

Antidepressants Market to 2018

Despite Safety Concerns, Selective Serotonin Re-uptake Inhibitors (SSRIs)
Continue to Dominate in the Absence of Effective Therapeutic Alternatives



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- Chapter three provides an overview of the global antidepressants market, including the market size, pricing trends, and treatment usage patterns during the forecast period (2004–2018), as well as the key drivers and restraints.
- Chapter four describes the therapeutic landscape of the global antidepressants market. This section includes detailed market sizing and an analysis of the trends in four major indications for which antidepressants are used in treatment: Major Depressive Disorder (MDD), Obsessive-Compulsive Disorder (OCD), Generalized Anxiety Disorder (GAD) and Panic Disorder (PD).
- Chapter five provides an analysis of the geographical landscape of the antidepressants market in the major global regions: the US, the top five countries in Europe (EU5) — Germany, France, the UK, Italy, and Spain and Japan.
- Chapter six presents a detailed pipeline analysis of the global antidepressants market including the most promising pipeline products.
- Chapter seven presents the competitive landscape, including a detailed analysis of the top companies operating in the antidepressants market. In addition, it includes benchmarking and detailed profiles of significant companies operating in this area.
- Chapter eight the major deals that have taken place in the global antidepressants market in recent years. Coverage includes Mergers and Acquisitions (M&As) and co-development and licensing agreements, whch are segmented on the basis of therapeutic focus, phase, geography, licensing type, and value.
- Chapter nine provides an appendix for the report, which includes key definitions and explanations of abbreviations used, details of the methodology and sources employed, and further useful information on GBI Research and its work.

Executive Summary

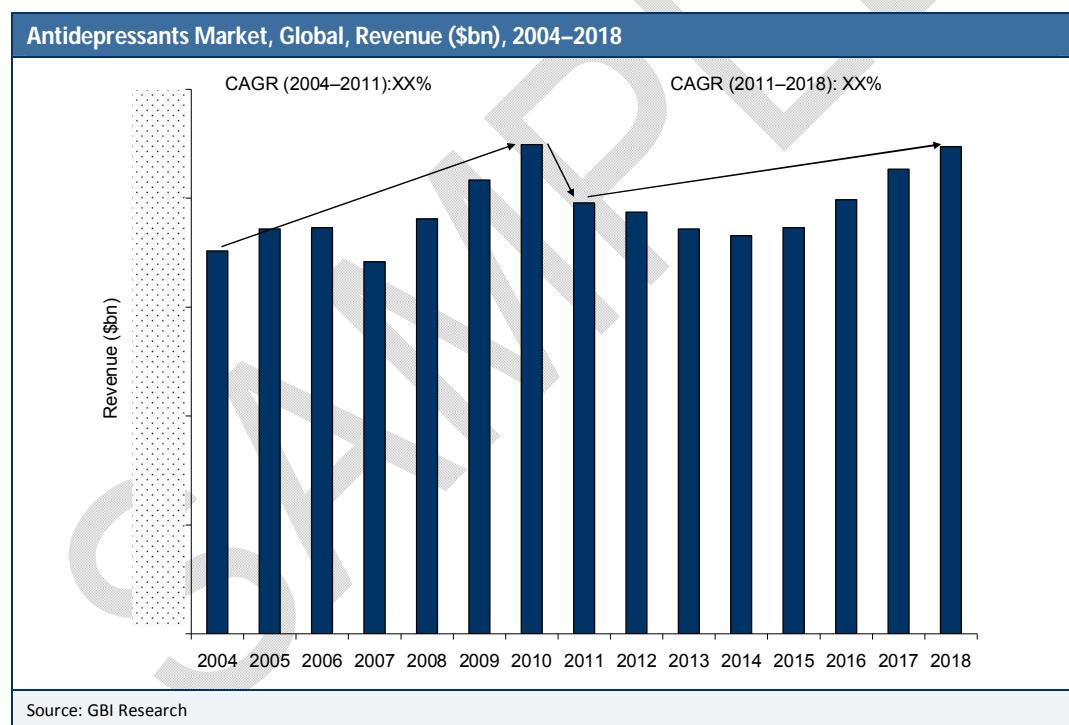
Global Antidepressant Market Witnesses Moderate Growth

Over the forecast period (2011–2018), the antidepressant market revenues will increase, to reach \$XX billion in 2018, at a CAGR of XX%

GBI Research has found that the global antidepressants market is growing moderately, with a high potential for further growth. Despite patent expiries and generic substitution, the market will continue to grow at a moderate rate, as antidepressants are widely used for treating a range of mood disorders that are increasing in prevalence. Antidepressant sales in the global market (US, UK, France, Germany, Spain, Italy and Japan) continue to be driven by leading brands such as Cymbalta (duloxetine), whose patent is set to expire in 2013. Lexapro (escitalopram), one of the therapies that previously drove the market, reached its patent expiration date in March 2012. Other drugs that have the potential to influence the market in the 2011–2018 forecast period include Viibryd (vilazodone), which is manufactured by Clinical Data (CLDA, now owned by Forest Laboratories), and Vortioxetine (Lu AA21004), by Lundbeck and Takeda.

Antidepressants are among the top three most prescribed classes of drugs in the US, along with cholesterol-lowering drugs and painkillers. The global antidepressants market for treating the four conditions covered in this report — Major Depressive Disorder (MDD), Obsessive-Compulsive Disorder (OCD), Panic Disorder (PD), and Generalized Anxiety Disorder (GAD) — was estimated at \$XX billion in 2011, having grown from \$XX billion in 2004 at a Compound Annual Growth Rate (CAGR) of XX%. During the forecast period, antidepressant market revenues will continue to increase at a CAGR of XX% to reach \$XX billion in 2018.

The below figure illustrates the growth of the global antidepressants market from 2004–2011, as compared to the forecast period from 2011–2018.



Although the current state of the overall pipeline and Research and Development (R&D) activity appears to be quite weak, the antidepressants market is still set for growth due to numerous driving factors, such as increased awareness and reduced stigma over mental health issues, increasing prevalence and diagnosis/prescription rates, and the lack of access to other available options. However, the exact nature of these conditions and the antidepressant medications used to treat them are not fully understood by current science, which cannot account comprehensively for either why the conditions may occur or why the medications may work. Without significant breakthroughs in scientific understanding, the potential success of development activity in this therapeutic area is clearly going to be restricted.

