Dermatology Therapeutics Market to 2018

Novel Biologics Targeting Interleukin-17 Receptor Presents New Options in Psoriasis Treatment

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GBI Research Report Guidance

The objective of updating GBI Research's coverage is to ensure that it represents the most up-to-date analysis of the industry. Changes to the industry taxonomy are built on the basis of company, association and competitor sources.

- Chapter two summarizes the introduction of the report.
- Chapter three gives an overview of the dermatology therapeutics market, its trends and the recent developments in the seven major markets.
- Chapter four estimates the market size of the US, the UK, France, Germany, Spain, Italy and Japan. The dermatology market sizes for these seven countries are estimated and forecasts to 2017 are given. A key analysis of the treatment usage pattern is also discussed.
- Chapter five covers the revenues until 2017 for the dermatological conditions covered in the report. It also analyzes the market revenues of the top seven countries individually with respect to each indication, and the branded and generic shares in 2010 and 2017. GBI Research analyzed the current landscape of the market, focusing on the key drivers and restraints influencing the markets for the different indications. The treatment flow algorithm and treatment usage pattern have been given along with the key trends from 2002 to 2017.
- Chapter six gives details on the current pipeline analysis of the dermatological disorders market. The section also contains a detailed analysis of the most promising pipeline products.
- Chapter seven analyzes the top companies operating in the dermatological disorders market. It includes benchmarking and detailed profiles of the top six companies operating in the dermatology markets on the basis of sales value.
- Chapter eight discusses in detail the strategic consolidations that have taken place within the global dermatology therapeutics market. A look into key licensing agreements is also given, with increasing focus on geographies.

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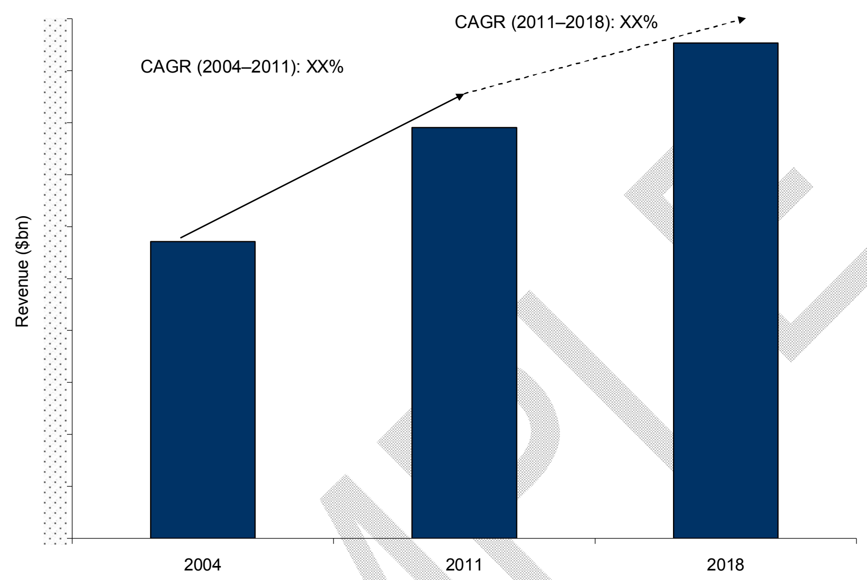
Executive Summary

GBI Research has found that the global dermatology therapeutics market is one of the more mature therapeutic markets in the pharmaceutical industry. Market revenue is only expected to increase moderately due to various restraints such as generic substitutions and the availability of alternative therapies such as surgery, phototherapy and natural Over-the-Counter (OTC) medications. Nevertheless, the global dermatology therapeutics market is an attractive market for larger pharmaceutical companies.

Psoriasis and acne are the most potential segments with over $XX billion in sales in 2011 and a strong, promising pipeline

The Dermatology Therapeutics Market is Forecast to Grow at a CAGR of XX% from 2011 to 2018

Dermatology Therapeutics Market to 2018, Global, Revenue Forecasts ($bn), 2004-2018



Source: GBI Research's Proprietary Epidemiology and Market Size Database [accessed on: May 29, 2012]; GBI Research's Proprietary Diseases Database [accessed on: May 29, 2012]

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The global dermatology therapeutics market for psoriasis, acne, rosacea, atopic dermatitis, herpes and alopecia covers the top seven established markets in the world: the US, Germany, France, Spain, the UK, Italy and Japan, and was estimated to be worth $XX billion in 2011. The market grew at a Compound Annual Growth Rate (CAGR) of XX% from 2004 to 2011. The market is expected to reach $XX billion by 2018 at a CAGR of XX%.

