Strategic Analysis Service

Strategic Analysis of the Therapeutic Peptides Market in Europe

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Strategic Analysis of the Therapeutic Peptides Market in Europe
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RESEARCH SCOPE & METHODOLOGY

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Strategic Analysis of the Therapeutic Peptides Market in Europe
Research Scope and Methodology
Strategic Analysis of the Therapeutic Peptides Market in Europe

Geographical Regions Covered:
Europe

Base Year : 2003
Forecast Period : 2004-2010

Research Methodology:
• Primary Research
• Frost & Sullivan Published Research Services
• Decision Support Databases
• Country Industry Forecasts
• Proprietary Databases
INTRODUCTION & BACKGROUND

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Strategic Analysis of the European Peptides Market in Therapeutic Applications
Introduction

• In this research service, peptides are small linear molecules made up of two or more (< 100) amino acids.

• Peptides have tremendous chemical and biological diversity. The simplicity of peptides that make them useful models of larger proteins is also an advantage in the clinic and modern drug discovery.

• They are important messengers that signal cells to initiate important biological functions. Regulation of these interactions occurs in both normal and disease states. These biological characteristics make them useful target molecules for drug development.

• High specificity, affinity and molecular recognition is the key to development of successful therapeutic peptide. They are highly active and are required in small amounts for drug formulations.

• In last two decades, a number of peptides with a range of biological activities have been identified. Many biologically active peptides occur naturally and some are manufactured synthetically, recombinantly and transgenically.

• Peptide pharmaceuticals have gained acceptance to date with wide use of Oxytocin, Cyclosporin, Salmon Calcitonin, Integillin and Zoladex.

• All peptides are required to be produced in strict compliance with current GMP regulations. A regular inspection of manufacturing capabilities and its approval by a regulatory authority is must to fully comply with all applicable regulations on safety, health and environment.
Market Overview

• The peptide therapeutics market is providing new commercial opportunities to biotechnology and pharmaceutical industries. To exploit these markets, biotechnology and pharmaceutical companies are actively pursuing the development of a variety of peptide-based technologies, peptide manufacturing technologies and drug delivery methods

• Therapeutic peptides are now viable alternatives to biopharmaceuticals, such as antibodies specially in case of cancer treatment due to their ability to penetrate tumours. They are increasingly making their way into clinical applications

• Therapeutic peptides are specifically manufactured to be used as drugs in the treatment of human disease. The manufacturing process must conform to very stringent standards of quality and purity to ensure patient safety

• Recent advances in drug delivery have re-focused attention on peptides. The market for peptide-based active pharmaceutical ingredients (APIs) is expected to grow with a growth rate nearly double the growth rate for APIs overall

• Germany and United Kingdom hold the largest therapeutic peptide market in Europe. Other major markets are Scandinavia, France, Italy and Spain

• In Greece, generic manufacturing alone is done. The peptides are produced in Greece but they are not used there
More than 40 peptides are in the world market out of which around four to five of them are marketed in Europe. Six are in the registration phase. About 270 peptides are in the clinical phase out of which for Europe, the number is 100. More than 400 are in advanced preclinical phases worldwide. For Europe, 150 are in advanced preclinical phases.
## Examples of Peptide Drug

<table>
<thead>
<tr>
<th>Peptide</th>
<th>Company</th>
<th>Therapy/Indication</th>
<th>Length</th>
<th>Status</th>
<th>Synthesis process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenocorticotropic Hormones (ACTH)</td>
<td></td>
<td>Inflammation</td>
<td>1-39 (1-24) for biological activity 24-39 confers stability</td>
<td>Commercial</td>
<td>Solution phase</td>
</tr>
<tr>
<td>Cyclosporin</td>
<td>Novartis (formerly Sandoz Ltd.)</td>
<td></td>
<td>11</td>
<td>Approved</td>
<td>Natural</td>
</tr>
<tr>
<td>Eptifibatide</td>
<td>Trimeris and Hoffman La-Roche</td>
<td>Acute coronary syndrome</td>
<td>7</td>
<td>Commercial</td>
<td>Solution phase</td>
</tr>
<tr>
<td>Fuzeon (T-20)</td>
<td>Trimeris and Hoffman La-Roche</td>
<td>HIV</td>
<td>36</td>
<td>Approved for people who have tries anti-HIV drugs in the past</td>
<td>Combined strategy with solid phase strategy and fragments ligation in solution</td>
</tr>
<tr>
<td>GnRH antagonists</td>
<td>Praecis, Takeda, Abbott</td>
<td>Prostate Cancer</td>
<td></td>
<td>Natural</td>
<td></td>
</tr>
<tr>
<td>Insulin</td>
<td></td>
<td>Pneumonia, Diabetes type I and type II</td>
<td>51</td>
<td>Commercial</td>
<td>Natural</td>
</tr>
</tbody>
</table>