1 Table of Contents

1	Table of Contents.....	6
1.1	List of Tables.....	9
1.2	List of Figures.....	11
2	Antidepressants Market to 2018 - Introduction	12
3	Market Overview	13
3.1	Introduction	13
3.2	Classification of Antidepressants.....	14
3.2.1	<i>Selective Serotonin Reuptake Inhibitors</i>	15
3.2.2	<i>Serotonin-Norepinephrine Reuptake Inhibitors</i>	15
3.2.3	<i>Noradrenergic and Specific Serotonergic Antidepressants</i>	15
3.2.4	<i>Norepinephrine Reuptake Inhibitors</i>	16
3.2.5	<i>Norepinephrine-Dopamine Reuptake Inhibitors</i>	16
3.2.6	<i>Norepinephrine-Dopamine Disinhibitors</i>	16
3.2.7	<i>Serotonin Antagonist and Reuptake Inhibitors</i>	16
3.2.8	<i>Tricyclic Antidepressants</i>	16
3.2.9	<i>Tetracyclic Antidepressants</i>	17
3.2.10	<i>Monoamine Oxidase Inhibitors</i>	17
3.2.11	<i>Others</i>	18
3.3	Adverse Effects.....	18
3.4	Major Marketed Products in the Antidepressants Therapy Area.....	18
3.5	Future Developments	20
3.6	Revenue	21
3.7	Annual Cost of Therapy.....	23
3.8	Treatment Usage Patterns	24
3.8.1	<i>Diseased Population</i>	25
3.8.2	<i>Diagnosed Population</i>	25
3.8.3	<i>Prescription Population</i>	25
3.9	Drivers and Restraints of the Antidepressants Market.....	26
3.9.1	<i>Drivers</i>	26
3.9.2	<i>Restraints</i>	27
4	Therapeutic Landscape	28
4.1	Antidepressants Market for Major Depressive Disorder	28
4.1.1	<i>Introduction</i>	28
4.1.2	<i>Revenue and Forecasts</i>	30
4.1.3	<i>Annual Cost of Therapy</i>	31
4.1.4	<i>Treatment Usage Patterns</i>	32
4.1.5	<i>Geographical Segmentation</i>	33
4.2	Drivers and Restraints for the Antidepressants Market for Major Depressive Disorder	35
4.2.1	<i>Drivers</i>	35
4.2.2	<i>Restraints</i>	35
4.3	Antidepressants Market for Obsessive-Compulsive Disorder	37
4.3.1	<i>Introduction</i>	37
4.3.2	<i>Revenue and Forecasts</i>	39
4.3.3	<i>Annual Cost of Therapy</i>	40
4.3.4	<i>Treatment Usage Patterns</i>	41
4.3.5	<i>Geographical Segmentation</i>	42
4.4	Drivers and Restraints for the Antidepressants Market for Obsessive-Compulsive Disorder	44
4.4.1	<i>Drivers</i>	44
4.4.2	<i>Restraints</i>	44
4.5	Antidepressants Market for Generalized Anxiety Disorder	45

4.5.1	<i>Introduction</i>	45
4.5.2	<i>Revenue and Forecasts</i>	46
4.5.3	<i>Annual Cost of Therapy</i>	48
4.5.4	<i>Treatment Usage Patterns</i>	49
4.5.5	<i>Geographical Segmentation</i>	51
4.6	Drivers and Restraints for the Antidepressants Market for Generalized Anxiety Disorder.....	53
4.6.1	<i>Drivers</i>	53
4.6.2	<i>Restraints</i>	54
4.7	Antidepressants Market for Panic Disorder.....	54
4.7.1	<i>Introduction</i>	54
4.7.2	<i>Revenue and Forecasts</i>	57
4.7.3	<i>Annual Cost of Therapy</i>	58
4.7.4	<i>Treatment Usage Patterns</i>	59
4.7.5	<i>Geographical Segmentation</i>	61
4.8	Drivers and Restraints for the Antidepressants Market for Panic Disorder	63
4.8.1	<i>Drivers</i>	63
4.8.2	<i>Restraints</i>	63
5	Geographical Landscape	65
5.1	The US.....	66
5.1.1	<i>Revenue and Forecasts</i>	66
5.1.2	<i>Annual Cost of Therapy</i>	68
5.1.3	<i>Treatment Usage Patterns</i>	69
5.2	EU5	71
5.2.1	<i>Revenue and Forecasts</i>	71
5.2.2	<i>Annual Cost of Therapy</i>	72
5.2.3	<i>Treatment Usage Patterns</i>	73
5.3	Japan.....	74
5.3.1	<i>Revenue and Forecasts</i>	74
5.3.2	<i>Annual Cost of Therapy</i>	75
5.3.3	<i>Treatment Usage Patterns</i>	76
6	Pipeline Analysis	78
6.1	Introduction	78
6.2	Summary of the Current Antidepressants R&D Pipeline	78
6.3	Profiles of Key Late-Stage Drugs in the Antidepressants Market	81
6.3.1	<i>Vortioxetine (Lu AA21004)</i>	81
6.3.2	<i>F-2695 (levomilnacipran)</i>	82
6.3.3	<i>LY-2216684 (edivoxetine)</i>	83
6.3.4	<i>OPC-34712</i>	83
6.3.5	<i>EB-1010/Amitafadine</i>	84
6.3.6	<i>PNB01</i>	85
7	Competitive Landscape	86
7.1	Competitive Profiling	86
7.1.1	<i>H. Lundbeck</i>	86
7.1.2	<i>AstraZeneca</i>	87
7.1.3	<i>Eli Lilly and Company</i>	88
7.1.4	<i>Forest Laboratories</i>	89
7.1.5	<i>Pfizer Inc.</i>	91
7.1.6	<i>GlaxoSmithKline</i>	92
7.1.7	<i>Bristol-Myers Squibb Company</i>	93
8	Strategic Consolidations	95
8.1	Merger and Acquisition Deals.....	95
8.1.1	<i>Paladin Labs Completes Acquisition of Labopharm</i>	95

