Neurodegenerative Diseases Market to 2018

New product entries in both niche and broader Parkinson's disease treatment will boost market despite patent cliff

GBI Research
Global Business Intelligence

GBI Research Report Guidance

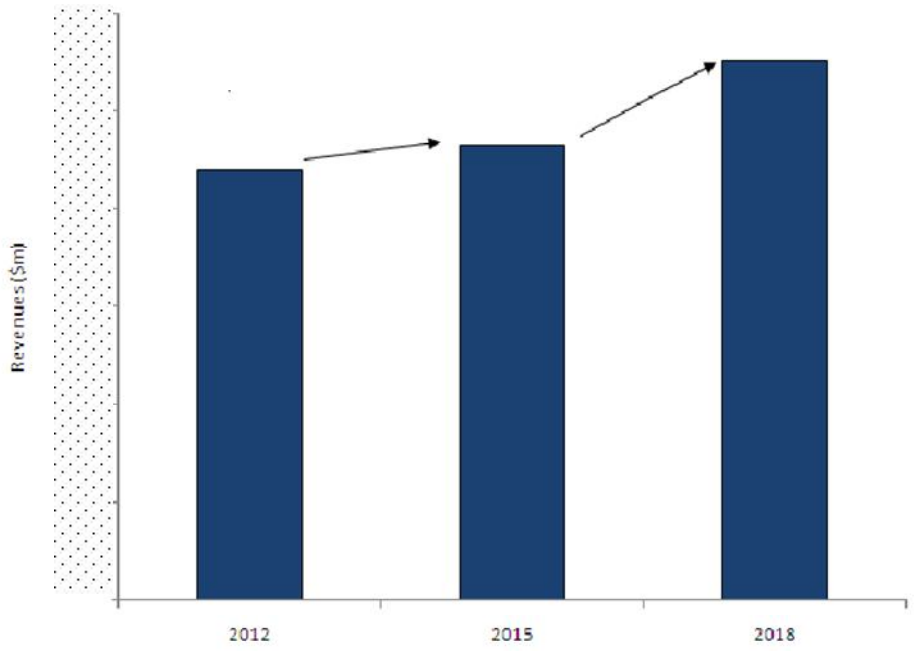
- The report starts with an executive summary detailing the key points that are driving the global neurodegenerative diseases market.
- Chapter three provides the market characterization of the neurodegenerative diseases market, including market size, pricing trends and treatment usage patterns in the 2004–2018 period, and the key market drivers and restraints.
- Chapter four describes the therapeutic landscape of the neurodegenerative diseases market. This section includes detailed market sizing and analysis of the trends in AD, PD, HD and ALS.
- Chapter five details the neurodegenerative diseases market in the major global regions: the US, the top five European countries (Germany, France, the UK, Italy and Spain), and Japan.
- Chapter six gives detailed pipeline analysis of the neurodegenerative diseases market (as of November 2012), as well as detailed analysis of the most promising pipeline products.
- Chapter seven analyzes the top companies operating in the neurodegenerative diseases market, with benchmarking and detailed company profiles.
- Chapter eight describes the major deals that have taken place in the global neurodegenerative diseases market in recent years. Coverage includes M&A and licensing agreements, segmented by therapeutic focus, phase, geography, licensing type and value.
- Chapter nine is the appendix to the report, which includes key definitions and explanations of abbreviations and details of the methodology and sources used.

Neurodegenerative Diseases Market to 2018: Executive Summary

Global Neurodegenerative Diseases Market to Witness Moderate Growth

The global neurodegenerative diseases market is expected to grow moderately from $XX billion in 2012 to $XX billion in 2018 at a Compound Annual Growth Rate (CAGR) of XX% from 2012–2015 and at a higher CAGR of XX% from 2015–2018. A number of competitive market entries are expected across all XX indications during the forecast period, mitigating the effects of numerous patent expiries. In addition, growth in the population over the age of XX across the seven major markets is expected to further drive this growth. The impact of these market entries is expected to present itself after 2015.

Neurodegenerative Diseases Market, Global, Revenue Forecast ($m), 2012–2018



Source: GBI Research Proprietary Database [Accessed February 11, 2013]

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2 Neurodegenerative Diseases Market to 2018: Introduction

The four indications included in this report are chronic, progressive diseases characterized by the gradual and permanent loss of neurons.

Alzheimer's Disease (AD), identified in 1901 by Alois Alzheimer, is the most common of the four. Its pathology is known to involve the formation of amyloid plaques and neurofibrillary tangles in the brain, leading to memory loss and dementia.

