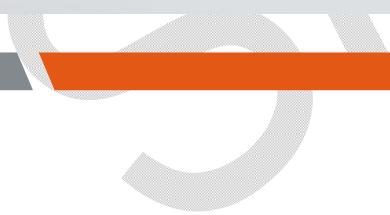




## Osteoporosis

### Global Drug Forecast and Market Analysis to 2022

GDHC43PIDR / Published January 2013



Osteoporosis: Key Metrics in the Nine Major Pharmaceutical Markets	
<b>2012 Epidemiology</b>	
Osteoporosis Prevalent Population	168.5 million
Osteoporosis Treated Population	13.5 million
Osteopenia Prevalent Population	457.8 million
Osteopenia Treated Population	6.1 million
<b>2012 Market Sales</b>	
US	\$2.7bn
5EU	\$1.5bn
Japan	\$543m
India	\$1.2bn
China	\$1.2bn
<b>Total</b>	<b>\$6.0bn</b>
<b>Pipeline Assessment</b>	
Number of drugs in Phase I-II	36
Number of first-in-class drugs (Phase IIb and III)	3
<b>Most Promising Pipeline Drugs</b>	
<b>Peak-Year Sales</b>	
Romosozumab (Amgen) [Molecule	\$905.3m
Odanacatib (Merck)	\$687.2m
BA-058 (Radius Health)	\$719.8m
<b>Key Events (2012–2022)</b>	
<b>Level of Impact</b>	
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	↑↑↑
<b>2022 Market Sales</b>	
US	\$3.9bn
5EU	\$2.2bn
Japan	\$623.5m
India	\$1.3bn
China	\$1.3bn
<b>Total</b>	<b>\$8.0bn</b>

Source: GlobalData

### Sales for Osteoporosis by Region 2012–2022

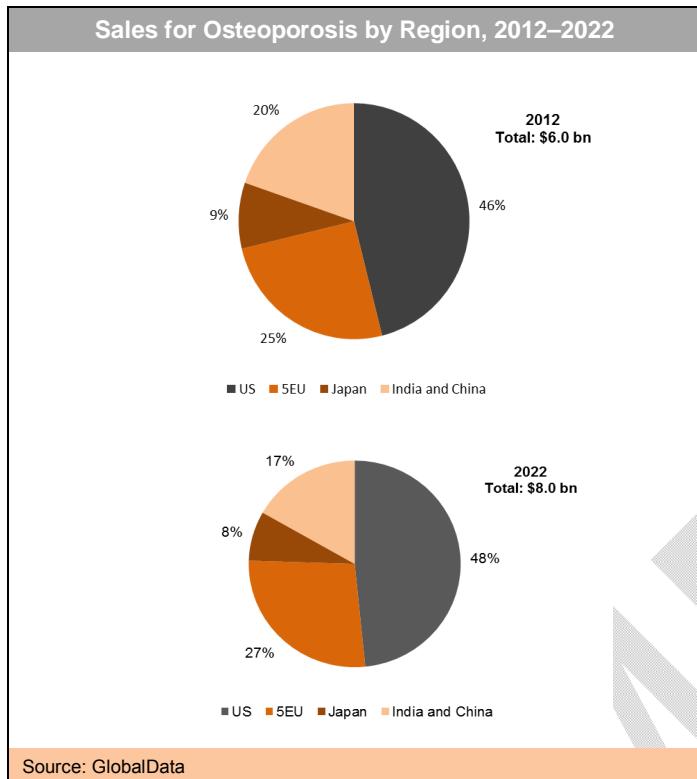
The global market according to this report includes the osteoporosis pharmaceutical markets in the United States, France, Germany, Italy, Spain, United Kingdom, Japan, China, and India. The global osteoporosis pharmaceutical market in the 2012 base year was just over \$6 billion US Dollars (USD), including 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.