8.1.2	<i>High River Acquires 6.5% Stake in Forest Laboratories</i>	95
8.1.3	<i>Forest Laboratories Completes Acquisition of Clinical Data</i>	95
8.1.4	<i>Azur Pharma Completes Merger with Jazz Pharmaceuticals in All Stock Transaction</i>	96
8.1.5	<i>Nuvo Research Acquires ZARS Pharma</i>	96
8.1.6	<i>Sun Pharmaceutical Acquires Remaining 24% Stake of Caraco Pharmaceutical</i>	97
8.2	Licensing Agreements	97
8.2.1	<i>Labopharm Enters into Licensing Agreement with Angelini Group for OLEPTRO</i>	97
8.2.2	<i>Omeros Expands Licensing Agreement with Daiichi Sankyo</i>	97
8.2.3	<i>Jazz Pharmaceuticals Enters into Sub-Licensing Agreement with Anchen</i>	97
8.2.4	<i>AstraZeneca Enters into Collaboration and Licensing Agreement with Targacept</i>	98
8.2.5	<i>Indevus Pharmaceuticals Enters into Licensing Agreement with Teva Pharmaceutical</i>	98
8.2.6	<i>Impax Laboratories Enters into Licensing Agreement with Wyeth</i>	98
8.2.7	<i>Mylan Enters into Licensing Agreement with GlaxoSmithKline</i>	98
8.2.8	<i>Tikvah Therapeutics Signs Licensing Agreement with Therapade Technologies</i>	98
8.2.9	<i>GlaxoSmithKline Signs an Agreement with Fabre-Kramer Pharmaceuticals</i>	99
8.2.10	<i>Jazz Pharmaceuticals Enters into Licensing Agreement with Solvay</i>	99
8.2.11	<i>Targacept Enters into Licensing Agreement with Yale University</i>	99
8.3	Co-Development Deals.....	99
8.3.1	<i>Lundbeck Enters into Co-Development Agreement with Otsuka Pharmaceutical</i>	99
8.3.2	<i>Eli Lilly Terminates Co-Development Agreement with Boehringer Ingelheim</i>	100
8.3.3	<i>Lundbeck Enters into Co-Development Agreement with Takeda</i>	100
9	Appendix	101
9.1	Market Definitions.....	101
9.2	Abbreviations	101
9.3	Sources.....	103
9.4	Research Methodology	104
9.4.1	<i>Coverage</i>	104
9.4.2	<i>Secondary Research</i>	104
9.4.3	<i>Primary Research</i>	105
9.5	Therapeutic Landscape	105
9.5.1	<i>Epidemiology-based Forecasting</i>	106
9.5.2	<i>Market Size by Geography</i>	107
9.6	Geographical Landscape	108
9.7	Pipeline Analysis	108
9.8	Competitive Landscape	108
9.8.1	<i>Expert Panel Validation</i>	108
9.9	Contact Us	108
9.10	Disclaimer.....	108

1.1 List of Tables

Table 1:	Global Antidepressants Market, Marketed Products, 2012.....	19
Table 2:	Antidepressants Market, Global, Revenue (\$bn), 2004–2011	21
Table 3:	Antidepressants Market, Global, Revenue Forecast (\$bn), 2011–2018.....	21
Table 4:	Antidepressants Market, Global, Annual Cost of Therapy (\$), 2004–2011	23
Table 5:	Antidepressants Market, Global, Annual Cost of Therapy (\$), 2011–2018	23
Table 6:	Antidepressants Market, Global, Treatment Usage Patterns (millions), 2004–2011.....	24
Table 7:	Antidepressants Market, Global, Treatment Usage Patterns (millions), 2011–2018.....	24
Table 8:	Antidepressants Market, MDD, Global, Revenue (\$bn), 2004–2011.....	30
Table 9:	Antidepressants Market, MDD, Global, Revenue Forecast (\$bn), 2011–2018.....	30
Table 10:	Antidepressants Market, MDD, Global, Annual Cost of Therapy (\$), 2004–2011	31
Table 11:	Antidepressants Market, MDD, Global, Annual Cost of Therapy (\$), 2011–2018	31
Table 12:	Antidepressants Market, MDD, Global, Treatment Usage Patterns (millions), 2004–2011	32
Table 13:	Antidepressants Market, MDD, Global, Treatment Usage Patterns (millions), 2011–2018	32
Table 14:	Antidepressants Market, MDD, Global, Market Segmentation by Geography (\$bn), 2004–2011	34
Table 15:	Antidepressants Market, MDD, Global, Market Segmentation by Geography (\$bn), 2011–2018	34
Table 16:	Common Obsessions and Compulsions in Obsessive-Compulsive Disorder	38
Table 17:	Antidepressants Market, Obsessive-Compulsive Disorder, Global, Revenue (\$bn), 2004–2011..	39
Table 18:	Antidepressants Market, Obsessive-Compulsive Disorder, Global, Revenue Forecast (\$bn), 2011–2018	39
Table 19:	Antidepressants Market, Obsessive-Compulsive Disorder, Global, Annual Cost of Therapy (\$), 2004–2011	40
Table 20:	Antidepressants Market, Obsessive-Compulsive Disorder, Global, Annual Cost of Therapy (\$), 2011–2018	40
Table 21:	Antidepressants Market, Obsessive-Compulsive Disorder, Global, Treatment Usage Patterns (millions), 2004–2011.....	41
Table 22:	Antidepressants Market, Obsessive-Compulsive Disorder, Global, Treatment Usage Patterns (millions), 2011–2018.....	41
Table 23:	Antidepressants Market, Obsessive-Compulsive Disorder, Global, Market Segmentation by Geography (\$m), 2004–2011.....	43
Table 24:	Antidepressants Market, Obsessive-Compulsive Disorder, Global, Market Segmentation by Geography (\$m), 2011–2018	43
Table 25:	Antidepressants Market, Generalized Anxiety Disorder, Global, Revenue (\$bn), 2004–2011	47
Table 26:	Antidepressants Market, Generalized Anxiety Disorder, Global, Revenue Forecast (\$bn), 2011–2018	47
Table 27:	Antidepressants Market, Generalized Anxiety Disorder, Global, Annual Cost of Therapy (\$), 2004–2011	48
Table 28:	Antidepressants Market, Generalized Anxiety Disorder, Global, Annual Cost of Therapy (\$), 2011–2018	48
Table 29:	Antidepressants Market, Generalized Anxiety Disorder, Global, Treatment Usage Patterns (millions), 2004–2011.....	50
Table 30:	Antidepressants Market, Generalized Anxiety Disorder, Global, Treatment Usage Patterns (millions), 2011–2018.....	50
Table 31:	Antidepressants Market, Generalized Anxiety Disorder, Global, Market Segmentation by Geography (\$m), 2004–2011.....	53
Table 32:	Antidepressants Market, Generalized Anxiety Disorder, Global, Market Segmentation by Geography (\$m), 2011–2018	53
Table 33:	Antidepressants Market, Panic Disorder, Global, Revenue (\$m), 2004–2011.....	57
Table 34:	Antidepressants Market, Panic Disorder, Global, Revenue (\$m), 2011–2018.....	57
Table 35:	Antidepressants Market, Panic Disorder, Global, Annual Cost of Therapy (\$), 2004–2011	58
Table 36:	Antidepressants Market, Panic Disorder, Global, Annual Cost of Therapy (\$), 2011–2018	58
Table 37:	Antidepressants Market, Panic Disorder, Global, Treatment Usage Patterns (millions), 2004–2011	59
Table 38:	Antidepressants Market, Panic Disorder, Global, Treatment Usage Patterns (millions), 2011–2018	60
Table 39:	Antidepressants Market, Panic Disorder, Global, Market Segmentation by Geography (\$m), 2004–2011	62

