## *Pipelines are Shifting to*

# Biotech Drugs

**TRENDING NOW:** Large molecules currently represent a dominant share of sales.


Kenneth Kaitin

The pharmaceutical industry, especially big pharma, has dramatically shifted its R&D focus from its historical concentration on small molecule drugs to include a rapidly increasing number of biotechnology products, according to a newly completed analysis from the Tufts Center for the Study of Drug Development. Biotech products, which accounted for only 7% of revenue generated by the 10 top selling pharmaceutical-biotech products worldwide in 2001, accounted for 71% of the 10 top selling products in 2012.

The transformation of big pharma has been driven as much by new technologies that have enabled development of new products that improve disease outcomes and command high prices as by the expiring patents on many top-selling small molecule drugs, according to Tufts CSDD Director Kenneth Kaitin.

Helping to drive that evolution has been the development of novel technology platforms over the last three decades, which have spurred an extensive pipeline of products across a wide range of therapeutic areas, he says. In 1989, for example, only 13 biotechnology products were commercially available. By 2012, that number had grown to 210.

"The notion that large pharmaceutical companies primarily develop small molecule drugs no longer holds," Mr. Kaitin says.

The analysis also found that:

- The number of biotech products in clinical trials grew 155% in 11 years, from 355 in 2001 to 907 in 2012, with big pharma in 2012 engaged in about 40% of all biotech products in clinical development.
- Financing of biotech research increased nearly 10-fold in a decade, from $10.5 billion in 2001 to $103 billion in 2012.
- Worldwide growth in biotechnology product sales grew 353% between 2001 and 2012, from $36 billion to $163 billion.

*For more information, visit csdd.tufts.edu.*

(Editor's Note: See this month's C-Suite to learn what biotechnology company leaders view as innovation drivers.)

## *Market for Predictive*
## PERSONALIZED DRUGS TO DOUBLE

The U.S. market for predictive personalized drugs is forecasted to double, increasing from $9.2 billion in 2013 to $18.2 billion in 2019, according to Decision Resources. The rapid growth reflects a strong pipeline of promising personalized medicines.

Oncology therapies will continue to dominate the predictive personalized medicine market, capturing 88% of U.S. sales in 2019. In addition, predictive personalized drugs to treat cancer indications are forecast to account for more than a third of total U.S. oncology sales in 2019.

"There's booming interest in personalized medicine and the development of pharmaceutical products that depend on the results of a pretreatment diagnostic or assay to determine use, most notably in oncology treatment," says Decision Resources Group Senior VP Kate Hohenberg.

*For more information, visit decisionresources.com.*

## *Biosimilars Market*
## TO RISE

The biosimilars market is expected to be worth $1.95 billion by 2018, according to MarketsandMarkets. The recombinant glycosylated proteins segment is the largest segment and accounts for a share of 40% of the global biosimilars market in 2013 at an estimated $314.2 million and is expected to grow at a CAGR of 17.5% from 2013 to 2018. The biggest factor behind the growth of this segment is the increasing demand for second-wave biosimilar products, such as insulin and interferon, for the treatment of diabetes and infectious disorders. Of all segments under the product category, the monoclonal antibodies segment is the fastest-growing segment at an estimated CAGR of more than 40% from 2013 to 2018.

By application, oncology is the largest and fastest-growing segment and accounts for a share of 25% of the global biosimilars market. This is attributed to the increasing prevalence of oncology along with the rise in aging population and the changing lifestyle.

Europe dominates the global biosimilars market with around a 40% share in 2013. The factors driving the European market are its well-defined regulatory guidelines; presence of various biosimilar drugs such as omnitrope, tevagrastim, and binocrits; numerous pipeline products; and more than 15 biologics going off patent in the coming years. Currently, Germany commands the highest share in the European market due to the presence of a reference pricing system.

The United States, on the other hand, has a very restricted biosimilars market because of the stringent regulatory environment in North America. The Asia-Pacific market is estimated to be the fastest-growing market. Asia-Pacific accounts for an overall share of 29% of the global biosimilars market. This large share of the market is mainly due to the semi-regulatory environment of the region that easily approves similar biologics in the market.

*For more information, visit marketsandmarkets.com.*

## *Healthcare Cloud*
## COMPUTING TO GROW

The cloud computing market in healthcare is estimated to grow at a CAGR of 20.5% from 2012 to 2017, according to a new report from MarketsandMarkets. The global healthcare cloud computing market revenue is expected to increase from $1.8 billion in 2011 to 5.4 billion by 2017.

Private, public, and hybrid clouds are the three deployment models across the healthcare industry. The healthcare industry has been slow to adopt public clouds due to its highly regulated nature, whereas the private and hybrid cloud models have a higher affinity. The healthcare cloud market by service models is further classified into software-as-a-service (SaaS), platform-as-a-service (PaaS), and infrastructure-as-a-service (IaaS).

