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Beyond Small Molecules

After a tough 2009, attendees at CPhI were looking for growth in biotech and nonpharmaceutical markets

[Rick Mullin](#)



Rick Mullin/C&EN (All)

THROUGH A GLASS DARKLY Contract service firms prognosticated the future of pharmaceutical chemicals in Paris.

If the contract manufacturing and service firms attending CPhI, the annual conference on pharmaceutical ingredients, expressed a guarded optimism, it is partly because they have lowered their expectations.

The pharmaceutical chemicals sector is showing signs of recovery from a steep drop in business in 2009. But business managers in Paris, where the meeting was held earlier this month, agreed that the double-digit growth rates of 2007 and 2008 for contract-manufactured small-molecule and biologic active pharmaceutical ingredients (APIs) are not likely to return this year or next.

The sector remains focused on a mix of pharmaceutical industry trends that predate the recession. These include an increase in outsourcing by major drug companies and the chronic doldrums in big pharma's small-molecule drug pipeline. The big drug firms are compensating for lack of innovation in the lab by expanding their biotech portfolios. As a result, some contract manufacturers are planning to boost biotech offerings or invest in specialized technologies for which demand is increasing.

Many big pharma customers are turning to the biopharmaceuticals market with plans to offer both proprietary and "biosimilar"—or generic biopharmaceutical—products, according to Peter Wittner, a senior consultant with London-based [Interpharm Consultancy](#) who spoke at a preconference seminar sponsored

by United Business Media (UBM), which hosts CPhI. Biologics are expected to grow at double-digit rates, or about twice as fast as traditional pharmaceuticals, Wittner said.

Merck & Co. plans to launch six biosimilars by 2017 through its Merck BioVentures business, he noted, and Pfizer estimates it will launch 10–15. Both AstraZeneca and Eli Lilly & Co. say they will participate in the market as well. Accordingly, they'll be looking for ways to manufacture complex molecules, Wittner said. And they will be looking for partners.

[Novasep](#) is among the contract service firms building a biotech-oriented business. Last year, the French synthesis and purification specialist purchased Henogen, a bioprocess development and manufacturing firm with expertise in *Escherichia coli*, yeast, mammalian cells, and viral vectors. Recently, Novasep formed a partnership with Cerenis Therapeutics, a French firm that focuses on developing drugs based on the high-density-lipoprotein cholesterol recombinant protein.

Jean Bléhaut, Novasep's business development manager, figures that one-third of his firm's business today is in biotech. "Before 2008, 95% of our work was in small molecules," he said. Biotech presents a major growth opportunity, given the need for chromatography in purification, "which is mandatory in biopharma," he added.

The drug industry's problems in the lab will also boost Novasep's synthesis and purification service businesses, Bléhaut predicted. "Our main driver is big pharma's pipeline weakness," he said. "Drug companies are struggling over a minefield of patented molecules, so that any new molecule will likely be very complicated with an increased need for advanced purification. Some chiral molecules have two or three asymmetric centers and are a nightmare to synthesize without the help of chiral chromatography."

Nor is Novasep going it alone. The company expanded its chromatography services this year in a partnership with instrAction, a German firm specializing in stationary-phase technology for mapping ligand structures and identifying active areas in functionalized polymers. instrAction boasts a library of more than 3,000 stationary-phase structures, according to Bléhaut. Novasep also has a three-year-old partnership with Chiral Technologies for large-scale chiral separations.

Novasep's sales slipped slightly in 2009 to about \$420 million, Bléhaut said. "But I think the industry is now seeing projects coming back." Much of the work will come from emerging pharma and biotech companies, according to Bléhaut, who estimates that 80% of new chemical entities will be generated outside the major drug companies.

Several other firms say they are expanding biotech-oriented contract manufacturing. Germany's [Chemie Uetikon](#) launched its biotech operation in 2007 with the acquisition of a start-up at Dublin City University, now operating as BioUetikon. The company is planning to expand operations in Dublin with the addition of single-use bioreactors, according to Heinz Sieger, Uetikon's chief executive officer.

Uetikon lost a major project last year and experienced no growth in sales. Sieger expects a repeat performance this year, although he notes that new business is starting to come in. "We are working four shifts, and in September, we were at full capacity," he said.