Table 40: Antidepressants Market, Panic Disorder, Global, Market Segmentation by Geography (\$m), 2011–2018	62
Table 41: Antidepressants Market, Global, Revenues by Geography (\$bn), 2004–2011.....	65
Table 42: Antidepressants Market, Global, Revenues by Geography (\$bn), 2011–2018.....	66
Table 43: Antidepressants Market, The US, Revenue (\$bn), 2004–2011.....	67
Table 44: Antidepressants Market, The US, Revenue Forecast (\$bn), 2011–2018.....	67
Table 45: Antidepressants Market, The US, Annual Cost of Therapy (\$), 2004–2011	68
Table 46: Antidepressants Market, The US, Annual Cost of Therapy (\$), 2011–2018	68
Table 47: Antidepressants Market, The US, Treatment Usage Patterns (millions), 2004–2011.....	69
Table 48: Antidepressants Market, The US, Treatment Usage Patterns (millions), 2011–2018.....	69
Table 49: Antidepressants Market, EU5, Revenue (\$bn), 2004–2011	71
Table 50: Antidepressants Market, EU5, Revenue Forecast (\$bn), 2011–2018	71
Table 51: Antidepressants Market, EU5, Annual Cost of Therapy (\$), 2004–2011.....	72
Table 52: Antidepressants Market, EU5, Annual Cost of Therapy (\$), 2011–2018.....	72
Table 53: Antidepressants Market, EU5, Treatment Usage Patterns (millions), 2004–2011	73
Table 54: Antidepressants Market, EU5, Treatment Usage Patterns (millions), 2011–2018	73
Table 55: Antidepressants Market, Japan, Revenue (\$m), 2004–2011	75
Table 56: Antidepressants Market, Japan, Revenue (\$m), 2011–2018	75
Table 57: Antidepressants Market, Japan, Annual Cost of Therapy (\$), 2004–2011	76
Table 58: Antidepressants Market, Japan, Annual Cost of Therapy (\$), 2011–2018	76
Table 59: Antidepressants Market, Japan, Treatment Usage Patterns (millions), 2004–2011	77
Table 60: Antidepressants Market, Japan, Treatment Usage Patterns (millions), 2011–2018.....	77
Table 61: Antidepressants Market, Pipeline, 2012.....	78
Table 62: Lundbeck, Antidepressant Pipeline Products, 2011	86
Table 63: AstraZeneca, Antidepressants Pipeline, 2011.....	88
Table 64: Eli Lilly and Company, Antidepressants Pipeline, 2011.....	89
Table 65: Forest Laboratories, MDD, Pipeline Products, 2011.....	90

1.2 List of Figures

Figure 1: Antidepressants Market, Global, Revenue (\$bn), 2004–2018	21
Figure 2: Antidepressants Market, Global, Annual Cost of Therapy (\$), 2004–2018	23
Figure 3: Antidepressants Market, Global, Therapeutic Usage Patterns (millions), 2004–2018.....	24
Figure 4: Antidepressants Market, MDD, Global, Revenue (\$bn), 2004–2018.....	30
Figure 5: Antidepressants Market, MDD, Global, Annual Cost of Therapy (\$), 2004–2018	31
Figure 6: Antidepressants Market, MDD, Global, Treatment Usage Patterns (millions), 2004–2018	32
Figure 7: Antidepressants Market, MDD, Global, Market Segmentation by Geography (\$bn), 2004–2018	34
Figure 8: Antidepressants Market, Obsessive-Compulsive Disorder, Global, Revenue (\$bn), 2004–2018..	39
Figure 9: Antidepressants Market, Obsessive-Compulsive Disorder, Global, Annual Cost of Therapy (\$), 2004–2018	40
Figure 10: Antidepressants Market, Obsessive-Compulsive Disorder, Global, Treatment Usage Patterns (millions), 2004–2018.....	41
Figure 11: Antidepressants Market, Obsessive-Compulsive Disorder, Global, Market Segmentation by Geography (\$m), 2004–2018.....	43
Figure 12: Antidepressants Market, Generalized Anxiety Disorder, Global, Revenue (\$bn), 2004–2018	47
Figure 13: Antidepressants Market, Generalized Anxiety Disorder, Global, Annual Cost of Therapy (\$), 2004–2018	48
Figure 14: Antidepressants Market, Generalized Anxiety Disorder, Global, Treatment Usage Patterns (millions), 2004–2018.....	50
Figure 15: Antidepressants Market, Generalized Anxiety Disorder, Global, Market Segmentation by Geography (\$m), 2004–2018.....	52
Figure 16: Antidepressants Market, Panic Disorder, Global, Revenue (\$m), 2004–2018.....	57
Figure 17: Antidepressants Market, Panic Disorder, Global, Annual Cost of Therapy (\$), 2004–2018	58
Figure 18: Antidepressants Market, Panic Disorder, Global, Treatment Usage Patterns (millions), 2004–2018	59
Figure 19: Antidepressants Market, Panic Disorder, Global, Market Segmentation by Geography (\$m), 2004–2018	62
Figure 20: Antidepressants Market, Global, Revenues by Geography (\$bn), 2004–2018.....	65
Figure 21: Antidepressants Market, The US, Revenue (\$bn), 2004–2018.....	67
Figure 22: Antidepressants Market, The US, Annual Cost of Therapy (\$), 2004–2018	68
Figure 23: Antidepressants Market, The US, Treatment Usage Patterns (millions), 2004–2018.....	69
Figure 24: Antidepressants Market, EU5, Revenue (\$bn), 2004–2018	71
Figure 25: Antidepressants Market, EU5, Annual Cost of Therapy (\$), 2004–2018	72
Figure 26: Antidepressants Market, EU5, Treatment Usage Patterns (millions), 2004–2018	73
Figure 27: Antidepressants Market, Japan, Revenue (\$m), 2004–2018	74
Figure 28: Antidepressants Market, Japan, Annual Cost of Therapy (\$), 2004–2018	75
Figure 29: Antidepressants Market, Japan, Treatment Usage Patterns (millions), 2004–2018.....	76
Figure 30: Antidepressants Market, SWOT Analysis, Lundbeck, 2011.....	87
Figure 31: Antidepressants Market, SWOT Analysis, AstraZeneca, 2011.....	88
Figure 32: Antidepressants Market, SWOT Analysis, Eli Lilly and Company, 2011	89
Figure 33: Antidepressants Market, SWOT Analysis, Forest Laboratories, 2011.....	90
Figure 34: Antidepressants Market, SWOT Analysis, Pfizer Inc., 2011.....	92
Figure 35: Antidepressants Market, SWOT Analysis, GlaxoSmithKline, 2011.....	93
Figure 36: Antidepressants Market, SWOT Analysis, Bristol-Myers Squibb, 2011.....	94
Figure 37: GBI Research Market Forecasting Model	107

