Antidepressants Market to 2018

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

GBI Research
Global Business Intelligence

GBI Research Report Guidance

- 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

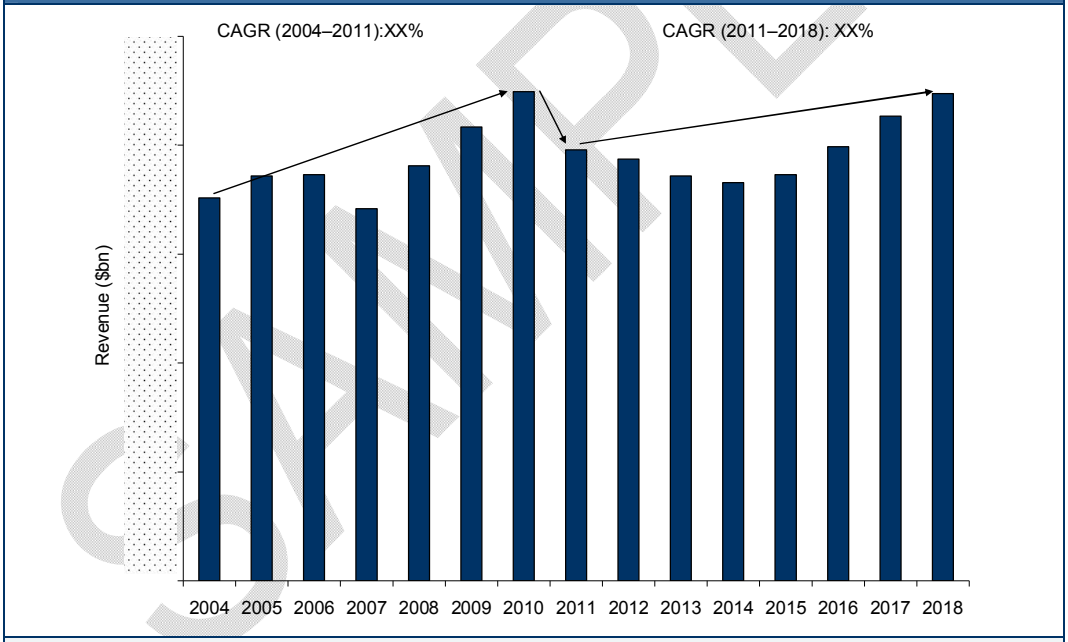
Over the forecast period (2011-2018), the antidepressant market revenues will increase, to reach $XX billion in 2018, at a CAGR of XX%

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.

Antidepressants Market, Global, Revenue ($bn), 2004–2018



Source: GBI Research

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

1.1 List of Tables

1.2 List of Figures

2 Antidepressants Market to 2018 - Introduction

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

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.

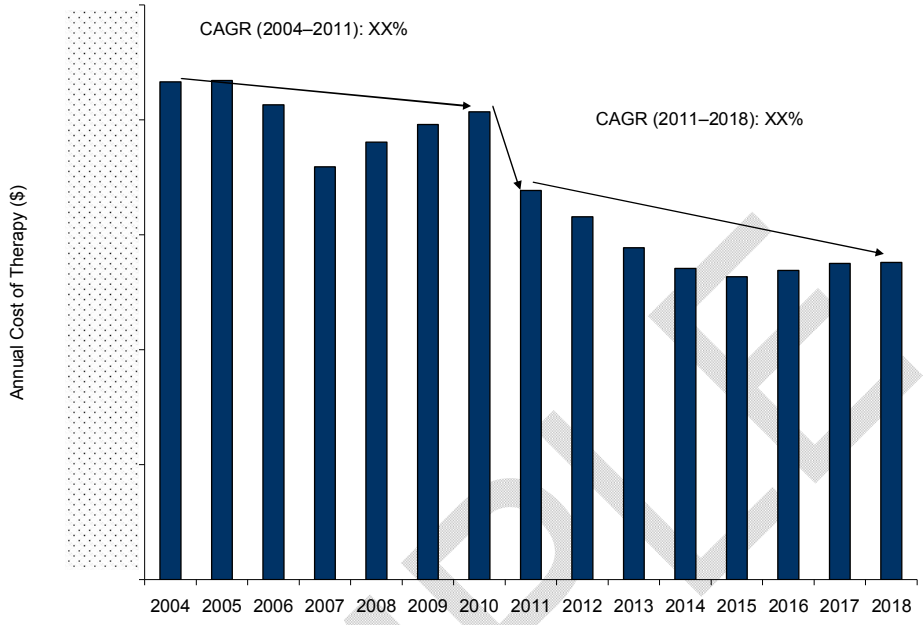
The OCD market is expected to grow the fastest among the antidepressant market segments due to the rising incidence and increasing awareness of the condition, with forecast revenue CAGR of XX%. The GAD market is the second highest growth segment in terms of potential revenue at a XX% CAGR, while the 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.

Figure 2: Antidepressants Market, Global, Annual Cost of Therapy ($), 2004–2018



Source: GBI Research

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.

