PharmaPoint

Osteoporosis

Global Drug Forecast and Market Analysis to 2022

GDHC43PIDR / Published January 2013

GlobalData

Osteoporosis: Key Metrics in the Nine Major Pharmaceutical Markets	
2012 Epidemiology	
Osteoporosis Prevalent Population	168.5 million
Osteoporosis Treated Population	13.5 million
Osteopenia Prevalent Population	457.8 million
Osteopenia Treated Population	6.1 million
2012 Market Sales	
US	$2.7bn
5EU	$1.5bn
Japan	$543m
India	$1.2bn
China	$1.2bn
Total	**$6.0bn**
Pipeline Assessment	
Number of drugs in Phase I–II	36
Number of first-in-class drugs (Phase IIb and III)	3
Most Promising Pipeline Drugs	**Peak-Year Sales**
Romosozumab (Amgen) [Molecule	$905.3m
Odanacatib (Merck)	$687.2m
BA-058 (Radius Health)	$719.8m
Key Events (2012–2022)	**Level of Impact**
Medicare subsidies on branded drugs begin at 2.5% for patients in the “donut hole” in 2013	↑↑
Launch of Prolia in Japan in 2013	↑↑↑
Launch of BA-058 in the US in 2015	↑↑↑
Launch of odanacatib in the US in 2015	↑↑↑
Launch of AMG-785 in the US in 2016	↑↑↑
2022 Market Sales	
US	$3.9bn
5EU	$2.2bn
Japan	$623.5m
India	$1.3bn
China	$1.3bn
Total	**$8.0bn**
Source: GlobalData	

Sales for Osteoporosis by Region 2012–2022

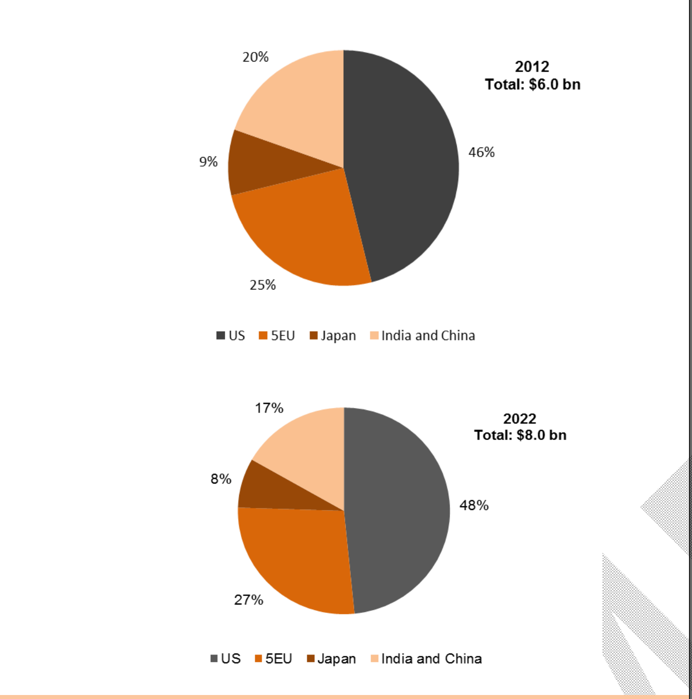
The global market according to this report includes the osteoporosis pharmaceutical markets in the United States, France, Germany, Italy, Spain, United Kingdom, Japan, China, and India. The global osteoporosis pharmaceutical market in the 2012 base year was just over $6 billion US Dollars (USD), including both branded and generic drugs. Over the forecast period, both the United States and the 5EU counties will grow in size. The United States will increase its market share to 47%, stealing market share from the emerging markets and Japan, which will lose 2% and 5% market share, respectively. The 5EU osteoporosis market will also have moderate growth, growing to 27% of the global market. The emerging markets covered in this report will grow moderately, due mainly to new product launches in China, which leads in the number of osteoporosis patients. In fact, the overall market size in India will likely decline by about 0.2% due to compulsory licenses and a government push toward lower-cost generics.

The table below presents the drivers and barriers in the global osteoporosis market during the forecast period.