### Current and Future Players Shift from Antiresorptives to Anabolics

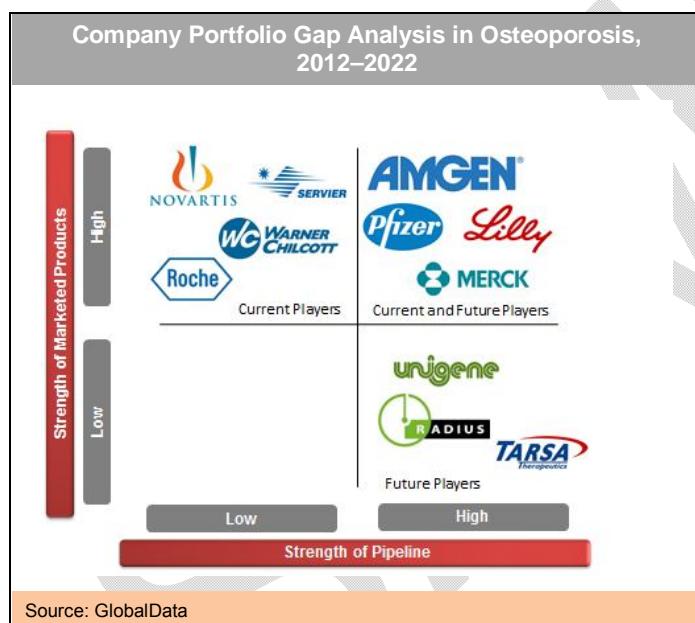
Historic leaders in the osteoporosis space include Eli Lilly, Novartis, Merck, Roche, Warner Chilcott, and most recently, Amgen. All of these companies have had or will have blockbuster drugs in this space. However, three of these major players—Novartis, Roche, and Warner Chilcott—will soon see a drop 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  $\kappa$ B 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.

## Executive Summary

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.



## 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 (strontium 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 practitioners 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.

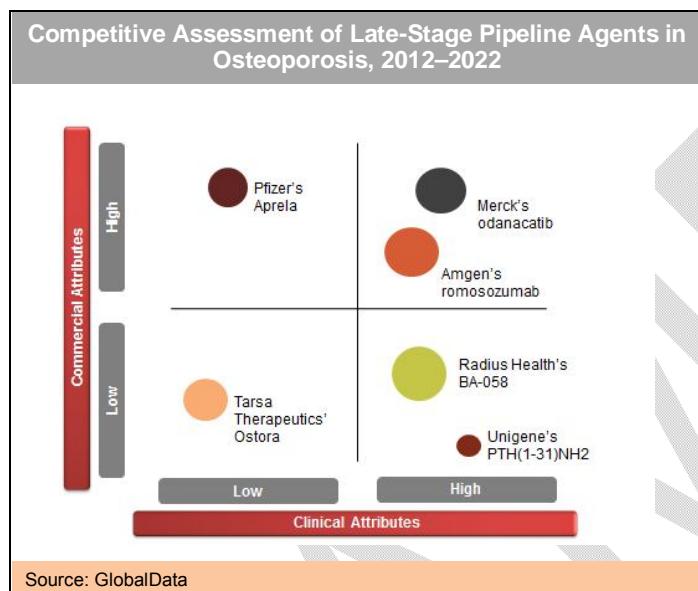
Amgen and UCB's romosozumab is a first-in-class, anti-sclerostin mAb that holds tremendous promise as an efficacious alternative to marketed drugs. Even in the absence of late-stage trial results, key opinion leaders (KOLs) interviewed for this report believe that romosozumab is a promising prospect 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.

## Executive Summary

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.