MDD market, with sales of \$XX billion in 2011, accounted for the majority of antidepressants market, with a share of XX%

2 Antidepressants Market to 2018 - Introduction

The global antidepressants market has a huge potential for growth due to the large population affected by depression and Anxiety Disorders (ADs). The market is growing at a moderate growth rate, driven in particular by the Major Depressive Disorder (MDD) and AD markets.

In 2011, the global antidepressants market for the four indications covered in this report – MDD, Obsessive-Compulsive Disorder (OCD), Generalized Anxiety Disorder (GAD), and Panic Disorder (PD) – was estimated at \$XX billion, representing a Compounded Annual Growth Rate (CAGR) of XX% between 2004 and 2011. The MDD market, with sales of \$XX billion in 2011, accounted for the vast majority of the total antidepressants market, with a share of XX%. The PD market, with sales of just over \$XX billion, was the second largest market segment, with an XX% share. The remaining markets such as the OCD market had sales of \$XX billion, accounting for XX% share of the market and the GAD market had sales of \$XX billion, with a XX% market share.

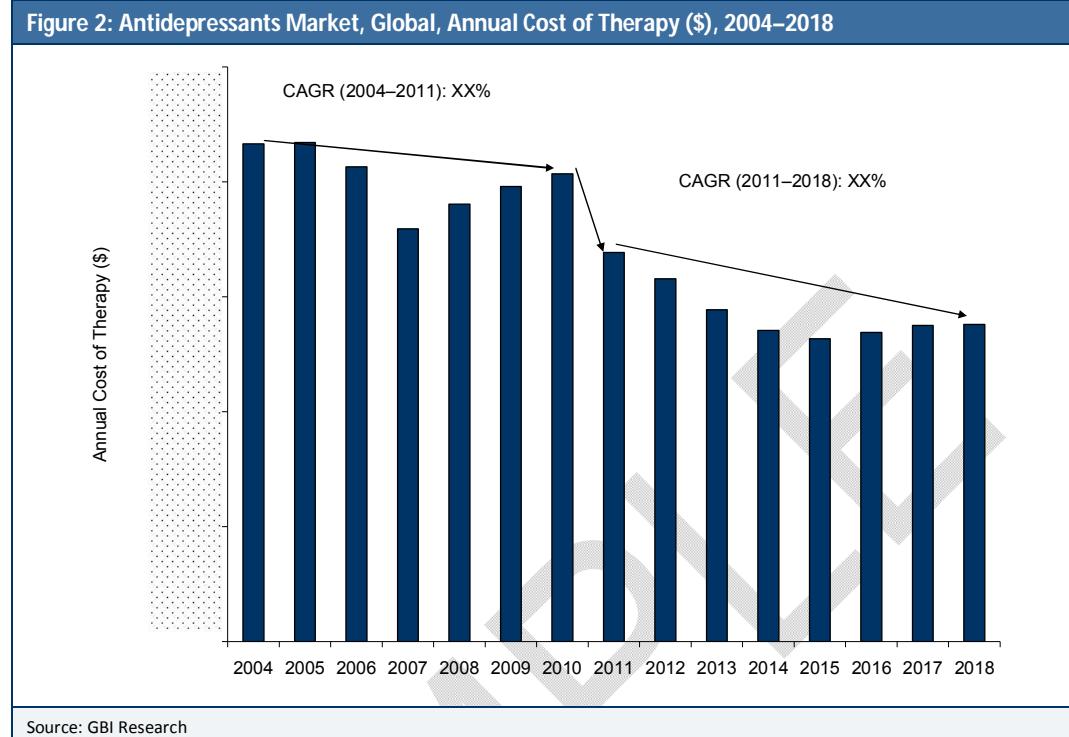
According to the National Center for Health Statistics of the Centers for Disease Control and Prevention (CDC), antidepressants were the second most commonly prescribed class of drugs in the US in 2009. Global antidepressant sales continue to be driven by the leading brands, such as Cymbalta (duloxetine) whose patents are set to expire in 2013. By 2018, the global antidepressants market is forecast to generate sales of \$XX billion, representing a CAGR of XX% between 2011 and 2018. Other drugs that have the potential to influence the market in the forecast period include Clinical Data's (CLDA) (now owned by Forest Laboratories) Viibryd (vilazodone), which is indicated for MDD, and Lundbeck and Takeda's vortioxetine, which is indicated for MDD and GAD.

The OCD market is expected to grow the fastest among the antidepressant market segments due to the rising incidence and increasing awareness of the condition, with forecast revenue CAGR of XX%. The GAD market is the second highest growth segment in terms of potential revenue at a XX% CAGR, while the PD market suggests a more modest growth of XX%. The MDD market is likely to show a barely significant growth of XX% to 2018, which is largely due to the effects of the patent expiries of major marketed products and the subsequent loss of revenue and reimbursement this entails, along with the lack of superior and innovative replacement products in the pipeline for this mature market.

There is considerable scope for improvement over the current treatment options with regard to the new antidepressants in development. The industry has so far struggled to improve on the current therapeutic options, partly because of the inadequate understanding of disease etiology in this area, and also due to the difficulty of establishing antidepressant efficacy in clinical trials; a notably high placebo effect and the lack of objective assessment criteria are serious drawbacks for scientific study. There are currently around 50 drugs that have recently been launched or are in clinical development; however, few of these therapies are novel or have compelling efficacy data.

3.7 Annual Cost of Therapy

Figure 2 illustrates the Annual Cost of Therapy (ACT) in the global antidepressants market from 2004–2011, as compared to the forecast period from 2011–2018.



In 2011, the average ACT for antidepressants was estimated to be \$XX, indicating a negative CAGR of XX% from 2004, when it was \$XX, as shown in Table 4. The decrease in the cost of therapy between 2004 and 2011 was due to the patent expiry of drugs such as Paxil, Zoloft, and Effexor.