Parkinson's Disease (PD) is caused by the progressive loss of dopaminergic neurons in the substantia nigra of the brain due to the formation of Lewy bodies, inclusions of the alpha-synuclein protein which accumulates in the brains of PD patients. This leads to the progressive loss of motor function in addition to a host of non-motor psychiatric symptoms.

Huntington's Disease (HD) is an inherited disease caused by a highly specific mutation in the Huntingtin gene, responsible for producing the protein of the same name. The disease mutant protein has a long tract of glutamine residues, making it susceptible to aggregation and plaque formation. Sufferers exhibit a number of psychiatric disorders and a characteristic set of random, involuntary movements known as chorea.

Finally, Amyotrophic Lateral Sclerosis (ALS), otherwise known as motor neuron disease, usually presents in patients with no family history of the disease, and has no known cause. Its pathophysiology involves the onset of muscle weakness due to the loss of motor neurons. Unlike the other three indications, its pathophysiology is not thought to involve the aggregation of protein.

The major similarity between these four markets is the lack of curative treatments. They are all characterized by a small number of branded products which can either delay disease onset or manage the major symptoms, and a variety of off-label products which are used to manage the different ranges of symptoms which present in each indication.

Little progress has been made towards the development of a disease-modifying treatment in any of the four indications, and a highly effective disease-modifying drug seems unlikely to enter the market during the forecast period. However, a number of late-stage molecules are expected to enter the market which effectively fill unmet needs as far as symptomatic treatment is concerned.

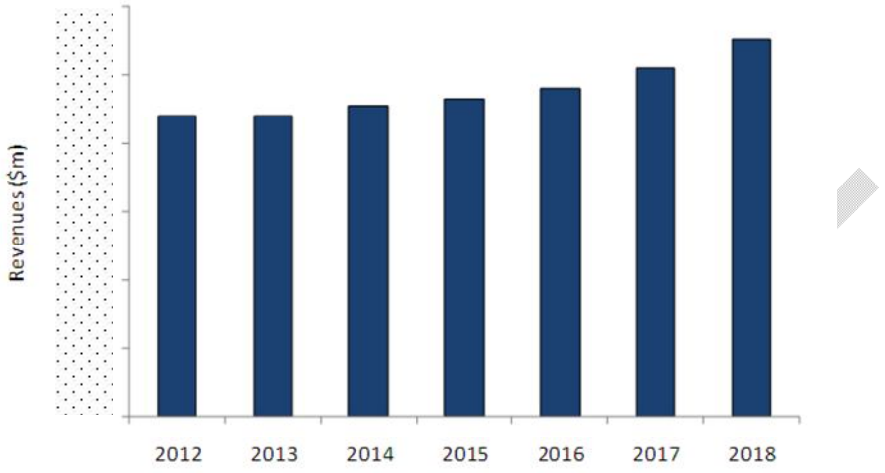
3 Neurodegenerative Diseases Market to 2018: Global Market Overview

3.1 Revenue

The markets for PD and HD are expected to experience growth during the forecast period, while the markets for AD and ALS are expected to shrink due to numerous patent expiries.

The aggregated market for neurodegenerative diseases is expected to increase from $XX billion in 2012 to $XX billion in 2018 at a Compound Annual Growth Rate (CAGR) of XX%. From 2012–2015, the market is expected to grow at a CAGR of XX%, while from 2015–2018 faster growth is expected at a CAGR of XX%. The markets for PD and HD are expected to experience growth during the forecast period, while the markets for AD and ALS are expected to shrink due to numerous patent expiries. Overall, this is expected to lead to moderate but steady growth throughout the forecast period.

Figure 1: Neurodegenerative Diseases Market, Global, Revenue Forecast ($m), 2012–2018



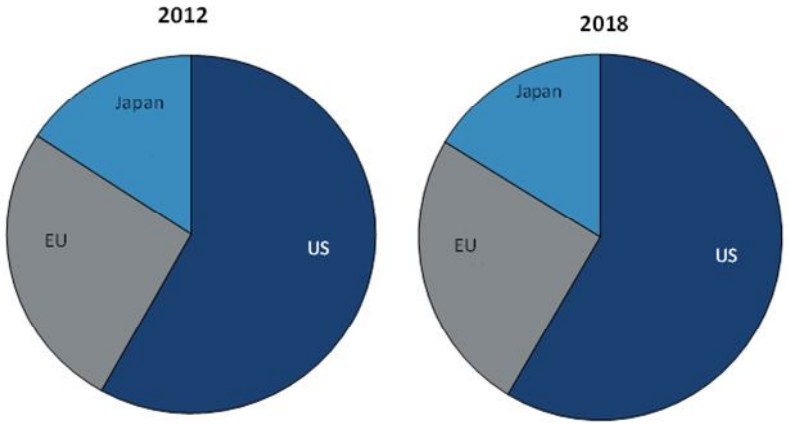
Source: GBI Research Proprietary Database [Accessed February 11, 2013]