## 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*

## 1 Table of Contents

1 Table of Contents .....	7
1.1 List of Tables.....	14
1.2 List of Figures .....	18
2 Introduction.....	19
2.1 Catalyst.....	19
2.2 Related Reports .....	19
2.3 Upcoming Related Reports.....	19
3 Disease Overview.....	20
3.1 Etiology and Pathophysiology.....	20
3.1.1 Etiology.....	20
3.1.2 Pathophysiology.....	23
3.1.3 Risk Factors.....	24
3.1.4 Quality of Life.....	24
3.2 Symptoms.....	25
4 Epidemiology.....	26
4.1 Risk Factors and Comorbidities .....	26
4.1.1 Advanced age and female sex are the leading risk factors for osteoporosis .....	26
4.1.2 Low body mass index (BMI) and physical inactivity can lead to significant bone loss.....	26
4.1.3 Previous osteoporotic fracture increases risk of subsequent fracture .....	27
4.1.4 Certain diseases and medications increase the risk of osteoporosis .....	28
4.1.5 Malnutrition and a nutrient-poor diet decrease BMD .....	28
4.1.6 Smoking is an independent risk factor for osteoporosis .....	29
4.1.7 Limited daily alcohol consumption may have a protective effect.....	29
4.2 Global and Historical Trends .....	30
4.2.1 United States .....	30
4.2.2 Five EU Markets .....	31
4.2.3 Asia .....	32

## Table of Contents

4.3 Forecast Methodology .....	34
4.3.1 Sources Used .....	35
4.3.2 Forecast Assumptions and Methods.....	38
4.3.3 Sources Not Used.....	41
4.4 Epidemiology Forecast (2012–2022) .....	42
4.4.1 Total Prevalent Cases of Osteoporosis.....	42
4.4.2 Age-Specific Prevalent Cases of Osteoporosis .....	43
4.4.3 Sex-Specific Total Prevalent Cases of Osteoporosis .....	44
4.5 Discussion.....	46
4.5.1 The Strength of GlobalData's Epidemiologic Projections.....	48
5 Disease Management.....	49
5.1 Treatment Overview .....	49
5.1.1 Diagnosis and Referral.....	49
5.1.2 Treatment Guidelines.....	50
5.1.3 Disease Management .....	51
5.2 United States .....	54
5.2.1 Diagnosis.....	54
5.2.2 Clinical Practice .....	55
5.3 United Kingdom.....	56
5.3.1 Diagnosis.....	56
5.3.2 Clinical Practice .....	57
5.4 France .....	58
5.4.1 Diagnosis.....	58
5.4.2 Clinical Practice .....	58
5.5 Germany .....	59
5.5.1 Diagnosis.....	59
5.5.2 Clinical Practice .....	60
5.6 Spain .....	61

## Table of Contents

5.6.1 Diagnosis.....	61
5.6.2 Clinical Practice .....	61
5.7 Italy .....	62
5.7.1 Diagnosis.....	62
5.7.2 Clinical Practice .....	63
5.8 Japan.....	63
5.8.1 Diagnosis.....	63
5.8.2 Clinical Practice .....	63
5.9 China .....	64
5.9.1 Diagnosis.....	64
5.9.2 Clinical Practice .....	65
5.10 India.....	65
5.10.1 Diagnosis.....	65
5.10.2 Clinical Practice .....	66
6 Competitive Assessment.....	67
6.1 Overview.....	67
6.2 Strategic Competitor Assessment.....	67
6.3 Product Profiles – Major Brands .....	71
6.3.1 Actonel (risedronate sodium).....	71
6.3.2 Evista (raloxifene hydrochloride) .....	75
6.3.3 Reclast (zolendronic acid).....	79
6.3.4 Forteo (teriparatide) .....	83
6.3.5 Prolia (denosumab).....	87
6.3.6 Protelos (strontium ranelate) .....	91
6.3.7 Miacalcin and Fortical (calcitonin-salmon) .....	94
6.3.8 Vivant/Conbriza (bazedoxifene).....	99
6.3.9 Recalbon/Bonoteo (minodronic acid hydrate) .....	103
6.3.10 Alendronate sodium .....	106