Table 4: Antidepressants Market, Global, Annual Cost of Therapy (\$), 2004–2011

Year	2004	2005	2006	2007	2008	2009	2010	2011	CAGR (%)
Annual Cost of Therapy									

Source: GBI Research

During the forecast period, the average ACT for antidepressants is expected to be significantly influenced by the effect of additional patent expiries and the introduction of lower-priced generics. As shown in Table 5, the average ACT is estimated to decline from \$XX in 2011 to \$XX in 2018, indicating a negative CAGR of XX%.

Table 5: Antidepressants Market, Global, Annual Cost of Therapy (\$), 2011–2018

Year	2011	2012	2013	2014	2015	2016	2017	2018	CAGR (%)
Annual Cost of Therapy									

Source: GBI Research

During the forecast period, the average ACT is expected to continue to decrease to \$XX, reflecting a negative CAGR of XX%. Prices paid for many drugs are, in fact, declining due to the loss of patent protection and the subsequent reduction in costs due to genericization. Also, third-party payers are becoming increasingly reluctant to pay inflated prices for first-line therapies due to the difficulties in the wider economic climate and the increasing incidence and prescription rates for these disorders.

The growth of the MDD market is forecast to be much slower, with a predicted CAGR of XX% between 2011 and 2018

4.1.2 Revenue and Forecasts

Figure 4 illustrates the growth of the global market for antidepressants in treating MDD from 2004–2011, as compared to the forecast period from 2011–2018. The market increased from \$XX billion in 2004 to \$XX billion in 2011 at a CAGR of XX%. This growth pattern occurred mainly during the latter part of this period, as a notable surge in revenues was seen after 2008 due to the launch of products such as Pristiq and Valdoxan.

The growth of the overall market for this indication is expected to slow during the forecast period due to significant patent expiries and the subsequent introduction of lower-priced generics, reaching \$XX billion by 2018. Revenues are predicted to drop in 2013, largely due to the patent expiries of Lexapro in 2012 and Cymbalta in 2013, before recovering slowly from 2014 and returning to a positive growth trajectory due to the launch of new drugs such as Viibryd, Lu AA21004 and levomilnacipran (F2695). These drugs, which offer better efficacy and safety profiles, along with disease-modifying properties, can offset the effects of the patent expiries. The growth during the forecast period will nevertheless be much slower than that previously registered, as the pipeline will struggle to satisfy the demand to fulfill the unmet need, with a predicted CAGR of XX% between 2011 and 2018.

Figure 4: Antidepressants Market, MDD, Global, Revenue (\$bn), 2004–2018

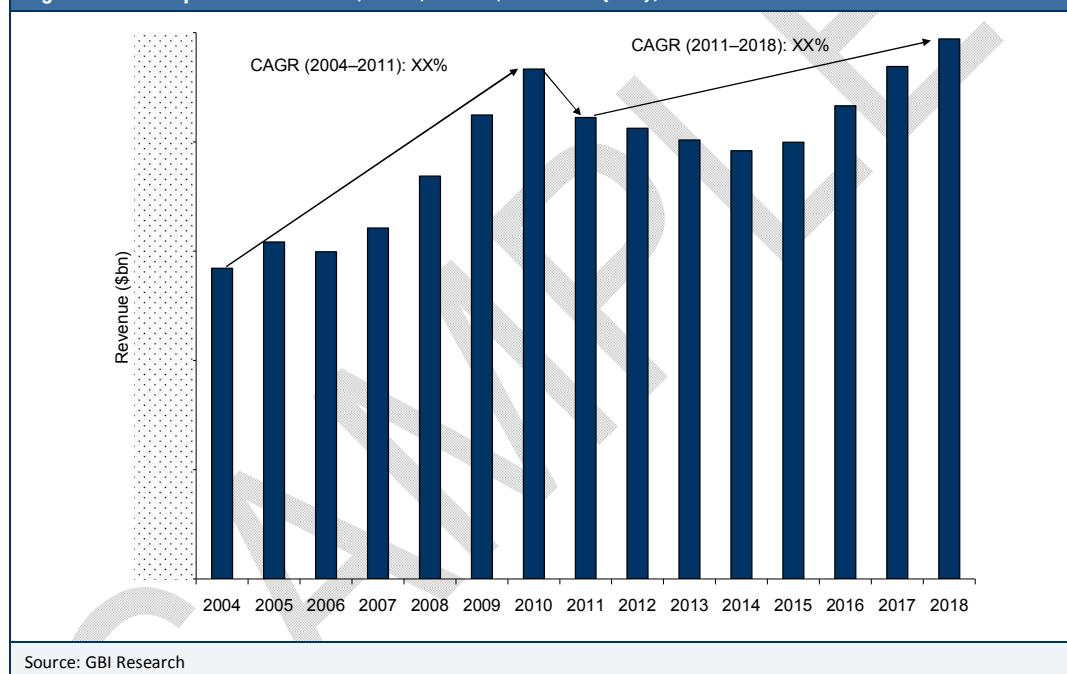


Table 8: Antidepressants Market, MDD, Global, Revenue (\$bn), 2004–2011

Year	2004	2005	2006	2007	2008	2009	2010	2011	CAGR (%)
Revenue	XX								

Source: GBI Research

Table 9: Antidepressants Market, MDD, Global, Revenue Forecast (\$bn), 2011–2018

Year	2011	2012	2013	2014	2015	2016	2017	2018	CAGR (%)
Revenue	XX								

Source: GBI Research

9 Appendix

9.1 Market Definitions

- **The global antidepressants market** includes antidepressant medications used for four indications – Major Depressive Disorder, Obsessive-Compulsive Disorder, Generalized Anxiety Disorder, and Panic Disorder, in the seven major markets – the US, the UK, Germany, France, Spain, Italy and Japan.
- **Prevalence Population:** Prevalence population is the estimated number of people at any given point of time in a year who are affected by the disorder(s).
- **Diagnosis Rate and Population:** Diagnosis rate is the percentage of the treatment seeking population that is diagnosed with the disorder(s); the diagnosis population refers to the number of people that are diagnosed.
- **Prescription Rate and Population:** Prescription rate is the percentage of the diagnosis population that is prescribed antidepressants. The prescription population refers to the number of people that are on antidepressants for the indication(s).