Psoriasis and acne have the most potential in the global dermatological disorders market, with over $XX billion in sales in 2011 and strong pipelines that include some promising molecules.

From 2004 to 2011, the global dermatology therapeutics market grew at a significant rate due to sales from major marketed products such as Propecia (finasteride) and finasteride-minoxidil combination products for the treatment of alopecia; Valtrex (valacyclovir hydrochloride), Zovirax (acyclovir), Famvir (famciclovir) and Zostavax (live zoster vaccine) for the treatment of herpes; Remicade (infliximab), Humira (adalimumab), Enbrel (etanercept) and Stelara (ustekinumab) for the treatment of psoriasis; Solodyn (minocycline), Ziana gel (clindamycin phosphate XX% and tretinoin XX%), Doryx (doxycycline hyclate) and Duac topical gel (clindamycin XX% and benzoyl peroxide XX%) for the treatment of acne; Oracea (doxycycline) for the treatment of rosacea; and Protopic (tacrolimus), Elidel (pimecrolimus) and Medrol (methylprednisolone) for the treatment of atopic dermatitis.

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2 Dermatology Therapeutics Market to 2018 - Introduction

The global dermatology therapeutics market generated approximately $XX billion in 2011. The market is estimated to reach revenues of $XX billion by 2018, growing at a Compound Annual Growth Rate (CAGR) of XX% during the forecast period. From 2004, the market grew at a CAGR of XX% to reach $XX billion in 2011. The report is limited to the following indications: alopecia, herpes (herpes simplex and Herpes Zoster; HZ), psoriasis, acne (also known as acne vulgaris), rosacea, and atopic dermatitis or eczema. The report covers the seven major markets, namely the US, the UK, Spain, Germany, Italy, France and Japan.

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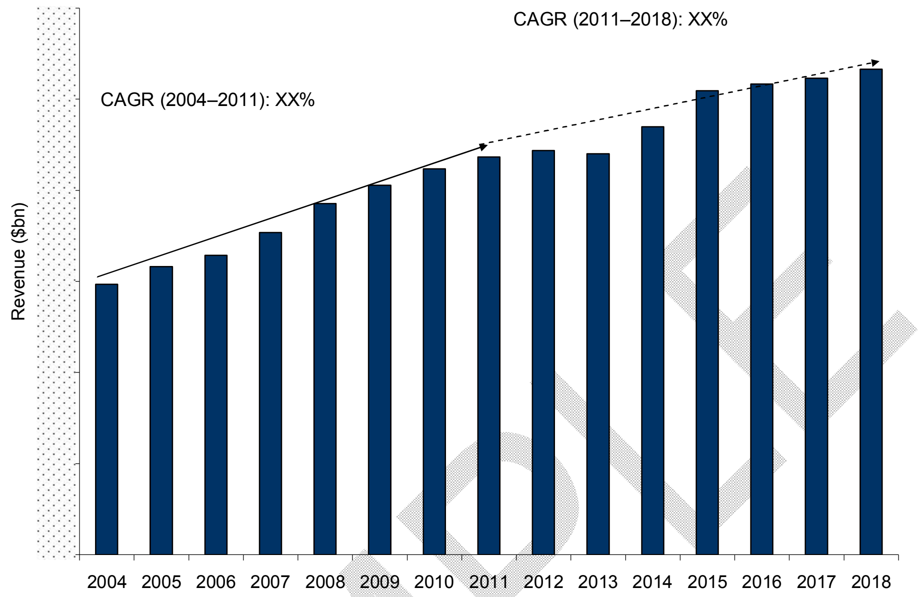
4.2 The US

4.2.1 Revenue

The figure below shows the revenue generated by the US during the historic (2004-2011) and forecast (2011-2018) periods for the dermatology market.

Figure 5: Dermatology Therapeutics Market, the US, Revenue Forecasts ($bn), 2004-2018



Source: GBI Research's Proprietary Epidemiology and Market Size Database [accessed on: May 29, 2012]; GBI Research's Proprietary Diseases Database [accessed on: May 29, 2012]

Table 9: Dermatology Therapeutics Market, the US, Revenue ($bn), 2004-2011

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

Source: GBI Research's Proprietary Epidemiology and Market Size Database [accessed on: May 29, 2012]; GBI Research's Proprietary Diseases Database [accessed on: May 29, 2012]

Table 10: Dermatology Therapeutics Market, The US, Revenue Forecasts ($bn), 2011-2018

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

Source: GBI Research's Proprietary Epidemiology and Market Size Database [accessed on: May 29, 2012]; GBI Research's Proprietary Diseases Database [accessed on: May 29, 2012]

The US dermatology therapeutics market was estimated to be worth $XX billion in 2011, indicating a growth rate of XX% between 2004 and 2011. The market is estimated to reach revenues of $XX billion by 2018, growing at a CAGR of XX% from 2011.