## Table of Contents

6.3.11 Ibandronate.....	109
7 Opportunity and Unmet Need.....	111
7.1 Overview.....	111
7.2 Unmet Needs .....	111
7.2.1 Disease Awareness and Early Diagnosis.....	111
7.2.2 Patient Compliance.....	112
7.2.3 Efficacy.....	113
7.2.4 Safety .....	113
7.2.5 Treatment Cost .....	114
7.2.6 Earlier Intervention.....	114
7.3 Unmet Needs Gap Analysis.....	115
7.4 Opportunity 1: Dual-Action Therapies .....	116
7.5 Opportunity 2: Osteoporosis Prevention Therapies .....	117
7.6 Opportunity 3: Dosing and Administration.....	118
8 Pipeline Assessment.....	119
8.1 Overview.....	119
8.2 Clinical Trial Mapping .....	120
8.2.1 Clinical Trials by Country.....	120
8.3 Clinical Trials by Phase and Trial Status .....	120
8.3.1 Overview of Selected Late-Phase Development Programs .....	122
8.4 Promising Drugs in Clinical Development .....	123
8.4.1 Aprela (bazedoxifene and conjugated estrogens) .....	124
8.4.2 Romosozumab (AMG-785).....	131
8.4.3 Odanacatib .....	137
8.4.4 BA-058 .....	143
8.4.5 PTH(1-31)NH <sub>2</sub> .....	148
8.4.6 Ostora (recombinant salmon calcitonin).....	153
9 Current and Future Players.....	158

## Table of Contents

9.1 Overview.....	158
9.2 Trends in Corporate Strategy.....	159
9.3 Company Profiles.....	160
9.3.1 Amgen .....	160
9.3.2 Merck.....	162
9.3.3 Eli Lilly .....	165
9.3.4 Pfizer .....	168
9.3.5 Radius Health .....	170
10 Market Outlook .....	173
10.1 Global Markets.....	173
10.1.1 Forecast.....	173
10.1.2 Drivers and Barriers – Global Issues .....	175
10.2 United States .....	177
10.2.1 Forecast.....	177
10.2.2 Key Events .....	180
10.2.3 Drivers and Barriers .....	180
10.3 France .....	182
10.3.1 Forecast.....	182
10.3.2 Key Events .....	185
10.3.3 Drivers and Barriers .....	185
10.4 Germany .....	187
10.4.1 Forecast.....	187
10.4.2 Key Events .....	190
10.4.3 Drivers and Barriers .....	190
10.5 Italy.....	192
10.5.1 Forecast.....	192
10.5.2 Key Events .....	195
10.5.3 Drivers and Barriers .....	195

## Table of Contents

10.6 Spain .....	197
10.6.1 Forecast.....	197
10.6.2 Key Events .....	200
10.6.3 Drivers and Barriers .....	201
10.7 United Kingdom.....	202
10.7.1 Forecast.....	202
10.7.2 Key Events .....	205
10.7.3 Drivers and Barriers .....	205
10.8 Japan.....	208
10.8.1 Forecast.....	208
10.8.2 Key Events .....	211
10.8.3 Drivers and Barriers .....	211
10.9 India.....	213
10.9.1 Forecast.....	213
10.9.2 Key Events .....	215
10.9.3 Divers and Barriers .....	216
10.10 China.....	217
10.10.1 Forecast .....	217
10.10.2 Key Events .....	219
10.10.3 Drivers and Barriers.....	220
11 Appendix .....	221
11.1 Bibliography .....	221
11.2 Abbreviations .....	237
11.3 Methodology .....	240
11.4 Forecasting Methodology .....	240
11.4.1 Diagnosed Osteoporosis Patients.....	240
11.4.2 Percent Drug-Treated Patients.....	240
11.4.3 Drugs Included in Each Therapeutic Class .....	241