The market is witnessing a surge in the adoption of technology and cloud computing and is expected to bring about a revolution in the healthcare IT market. Healthcare organizations are expected to deliver more while limiting healthcare costs at the same time. Despite this, a few factors restrain the growth of this market with security and privacy concerns being the primary reasons for slow adoption of this technology.

*For more information, visit marketsandmarkets.com.*

## *Drug Delivery Systems* MARKET TO EXPAND

The global market for advanced drug delivery systems was valued at $176.7 billion in 2012 and is expected to reach nearly $182 billion in 2013. BCC Research projects the market to grow to nearly $212.8 billion by 2018, and register a five-year compound annual growth rate of 3.2% from 2013 to 2018.

This market is driven by biologics and administration of medication through nontraditional routes such as rectal, vaginal, implants or transdermal. Also, some traditional pharmaceuticals are more effective and cause fewer side effects if delivered in forms that allow a continuous or extended release of the drug. These factors, along with new developments in targeted drug delivery, are helping in the treatment of diseases locally with minimal harm to healthy surrounding cells. This is leading to expansion in the advanced drug delivery market.

The development of new drugs necessitates the development of different drug delivery systems, which may be already under patent, and this also forces companies to collaborate. Targeted drug delivery, which includes liposomes, nanoparticles and monoclonal antibodies, was the largest revenue generator for this market during 2011 to 2013.

*For more information, visit bccresearch.com.* PV

## THERAPEUTIC TRAX...

### AUTOIMMUNE

The high cost per-patient per-year of biologics and novel oral therapies for the treatment of rheumatoid arthritis (RA) and psoriasis often results in reimbursement hurdles that limit patients' ability to access these therapies. Among RA patients in the United States who are eligible but do not receive a biologic/novel oral therapy (about 10% of disease-modifying antirheumatic-treated RA patients), more than 35% do not receive treatment because of cost-related issues, and about 20% do not receive treatment because of payer restrictions.

In an attempt to control the increasing costs associated with biologics/novel oral agents, particularly the non-TNF-alpha inhibitors, payers frequently use a wide range of strategies and tactics such as prior authorization, step-therapy requirements, and blocking copay assistance programs for nonpreferred agents.

Source: Decision Resources, Strategic Insights Trends in Reimbursement for Immune Biologics: Strategies for Success

*For more information, visit decisionresources.com.*

### BLOOD DISORDERS

The recombinant hemophilia A market is crowded with many treatment options for patients, including Baxter's Advate and Recombinate, Bayer's Kogenate FS/Helixate NexGen, CSL Behring's Helixate FS and Pfizer's Xyntha/ReFacto. In contrast, Pfizer's BeneFIX has long been the sole recombinant therapy option for hemophilia B patients.

The total recombinant hemophilia market was $5.32 billion in 2012 and is expected to grow to $6.41 billion in 2022 at a compound annual growth rate of 1.89%.

Source: GlobalData, PharmaPoint: Hemophilia A and B - Global Drug Forecast and Market Analysis to 2022

*For more information, visit globaldata.com.*

### CANCER

The global market for uterine cancer treatments and diagnostics was valued at $17.4 billion in 2012 and was expected to reach $17.8 billion by 2013. The market is expected to grow to $21.6 billion in 2018, and register a five-year CAGR of 3.9% from 2013 to 2018.

Source: BCC Research, Therapies and Diagnostics for Uterine Cancer

*For more information, visit bccresearch.com.*

Oncologists in China are embracing Roche's Herceptin as the targeted therapy for treating HER2+ gastric cancer in the first-line setting. The outlook for the use of Herceptin in this patient subpopulation is promising, and oncologists expect that the proportion of HER2+ gastric cancer patients treated with Herceptin could double by 2016.

Source: Decision Resources, Gastric Cancer in China: Physician and Payer Perspectives on Optimizing Market Access for Premium-Priced Treatment

*For more information, visit decisionresources.com.*

Roche/Genentech/Chugai's Avastin will penetrate nearly all segments of the ovarian cancer market through 2022, driving growth of the angiogenesis inhibitor drug class and contributing to annual growth of about 10% of the overall ovarian cancer market. In addition, the launch of three new angiogenesis inhibitors, Amgen's trebananib, Boehringer Ingelheim's nintedanib, and GlaxoSmithKline's Votrient, will contribute to sales within this drug class, which is set to continue to dominate the treatment of ovarian cancer, accounting for 58% of total sales in 2022.

Source: Decision Resources, Pharmacor Ovarian Cancer advisory service

*For more information, visit decisionresources.com.*

The market value for monoclonal antibodies (mAbs) in breast cancer treatment will experience an increase from $4.8 billion in 2012 to $10.9 billion in 2019, demonstrating a CAGR of 12.2%. This double-digit increase will be driven mainly by the uptake of two recent approvals, Perjeta and Kadcyla, along with the rapid year-on-year growth in specialty pharmaceuticals in the U.S., which boasts the largest regional market for breast cancer treatment. Roche is currently the dominant player within this market, with a franchise of drugs (including the blockbuster Herceptin) that target the human epidermal growth factor receptor-2 (HER-2), which is overexpressed in 20% to 25% of breast cancer patients.