Osteoporosis Market – Drivers and Barriers, 2012–2022	
Drivers	**Barriers**
The single most important driver of growth in the osteoporosis marketplace will be the transition from antiresorptive agents to anabolic therapies.	The largest barrier to this market is patient compliance. Osteoporosis does not have a strong pain point, and with current efficacy, safety, and dosing, many patients abandon therapies.
Screening and public awareness of osteoporosis will increase the overall diagnosed patient pool and thus the treated patient pool.	A plethora of generic products hitting the market between 2012 and 2015 will make product launches difficult because of increased access to affordable medications.
Source: GlobalData, based on KOL Interviews conducted in September 2012	

The figure below illustrates the global osteoporosis sales for the seven major markets (US, 5EU, and Japan) and India and China during the forecast period.

Sales for Osteoporosis by Region, 2012–2022



Source: GlobalData

Current and Future Players Shift from Antiresorptives to Anabolics

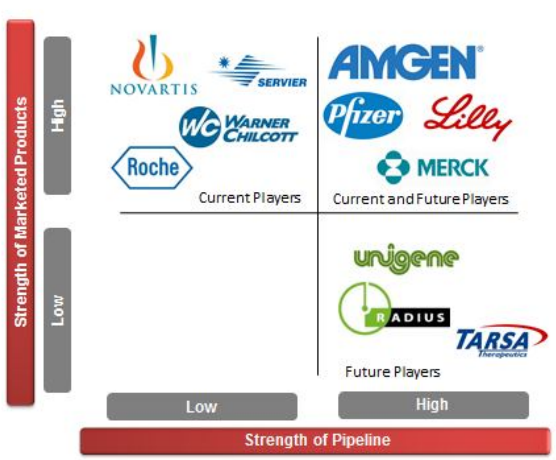
Historic leaders in the osteoporosis space include Eli Lilly, Novartis, Merck, Roche, Warner Chilcott, and most recently, Amgen. All of these companies have had or will have blockbuster drugs in this space. However, three of these major players—Novartis, Roche, and Warner Cilcott—will soon see a drop in patient share with the loss of market exclusivity of their bisphosphonates, Reclast (zoledronic acid), Boniva (ibandronate), and Actonel (risedronate), respectively. Eli Lilly will also be facing the patent expiry of its blockbuster selective estrogen receptor modulator (SERM) Evista (raloxifene) within the next two years.

Future leaders during the forecast period will include Amgen, Eli Lilly, Merck, and Radius Health, which have late-stage pipeline products that will reshape the osteoporosis market once launched. Amgen could surface as the overall market leader with its anti-receptor activator of nuclear factor κB ligand (RANKL) monoclonal antibody (mAb), Prolia (denosumab), and anti-sclerostin mAb, romosozumab. GlobalData believes that Eli Lilly will also maintain its leading position with its parathyroid hormone (PTH) analog, Forteo (teriparatide) and early Phase II pipeline product, blosozumab. However, Lilly will face stiff competition from Amgen's AMG-785 and the up-and-coming Radius Health's BA-058.

The currently marketed products in the osteoporosis space are all antiresorptive therapies. These include bisphosphonates, calcitonin, SERMs, and anti-RANKL antibodies. These classes of drugs have been successful since the mid-1990s, and GlobalData expects them to remain successful over the forecast period. However, there has been a major paradigm shift in development strategies for late- and mid-stage osteoporosis product development. Pharmaceutical companies have shifted their focus to the development of anabolic drugs rather than antiresorptive therapies. Anabolic drugs work against osteoporosis progression in a manner opposite that of the antiresorptives, by stimulating the formation of new bone rather than the retardation of bone resorption.

The figure below provides an analysis of the company portfolio gap in osteoporosis for the forecast period.

Company Portfolio Gap Analysis in Osteoporosis, 2012–2022



Source: GlobalData

Current Therapies Leave Unmet Needs in the Osteoporosis Market

The current osteoporosis therapeutics market comprises several classes of treatment options, but there are still unmet needs within the indication. Drug safety and efficacy remain the most outstanding physician concerns within the treated population, as all of the current drugs come with the potential for serious side effects or are inconvenient to administer. Table lists the prominent unmet needs in the osteoporosis market, along with along with a numerical value to depict the level of attainment of these needs in different markets (1 = low attainment, 5 = high attainment). The table below also ranks the relative importance of each of the unmet needs on a scale of low, moderate, or high.