## Table of Contents

11.4.4 Launch and Patent Expiry Dates .....	241
11.4.5 General Pricing Assumptions .....	242
11.4.6 Individual Drug Assumptions .....	242
11.4.7 Generic Erosion .....	246
11.4.8 Pricing of Pipeline Agents .....	246
11.5 Physicians and Specialists Included in this Study .....	247
11.5.1 About the Authors .....	248
11.5.2 Global Head of Healthcare .....	249
11.6 About GlobalData .....	250
11.7 Contact Us .....	250
11.8 Disclaimer .....	250

**SAMPLE**

**1.1 List of Tables**

Table 1: Etiology of Primary Osteoporosis.....	20
Table 2: Etiology of Secondary Osteoporosis .....	22
Table 3: Symptoms of Osteoporosis.....	25
Table 4: Nine Major Markets, Sources of Osteoporosis Prevalence Data.....	34
Table 5: Nine Major Markets, Prevalent Cases of Osteoporosis, N (millions), 2012–2022 .....	42
Table 6: Nine Major Markets, Prevalent Cases of Osteoporosis, By Age, N (millions), %, 2012 .....	43
Table 7: Diagnostic Tests for Osteoporosis .....	49
Table 8: T-Score Ranges for Determination of BMD.....	50
Table 9: Treatment Guidelines for Osteoporosis.....	51
Table 10: Most Prescribed Drugs for Osteoporosis by Therapeutic Class in the Global Markets, 2012 .....	52
Table 11: Leading Treatments for Osteoporosis, 2012 .....	70
Table 12: Product Profile – Actonel .....	72
Table 13: Actonel SWOT Analysis, 2012.....	73
Table 14: Global Sales Forecasts (\$m) for Actonel, 2012–2022 .....	74
Table 15: Product Profile – Evista .....	76
Table 16: Evista SWOT Analysis, 2012 .....	77
Table 17: Global Sales Forecasts (\$m) for Evista, 2012–2022.....	78
Table 18: Product Profile – Reclast .....	80
Table 19: Reclast SWOT Analysis, 2012.....	81
Table 20: Global Sales Forecasts (\$m) for Reclast, 2012–2022.....	82
Table 21: Product Profile – Forteo.....	83
Table 22: Mean Percent Change from Baseline in BMD with Forteo vs. Placebo in Postmenopausal Women with Osteoporosis .....	84
Table 23: Forteo SWOT Analysis, 2012 .....	85
Table 24: Global Sales Forecasts (\$m) for Forteo, 2012–2022 .....	86
Table 25: Product Profile – Prolia .....	87

## Table of Contents

Table 26: Prolia SWOT Analysis, 2012.....	89
Table 27: Global Sales Forecasts (\$m) for Prolia, 2012–2022 .....	90
Table 28: Product Profile – Protelos .....	91
Table 29: Protelos SWOT Analysis, 2012.....	92
Table 30: Global Sales Forecasts (\$m) for Protelos, 2012–2022 .....	94
Table 31: Product Profile – Miacalcin and Fortical Nasal Spray .....	95
Table 32: Adverse Events with Miacalcin Nasal Spray.....	96
Table 33: Miacalcin and Fortical Nasal Spray SWOT Analysis, 2012 .....	97
Table 34: Global Sales Forecast (\$m) for Miacalcin Nasal Spray, 2012–2022 .....	98
Table 35: Global Sales Forecast (\$m) for Fortical Nasal Spray, 2012–2022.....	99
Table 36: Product Profile – Viviant/Conbriza .....	100
Table 37: Viviant/Conbriza SWOT Analysis, 2012 .....	101
Table 38: Global Sales Forecasts (\$m) for Viviant/Conbriza, 2012–2022.....	102
Table 39: Product Profile – Recalbon/Bonoteo .....	103
Table 40: Recalbon/Bonoteo SWOT Analysis, 2012.....	104
Table 41: Global Sales Forecasts (\$m) for Recalbon/Bonoteo, 2012–2022.....	105
Table 42: Global Sales Forecasts (\$m) for alendronate, 2012–2022.....	108
Table 43: Global Sales Forecasts (\$m) for ibandronate, 2012–2022.....	110
Table 44: Overall Unmet Needs – Current Level of Attainment.....	111
Table 45: Clinical Unmet Needs – Gap Analysis, 2012.....	115
Table 46: Osteoporosis – Clinical Trials by Phase and Status, 2012.....	121
Table 47: Osteoporosis – Pipeline, 2012 .....	123
Table 48: Comparison of Therapeutic Classes in Development for Osteoporosis, 2012 .....	123
Table 49: Product Profile – Aprela.....	125
Table 50: Aprela SWOT Analysis, 2012 .....	129
Table 51: Global Sales Forecasts (\$m) for Aprela, 2012–2022 .....	130
Table 52: Product Profile – Romosozumab .....	131
Table 53: Romosozumab SWOT Analysis, 2012 .....	135

