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# Biologics

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US Industry Study with Forecasts for **2015 & 2020**

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Study #2792 | September 2011 | \$4900 | 316 pages

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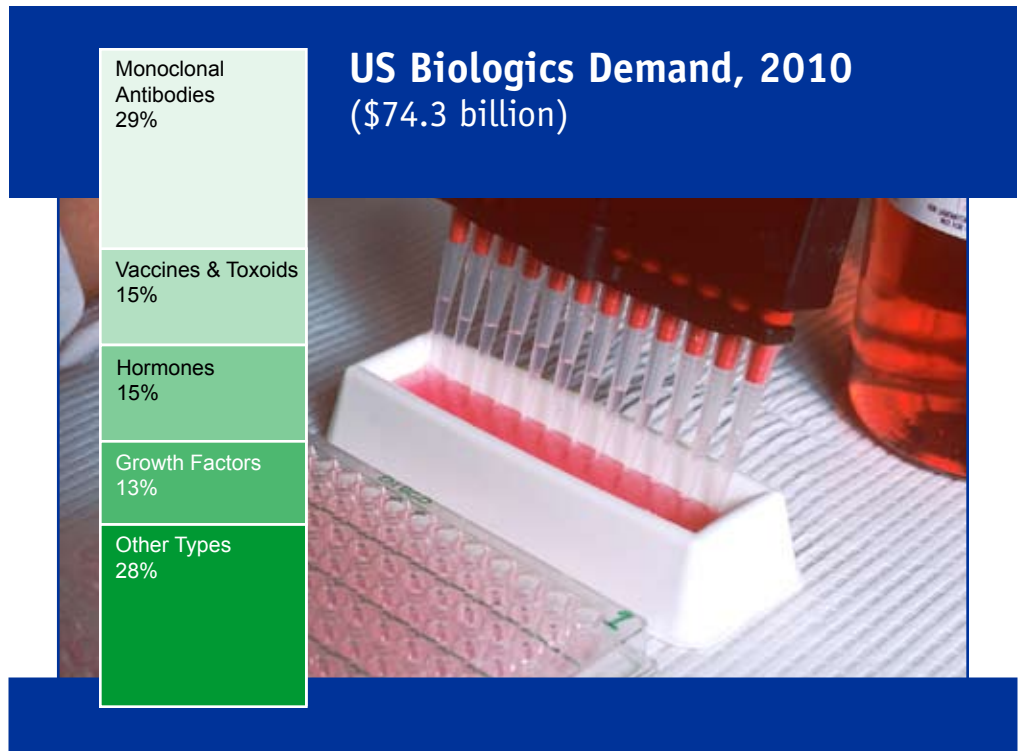
*Gains will be driven by dramatic shifts in production technology and an expansion in the number of targeted diseases, including cancer, diabetes and other serious medical conditions.*

## US demand to rise 6.5% annually through 2015

US demand for biologics is expected to grow 6.5 percent per year to \$102 billion in 2015, driven by dramatic shifts in production technology and an expansion in the number of targeted diseases. New biologics are being developed for the treatment of cancer, diabetes and other serious medical conditions, many of which are seeing their incidence rise in the US population. While growth in market value will slow from the double-digit advances registered during the past decade, this is primarily a function of restrained pricing, which will mask to some extent continued robust gains in market penetration.

## Monoclonal antibodies to remain key segment

Biologics such as insulin, vaccines and various blood products have been available for many years. However, the more recent introduction of recombinant DNA technology has allowed manufacturers to develop a wide range of new products with very specific applications. For example, monoclonal antibodies that destroy targeted antigens -- such as cancer cells -- can now be purified, cloned and introduced into patients to instigate immune responses. Of more than 40 brand-named monoclonal antibodies currently available in the US, 26 have received FDA approval since 2000, and 15 of the 26 since 2005. These products have quickly established



themselves as effective therapies for many forms of cancer, macular degeneration, rheumatoid arthritis and other diseases. New antibodies are under intensive investigation, and are expected to be introduced to market during the forecast period.