Source: Elsevier Ltd., Frost & Sullivan
# Examples of Peptide Drug

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</tr>
</thead>
<tbody>
<tr>
<td>Luteinizing Hormone-Releasing Hormone (LH-RH) and analogues</td>
<td>Takeda, Abbott</td>
<td>Prostate cancer</td>
<td>9-20</td>
<td>Commercial</td>
<td>Solid phase and solution phase</td>
</tr>
<tr>
<td>Oxytocin</td>
<td></td>
<td></td>
<td>9</td>
<td>Commercial</td>
<td>Solution phase</td>
</tr>
<tr>
<td>Salmon Calcitonin</td>
<td>NOBEX, Emisphere, Novartis</td>
<td>Osteoporosis</td>
<td>32</td>
<td>Commercial</td>
<td>Natural, solution phase, solid phase</td>
</tr>
<tr>
<td>Somatostatin analogues</td>
<td></td>
<td>Cancer</td>
<td>14</td>
<td>Approved</td>
<td>Solution phase and solid phase</td>
</tr>
<tr>
<td>Protegrin</td>
<td>Intrabiotics</td>
<td>Antimicrobial</td>
<td></td>
<td>Commercial</td>
<td>Solid phase</td>
</tr>
<tr>
<td>Vasopressin analogues</td>
<td></td>
<td>Diabetes insipidus, a condition of frequent urination and extreme thirst</td>
<td></td>
<td>Approved</td>
<td>Solution phase and solid phase</td>
</tr>
<tr>
<td>beta - amyloid</td>
<td>Praecis</td>
<td>Alzheimer's disease</td>
<td></td>
<td>Commercial</td>
<td></td>
</tr>
</tbody>
</table>
Therapeutic Peptides Market: Market Segmentation (Europe), 2003

European Therapeutic Peptides Market

Customer Base

Innovative

Generic

Segmentation is done on the basis of customers

Source: Frost & Sullivan
Therapeutic Peptides Market: Market Segmentation (Europe), 2003

European Therapeutic Peptides Market

Therapeutic Categories

- Central Nervous System
- Cardiovascular
- Oncology
- Metabolic Diseases
- Gastrointestinal
- Infection
- Inflammation
- Dermatology
- Antimicrobials
- Antiviral
- Others

Segmentation is done on the basis of therapeutic categories

Source: Frost & Sullivan
MARKET DYNAMICS

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Strategic Analysis of the Therapeutic Peptides Market in Europe
Therapeutic Peptides Market: Industry Challenges (Europe), 2003-2010

Time to market and gaining financial advantage out of it present challenges

Large scale manufacturing presents strategic challenges with technical and cost issues

High R&D and marketing expenses present challenges. Absence of funding for early phase projects is also a major challenge

Growing price sensitivity and increasing competition erode prices

Problems with peptide delivery (they are easily degraded in the stomach) have held back research and companies have focused instead on small molecule drugs

Increasing complexity of the target presents technical challenge to achieve success cost competitively

Low-cost competition from Asian countries presents strategic growth questions

Ability to have in-house production of raw material

Source: Frost & Sullivan
Therapeutic Peptides Market: Key Market Drivers (Europe), 2003-2010

Major drivers fuelling growth of the therapeutic peptides market for the period 2003-2010 include:

• Increasing number of project developments
• Major R&D activities in early stages
• Competition from small molecules and clinical advantages over them
• Technologies for cost-effective manufacturing
• Modern and sophisticated formulation techniques
• More outsourcing by pharmaceutical companies
• Novel offers for unmet medical needs in many therapeutic areas
• Advances in genomics and proteomics creates an increasing demand for small peptide and peptidomimetic drugs. Human genome sequencing has also encouraged peptide research
• Cost-effective supply of peptide building blocks such as amino acids and small peptides
• Low toxicity and high potency
• Recent relaxation on the venture capital investment
Therapeutic Peptides Market: Key Market Drivers (Europe), 2003-2010

Key Drivers for Market Development

- Research and development activities
- Increasing number of project developments
- Technologies for cost-effective manufacturing
- Novel offer for unmet medical needs in many therapeutic areas
- Technological innovations

2003 2010 and beyond
Major factors restraining growth of therapeutic peptides market for the period 2003-2010 include:

- Cost of manufacturing a peptide is higher than that for a small molecule
- Stability of peptides *in vivo* and its half life
- Problems with delivery of peptide
- Lack of funding for pharmaceuticals and biotechnology companies involved in peptide studies either for research, target validation or therapeutics
- Increasing outsourcing to Asian low-cost manufacturers
- Cost problems with large scale manufacturing
Therapeutic Peptides Market: Key Market Restraints (Europe), 2003-2010

- Delivery a major problem and instability of peptide in vivo
- Cost of manufacturing
- Lack of funding
- Low-cost competition from Asia
- Long wait for therapeutic development
Key Market Trends

The growth rate of the therapeutic peptides market is expected to be affected by the following market trends:

- New entrants, product developments and launches creating technology innovations and spurring demand
- Increasing use of peptide research in pharmaceutical and biotechnology studies
- Demonstration of scale-up ability
- The need for new diseases in therapeutic categories such as oncology, CNS disorders and infection provides financial incentives for the development of new peptide therapies
- More than 40 peptide based products are in the market worldwide with ~6 in registration process. About 270 in the clinical phase and 400 in the advanced preclinical phase. In Europe, about four to six peptide based products are in the market
- In coming years, recently approved new chemical entities and generics will boost the market
- By 2006 to 2007, it is expected that Asian manufacturers will be able to develop regulatory compliant capabilities and will present competition to the European manufacturers. Also the number of European manufacturers and their capacities are increasing, which is also affecting raw material manufacturers and the entire industry
- Market faces the challenge to produce peptide in kilograms and tons
- The supplier-customer relationship is becoming more complex requiring improved product and technological portfolios for suppliers
Key Technology Trends

The growth rate of therapeutic peptides market is expected to be affected by the following technology trends:

• Multiple technologies have witnessed advancements
• Advancements in peptide delivery technologies such as oral delivery techniques, transdermal patches, aerosols and others
• Identification and application of modified amino acids for peptide stability
• Discovery of positively charged amino acids
• Modifications in peptide backbone
• Phage display-derived peptides provide therapeutic alternatives to antibodies, and their development offers business benefits
• Rapid progress in biotechnology is not matched by progress in formulation and development of peptide drug delivery systems
• Continuous improvements in screening technologies give additional advantage