## Table of Contents

Table 54: Global Sales Forecasts (\$m) for Romosozumab, 2012–2022.....	136
Table 55: Product Profile – Odanacatib .....	137
Table 56: Odanacatib SWOT Analysis, 2012.....	141
Table 57: Global Sales Forecasts (\$m) for Odanacatib, 2012–2022 .....	142
Table 58: Product Profile – BA-058 .....	143
Table 59: BA-058 SWOT Analysis, 2012.....	146
Table 60: Global Sales Forecasts (\$m) for BA-058, 2012–2022 .....	147
Table 61: Product Profile – PTH(1-31)NH <sub>2</sub> .....	148
Table 62: PTH(1-31)NH <sub>2</sub> SWOT Analysis, 2012 .....	151
Table 63: Global Sales Forecasts (\$m) for PTH(1-31)NH <sub>2</sub> , 2012–2022.....	152
Table 64: Product Profile – Ostora .....	154
Table 65: Ostora SWOT Analysis, 2012.....	156
Table 66: Global Sales Forecasts (\$m) for Ostora, 2012–2022.....	157
Table 67: Key Companies in the Osteoporosis Market, 2012.....	158
Table 68: Amgen's Osteoporosis Therapy Portfolio Assessment, 2012.....	161
Table 69: Amgen SWOT Analysis, 2012 .....	161
Table 70: Merck's Osteoporosis Therapy Portfolio Assessment, 2012 .....	163
Table 71: Merck SWOT Analysis, 2012 .....	164
Table 72: Eli Lilly's Osteoporosis Therapy Portfolio Assessment, 2012.....	166
Table 73: Eli Lilly SWOT Analysis, 2012.....	166
Table 74: Pfizer's Osteoporosis Therapy Portfolio Assessment, 2012.....	168
Table 75: Pfizer SWOT Analysis, 2012.....	169
Table 76: Radius Health's Osteoporosis Therapy Portfolio Assessment, 2012.....	171
Table 77: Radius Health SWOT Analysis, 2012.....	171
Table 78: Global Sales Forecasts (\$) for Osteoporosis, 2012-2022 .....	174
Table 79: Osteoporosis Market – Drivers and Barriers, 2012–2022 .....	175
Table 80: US Sales Forecasts (\$) for Osteoporosis, 2012-2022 .....	178
Table 81: Key Events Impacting Sales for Osteoporosis in the US, 2012–2022 .....	180

