Streamlining the Path to Market Supply

Expert CMOs Provide High-quality Peptide APIs to Pharmaceutical Innovators

More and more active pharmaceutical ingredients are based on peptides. However, the production of peptide APIs is demanding and requires special know-how and equipment. AmbioPharm specializes in the development and production of peptides and peptide-related products. The US company recently opened a branch in Zurich, Switzerland, to serve European customers from there and to establish and expand partnerships. Michael Postlethwaite, senior director, Sales & Business Development, European Territories, at AmbioPharm, explains market trends and his company's growth strategy, particularly in Europe.

CHEManager: Mr. Postlethwaite, what trends are currently dominating the peptide market?

Michael Postlethwaite: The peptide field is responding strongly to the current Covid crisis, where there is great promise in peptides being developed for acute Covid symptoms and the longer-term effects of this debilitating condition. Aside from this, cancer and diabetes continue to dominate the clinical and commercial peptide API space. New targets and peptide-based treatments for cancer are being discovered all the time, often based on new approaches and new technologies like toxin conjugates.

It should be noted that one of the oldest peptides on the market, Goserelin, is still hard-hitting and one of the higher grossing peptides on the market. The GLP-1 market is immense, and continuously innovated by dual-agonist molecules, co-formulations for greater efficacy and ever greater improvements in pharmacokinetics brought about by molecular design. The rise of innovative manufacturing processes and in particular oral peptide molecules and formulations such as Semaglutide has energized this segment.

What are the growth drivers on the peptide market?

M. Postlethwaite: The peptide market has shown strong and consistent growth over the previous years, with 8–9% growth year on year. This is expected to continue as the 'druggability' of peptides improves, as does the discovery of new targets and innovation. Cancer and metabolic conditions will continue to drive growth, but there are many new areas being explored. For example, treatments for Alzheimer's will be a huge driver if successful, as would treatments for pain, maybe using nature's toxins as templates, novel antimicrobials and even cosmetics/cosmeceuticals. AmbioPharm is well positioned with expertise and capacity for all of these.

What has triggered the upswing of peptide chemistry in the pharmaceutical industry?

M. Postlethwaite: Peptide therapeutics have suffered in the past from challenges such as poor pharmacokinetics, high manufacturing costs, parenteral routes of administration, et cetera. However, peptides offer high selectivity, efficacy and are relatively safe and well-tolerated as a drug class. As technology and manufacturing know-how increased across the peptide field, this has led the costs downwards, becoming much more attractive to innovators, and to long-term medicine development. Being a highly specialized area of manufacturing, CMOs have established the expertise, equipment and GMP infrastructure to provide the highest quality peptide API to the pharmaceutical industry.

Michael Postlethwaite, AmbioPharm

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Where do you see the critical success factors for a CMO to grow in the peptide market?

M. Postlethwaite: There are many factors that contribute to successful growth within the peptide field. From the perspective of a CMO, we must meet the needs of our customers and sponsors. These are often driving the requirements as we move forwards. Innovation is key as technology is constantly changing, as are the challenges brought to us by our customers in terms of chemistry, material requirements and demand, quality, cost and timelines. AmbioPharm has developed expert know-how and capacity to respond to these demands, and provides cutting-edge innovation to manufacturing, while adhering to the strict quality guidelines existing in all

the different territories across the globe. In addition, we have built up the largest capacity for GMP manufacture in the peptide field, setting ourselves up for the growth of the peptide market.

Environmental awareness has accelerated the peptide field towards 'green chemistry' approaches to manufacturing. Many sponsors now consider this when innovating a new peptide, but also in the process of selection of a CMO for manufacturing clinically and commercially. AmbioPharm has taken huge steps in this direction to embrace the reduction of solvents, as well as recycling solvents, and to introduce less solvent-intensive approaches to synthetic peptide manufacture. This can also have a benefit of cost reduction once technology and infrastructure are established.

What role does the European market play in the expected growth?

M. Postlethwaite: The largest market for peptide therapeutics has been in North America, however, Europe has always provided a significant and growing market. Increasing prevalence of conditions such as diabetes and cancer within the European territories lends itself to market growth. There are many innovators in the peptide field located within Europe, and investment into development of peptide-based medicines is very strong. In addition, many top-tier academic institutes are located throughout Europe, often in the vicinity of hubs for innovation or academic/industry exchange. Several peptide blockbusters have originated in Europe, e.g. liraglutide, and the peptide pipelines of European companies both large and small are strong.

How do you position AmbioPharm in this market?

M. Postlethwaite: In other territories, especially in the USA where the headquarters are located, AmbioPharm is already strongly established. Our company has already established manufacturing capability and know-how and has devoted much investment into responding to the needs of the peptide market in terms of batch sizes and manufacturing timelines. Our philosophy is that with our unique approach to large-scale manufacturing, we can capture cost-savings and efficiencies during synthesis by leveraging our Shanghai synthesis capacity, located near the points of supply of most starting materials, and follow it up with the large-scale downstream capacities and isolation capabilities in North Augusta, USA.

In Europe, the market strongly suggests a need for readily available capacity for large-scale peptide manufacturing, and that is what we are here to deliver. We have capacity from grams to multi-tens of kilo batch sizes to sponsors in all phases of development and commercial supply with minimal lead-times. Process development, analytical validation etc. are also managed with minimal lead-time and highest efficiency, streamlining the path to market supply.

What specific peptide manufacturing capabilities and technologies does AmbioPharm have in the US and in China?

M. Postlethwaite: Since its inception AmbioPharm has had significant growth and boasts world-class facilities in both Shanghai and South Carolina in the USA. The Shanghai facility has recently moved into a dedicated state-of-the-art campus and encompasses all aspects of peptide manufacturing, including large-scale facilities for liquid-phase and solid-phase peptide synthesis, respectively. This is backed up by appropriate downstream facilities, including large-scale HPLC columns, and significant lyophilization capacity.

The North Augusta facility in South Carolina has also undergone a large expansion and encompasses the largest scale downstream facilities in the peptide field, including large-scale HPLC purification and scale-appropriate isolation, mainly lyophilization. The new processing buildings in North Augusta also house large-scale development and manufacturing capacity for alternative isolation techniques such as crystallization and precipitation, as well as the infrastructure needed to install a spray-drying suite that is currently in advanced evaluation.

Both sites, Shanghai and North Augusta, have the appropriate analytical capabilities needed for GMP API release and are overseen by the same stringent quality system, which is fully FDA compliant.

With these facilities, we are confident that we can supply from milligrams to multi-hundreds of kilograms per year of the best quality R&D and GMP peptide APIs in a cost-effective and timely way.

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