Overall Unmet Needs – Current Level of Attainment

Unmet Need	Current Level of Attainment	Relative Importance
Disease Awareness and Early Diagnosis	1	High
Patient Compliance	2	High
Efficacy	3	High
Safety	2	High
Treatment Costs	3	Medium
Earlier Intervention	1	Medium

Source: GlobalData, based; Based on primary research interviews with specialists in G7 markets

A handful of late-stage pipeline products are positioned to reduce the level of unmet need in the treatment of osteoporosis. Merck's odanacatib, for example, provides a very selective approach in targeting specific factors responsible for bone deterioration. Amgen and UCB's romosozumab (previously known as AMG-785) likewise has the potential to address the need for treatments with greater efficacy. In Phase II studies, it showed a significant increase in hip, spine and femoral neck bone mineral density (BMD). Romosozumab is an anti-sclerostin mAb, which acts on osteocyte activity, controlling bone resorption (Winkler, 2003). In addition, Radius Health's BA-058, a PTH-related protein, has shown potential in the realm of hormone replacement therapy. In a Phase II clinical trial in which the drug was compared with teriparatide, BA-058 showed a dose-dependent increase in percent BMD after 24 weeks, which was significantly higher than other anabolic treatments (Hattersley, et al., 2012).

Entry Opportunities for Osteoporosis Market Access

Given that efficacy is a leading concern among physicians interviewed for this report, a key opportunity for drug makers looking to enter the osteoporosis space is to create dual-action therapies that both stimulate bone formation and slow bone resorption. Currently, Protelos (strontrium ranelate) claims to have this type of action; however, the drug is not available in the US, and it is disputed whether this dual action actually occurs. Another major opportunity for drug developers is in treatments for the prevention of osteoporosis. Drugs for this indication would be targeted for and would treat individuals with a BMD between 0 and -2, who are considered to have normal-to-osteopenic bone density. Lastly, osteoporosis therapies are plagued by low compliance that is caused, in part, by inconvenient dosing. More therapies with less frequent dosing are needed to increase patient compliance.

Novel Anabolic and Antiresorptive Therapies Will Control the Market by 2022

By the end of the 10-year forecast period, we anticipate that the osteoporosis market will have undergone a fundamental shift in the types of drugs that are preferred by physicians. While the bisphosphonates will undoubtedly maintain a stronghold in the treatment paradigm, their status as the gold standard will be increasingly challenged by the novel anabolic and antiresorptive products entering the market. In terms of patient share trends, we expect that general practioners will be slow to abandon the bisphosphonates, which will become available generically during the first half of the forecast period. However, new market entrants will dominate the market in terms of sales figures.

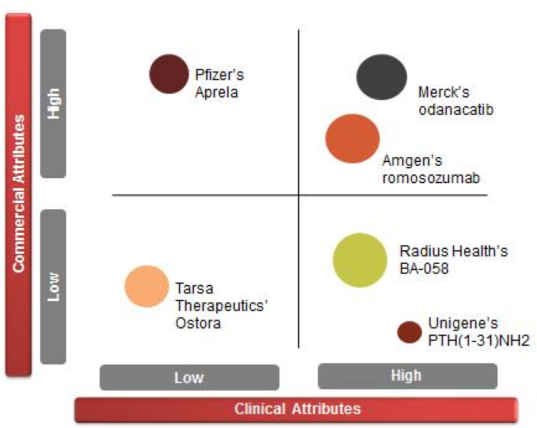
Amgen and UCB's romosozumab is a first-in-class, anti-sclerostin mAb that holds tremendous promise as an efficacious alternative to marketed drugs. Even in the absence of late-stage trial results, key opinion leaders (KOLs) interviewed for this report believe that romosozumab is a promising prospect for the future treatment of osteoporosis. Romosozumab is projected to grow to around $905m in osteoporosis-specific sales over the forecast period, increasing at a Compound Annual Growth Rate (CAGR) of 17% globally.

