Exploiting opportunities in high potency API manufacture

Cambrex has redefined its strategy to concentrate on the provision of chemistry and biology services to the life sciences industry, one of its major platforms being the manufacture of high potency APIs. Gary Mossman describes the company's prospects in this expanding business area.

Founded in 1981, Cambrex Corporation is an innovative life sciences company dedicated to providing products and services to accelerate the discovery and commercialisation of therapeutics. The company primarily supplies its products and services worldwide to research organisations, pharmaceutical, biopharmaceutical biotech and generic drug companies.

Cambrex operates as three main business segments: Bioproducts, Biopharma, and Human Health. The Bioproducts segment consists of products and services supplied to the life sciences market to support drug discovery and disease research, drug development and the production of biopharmaceuticals. The Biopharma segment consists of contract biopharmaceutical manufacturing services. The Human Health segment primarily consists of products derived from organic chemistry and includes products supplied to innovative pharmaceutical and generic drug companies. The company also provides custom development, custom manufacturing, contract research, route selection, process development and analytical services to large and emerging innovative pharmaceutical companies. Active pharmaceutical ingredients (APIs) and pharmaceutical intermediates represent more than nine-tenths of the revenue of the Cambrex Human Health segment.

Cambrex has been supplying the life sciences sector with cGMP pharmaceutical ingredients and intermediates since the early 1990s.

Established in high potency APIs

Cambrex first entered the life sciences arena in 1991, with its acquisition of what is currently its Cambrex Charles City business in Iowa, which was originally focused on animal feed and fine chemicals. Over the next several years, the base business shifted to the development and manufacture of active pharmaceutical ingredients (APIs) through both organic growth and the acquisitions of Cambrex Karlskoga and Cambrex Profarmaco (in Sweden and Italy, respectively). These businesses now manufacture more than 120 APIs, including controlled substances.

In 1999, Cambrex began manufacturing potent compounds with the construction of a high potency production facility at Charles City. More recently, the company has emerged as a leading supplier of contract development and manufacturing services for highly potent and cytotoxic compounds with fully integrated development programmes. Its facilities in North Brunswick (in New Jersey) and Charles City regularly handle potent compounds and generate toxicology-lot quantities through to full-scale commercial quantities of highly potent and cytotoxic APIs. Kilo-lab scale isolators have been added to the two sites and further expansion is in the planning stages.

Technological capabilities

"Cambrex posesses the isolation equipment and systems required to protect our employees from the product and the product from contamination," says Gary Mossman, executive vice president and chief operating officer. "Our kilo-lab isolator located in North Brunswick, New Jersey was the first of its kind, allowing for the production of high potency compounds in 150-litre reactors, isolation of the solid product, drying and packaging, all within one contained unit. Cambrex also has experience with tangential flow filtration and lyophilisation of high potency APIs. We have been able to differentiate ourselves based on our performance, technology platforms, varied scales of development and manufacturing services and world-class cGMP regulatory record in this area," he says.

MEET GARY MOSSMAN OF CAMBREX

Gary Mossman joined Cambrex in February 2003 as President of the Pharmaceuticals Business Unit and was appointed to the position of President and Chief Executive Officer of the Cambrex Pharmaceutical and Biopharmaceutical Business Units in October 2003. In August 2004, he was appointed to his current position of Executive Vice President and Chief Operating Officer. Prior to joining Cambrex, he was with Dixie Chemical Company from 1983 to 2003, serving in the role of President since 1990. From 1979 to 1980, he was General Manager, Thiokol Specialty Chemicals Division, and from 1972 to 1979 he was President and Cofounder of Southwest Specialty Chemical Company.

Cambrex provides development services and has facilities that handle highly-contained processes under cGMP conditions from gram scale to commercial volumes.

"Cambrex clients have focused on polymorph selection as a key specification in the production of their APIs," he adds. "In anticipation of this, our experts work with clients to identify the appropriate polymorphs and develop a process that will produce the desired product, supported by analytical methods consistent with the specification."

Business strategy in high potency APIs

Mossman says the company's strategy is to partner with clients throughout the development pipeline from batches needed for tox studies through to commercial manufacture: "In support of this, we have manufacturing capabilities from lab to full-scale in all occupational exposure bands (OEBs) allowing us to safely handle products with occupational exposure limits (OELs) less than 1 microgram per cubic meter per eight-hour time period. Our newly constructed kilo lab in Charles City, Iowa is currently undergoing further expansion to be able to handle more high potency programmes. Our facility in North Brunswick, New Jersey has chemical development labs and kilo lab capabilities for high potency products."

Cambrex concentrates on higher-value products and services for specific niche markets by focusing on products that require specialised technology, regulatory or handling expertise. In some cases, the company has chosen to source certain raw materials from Asia and then utilise its technological skills and quality systems to add value later in the process: "Our continued utilisation of design and lean six sigma methologies have also given us an advantageous cost position in these higher-value product areas," says Mossman.

"The US market, which is the world leader in pharmaceutical development, is currently keeping us the busiest. All of our clients value our world-class cGMP regulatory record, performance history, the ease of travel to visit our facilities located in the USA and Europe, and the ability to meet with the project team on short notice. Several of our customers have satisfied their need for two sources by qualifying Cambrex at sites on two continents, the USA and Europe," he says.

Future growth, collaborations and alliances

"Cambrex has been performing extremely well in the custom development and manufacturing sector and the success in high potency development is leading to further growth," says Mossman. "Our performance track record has become a major competitive differentiation to generate repeat business and a sound reference for new customers. We have a number of strategic alliances including those publicly announced with ABC Laboratories, based in Columbia, Missouri, and Dextra Labs, based in Reading, UK, which complement the services Cambrex offers the market.

"Typically, Cambrex enters into secrecy agreements with clients which can restrict our ability to make public announcements regarding new alliances. However, in the past year, the Cambrex development pipeline has increased from 39 to 62 projects, including many high potency projects. Our talented sales force continues to keep our pipeline full well into the future. Since Cambrex has the needed facilities with the latest equipment to ensure staff, the product and the environment are protected, as well as a robust pipeline of new projects and a world-class regulatory record, our prospects appear to be very good."

Mossman notes that capital markets are pressuring pharmaceutical companies to achieve double-digit earnings growth and that this has had an effect on how pharma companies deal with their suppliers: "Over the next ten years, pharma companies are expected to continue to pressure their suppliers to reduce costs. As a result of this, we expect to see further consolidation in the contract development and manufacturing industry and the potential 'mothballing' of large production facilities. Traditional pharma companies will continue to maximise usage of their API production facilities. However, we expect them to continue to rely on companies like Cambrex for assistance in developing the overflow of compounds in their clinical pipelines, particularly those that require special handling capabilities or technologies.

"Our early and continuing success with design and lean six sigma methologies enable us to deliver competitive pricing. This advantageous cost position, our experience, special handling capabilities and proprietary technologies and products, a broad base of general capabilities and an excellent regulatory record, will continue to offer opportunities for differentiation for Cambrex in the market place," he concludes. sp²

FURTHER INFORMATION

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