemicals

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After a five-year downturn, cautious optimism is taking hold among API manufacturers.

The mood among exhibitors at this year's Informex trade show in Las Vegas was the brightest it has been in several years. Although 2005 looks like it will deliver slight improvement from the ugliness of the first years of the decade, manufacturers of active pharmaceutical ingredients (APIs) are looking for a return to real profitability in 2006.

The optimism is a reflection of the general strong performance throughout the contract services industry. In a classic case of "a rising tide raising all ships," the entire industry is being buoyed by an apparent flood of new candidates hitting late-phase development. Clinical CROs reported that fourth-quarter 2004 contract signings for Phase II and III studies were at near-record levels. The upturn in late-development activity means an increase in inquiries and contracts for API manufacturers, who don't start generating significant revenue until a candidate gets into Phase III and nears commercial launch.

The favorable pipeline developments have dovetailed nicely with a concerted effort by API manufacturers to improve the effectiveness of their sales and marketing efforts. In his year-end review, **Lonza** CEO Stefan Borgas (Basel, Switzerland, www.lonza.com) focused on his company's efforts to build its pipeline of research and development projects, which he says stands at nearly 100 currently but is not yet large enough. Borgas said that a large pipeline of development candidates is critical to diversifying the risk of candidate failure and ensuring an adequate flow of new commercial projects.

Cambrex CEO John Leone (East Rutherford, NJ, www.cambrex.com) also talked about his company's efforts to build up its sales force during his fourth-quarter review. **DSM Pharmaceuticals** (The Netherlands, www.dsm.com) also is revitalizing its sales and marketing capabilities. One interesting trend in sales force restructuring has been the effort by API manufacturers that have

chemical and biological manufacturing capabilities to integrate formerly separate sales teams into a single unit. The combined sales forces reflect the fact that most major pharmaceutical companies, and many smaller ones, have small- and large-molecule candidates in their pipelines. API buyers from those companies prefer a single point of contact with their manufacturers.

Despite the upturn in late-phase development activities, API manufacturers still face a number of obstacles. They continue to get hammered by low-cost competition from Eastern Europe and Asia, especially for early-stage intermediates and increasingly for generic APIs. An additional problem, according to Lonza's Borgas, is a trend toward "short-term supply chain thinking" aimed at taking maximum advantage of price leverage. Borgas says his company now seldom sees orders covering 3–4 years and must contend with companies procuring supplies on a "batch-by-batch" basis.

One problem API manufacturers still contend with is a seeming inability to differentiate themselves in the market. They continue to try to compete on the basis of technical capabilities and capacity, but it has become a game of "keeping up with the Joneses." Last year, everyone was announcing the expansion of their high-potency capabilities; this year it's high-energy (*i.e.*, potentially explosive) reactions.

A key development in recent months has been for API manufacturers to establish R&D operations in Asia. **Lonza**, **Albany Molecular Research**, **Dow Chemical**, and **Degussa**, among others, have all announced new R&D operations in either China or India. These new facilities are an acknowledgment that pharmaceutical companies have gotten very comfortable with sourcing in low-cost locations, and are, in fact, opening their own research facilities in those countries.

It's a bit premature to say just how the competition in the API sector will play out. We're guessing that large companies with small- and large-molecule capabilities, global supply chain skills, and a business development team capable of offering those as solutions to pharma company clients, will be winners in the years ahead.



Outsourcing Outlook

Lure of proprietary products

Two major providers of contract services let it be known in recent months that they will be launching proprietary products in the near future. In presentations to Wall Street analysts, Robert Walter, CEO of **Cardinal Health** (Dublin, OH, www.cardinal.com), announced that his company will soon launch its own line of injectable generic products in the United States. The announcement follows the appointment of a former generics executive, Joseph Papa, to CEO of Cardinal Health's Pharmaceutical Technologies and Services contract manufacturing business. It also reflects the high profitability that Cardinal Health has experienced from generics sold through its wholesale distribution business.

The move will put Cardinal Health in direct competition with other companies that perform contract manufacturing of injectables and offer a proprietary product line, including **Hospira**, **Ben Venue**, and **Baxter**. Thanks to its huge presence in the hospital market, Cardinal Health is likely to be a fearsome competitor. In ad-

dition to its wholesale distribution operations, the company is the leading contract operator of hospital pharmacies and a major seller of medical-surgical supplies. Following last year's acquisition of **Alaris**, it is also a major provider of electronic pumps for administering injectable drugs.

Cambrex CEO John Leone let it be known in his fourth-quarter financial review that his company will be launching its first proprietary product by the end of 2005. Leone provided few details, other than to say the new product will be for wound healing and that it's the first foray into making Cambrex a specialty pharmaceuticals company.

In fact, Leone talked about several new lines of business at Cambrex to help reduce the company's dependence on its API business. The company is offering a proprietary taste-masking technology, with **Novartis Consumer Health** as its first licensee, and has begun offering small-scale contract injectables manufacturing services from its Walkersville, Maryland, facility. It also continues to invest in capabilities at its small- and large-molecule API businesses.

The moves by Cardinal Health and Cambrex make the obvious point that expertise and assets accumulated in the services business can be readily applied to proprietary products. Whether it can be done profitably is another question, however. **aaiPharma** tried converting itself from a CRO to a specialty pharma company in just three years through acquisitions, and found itself on the brink of bankruptcy. Its experience demonstrates that it takes a lot more than development and manufacturing know-how to be a successful drug company.

On the other hand, **Quintiles Transnational Corp.** (Rockville, MD, www.quintiles.com) has used its development and sales and marketing expertise to guide a venture capital program that invests in individual products and companies. That approach has allowed Quintiles to profit from proprietary products using its expertise and assets but without converting itself into a pharmaceutical company. It will be interesting to see how the new ventures by Cardinal Health and Cambrex work out. **PT**

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