Excipients

US Industry Study with Forecasts for 2018 & 2023

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US demand to rise 4.3% annually through 2018

Demand for pharmaceutical excipients in the US is projected to rise 4.3 percent per year to $2.0 billion in 2018. While continued growth in pharmaceutical output will be the primary driver of increases in excipient demand, gains will accelerate as excipients play a larger role in bringing additional value to pharmaceutical products by improving properties such as the controlled release or improved absorption of active ingredients. However, the growing share of generics in the pharmaceutical industry will continue to make the cost of excipients an important factor for pharmaceutical manufacturers seeking to reduce production expenses. As a result, the best growth prospects are expected for products that offer a good balance among performance, compatibility with other excipients, and overall cost. Excipients for use in parenteral preparations will offer good opportunities as output of these formulations is expected to rise at a healthy pace going forward. Excipients in oral formulations such as tablets and capsules will also see strong growth as shipments of oral preparations are expected to accelerate.

Specialty blends to benefit from industry trends

A major development in the excipient and pharmaceutical industries is the increased dependence on specialty excipient blends, which can add value to a pharmaceutical product by differentiating it from competitive products and by optimizing the production process. These value-added excipient blends are often formulated for use in specific manufacturing processes such as direct compression or wet granulation, and are optimized for certain performance characteristics such as delayed- or extended-release oral tablets. Product differentiation will play an increasingly important role going forward as generic pharmaceutical products increase their market share and as consumers take a more active role in choosing their drugs from among a wide range of products with the same active pharmaceutical ingredients.

Product versatility to be key factor, favor polymers

Product versatility will be a key factor impacting product mix in excipient demand going forward, especially as specialty excipient blends play an increasingly important role in pharmaceutical formulation. Polymers -- including cellulose derivatives, povidone, starch, polyethylene glycol, acrylic polymers, and natural gums -- are expected to benefit especially from this trend as many of these products can function in multiple applications and are easily formulated with other excipients. These favorable characteristics will serve to offset the higher prices associated with some polymers.
Demand for propylene glycol-based excipients is expected to rise 4.9 percent per year to $140 million in 2018, representing 107.3 million pounds. While propylene glycol is used in most types of pharmaceutical dosage formulations, it is most commonly found in parenteral pharmaceuticals. Expecting increases in parenteral pharmaceutical shipments through 2018 will support demand for propylene glycol. As a solvent, propylene glycol is more effective than competing products such as glycerin, which will also promote demand for propylene glycol despite its slightly higher price. While propylene glycol is sensitive to the price of petroleum and related products, manufacturers are shifting production of propylene glycol from petroleum sales and exploiting the oversupply of glycerin, which is already oversupplied, by converting glycerin to propylene glycol in a highly specific distillation process.

Propylene glycol compounds (including the kelp derivative propylene glycol alginate) are produced through the hydration of propylene oxide or the conversion of glycerol. The compounds are generally recognized as safe by the US Food and Drug Administration (FDA), as inside the body they are metabolized into lactic acid. Based on their hygroscopic, miscible, non-toxic, and water soluble properties, propylene glycol and derivatives are used widely as emulsifying, suspending, and stabilizing agents in parenteral, topical, and oral liquid pharmaceutical preparations. The compounds also serve as plasticizers in controlled-release solid oral drug formulations.

ABILIFY, CONCERTA, DEPAKOTE ER, DETROL LA, KALETRA (oral solution), LEVAQUIN (oral solution), LYRICA, NEXIUM, PREMARIN (cream), PROTONIX, RISPERDAL, and ZYRTEC (syrup) are among the large-selling proprietary medicines that contain propylene glycol excipients. Dow Chemical is the leading producer of these excipients for pharmaceutical and other applications.

<table>
<thead>
<tr>
<th>TABLE III-12</th>
<th>STARCH EXCIPIENT DEMAND BY TYPE &amp; APPLICATION (million dollars)</th>
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<tbody>
<tr>
<td>Item</td>
<td>2003</td>
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<td>Polymer Excipient Demand</td>
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</tr>
<tr>
<td>% starch</td>
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<tr>
<td>Starch Excipient Demand</td>
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<td>By Type:</td>
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<td>Pregelatinized Starch</td>
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Ligand Pharmaceuticals Incorporated
11119 North Torrey Pines Road, Suite 200
La Jolla, CA  92037
858-550-7500
http://www.ligand.com

Revenues:  $49 million (2013)
Research and Development Expenditures:  $9 million (2013)
Employment:  20 (February 2014)

Key Products:  modified cyclodextrin technology and products

Ligand Pharmaceuticals is a biotechnology company focused on the discovery and early stage development of pharmaceuticals that address the unmet medical needs of patients with hepatitis, Alzheimer’s disease, diabetes, anemia, asthma, osteoporosis, and other diseases. The Company conducts research and development activities internally and via collaborations with global pharmaceutical companies. In addition, Ligand Pharmaceuticals generates royalty revenues as a result of collaboration with certain pharmaceutical partners. The Company operates in two segments: Ligand and CyDex.

The Company participates in the US excipients industry through the CyDex segment, which had 2013 revenues of $28 million. The segment, which does business through the CyDex Pharmaceuticals Incorporated subsidiary (Lenexa, Kansas), a firm that develops and commercializes specialty pharmaceuticals based on its innovative drug delivery technologies, and licenses and commercializes its CAPTISOL technology for use in drug development and formulation activities. CAPTISOL technology incorporates CAPTISOL modified cyclodextrins, which are designed to improve the stability, bioavailability, safety, solubility, and dosing of active pharmaceutical ingredients. CyDex

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