

What's fueling the biotech engine—2012 to 2013

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Biologics sales grew at an incredible rate during the past 18 months, especially when compared with pharmaceuticals. But with pressure on pricing and biosimilars looming, how long will it be until biologics' last hurrah?

In 2012, the US biotech sector grew at a high double-digit rate, driven by rapid uptake of several recently launched monoclonal antibodies (mAbs) and diabetes products. Total sales of biologics in the United States during that period reached ~\$63.6 billion, an 18.2% increase over 2011 sales (Fig. 1). This is more than sevenfold higher than sales in the pharmaceutical sector overall, which experienced growth of only 2.5% in 2012 (<http://www.imshealth.com/portal/site/ims>). The outlook for continued growth in 2013–2014 looks rosy as new product launches and the expansion of indications of existing products are likely to continue to drive sales of the biotech sector.

In the long term, biosimilars and reimbursement issues could push down sales. Even so, the machinations of innovators and manufacturers of brand products to introduce layers of biosimilars legislation at the state level could delay the threat from biosimilars¹. Additionally, although some payers have shifted biologics to higher co-pay tiers, the seriousness of the diseases targeted by biologic drugs makes it harder for payers not to cover these drugs.

Here I analyze the market trends observed in 2012 and the first three-quarters of 2013 for nine classes of biologics. For each of these classes, I provide a discussion on sales volume, pricing, indication expansions, competition within biologics and from small-molecule drugs, safety issues and promising new candidates. On the basis of the sales trends, I have categorized products within each respective therapeutic class as market leaders (where sales are greatest for an indication), rising stars

(where sales show rapid growth) or laggards (where sales underperformed). The methodology applied in this article is essentially the same as that used in previous biotech market overviews published in this journal^{2–7}. Blockbuster products are defined as those with US sales of at least one billion dollars. The following sections cover each of the nine classes of biologics in descending order of accrued sales.

mAbs

In 2012, mAbs maintained their ranking as the highest selling class of biologics, with their US sales reaching ~\$24.6 billion, an 18.3% growth over their 2011 sales, vaulting Roche, with 11 monoclonals in the market, into the top spot among companies with biologic products (Figs. 2 and 3). 2012's growth rate was nearly twice the rate during 2009–2011 (on average 11%). The growth of the mAbs sector was driven by high growth in sales of both mAbs for oncology and anti-inflammatory disorders (Fig. 4). Approximately half of the growth in 2012 sales was due to ~70% increase in sales of recently launched mAbs, such as the arthritis drugs from Roche (Basel)—anti-IL-2 humanized IgG1k mAb Actemra (tocilizumab)—and from Janssen (Horsham, PA, USA)—anti-IL12/23 human IgG1k mAb Stelara (ustekinumab). Other mAbs

include Amgen's (Thousand Oaks, CA, USA) anti-RANK ligand human IgG2k mAb Xgeva (denosumab), approved in 2012 for bone cancer (the same molecule was approved in 2010 for skeletal events associated with bone metastases, and for osteoporosis, under the brand name Prolia); and Bristol-Myers Squibb's (BMS, New York) cytotoxic T lymphocyte-associated protein 4 (CTLA-4)—targeting human IgG1k mAb Yervoy (ipilimumab).

Five new mAbs were approved in 2012–2013: GlaxoSmithKline's (GSK; London) human IgG1k mAb against *Bacillus anthracis* toxins, Abthrax (raxibacumab); Roche's anti-CD20 humanized IgG1k mAb for chronic lymphocytic leukemia, Gazyva (obinutuzumab), as well as its human epidermal growth factor receptor 2 protein (HER2) dimerization inhibitor, humanized IgG1k mAb Perjeta (pertuzumab), and Herceptin-DM1 maytansinoid drug conjugate, Kadcyca (ado-trastuzumab emtansine), both for breast cancer; and Navidea's (Dublin, OH, USA) Lymphoseek (technetium Tc 99m tilmanocept), a lymph node imaging agent. With these new products, there are now 40 US Food and Drug Administration (FDA)-approved mAbs, and sales of these drugs constitute ~38.5% of the total biologics market.

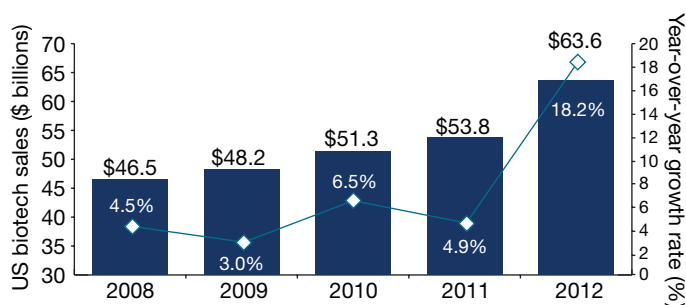


Figure 1 Growth trends in the US biotech market for biologic drugs (2008–2012).

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