## US approval of biosimilars to spur new biologics

A growing global market for biosimilars (also known as follow-on biologics) is gaining momentum in response to the expiration of patents for a number of key biologics and consumer demand to reduce treatment costs. Europe has led the global regulatory process to make biosimilars available but to date US

approvals have lagged behind those in the international community. The FDA has allowed only a few biosimilars for sale in the US, generally following procedures for small molecule generics. However, the FDA has announced plans to release new regulatory guidelines by the end of 2011 that will clarify the approval process for follow-on biologics. Once biosimilars can be approved for US sale, they are expected to make lower-cost biologic treatments more widely available, presenting a challenge to some longstanding proprietary products. The push for approval of biosimilars is also expected to spur the creation of new biologic products and applications.

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## Sample Text, Table & Chart

### PRODUCTS

#### Erythropoietins

Demand for erythropoietins (EPOs) is expected to decline from 2015 to 2020. The introduction of NESP, erythropoietin with a longer half-life and more frequent dosing, is expected to reduce demand. EPO has also been used with increasing frequency in cancer patients.

**SAMPLE TEXT**

EPOs are also used as hemopoietin, regulating the production of red blood cells. Common functions of EPO include stimulating brain response to neuronal injury and wound healing. EPO is available through recombinant DNA technology and is used to stimulate the development of red blood cells in patients with anemia associated with kidney disease, HIV or cancer treatments (chemotherapy or radiation). Exogenous EPO has also been used as a performance-enhancing drug, or doping agent. It can often be detected in blood and urine tests because it is slightly different from the endogenous protein. Darbepoetin alfa was found in athletes in 2002 at the Winter Olympic Games, and has been associated with the Tour de France. An alternative to doping with EPO is athletic training at high altitudes, which also increases the number of red cells in the blood.

Erythropoietin has been associated in several studies with increased risk of death and tumor growth in cancer patients receiving it for chemotherapy-related anemia. In a separate randomized trial, erythropoietin was shown not to have changed the number of blood transfusions required for critically ill patients -- a finding that surprised researchers. In 2008, the FDA supported keeping exogenous erythropoietin and Johnson & Johnson available for continued use by cancer patients. However, EPO has experienced declining demand since 2000 in response to these findings. Also challenging demand for EPO is the development of NESP, a glycoprotein with anti-anemic characteristics and a longer half-life than erythropoietin. NESP is now used with

72

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**TABLE III-4**  
**HORMONES DEMAND**  
 (million dollars)

| Item                          | 2000 | 2005 | 2010 | 2015 | 2020 |
|-------------------------------|------|------|------|------|------|
| Resident Population (million) | 280  | 290  | 300  | 310  | 320  |
| \$ hormones/capita            |      |      |      |      |      |
| Hormones Demand               |      |      |      |      |      |
| Insulin                       |      |      |      |      |      |
| Human Growth Hormone          |      |      |      |      |      |
| Teriparatide                  |      |      |      |      |      |
| Follicle Stimulating Hormone  |      |      |      |      |      |
| Estrogen                      |      |      |      |      |      |
| Calcitonin                    |      |      |      |      |      |
| Thyrotropin                   |      |      |      |      |      |
| Corticotropin                 |      |      |      |      |      |
| Other Hormones                |      |      |      |      |      |
| % hormones                    |      |      |      |      |      |
| Total Biologics Demand        | 200  | 210  | 220  | 230  | 240  |

**SAMPLE TABLE**

**CHART V-1**

**US BIOLOGICALS MARKET SHARE**  
 (\$74.3 billion, 2010)



**SAMPLE CHART**

## Sample Profile, Table & Forecast

**TABLE IV-3**  
**CANCER BIOLOGICS DEMAND**  
(million dollars)

| Item                              | 2000 | 2005 | 2010 | 2015 | 2020 |
|-----------------------------------|------|------|------|------|------|
| Resident Population (million)     |      |      |      |      |      |
| \$ cancer biologics/capita        |      |      |      |      |      |
| Cancer Biologics Demand           |      |      |      |      |      |
| Monoclonal Antibodies             |      |      |      |      |      |
| Growth Factors                    |      |      |      |      |      |
| Blood & Blood Products            |      |      |      |      |      |
| Immunomodulators                  |      |      |      |      |      |
| Vaccines & Toxoids                |      |      |      |      |      |
| Other                             |      |      |      |      |      |
| % cancer                          |      |      |      |      |      |
| Human Healthcare Biologics Demand |      |      |      |      |      |

**SAMPLE  
TABLE**

### COMPANY PROFILES

#### Biogen Idec Incorporated

133 Boston Post Road  
 Weston, MA 02493  
 781-464-2000  
<http://www.biogenidec.com>

Revenues: \$ (2010)  
 US Revenues: \$ (2010)  
 Research and Development: \$ (2010)  
 Employment: (2010)

**SAMPLE  
PROFILE**

Key Products: Immunomodulators

Biogen Idec is a global pharmaceutical company for human oncology, neurology and immunology. It manufactures markets and licenses various products used to treat non-Hodgkin's lymphoma, rheumatoid arthritis, Crohn's disease, multiple sclerosis and psoriasis.

