

Building business in therapeutic peptides

PolyPeptide Laboratories Group has expanded its business in the peptides sector through the recent acquisition of French company NeoMPS and its US subsidiary, and is also aiming to meet increased demand through the construction of a new facility near Mumbai, India. Rodney Lax, director of sales and marketing at PolyPeptide Laboratories Inc in Torrance, California, USA, outlines the strategy for the future.

Following its acquisition of the peptide manufacturing Group NeoMPS from Isochem, the fine chemicals subsidiary of French company Groupe SNPE, in November of last year, the PolyPeptide Laboratories Group has increased its manufacturing capacity and capabilities for small-scale custom peptides for research and large-scale peptide manufacture for therapeutic applications. The Group says such capabilities complement its long-established core strength in GMP manufacturing and will help service a range of projects from conception to commercialisation. NeoMPS was formed by the 2004 merger of France-based Neosystem and California-based Multiple Peptide Systems, both of which were launched as independent companies in 1986.

"The addition of NeoMPS to the PolyPeptide Laboratories Group is a great fit, and offers customers of both companies an even more comprehensive range of services for every stage of development," says Rodney Lax, director of sales and marketing at PolyPeptide Laboratories Inc.

With the NeoMPS acquisition, PolyPeptide Laboratories Group operates GMP facilities in the USA (Torrance and San

Diego, California), France (Strasbourg), Denmark (Hillerød) and Sweden (Malmö). Ongoing expansions in Malmö, Torrance, and Strasbourg are continuing as planned. The Group has also nearly completed construction of a GMP facility in Mumbai, India that will be focused on generic peptides.

Long history in peptides

The PolyPeptide Laboratories Group is a leading provider of custom and generic GMP-grade peptides for a range of pharmaceutical and biotechnology applications. With corporate roots that began in the 1950s, the Group was formally launched in 1996 when Peptech A/S based in Hillerød, Denmark and the Ferring Peptide Production Company based in Malmö, Sweden merged and took on the PolyPeptide Laboratories name.

"Both companies had been manufacturing peptides for a substantial length of time," says Lax. "The manufacture of ACTH (1-39) was started in Malmö in 1952, over 55 years ago. In 1997, the US subsidiary was also founded. This was followed in 1998 by the acquisition of two smaller European peptide companies. Work on our Indian subsidiary started in 2006

and in 2007 we acquired NeoMPS. With the exception of our Indian project, the Group has grown by amassing existing peptide expertise. Twelve years ago, no one had heard of us: today we are the undisputed second-largest independent manufacturer of peptide APIs in the world. Of course, we have been helped by the enormous growth of interest in peptide therapeutics over the past ten years and by a relative lack of competitors that have proven ability to take peptides all the way to approval."

Expanded portfolio

Until the acquisition of NeoMPS, the PolyPeptide Laboratories Group was almost entirely focused on GMP manufacture. NeoMPS has a much broader range of peptide services, including the manufacture of cosmetic peptides, radio-labeled peptides, exotic amino acids, organics and an extensive catalogue in addition to GMP and non-GMP manufacturing of custom peptides for therapeutic indications.

"The NeoMPS customer base hardly overlapped with that of PolyPeptide," says Lax. "Both NeoMPS facilities also have additional capacity to expand. The actual 'fit' is even better than we originally

Meet Rodney Lax of PolyPeptide Laboratories Group

Rodney Lax completed a BSc in Biochemistry at the University of Birmingham (UK) in 1967 and obtained his PhD from the Institute of Cancer Research (London, UK) in 1972. From 1970 to 1975 he held a scientific assistant position at the University of Ulm (Germany) before moving to the University of Essen (Germany) in 1975, where he obtained his lectureship in 1978 and his associate

professorship in 1985. His research background is in biochemical endocrinology. He worked for various biotech companies in Germany from 1986 onwards and was instrumental in setting up Saxon Biochemicals GmbH and WHERL GmbH before the latter company was acquired by the PolyPeptide Laboratories Group in 1998. Dr Lax moved to PolyPeptide Laboratories Inc in 2003.



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anticipated. It will help the Group become even stronger and acquire more customers at earlier phases of pharmaceutical peptide development."

The Indian facility will start operations later this year and will initially concentrate on the solid phase (SPPS) manufacture of peptide generics, but other technology may be introduced or proprietary peptides manufactured there. The facility is only one of three planned for the company's six-acre site and will manufacture according to cGMP to meet FDA and EMEA requirements.

"Independent of India and NeoMPS, we have continued to expand within existing walls. We have much larger Development Groups now in both the USA and Europe. As projects become more complex and quality requirements more stringent, we need to invest more in early development, as well as in the expansion of our large-scale manufacturing capacity," says Lax.

Importance of technology development

"Technology development is a strong focus for our company," he says. "Within our core technology of peptide manufacturing, including all aspects of synthesis, purification, and isolation, we are constantly looking for improvements in chemistry and in process engineering to keep us at the forefront. Our worldwide network of chemists stays in close contact with the industrial and academic communities to ensure that we are kept aware of any technological developments or nuances in the field. Efficient, cost-effective large-scale process development and manufacturing, together with commitment to the highest level of quality and regulatory compliance, is the key to the success of our company, and therefore technology development is always a priority."

PolyPeptide Laboratories Group: A brief company history

2008 – Indian facility completed
2007 – Acquisition of NeoMPS Group
2006 – Construction of Indian facility commenced
1998 – Acquisition of WHERL GmbH and Prague PolyPeptide Laboratories
1997 – US subsidiary established in Torrance, California
1996 – Acquisition of PepTech A/S and foundation of the PolyPeptide Laboratories Group
1952 – Start of peptide manufacturing at Malmö facility



As project requirements grow and lot sizes increase, large-scale purification equipment is used for the manufacture of GMP peptides

Until the acquisition of NeoMPS, most of the PolyPeptide Laboratories Group's business was in North America and in Northern Europe. This is changing since the NeoMPS acquisition:

"There are obvious opportunities in Asia and in the Indian subcontinent," says Lax. "The growth of the peptide generic market has been very strong over the past two to three years. We believe that the market will continue to grow for at least another 10-15 years as genomic and proteomic research generates new targets and lead candidates. Many of the hurdles that faced peptides in the past, including drug delivery and patient compliance issues, cost of goods, biological half-life, etc have been overcome. Peptide drugs are almost universally non-toxic. Their structures are usually based on parent molecules whose specificity has been honed by evolution of millennia so the risk of unanticipated side effects, as seen in so many small molecules, is low. Apart from the growing number of new molecules, the scale of manufacture is increasing too. Technologies may change, that is the nature of progress, but peptide-based drugs have a bright future.

"Our views on the likelihood of consolidation within the peptide industry are mixed. PolyPeptide Laboratories, as well as other major players in the field, has made acquisitions in the past five years and caused some of that consolidation to occur, but – seen objectively – there are probably too few players right now. There are certainly less than five companies out there – with any track record – that can provide GMP services in the peptide sector from a few grams up to 100 kg or more. That will not change quickly either. This is a business that relies exceptionally strongly on its human resources. There are not that many experienced industrial peptide chemists available.

"Peptides are very versatile molecules and we are continuously surprised and excited to see how they can be applied to meet previously unmet medical needs. As the peptide sequences become more complex and regulatory requirements more demanding, PolyPeptide Laboratories looks forward to working with the pharmaceutical community in solving manufacturing issues in this challenging field of medical development. We look forward to being their partner of choice when bringing new peptide therapeutics into the marketplace," Lax concludes. ^{sp²}

Further information

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