The US contributed XX% of the total dermatology therapeutics market in 2011. The US dermatology therapeutics market is quite fragmented and continues to grow at a moderate rate.

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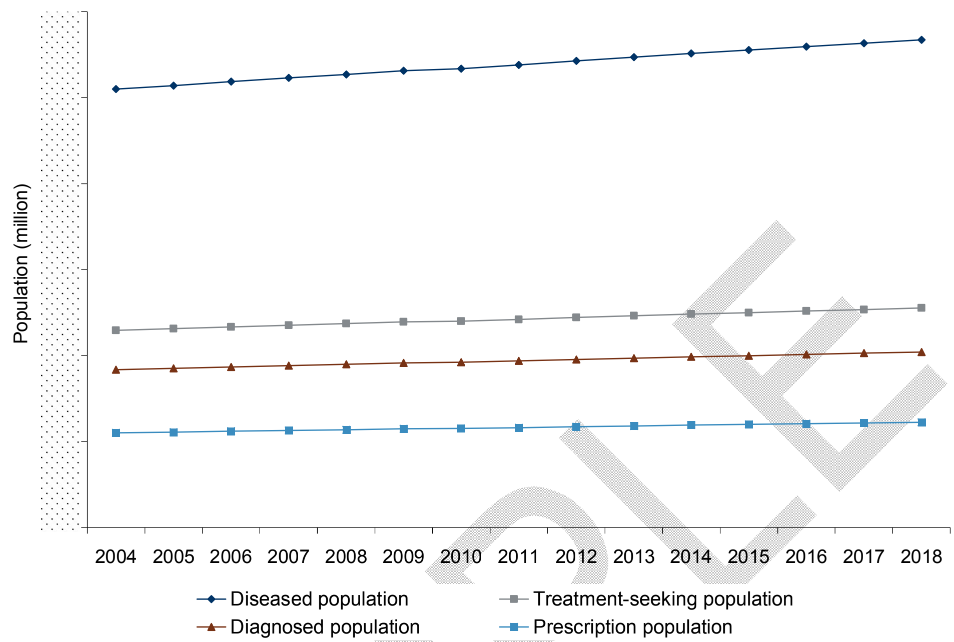
5.1.4 Treatment Usage Pattern

The figure below shows the cumulative global population across various parameters during the historic (2004-2011) and forecast (2011-2018) periods for the alopecia therapeutics market.

Figure 19: Alopecia Therapeutics Market, Global, Treatment Usage Pattern (million), 2004-2018



Source: GBI Research's Proprietary Epidemiology and Market Size Database [accessed on: May 31, 2012]

Table 35: Alopecia Therapeutics Market, Global, Treatment Usage Pattern (million), 2004-2011

Year	2004	2005	2006	2007	2008	2009	2010	2011	CAGR (%)
Diseased population									
Treatment-seeking population									
Diagnosed population									
Prescription population									

Source: GBI Research's Proprietary Epidemiology and Market Size Database [accessed on: May 31, 2012]

Table 36: Alopecia Therapeutics Market, Global, Treatment Usage Pattern (million), 2011-2018

Year	2011	2012	2013	2014	2015	2016	2017	2018	CAGR (%)
Diseased population									
Treatment-seeking population									
Diagnosed population									
Prescription population									

Source: GBI Research's Proprietary Epidemiology and Market Size Database [accessed on: May 31, 2012]

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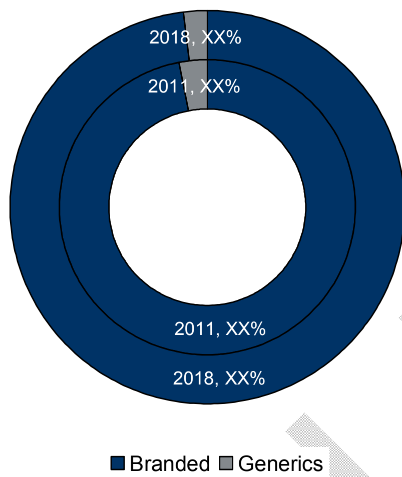
5.3.2.2 Branded Versus Generics

The figure below represents the current (2011) and forecast (2018) market shares captured by branded and generic drugs in the psoriasis therapeutics market.