9.2 Abbreviations

5-HT:	Serotonin
ACNP:	American College of Neuropsychopharmacology
ACT:	Annual Cost of Therapy/Treatment
AD:	Anxiety Disorder
ADHD:	Attention Deficit Hyperactivity Disorder
ADT:	Antidepressant Therapy
AIDS:	Acquired Immunodeficiency Syndrome
APA:	American Psychiatric Association
AUC:	Area Under the Curve
BCI:	Brain Cells Inc.
BDI:	Beck Depression Inventory
BD:	Bipolar Disorder
BI:	Boehringer Ingelheim
BMS:	Bristol-Myers Squibb
BPD:	Borderline Personality Disorder
CAGR:	Compounded Annual Growth Rate
CAT:	Cognitive Analytic Therapy
CBT:	Cognitive Behavioral Therapy
CDC:	Centers for Disease Control and Prevention
Cmax:	Maximum Plasma Concentration (of a drug)
CLDA:	Clinical Data
CNS:	Central Nervous System
CR:	Controlled Release
DALYs:	Disability-Adjusted Life Years
DAT:	Dopamine Transporter
DBSA:	Depression and Bipolar Support Alliance

DRI: Dopamine Reuptake Inhibitor
DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision
ECT: Electroconvulsive Therapy
EMA: European Medicines Agency
ER: Extended Release
EUS: Top Five Countries in Europe
FDA: Food and Drug Administration
FIC: First in Class
GABA: Gamma-Aminobutyric Acid
GAD: Generalized Anxiety Disorder
GAD-7: Generalized Anxiety Disorder 7-item scale
GSK: GlaxoSmithKline
HAM-D (or HDRS): Hamilton Depression Rating Scale
HIV: Human Immunodeficiency Virus
IRB: Institutional Review Board
M&A: Mergers and Acquisitions
MADRS: Montgomery-Asberg Depression Rating Scale
MADRS-CR: Montgomery-Asberg Depression Rating Scale-Clinician Rated
MAOI: Monoamine Oxidase Inhibitor
MDD: Major Depressive Disorder
MT1: Melatonin Receptor 1
MMRM: Mixed-Effects Model Repeated Measure
MGH CPFQ: Massachusetts General Hospital Cognitive and Physical Functioning Questionnaire
MRI: Magnetic Resonance Imaging
NaSSAs: Noradrenergic and Specific Serotonergic Antidepressants
NIDA: National Institute on Drug Abuse
NCBI: National Center for Biotechnology Information
NDA: New Drug Application
NDDI: Norepinephrine-Dopamine Disinhibitor
NDRIs: Norepinephrine-Dopamine Reuptake Inhibitor
NET: Norepinephrine Transporter
NHS: National Health Service (UK)
NIMH: National Institute of Mental Health
NNR: Neuronal Nicotinic Receptor
NRI: Norepinephrine Reuptake Inhibitor
OCD: Obsessive-Compulsive Disorder
PD: Panic Disorder
PDE7: Phosphodiesterase 7

PDSS:	Panic Disorder Severity Scale
PET:	Positron Emission Tomography
PMDD:	Premenstrual Dysphoric Disorder
PTSD:	Post-Traumatic Stress Disorder
R&D:	Research and Development
RIMA:	Reversible Inhibitor of Monoamine Oxidase A
SARI:	Serotonin Antagonist and Reuptake Inhibitor
SERT:	Serotonin Transporter
SNRI:	Serotonin-Norepinephrine Reuptake Inhibitor
SSRI:	Selective Serotonin Reuptake Inhibitors
TCA:	Tricyclic Antidepressant
TeCAs:	Tetracyclic Antidepressants
TRI:	Triple Reuptake Inhibitor
WHO:	World Health Organization
Y-BOCS:	Yale-Brown Obsessive-Compulsive Scale

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9.4 Research Methodology

GBI Research's dedicated research and analysis teams consist of experienced professionals with a pedigree in marketing, market research, consulting backgrounds in the industry, and advanced statistical expertise.

GBI Research adheres to the codes of practice of the Market Research Society (www.mrs.org.uk) and the Strategic and Competitive Intelligence Professionals (www.scip.org).

All GBI Research databases are continuously updated and revised. The following research methodology is followed for all databases and reports.

9.4.1 Coverage

The objective of updating GBI Research's coverage is to ensure that it represents the most up-to-date vision of the industry possible.

Changes to the industry taxonomy are built on the basis of extensive research of company, association and competitor sources.

Company coverage is based on three key factors: market capitalization, revenues, and media attention/innovation/market potential.

- An exhaustive search of 56 member exchanges is conducted and companies are prioritized on the basis of their market capitalization.
- The estimated revenues of all major companies, including private and governmental, are gathered and used to prioritize coverage; and
- Companies which are making the news, or which are of particular interest due to their innovative approach are prioritized.

GBI Research aims to cover all major news events and deals in the medical industry, updated on a daily basis.

The coverage is further streamlined and strengthened with additional inputs from GBI Research's expert panel (see below).

9.4.2 Secondary Research

The research process begins with exhaustive secondary research on internal and external sources being carried out to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

- Company websites, annual reports, financial reports, broker reports, investor presentations and US Securities and Exchange Commission (SEC) filings;
- Industry trade journals, scientific journals and other technical literature;
- Internal and external proprietary databases;

- Relevant patent and regulatory databases;
- National government documents, statistical databases and market reports;
- Procedure registries; and
- News articles, press releases and web-casts specific to the companies operating in the market.

9.4.3 Primary Research

GBI Research conducts hundreds of primary interviews a year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

- It provides first-hand information on the market size, market trends, growth trends, competitive landscape, future outlook and so on;
- Helps in validating and strengthening the secondary research findings; and
- Further develops the analysis team's expertise and market understanding.

Primary research involves e-mail correspondence and telephone interviews, as well as face-to-face interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: CEOs, VPs, marketing/product managers, market intelligence managers and national sales managers;
- Hospital stores, laboratories, pharmacies, distributors and paramedics;
- Outside experts: investment bankers, valuation experts, research analysts specializing in specific medical markets; and
- Key Opinion Leaders: Physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of medical equipment.

The report consists of the following four major sections:

- Therapeutic Landscape
- Geographic Landscape
- Pipeline Analysis
- Competitive Analysis

9.5 Therapeutic Landscape

- Revenues for each indication, by geography, are arrived at by utilizing the GBI Research market forecasting model. The global revenue for each indication is the sum value of revenues of all seven regions.
- The annual cost of therapy for each indication is arrived at by considering the cost of the drugs, dosage of the drugs and the duration of therapy.
- The treatment usage pattern, which includes quantitative data on the diseased population, diagnosed population and treated population for an indication, is arrived at by referring to various sources as mentioned below.

GBI Research uses the epidemiology-based treatment flow model to forecast market size for therapeutic indications.

