Ingredients

Fine Chemical Companies Maintain Growth Despite Challenges

Pharmaceutical fine chemical companies and contract manufacturers are seeing a rise in demand for their products and services, and say that the outlook for the industry is positive despite a number of challenges. Companies with operations in all geographic regions expect to see further growth in their businesses and have outlined plans for expansion. "The pharmaceutical fine chemical market is growing at 3%-4%/year in volume terms, which is partly offset by unit price erosion of 2%/year resulting in net growth of about 1%-2%/year," says Enrico Polastro, v.p. and senior industry specialist at Arthur D. Little (Brussels). The global pharma fine chemical merchant market, excluding captive production, is estimated at about $40 billion/year, "and intermediates account for 15% of the total, off-patent active pharmaceutical ingredients [API] account for 60%, and custom synthesis accounts for 25%," Polastro says. Several other estimates put the value of the API market much higher than $40 billion/year but they are not accurate, he says. "Estimates that value the API market to be substantially larger, at $80 billion based on the rule that 10% of pharmaceutical sales represent the value of the API, cannot be substantiated," Polastro says.

Challenges faced by the contract-manufacturing market for pharma fine chemicals are varied and complex, experts say. "The market is still suffering from overcapacity with too many competitors chasing too few opportunities," Polastro says. "The much-predicted industry consolidation is yet to happen and hardly any capacity is being retired. There are few new product opportunities in custom synthesis while the generics pipelines are also getting smaller. Customers continue to exert leverage to extract price concessions from suppliers as they are facing tighter health-care budgets."

Dishman Pharmaceuticals & Chemicals (Ahmedabad, India), a manufacturer of APIs and intermediates, says that the contract-manufacturing market is still recovering from the global economic crisis, but that the company is achieving good results due to its strong pipeline of projects. Dishman had consolidated sales of Rs11.2 billion ($203 million) in the fiscal year ended March 31, 2012, an increase of 13% compared with the previous fiscal year.

"This growth is impressive consideration that the contract-manufacturing industry is still working its way through the combined effects of a global economic downturn, a decrease in the pipelines of major pharma companies, and a reduction in early-phase development projects from small pharma companies," says Christian Dowdeswell, commercial director at Dishman. The Dishman group, consisting of Dishman Pharmaceuticals & Chemicals, and pharma process-development and API subsidiary Carbogen Amcis (Bubendorf, Switzerland), however, "has an exciting pipeline of projects and is working with a wide spread of customers on launching new APIs," Dowdeswell says.

COOK: *Acquiring assets in India and North America.*

DOWDESWELL: *Firms in a recovery phase.*

Pharma fine chemical firms say they are seeing a rise in demand despite the challenges, and that they expect further growth. Companies are also working to expand their businesses through organic and inorganic routes.

Aesica Pharmaceuticals (Newcastle upon Tyne, U.K.), a provider of APIs, formulations, and custom synthesis, reports a rise in demand for APIs. "The trend over the last few years has been for large pharma companies to outsource more of the manufacturing process to minimize their overheads, and there has also been a trend of large pharma companies merging to create value and consolidate their assets, capabilities, and product portfolios," says Kevin Cook, managing director/API business unit at Aesica. "While large pharma companies concentrate on research and development to discover new compounds, and also on marketing and branding, we continue to see a rise in demand for outsourced services, and we are seeing an increase in demand in API and formulated products, and in the API and formulation development arena."

Growth in API demand from Western countries is 7%-9% and growth in API demand from Asia is 15%-20%, Cook says. "As far as requests for proposals for Aesica and the business that we are bidding on are concerned, we have seen a 25% increase in companies asking us to bid on new business."

Aesica, which was formed in 2004, recorded sales of $250 million in 2011. "We have seen a six-fold increase in our revenues in the last five years, and that has been through organic and inorganic growth," Cook says.

Aesica says it plans to expand internationally including the establishment soon of API capabilities in North America and Asia. Aesica's manufacturing and development locations are currently all in the U.K and the rest of Europe. "Aesica supplies APIs and API development services to North America and the value of that business was about $16 million in 2011, which accounted for 25% of Aesica's total API business," Cook says.

Aesica says it plans to make an acquisition soon in North America. "We are in discussions [with an acquisition target in North America]," Cook says. "In the not-too-distant future, I am expecting to make a significant announcement about this development. This will be a small-scale API development and commercialization facility, and we will look to establish formulation-development and solid-state capability within that asset, so that we can offer a total service to big and emerging pharma customers for pre-launch, scale-up, and delivery."

Aesica is also looking at a possible acquisition in India. "Having manufacturing capacity in Asia is an important part of Aesica's strategy," Cook says. "We are actively pursuing an acquisition in India. The discussions are not as advanced as on the North American acquisition, and we expect to be able to make an announcement in late 2012 or early 2013."