Merck's odanacatib is a first-in-class, orally-administered inhibitor of cathepsin K, a lysosomal protease that has very strong collagenase activity. Based on clinical trials conducted to date, odanacatib will most likely be positioned as a first-line therapy for the treatment of osteoporosis among postmenopausal women. Odanacatib is projected to grow to around $678m in osteoporosis-specific sales over the forecast period, increasing at a CAGR of 17% globally.

BA-058 is a first-in-class, subcutaneously-administered anabolic human parathyroid hormone-related protein (PTHrP), similar to recombinant PTH therapies, such as Forteo. However, in clinical trials published to date, BA-058 has shown better efficacy than Forteo, without the risk of osteosarcoma. BA-058 is projected to grow to around $720m in osteoporosis-specific sales over the forecast period, increasing at a CAGR of 21% globally.

The figure below provides a competitive assessment of the late-stage pipeline agents in development for osteoporosis for the forecast period.

Competitive Assessment of Late-Stage Pipeline Agents in Osteoporosis, 2012–2022



Source: GlobalData

What Do the Physicians Think?

"[The] [b]iggest need right now is that patients just don't want to take our drugs. And we live in this environment that's just becoming increasingly poisonous as far as patient perception [is concerned]. I think the WHO has done a fairly nice job with the FRAX calculator. Is it perfect? No. You still need clinical judgment, but that's what doctors are doing. We need some way to convey risk as well."

Key opinion leader, September 2012

"We are in dire need of new medications, and more anabolic therapies have just immense potential. If you have a bone anabolic agent that doesn't carry the black box warning of osteosarcoma, that would be a really good thing."

Key opinion leader, September 2012

"The NOG guidelines that are in place in the UK and that are being implemented for harmonization throughout Europe gives you a differing percentage based upon the age of the individual, so that younger people get treated at lower 10-year risk and older people get treated at higher 10-year risk."

Key opinion leader, September 2012

"The parathyroid hormone will only be used, or it should be used, in the population once the patent has expired, and demosumab will have an important part of the market over the next five years, unless [reimbursement] limitations are put in some countries."

Key opinion leader, September 2012

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2 Introduction

2.1 Catalyst

Despite its maturity, the osteoporosis market is expected to undergo substantial change between 2012 and 2022. Most importantly, the “gold-standard” bisphosphonates will lose patent protection by the end of 2013, which will result in flooding of the marketplace with less expensive generic versions of these physician- preferred medications. In addition, Eli Lilly’s blockbuster Evista (raloxifene), the only available selective estrogen receptor modulator (SERM) in the US, will lose patent protection in 2014, which will result in flooding of the market with yet more affordable generic options. Also, during the forecast period covered by this report, osteoporosis drug development research will lead to the launches of a wave of novel anabolic drugs with greater efficacy and safety, causing a major market shift away from antiresorptive drugs. The number of companies vying for patient share will shrink by as much as 50%, as established players exit the market or acquire smaller players. Lastly, the aging of the population in developed markets will result in a larger patient pool.

These changes in the osteoporosis market will be reflected in the slow market growth during the forecast period, increasing from $6 billion to $8 billion in 2012 at a Compound Annual Growth Rate (CAGR) of 3%.

2.2 Related Reports

- GlobalData (2012). PharmaPoint - Rheumatoid Arthritis. Global Drug Forecast and Market Analysis: Event-Driven Update. GDHC25PIDR.
- GlobalData Healthcare Policy Analysis 2012 – Regulatory, Pricing, and Reimbursement, July 2012, GDH001HPM

2.3 Upcoming Related Reports

- GlobalData (2012). PharmaPoint – Breast Cancer. Global Drug Forecast and Market Analysis.
- GlobalData (2012). PharmaPoint – Chronic Heart Failure. Global Drug Forecast and Market Analysis.
- GlobalData (2012). PharmaPoint – Dyslipidemia. Global Drug Forecast and Market Analysis.

11.6 About GlobalData

GlobalData is a leading global provider of business intelligence in the Healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

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