9.5.1 Epidemiology-based Forecasting

The forecasting model used at GBI Research makes use of epidemiology data gathered from research publications and primary interviews with physicians to represent the treatment flow patterns for individual diseases and therapies. The market for any disease segment is directly proportional to the volume of units sold and the price per unit.

Sales = Volume of Units sold X Price per Unit

The volume of units sold is calculated on the average dosage regimen for that disease, duration of treatment and number of patients who are prescribed drug treatment (prescription population). Prescription population is calculated as a percentage of the population diagnosed with a disease (diagnosis population). Diagnosis population is the population diagnosed with a disease expressed as a percentage of the population that is seeking treatment (treatment-seeking population). Prevalence of a disease (diseased population) is the percentage of the total population who suffer from a disease/condition.

Data on treatment seeking rate, diagnosis rate and prescription rate, if unavailable from research publications, are gathered from interviews with physicians and are used to estimate the patient volumes for the disease under consideration. Therapy uptake and compliance data are fitted into the forecasting model to account for patient switching and compliance behavior.

To account for differences in patient affordability of drugs across various geographies, macroeconomic data such as inflation and GDP, and healthcare indicators such as healthcare spending, insurance coverage and average income per individual are used.

Annual cost of treatment is calculated using product purchase frequency and the average price of the therapy. Product purchase frequency is calculated from the dosage data available for the therapies and drug prices are gathered from public sources.

The epidemiology-based forecasting model uses a bottom-up methodology and makes use of estimations in the absence of data from research publications. Such estimations may result in a final market value which is different from the actual value. To correct this 'gap' the forecasting model uses 'triangulation' with the help of base year sales data (from company annual reports, internal and external databases) and sales estimations.

Analogous Forecasting Methodology

Analogous forecasting methodology is used to account for the introduction of new products, patent expiries of branded products and subsequent introduction of generics. Historic data for new product launches and generics penetration are used to arrive at robust forecasts. Increase or decrease of prevalence rates, treatment seeking rate, diagnosis rate and prescription rate are fitted into the forecasting model to estimate market growth rate.

The proprietary model enables GBI Research to account for the impact of individual drivers and restraints in the growth of the market. The year of impact and the extent of impact are quantified in the forecasting model to provide close-to-accurate data sets.

Diseased Population

The diseased population for any indication is the prevalence. The prevalence rates are usually obtained from various journals, online publications, sources such as the World Health Organization (WHO) or associations and foundation websites for that particular disease.

Diagnosis Population

Out of the patients who undergo diagnostic tests to confirm a disease, only a few people get diagnosed with the disease. This number as a percentage of the treatment seeking population is the diagnosis rate. The diagnosis population is primarily driven by the sensitivity of the diagnostic tests, state-of-the-art technology, patient access to these diagnostic tests and cost of the diagnostic tests.

Prescription Population

For any disease, multiple treatment options exist. For example, in cancer treatment various treatment options such as surgery, radiation therapy, and drug therapy are available. Prescription population is defined as the number of patients who are prescribed drug therapy. This is calculated as a percentage of the diagnosis population. The prescription population is primarily driven by the age at which the disease is diagnosed, the disease stage, patient health and cost of drug treatment.

9.5.2 Market Size by Geography

The treatment usage pattern and annual cost of treatment in each country has been factored in while deriving the individual country market size.

Forecasting Model for Therapeutic Areas

GBI Research Market Sizing Model			
Disease Population			
General Population			743,535,048
Qualifying condition 1 (Age/Sex/Occupation etc)			
Qualifying condition 2 (Age/Sex/Occupation etc)			
Prevalence tissue valve disease	0.2%		1,784,484
Qualifying condition (complication, severity)			
DISEASED POPULATION			1,784,484
Treatment Flow Patterns			
Treatment Seeking Rate (Symptoms/Dis Awareness)	89%		1,588,191
Diagnosis Rate (Clinical and Diagnostic Tests)	75%		1,191,143
Prescription Rate (Physician Perception, Treatment Effectiveness)			
Tissue Valve	70%		833,800
Other Treatments for Valve (Surg/Med/None)			-
Fulfillment			
Availability		NA	
Willingness to Use (Patient Perceptions)		NA	
Ready to Use (Surgery eligibility, Reuse etc)		NA	
Affordability at Price			
HE as % of GDP spend			
Average Income (per individual)			
Patient Out-of-pocket Budget (Annual)			
Budget allocation to one-time surgery			
Budget allocation to other health needs			
Average Payor Coverage			
Patient Liability			
Target Price (@20% pat lab)			
ASP for Cost of Therapy			
TOTAL PATIENT VOLUMES			
Product Purchase Frequency		1	
TOTAL UNIT VOLUMES			
Pricing per Unit	\$ 18,000		
Inflation			
Price Decrease due to competition			
Market Value			

Source: GBI Research

The above figure represents a typical forecasting model followed in GBI Research. As discussed previously, the model is built on the treatment flow patterns. The model starts with the general population, then diseased population as percentage of general population, and then follows treatment-seeking population as a percentage of diseased population and diagnosis population as a percentage of treatment-seeking population. Finally, the total volume of units sold is calculated by multiplying the prescription population by average dosage per year per patient.

9.6 Geographical Landscape

GBI Research analyzes seven major geographies: the US, the top five countries in Europe (the UK, Germany, France, Spain, Italy), and Japan. The total market size for each country is provided, which is the sum value of the market sizes of all the indications for that particular country.

Articles from research journals and agency publications are the source of data for estimation of market size and making forecasts.

9.7 Pipeline Analysis

This section provides a list of molecules at various stages in the pipeline for various indications. The list is sourced from internal databases and validated for the accuracy of phase and mechanism of action using ClinicalTrials.gov and company websites. The section also includes a list of promising molecules which is narrowed down based on the results of the clinical trials at various stages and the novelty of mechanism of action. The latest press releases issued by the company and news reports are also the source of information for the status of the molecules in the pipeline.

9.8 Competitive Landscape

Profiles of leading players are provided along with an overview of key products marketed by the companies for various indications. GBI Research also aims to cover all major M&A, licensing deals and co-development deals related to the market. This section is sourced from the companies' websites, company annual reports and internal databases.

9.8.1 Expert Panel Validation

GBI Research uses a panel of experts to cross-verify its databases and forecasts.

GBI Research's expert panel comprises marketing managers, product specialists, international sales managers from numerous companies, academics from research universities, KOLs from hospitals, consultants from venture capital funds and distributors/suppliers of medical equipment and other products.

Historic data and forecasts are relayed to GBI Research's expert panel for feedback and adjusted in accordance with their feedback.

9.10 Disclaimer

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