Private equity firm Silverfleet Capital (London) replaced Lloyds TSB Development Capital in 2011 as Aesica's majority shareholder. Aesica says the change of ownership is leading to further expansion of the company. "The Silverfleet investment in Aesica is an exciting opportunity for us," Cook says. "Silverfleet has bought into our growth strategy and our global strategy, and that allows us to accelerate our growth plans. In addition to the acquisition in North America, we are looking at options for

commercial-scale manufacturing and development sites in Asia [including] China. And we are clear that we would need to have an additional API manufacturing facility in Europe, and so Aesica is looking at a potential acquisition in Europe."

Dishman says it has an advantage over many of its competitors because it has manufacturing facilities in Asia and Europe. The Dishman group has facilities in China, France, India, the Netherlands, Switzerland, and the U.K. The "global nature of our manufacturing base enables us to rapidly supply clinical APIs in the development phase [in Europe] and transfer projects to our Asian manufacturing facilities at an appropriate point," Dowdeswell says. "This may be pre-launch or post-launch of a product, or as part of the product life-cycle management. This plays particularly well to the strategies of large pharma companies. On this basis, we expect particular growth in the oncology products business."

Dishman says it restructured some of its European facilities last year, and that the restructuring has benefited the company. Carbogen Amcis, due to a worldwide decline in demand for early-phase API development, restructured its operations at Bubendorf, Aarau, and Hunzenschwil, Switzerland in 2011. About 60 of the company's 350 employees in Switzerland were laid off as a result.

"The restructuring [in Switzerland] was completed nine months ago and has enabled us to improve profitability and capture many more projects," Dowdeswell says. The company did not disclose financial results for Carbogen Amcis, but "there has been a significant improvement in sales and profitability at our Swiss sites," Dowdeswell says. "We see in the market that many companies are yet to [restructure their operations] and we anticipate some consolidation in the contract-manufacturing industry to match the consolidation in the customer base."

Dishman told *CW* early this year that the company was in discussions to divest its large-scale facility in the Shanghai Chemical Industrial Park (SCIP) at Caojing, China but it has since abandoned those plans. The Caojing facility produces pharma intermediates, APIs, and highly potent APIs. It started operating in 2010 and was expanded in 2011 to manufacture class II and III highly potent APIs. Dishman did not disclose reasons why it was considering the sale, but reports said that the company was trying to reduce its debt. "The facility in SCIP remains an integral part of our organization," Dowdeswell says. "We have several projects where these facilities will be required for commercial manufacturing and the Shanghai facility will remain within the Dishman group."

» The much-predicted industry consolidation is yet to happen. «

Dishman remains bullish about its growth and expansion prospects, and the company has made a number of investments in its other facilities. A vitamin D production plant came online at Dishman's Bavla, India site at the end of 2011, and this supports the Dishman Vitamins and Chemicals (Veenendaal, the Netherlands) business. The business also opened a production facility for vitamin D analogues in

the Netherlands. Carbogen Amcis has a highly potent API manufacturing plant at Bavla that opened last year. The plant "is filling up, to the extent that we now look at expanding operations into two unused manufacturing suites," Dowdeswell says. Dishman has been planning another facility at Bavla for API contract manufacturing. This facility will be built when demand increases and the company says it is assessing the timing for the project. Carbogen Amcis, as part of the group expansion, acquired Creapharm Parenterals (Riom, France), a contract-development and manufacturing company specializing in liquid, semi-solid, and injectable aseptic dosage forms. Creapharm Parenterals was renamed Carbogen Amcis SAS. The acquisition "enables us to offer formulation services to support clinical development," Dowdeswell says. "Carbogen Amcis SAS was restricted to liquid products at the time of acquisition, but some solid-dosage forms will shortly be brought online, notably gel capsules," he says.

ELUT: *Double-digit percentage growth in sales.*

Asymchem (Morrisville, NC), a research-based contract manufacturer of pharma intermediates, APIs, and drug products, says that the trend in the pharma industry to outsource manufacturing has provided many opportunities for the company. Asymchem, which was established in 1995, may be headquartered in the U.S., but all of its four production and R&D sites are in China. "There is no doubt that recent times have provided more opportunities because of an industry-wide rise in outsourcing of manufacturing," says Elut Hsu, senior v.p./business development at Asymchem. "Budget cuts and changing pharma regulations have caused the market to look for new ways to maximize their dollar, and the contract-manufacturing organization has become a key part of this strategy for many pharma companies. From Asymchem's vantage point, this trend will remain steady over the next few years," she says.

Asymchem says that more than 80% of the company's business comes from U.S. pharma and biotechnology customers. The company has, however, been seeing steady growth in sales in Europe and Asia. "As outsourcing becomes more widespread through the industry, we expect this increase" in sales from Europe and Asia to continue," Elut says. Asymchem is a privately held company and does not disclose annual revenues, but "our business has experienced double-digit percentage growth year on year," Elut says.

Asymchem has two production facilities at Tianjin, and one each at Fuxin and Dunhua. "All of our production and R&D facilities are spread throughout China and it has served our business model well to maintain this layout. We do not have plans to build a site outside of China at this time," Elut says. The company has plans for a third production facility at Tianjin. Asymchem completed construction of the first phase of a large-scale facility at Dunhua last year, and the company aims to complete the second and third phase of construction of the facility from late 2012 into 2013.

—DEEPTI RAMESH