Source: GBI Research, Monoclonal Antibodies Market in Breast Cancer to 2019

*For more information, visit gbiresearch.com.*

Because of the growing prevalence of prostate cancer and the launch of new products for the condition, the prostate cancer treatment market will increase from $4.1 billion in 2012 to

$8 billion by 2019, at a CAGR of 10.1%. The overall prevalence of prostate cancer across the eight leading markets (the U.S., UK, France, Germany, Italy, Spain, Japan, and Canada) is expected to increase from 3.3 million in 2012 to 3.9 million by 2019

Source: GBI Research, Prostate Cancer Therapeutics Market to 2019

*For more information, visit gbiresearch.com.*

The acute lymphocytic leukemia therapeutics market will be worth $3.78 million by 2020. This market has experienced stagnant growth in the past few years. The increasing incidence rate of acute lymphocytic leukemia and upcoming innovative therapies are the major factors that further propel the growth of this market. But the high costs of therapies as well as the adverse events associated with therapies are factors that inhibit the growth of the market to a certain extent. The U.S. has the largest market in 2013 with a market share of about 55% to 60% of the ALL market.

Source: MarketsandMarkets, Acute Lymphocytic Leukemia Therapeutics Market (Pipeline Forecast & Market Forecast in G8 Countries) (2010 – 2020)

*For more information, visit marketsandmarkets.com.*

## CARDIOVASCULAR

The global market for cardiovascular disease — comprised of heart failure, myocardial infarction, and acute coronary syndrome — is expected to grow at a moderate rate, from $13.7 billion in 2012 to $18.2 billion by 2019, at a CAGR of 4.1%. Of the eight major markets (the U.S., France, Germany, Italy, Spain, UK, Japan, and Canada), the U.S. will boast the largest value, from $6.1 billion in 2012 to $8.49 billion by 2019, at a higher CAGR of 4.7%. This growth is partially due to the increase of the treatment population, which is forecast to jump from 14 million in 2012 to 16 million by 2019, at a CAGR of 1.6%. New drugs are also expected to have a positive impact upon the CVD market, including LCZ696 and Serelaxin by Novartis, AZD6140 by AstraZeneca and BAY81-8781 by Bayer.

Source: GBI Research, Cardiovascular Diseases Therapeutics in Major Developed Markets to 2019 – Increasing Prevalence and Promising Novel Drugs offset Patent Cliff Threat

*For more information, visit gbiresearch.com.*

## CNS DISORDERS

Newly approved in the EU, Abilify Maintena is set to become the leading injectable schizophrenia treatment within the next three years. The drug is expected to generate annual sales of up to $842 million by 2021 in the U.S., Japan, and five major EU markets. The development of injectable formulations represents one of the final strategies left for companies to drive growth through this mature market. The value of depot formulations will increase from $1.1 billion in 2012 to $1.4 billion by 2021 in the seven major markets. The overall schizophrenia market is expected to decline due to limited novelty in the development pipeline and generic erosion of key marketed brands, with a market worth $4.1 billion by 2021.

Source: Datamonitor Healthcare

*For more information, visit datamonitorhealthcare.com.*

## GASTROINTESTINAL

Opportunity exists in the U.S. for novel agents in Crohn's disease and ulcerative colitis, because of discontinued use of leading anti-TNF agents driven by efficacy failures. While improved efficacy will determine uptake, cost-related issues will drive favorable formulary inclusion of emerging agents. A lack of initial response or waning efficacy over time are the main reasons that patients discontinue treatment with leading anti-TNFs, Janssen's Remicade and AbbVie's Humira in Crohn's disease and ulcerative colitis, according to surveyed gastroenterologists. Furthermore, gastroenterologists estimate that one-fifth of their patients taking these agents express dissatisfaction and are eager to switch to an alternative therapy that can achieve higher rates of clinical remission and maintain clinical remission.

Source: Decision Resources, U.S. Physician & Payer Forum report entitled Promising Pipelines for Crohn's Disease and Ulcerative Colitis: Payer and Prescriber Receptivity as the Market for Premium-Priced Therapies Expands Beyond the TNF-alpha Inhibitors

*For more information, visit decisionresources.com.*

## HIV

Major-market sales of antiretroviral (ARV) drugs for HIV will decrease marginally over the next decade, from an estimated $13.4 billion in 2012 to $13.1 billion in 2022 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. A key driver of sales growth in the HIV market is the increasing uptake of new, premium-priced agents, including integrase inhibitors and integrase inhibitor-based STRs. Of the emerging therapies, the recently launched integrase inhibitor dolutegravir (ViiV's Tivicay) is poised for commercial success during the 2012-2022 forecast period.

Source: Decision Resources, Pharmacor advisory service, Human Immunodeficiency Virus (HIV)

*For more information, visit decisionresources.com.*

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