## Table of Contents

Table 82: Osteoporosis Market – Drivers and Barriers in the United States, 2012–2022 .....	180
Table 83: France Sales Forecasts (\$) for Osteoporosis, 2012-2022.....	183
Table 84: Key Events Impacting Sales for Osteoporosis in France, 2012–2022 .....	185
Table 85: Osteoporosis Market – Drivers and Barriers in France, 2012–2022 .....	185
Table 86: Germany Sales Forecasts (\$) for Osteoporosis, 2012-2022 .....	188
Table 87: Key Events Impacting Sales for Osteoporosis in Germany, 2012–2022 .....	190
Table 88: Osteoporosis Market – Drivers and Barriers in Germany, 2012–2022 .....	190
Table 89: Italy Sales Forecasts (\$) for Osteoporosis, 2012-2022 .....	193
Table 90: Key Events Impacting Sales for Osteoporosis in Italy, 2012–2022 .....	195
Table 91: Osteoporosis Market – Drivers and Barriers in Italy, 2012–2022 .....	195
Table 92: Spain Sales Forecasts (\$) for Osteoporosis, 2012-2022 .....	198
Table 93: Key Events Impacting Sales for Osteoporosis in the Spain, 2012–2022 .....	200
Table 94: Osteoporosis Market – Drivers and Barriers in Spain, 2012–2022 .....	201
Table 95: UK Sales Forecasts (\$) for Osteoporosis, 2012-2022 .....	203
Table 96: Key Events Impacting Sales for Osteoporosis in the UK, 2012–2022 .....	205
Table 97: Osteoporosis Market – Drivers and Barriers in the United Kingdom, 2012–2022 .....	205
Table 98: Japan Sales Forecasts (\$) for Osteoporosis, 2012-2022 .....	209
Table 99: Key Events Impacting Sales for Osteoporosis in Japan, 2012–2022 .....	211
Table 100: Osteoporosis Market – Drivers and Barriers in Japan, 2012–2022 .....	211
Table 101: India Sales Forecasts (\$) for Osteoporosis, 2012-2022 .....	214
Table 102: Key Events Impacting Sales for Osteoporosis in India, 2012–2022 .....	215
Table 103: Osteoporosis Market – Drivers and Barriers in India, 2012–2022 .....	216
Table 104: China Sales Forecasts (\$) for Osteoporosis, 2012-2022 .....	218
Table 105: Key Events Impacting Sales for Osteoporosis in the China, 2012–2022 .....	219
Table 106: Osteoporosis Market – Drivers and Barriers in China, 2012–2022.....	220
Table 107: Key Launch Dates .....	241
Table 108: Key Patent Expiries .....	241
Table 109: Number of High-Prescribing Physicians Surveyed .....	247

## 1.2 List of Figures

Figure 1: Nine Major Markets, Prevalent Cases of Osteoporosis, By Age, N (millions), 2012 ..44
Figure 2: Nine Major Markets, Prevalent Cases of Osteoporosis, By Sex, N, 2012 .....45
Figure 3: Osteoporosis Therapeutics – Ongoing Clinical Trials by Country, 2012.....120
Figure 4: Osteoporosis Therapeutics – Late-Phase Development Programs of Leading Pipeline Drugs.....122
Figure 5: Company Portfolio Gap Analysis in Osteoporosis, 2012–2022.....124
Figure 6: Company Portfolio Gap Analysis in Osteoporosis, 2012–2022.....159
Figure 7: Global Sales for Osteoporosis by Region, 2012–2022 .....175
Figure 8: Sales for Branded Osteoporosis Drugs in the United States by Drug Class, 2012–2022 ..179
Figure 9: Sales for Branded Osteoporosis Drugs in France by Drug Class, 2012–2022 .....184
Figure 10: Sales for Branded Osteoporosis Drugs in Germany by Drug Class, 2012–2022...189
Figure 11: Sales for Branded Osteoporosis Drugs in Italy by Drug Class, 2012–2022.....194
Figure 12: Sales for Branded Osteoporosis Drugs in Spain by Drug Class, 2012–2022 .....199
Figure 13: Sales for Branded Osteoporosis in the UK by Drug Class, 2012–2022.....204
Figure 14: Sales for Branded Osteoporosis Drugs in Japan by Drug Class, 2012–2022.....210
Figure 15: Sales for Branded Osteoporosis Drugs in India by Drug Class, 2012–2022.....215
Figure 16: Sales for Branded Osteoporosis Drugs in China by Drug Class, 2012–2022 .....219

## 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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