Figure 31: Psoriasis Therapeutics Market, Global, Revenue Segmentation (%), 2011 and 2018



Source: GBI Research's Proprietary Products Database [accessed on: May 29, 2012]; GBI Research's Proprietary Pipeline Products Database [accessed on: May 7, 2012]

LAS41002, CF101, AIN457, CC-10004, anti-CD6 monoclonal antibody, AMG 827 and MK-3222 are some of the major pipeline molecules for the treatment of psoriasis that will increase the psoriasis therapeutics market during the forecast period by increasing the share of branded molecules to XX%.

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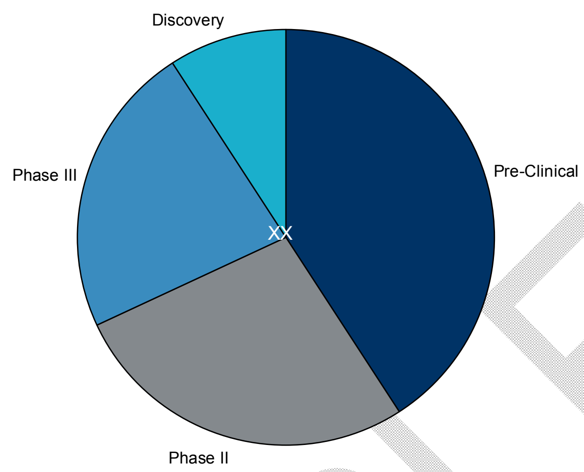
7.1.2 Research and Development Pipeline - Herpes

The figure below shows the percentage of molecules across the various stages of development in the herpes R&D pipeline.

Figure 61: Dermatology Therapeutics Market, Herpes, R&D Pipeline by Phase (%), 2012



Source: GBI Research's Proprietary Clinical Trials Database [accessed on: May 7, 2012]; GBI Research's Proprietary Pipeline Products Database [accessed on: May 7, 2012]

The herpes developmental pipeline is weak, with only XX molecules in the various phases of clinical development. However, there are some promising molecules in the Phase III and Phase II stages of development. The present clinical pipeline for HZ therapeutics is weak; XX% of the molecules in the pipeline are being developed for herpes simplex.

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11 Dermatology Therapeutics Market to 2017 - Appendix

11.1 Market Definitions

The **global dermatology therapeutics market** includes alopecia, herpes (herpes simplex and herpes zoster), psoriasis, acne, rosacea and atopic dermatitis in the top seven markets: the US, the UK, Germany, France, Spain, Italy and Japan.

GDP - It is defined as the market value of goods and services produced by a country in a year. It is the most widely used measurement of economic output of a country.

Total healthcare expenditure - The sum of expenditure on healthcare and healthcare-related items.

Out-of-pocket healthcare expenditure - Health care costs that are not covered by insurance; such as deductibles, coinsurance, co-payments, and non-covered expenses.

Essential drugs - According to the World Health Organization, essential drugs are 'those that satisfy the primary health care needs of the population'.

Weighted average price - It is determined by assigning a weight (number) to each quantity to be averaged. The weight assigned is based on the relative importance of each quantity.

Ceiling prices - The maximum price, set by law, at which a manufacturer can sell its products.

Wholesale price index - It measures and tracks the alterations in product prices before reaching the retail level.

11.2 Abbreviations

ACT - Annual Cost of Treatment

APL - Acute Promyelocytic Leukemia

ASAPS - American Society of Aesthetic Plastic Surgery

AWP - Average Wholesale Price

CAGR - Compound Annual Growth Rate

cAMP - Cyclic Adenosine Monophosphate

CIS - Commonwealth of Independent States

COX - Cyclooxygenase

DHT - Dihydrotestosterone

DNA - Deoxyribonucleic Acid

DPCO - Drugs (Price Control) Order

ETR - Erythematotelangiectatic Rosacea

FDA - Food and Drug Administration

GDP - Gross Domestic Product

HCT - Hematopoietic Cell Transplantation

HIV - Human Immunodeficiency Virus

HSV - Herpes Simplex Virus

HZ - Herpes Zoster

IL - Interleukin

IND - Investigational New Drug

IPA - Indian Pharmaceutical Alliance

ISGA - Investigator's Static Global Assessment

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ISHRS - International Society of Hair Restoration Surgery