[Almac](#) also forecasts growth in the biotech part of its business. "The future of small molecules is unclear," said Denis Geffroy, the Northern Ireland firm's vice president of business development. Almac has seen "tremendous growth" in its six-year-old peptides business. "Thirty percent of what we do is in peptides," he said. "If we didn't launch that business, we'd be in very different shape right now. But we certainly don't want to bury the small molecule."

Geffroy acknowledges that the biotech business was hardest hit by the recession. Venture capital spending dried up, putting a halt to many drug development projects and the associated contract work. "It's trickling back," he said. "But companies are glad to be getting \$1 million in venture capital backing, whereas they used to get \$10 million."

Joseph Pont, head of marketing for custom manufacturing at [Lonza](#), anticipates steady growth ahead in small molecules, driven in part by demand for drugs in emerging markets, especially China. "But there is an innovation gap, and big pharma is struggling," he said, noting that major drug companies have worked to bolster their biotech pipelines in recent years.

Lonza, which has long offered both small-molecule and biologic contract manufacturing, recently signed an agreement with GlaxoSmithKline under which it will manufacture batches for five GSK antibody-based drug candidates in Phase I and II clinical trials and provide GSK with capacity for later-stage production.

According to Pont, Lonza is also interested in adding fill-and-finish services, as finished-drug formulation is called, to its contract services offerings. Last year, the firm made an offer to purchase Patheon, a drug formulation specialist, but Patheon's board rejected the bid. Lonza continues to look for a fill-and-finish asset "with the right fit," Pont said. "We don't want to be just another company churning out tablets. We could have cheaply purchased large pharma assets if we wanted to do that."

Roger LaForce, general manager of [Fabbrica Italiana Sintetici \(FIS\)](#), an Italian contractor focused almost exclusively on small-molecule APIs, sees growth ahead for small molecules, driven largely by the demand for drugs in China and other developing markets. "Large pharmaceutical companies are not exactly walking away from small molecules," he said.



LaForce

FIS is currently extending its capability to synthesize oncology-related APIs, LaForce said. The family-owned firm added a 10- to 20-kg facility in the second half of 2011 at a cost of about \$7 million. FIS currently operates a smaller kilo lab and a larger production unit with capacity up to 100 kg.

"But we are looking into biotech," LaForce said. FIS is at the pilot stage of building a biocatalysis platform, according to LaForce, and the company is looking for a biotech firm with interesting technology. "We are evaluating targets."

Across CPhI's exhibit halls, companies were reporting a turnaround in sales this year, often due to strength in nonpharma markets. Sales at [SAFC](#), the fine chemicals arm of Sigma-Aldrich, are up 10% in the first half of 2010, President Gilles Cottier said. Areas outside small-molecule pharmaceutical chemicals are having the biggest impact on sales growth. "Our business targeted to electronic chemicals is growing extremely strongly this year," Cottier explained.

SAFC's life-sciences-oriented businesses are also doing well, he added. "Our business in raw materials for bioproduction is very strong as customers continue to develop more and more biologic drugs."



Cottier

Sales are up over last year at fluorochemicals specialist [Halocarbon](#) Products. "Even more encouraging than the sales increase is the large number of inquiries we've been receiving for new compounds," CEO Peter Murin said. Halocarbon has expanded its offering to the electronics industry. It can now offer 1,1,1-trifluoroacetone and its derivatives for use in synthesizing photoresists.

Endeavour Speciality Chemicals enjoyed robust sales of flavor and fragrance chemicals during the economic downturn, according to Jordi Robinson, sales manager. The company was acquired by fellow

British firm [Robinson Brothers](#) in 2008, and he attributes Endeavour's strength in the sector in part to its ability to supply commercial volumes of its specialty products from Robinson Brothers' larger facilities.

The combined companies offer novel intermediates and building blocks derived largely from sulfur and heterocyclic chemistries. Other nonpharma markets for the companies include imaging and electronics. Overall sales should reach about \$40 million in 2010, according to Robinson.

Although UBM has not released audited attendance figures for CPhI, Richard Kerns, director of European operations for Impress Public Relations, a UBM partner, said attendance "will easily surpass" the 25,000 who attended the 2009 event in Madrid. The number of exhibitors reached 1,934, an increase of 7%.

More On This Topic

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