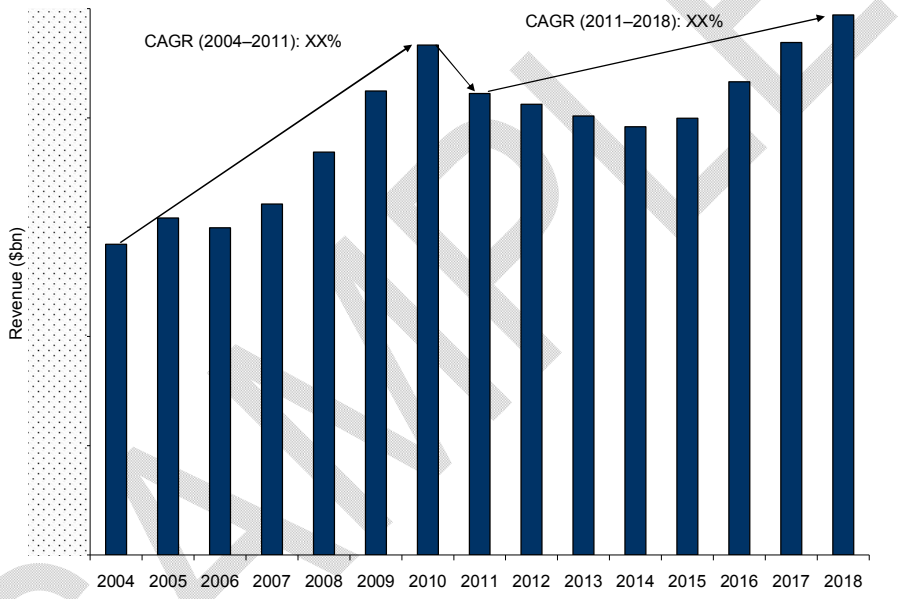
4.1.2 Revenue and Forecasts

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

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



Source: GBI Research

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

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

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									

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

EU5: 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

9.3 Sources

- Abbott (2011). Luvox CR Prescribing Information. Abbott. Available from: http://www.luvoxcr.com/LUVOX-CR-PI.pdf.
- AstraZeneca (2012a). Seroquel Prescribing Information. AstraZeneca. Available from: http://www1.astrazeneca-us.com/pi/seroquel.pdf.
- AstraZeneca (2012b). Seroquel XR Prescribing Information. AstraZeneca. Available from: http://www1.astrazeneca-us.com/pi/seroquelxr.pdf.
- Bristol-Myers Squibb (2012). Abilify Prescribing Information. Bristol-Myers Squibb. Available from: http://packageinserts.bms.com/pi/pi_abilify.pdf.
- Eli Lilly (2011). Prozac Prescribing Information. Eli Lilly. Available from: http://pi.lilly.com/us/prozac.pdf.
- Eli Lilly (2012). Cymbalta Prescribing Information. Eli Lilly. Available from: http://pi.lilly.com/us/cymbalta-pi.pdf.
- GlaxoSmithKline (2011a). Paxil Prescribing Information. GlaxoSmithKline. Available from: http://us.gsk.com/products/assets/us_paxil.pdf.
- GlaxoSmithKline (2011b). Wellbutrin Prescribing Information. GlaxoSmithKline. Available from: http://us.gsk.com/products/assets/us_wellbutrin_tablets.pdf.
- GlaxoSmithKline (2011c). Wellbutrin XL Prescribing Information. GlaxoSmithKline. Available from: http://us.gsk.com/products/assets/us_wellbutrinXL.pdf.
- Hvenegaard MG, et al. (2012). Identification of the cytochrome P450 and other enzymes involved in the in vitro oxidative metabolism of a novel antidepressant, Lu AA21004. *Drug Metabolism and Disposition*, 40(7): 1357-1365.
- International OCD Foundation. (2012). Available from: http://www.ocfoundation.org/O_C.aspx. [Accessed August 14th, 2012].
- Merck (2012). RemeronSolTab Prescribing Information. Merck. Available from: http://www.merck.com/product/usa/pi_circulars/r/remeronsol/remeronsoltab_pi.pdf.
- Pfizer (2011a). Effexor prescribing information. Pfizer. Available from: http://labeling.pfizer.com/showlabeling.aspx?id=99 [Accessed August 14th, 2012].

- Pfizer (2011b). Effexor XR prescribing information. Pfizer. Available from: http://labeling.pfizer.com/showlabeling.aspx?id=100 [Accessed August 14th, 2012].
- Pfizer (2011c). Pristiq prescribing information. Pfizer. Available from: http://labeling.pfizer.com/showlabeling.aspx?id=497 [Accessed August 14th, 2012].
- Pfizer (2011d). Zoloft prescribing information. Pfizer. Available from: http://labeling.pfizer.com/ShowLabeling.aspx?id=517 [Accessed August 14th, 2012].
- Roche (2010). Klonopin Prescribing Information. Roche. Available from: http://www.gene.com/gene/products/information/klonopin/pdf/pi.pdf.
- Taylor JM, et al. (2006). Early Onset of Selective Serotonin Reuptake Inhibitor Antidepressant Action: Systematic Review and Meta-analysis. *Archives of General Psychiatry*, 63(11):1217-1223.
- World Health Organization (WHO) (2012). Mental health. Depression. Available from: http://www.who.int/mental_health/management/depression/definition/en/. [Accessed August 14th, 2012].

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

Figure 37: GBI Research Market Forecasting Model

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 liab)		
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