JAK - Janus Kinase

MAA - Marketing Authorization Application

MPB - Male Pattern Baldness

MRSA - Methicillin-Resistant *Staphylococcus aureus*

NASHA - Non-Animal Stabilized Hyaluronic Acid

NDA - New Drug Application

NDRC - National Development and Reform Commission

NLEM - National List of Essential Medicines

NPPP - National Pharmaceutical Pricing Policy

NSAID - Non-Steroidal Anti-Inflammatory Drug

OPT - Oral Psoriasis Treatment

OTC - Over the Counter

PASI - Psoriasis Area Severity Index

PBS - Pharmaceutical Benefits Scheme

PCI - Planning Commission of India

PDT - Photodynamic Therapy/Treatment

PGA - Physician's Global Assessment

PHN - Postherpetic Neuralgia

PPACA - Patient Protection and Affordable Care Act

PUVA - Psoralen and Ultraviolet A

R&D - Research and Development

RXR - Retinoid X Receptor

RAR - Retinoic Acid Receptor

RNA - Ribonucleic Acid

SFDA - State Food and Drug Administration

TNF - Tumor Necrosis Factor

TNFR - Tumor Necrosis Factor Receptor

UVB - ultraviolet B

VZV - Varicella-Zoster Virus

WAP - Weighted Average Price

WHO - World Health Organization

WPI - Wholesale Price Index

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11.4 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 medical devices 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.

11.4.1 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 decided 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, with its databases updated on a daily basis.

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

11.4.2 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 Exchanges 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.

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- Procedure registries.
- News articles, press releases and webcasts specific to the companies operating in the market.

11.4.3 Primary Research

GBI Research conducts hundreds of primary interviews each 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, etc.
- Helps in validating and strengthening the secondary research findings; and
- Further develops the analysis team's expertise and market understanding.

Primary research involves email interactions, telephone interviews, and 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 equipment 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:

Geographic Landscape

Therapeutic Landscape

Pipeline Analysis

Competitive Analysis

11.5 Therapeutic Landscape

The revenues for each indication, by geography, are arrived at by utilizing the GBI Research market forecasting model. The global revenues for each indication are a summarized value of the 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 the therapy.

The generic share of the market for each indication is obtained by calculating the prescription share for generic drugs and the respective cost of treatment.

The treatment usage pattern, which includes quantitative data on diseased population, treatment-seeking population, diagnosed population and treated population for an indication, is arrived at by referring to various sources, as described below.

The marketed drugs section contains an overview of the drugs, their mechanism of action, efficacy and safety issues related to the drugs. The drugs profiled in this section are chosen based on estimated revenues and their mechanism of action.

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

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11.5.1.1 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 based on the average dosage regimen for that disease, the duration of treatment, and the number of patients who are prescribed drug treatment (the prescription population). The prescription population is calculated as a % of the population diagnosed with a disease (the diagnosis population). The diagnosis population is the population diagnosed with a disease expressed as a % of the population that is seeking treatment (the treatment-seeking population). The prevalence of a disease (diseased population) is the % 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 in 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 that 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

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

Treatment-Seeking Population

The treatment-seeking population is always calculated as a % of prevalence. The number denotes the actual number of patients who are reported as going to hospitals to get diagnosed for a disease. The treatment-seeking population is primarily driven by the onset of symptoms, patient awareness, and the severity of the 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 % 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.

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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. The prescription population is defined as the number of patients who are prescribed drug therapy. This is calculated as a % 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 the cost of drug treatment.

11.5.2 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 88: 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 constructed by 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 a % of general population, and then follows the treatment-seeking population as a % of the diseased population, and the diagnosed population as a % of the treatment-seeking population. Finally, the total volume of units sold is calculated by multiplying the treated population by the average dosage per year per patient.

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Articles are used from research journals and agency publications, such as National Alopecia Areata Foundation, Hair Foundation, Australian Herpes Management Forum, Herpes Viruses Association, National Shingles Foundation, Psoriasis Association, National Psoriasis Foundation, American Academy of Family Physician, National Rosacea Society, National Eczema Association, Ministry of Health and Family Welfare, Pharma China. The marketed drugs section is constructed from company websites and internal databases.

11.6 Geographical Landscape

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

11.7 Pipeline Analysis

This section provides a list of molecules at different 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 at 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 the mechanism of action.

11.8 Competitive Landscape

Profiles of leading players are provided, along with an overview of key products marketed by the companies for various indications. An analysis of strengths, weaknesses, opportunities and threats of each company with respect to various indications is also listed.

GBI Research aims to cover all major MERGERS AND ACQUISITIONS, licensing deals and co-development deals related to the market. This section is sourced from the companies' websites and internal databases.

11.8.1 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 medical device companies, academics from research universities, and key opinion leaders from hospitals.

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

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