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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		
<b>Disease Population</b>		
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)		
<b>DISEASED POPULATION</b>		<b>1,784,484</b>
<b>Treatment Flow Patterns</b>		
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)		-
<b>Fulfillment</b>		
Availability	NA	
Willingness to Use (Patient Perceptions)	NA	
Ready to Use (Surgery eligibility, Reuse etc)	NA	
<b>Affordability at Price</b>		
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		
<b>TOTAL PATIENT VOLUMES</b>		
Product Purchase Frequency	1	
<b>TOTAL UNIT VOLUMES</b>		
<b>Pricing per Unit</b>		
Inflation		
Price Decrease due to competition		
<b>Market Value</b>		

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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