The Company participates in the US biologics industry through the production of monoclonal antibodies and immunomodulators. Biogen Idec's primary monoclonal antibody offering is TYSABRI, which is used for the treatment of Crohn's disease and relapsing forms of multiple sclerosis. TYSABRI, which is made at Biogen Idec's Research Triangle Park, North Carolina facility, is being developed and co-marketed through an agreement between the Company and Elan Corporation plc (Ireland). In 2010, the Company's US revenues from TYSABRI accounted for \$253 million. The Company is also conducting research and development activities related to daclizumab, a monoclonal antibody targeted at relapsing forms of multiple sclerosis. In May 2010, the Company commenced a Phase 3 study of daclizumab. Biogen Idec is developing and commercializing this product through an agreement with Abbott Laboratories (Abbott Park, Illinois). In January

"Demand for cancer-related vaccines is forecast to grow 30 percent per year to exceed \$2 billion in 2015. Vaccines, once the purview of prevention against infectious disease, are now under investigation for their use in preventing and treating several forms of cancer. Demand for cancer vaccines is expected to grow rapidly over the forecast period as these products are approved and develop their place in various market niches."

--Section IV, pg. 117

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**OTHER STUDIES**

**World Nutraceutical Ingredients**

This study analyzes the world nutraceutical ingredient industry. It presents historical demand data for the years 2000, 2005 and 2010, and forecasts for 2015 and 2020 by product (e.g., nutrients and minerals, vitamins, herbal and non-herbal extracts), world region and major country. The study also considers market environment factors, details industry structure, evaluates company market share and profiles industry players.

#2799 ..... November 2011 ..... \$4900

**Cosmeceuticals**

US demand for cosmeceutical products is expected to increase 5.8 percent annually through 2015. Injectables and skin care products will see the fastest growth, based on anti-aging benefits. Among chemicals, antioxidants will remain the largest category, while botanicals continue to see the fastest gains.

This study analyzes the \$6.5 billion US cosmeceuticals industry, with forecasts for 2015 and 2020 by product and chemical. The study also evaluates company market share and profiles industry competitors.

#2758 ..... July 2011 ..... \$4900

**Excipients**

US excipients demand will advance 3.9 percent yearly through 2015, driven by continued growth in US pharmaceutical production and the increasing importance of excipients in drug formulation. Polymers will remain the top-selling type based on their use as fillers and binders in tablets. Fillers and diluents will remain the leading application and grow the fastest. This study analyzes the \$1.5 billion US excipients industry, with forecasts for 2015 and 2020 by product and application. The study also evaluates company market share and profiles industry players.

#2736 ..... May 2011 ..... \$4800

**World In Vitro Diagnostic Products**

Global demand for *in vitro* diagnostic (IVD) products will increase 7.1 percent annually through 2015. The US, Western Europe and Japan will remain the dominant markets, while developing world demand grows the fastest. Molecular diagnostics, cellular analysis and pathology products will be the fastest growing technologies. This study analyzes the \$43.8 billion world IVD product industry, with forecasts for 2015 and 2020 by product, application, world region and for 14 countries. The study also evaluates company market share and profiles 25 industry participants.

#2724 ..... March 2011 ..... \$6100

**Vaccines**

US demand for vaccines will advance 5.6 percent annually through 2014, driven by the development of new vaccines to treat complex human diseases, such as cancer. Public health recommendations for adult and adolescent immunization will produce continued strong sales in this segment, which has reached the level of pediatric vaccines sales. This study analyzes the \$10.8 billion US vaccines industry, with forecasts for 2014 and 2019 by product. It also evaluates company market share and profiles US industry competitors.

#2667 ..... August 2010 ..... \$4700

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