Table 1: Neurodegenerative Diseases Market, Global, Revenue Forecast ($m), 2012–2018

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

Source: GBI Res earch Proprietary Database [Accessed February 11, 2013]

Figure 2: Neurodegenerative Diseases Market, Global, Revenue Forecast by Geography ($m), 2012 and 2018



Source: GBI Research Proprietary Database [Accessed February 11, 2013]

Table 2: Neurodegenerative Diseases Market, Global, Revenue Forecast by Geography ($m), 2012–2018

Year	2012	2013	2014	2015	2016	2017	2018	CAGR (%)
US ($m)								
Top five European countries ($m)								
Japan ($m)								

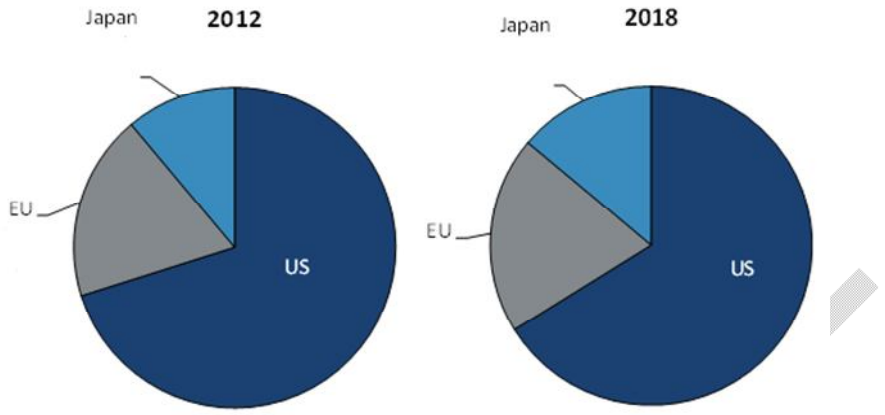
Source: GBI Research Proprietary Database [Accessed February 11, 2013]

4.1.4 Geographical Landscape

The US is currently the largest market for AD, in which an estimated XX% of the global revenues are generated.

The US is currently the largest market for AD, in which an estimated XX% of the global revenues are generated. Although the geographic distribution of the AD market is expected to remain relatively stable during the forecast period, declining US revenues are expected to reduce its overall share of the global market, if only slightly. In contrast, revenues for AD treatments are expected to increase in Japan during the forecast period, increasing the share of this market by XX%.

Figure 7: Alzheimer's Disease Market, Global, Revenue Forecast by Geography ($m), 2012 and 2018



Source: GBI Research Proprietary Database [Accessed February 11, 2013]

Table 7: Alzheimer's Disease Market, Global, Revenue Forecast by Geography ($m), 2012–2018

Year	2012	2013	2014	2015	2016	2017	2018	CAGR (%)
US ($m)								
Top Five European countries ($m)								
Japan ($m)								

Source: GBI Research Proprietary Database [Accessed February 11, 2013]

7 Appendix

7.1 Market Definitions

- **The global neurodegenerative diseases market** covers AD, PD, HD and ALS in the seven major markets: the US, the UK, Germany, France, Spain, Italy and Japan.
- **Prevalence population**: The 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**: The diagnosis rate is the percentage of the treatment-seeking population that has been diagnosed with the disorder(s). The diagnosis population refers to the number of people that have been diagnosed.
- **Prescription rate and population**: The prescription rate is the percentage of the diagnosis population that is prescribed medication. The prescription population refers to the number of people that are on medication for the indication(s).

7.2 Abbreviations

AChE: Acetylcholinesterase

ACOT: Annual Cost of Therapy

AD: Alzheimer's Disease

ALS: Amyotrophic Lateral Sclerosis

AMPA: Alpha-Amino-3-Hydroxy-5-Methyl-4-Isoxazolepropionic Acid

APP: Amyloid Precursor Protein

BDNF: Brain-Derived Neurotrophic Factor

CAGR: Compound Annual Growth Rate

COMT: Catechol-O-Methyltransferase

CT: Computed Tomography

CTA: Clinical Trial Application

DA: Dopamine

GDNF: Glial-Derived Neurotrophic Factor

GPCR: G-Protein Coupled Receptor

GSK 3: Glycogen Synthase Kinase 3

HD: Huntington's Disease

IND: Investigational New Drug

IVIG: Intravenous Immunoglobulin

LRRK: Leucine-Rich Repeat Kinase

LSD-1: Lysine-Specific Demethylase 1

mAb: monoclonal Antibody

mAChR: Muscarinic Acetylcholine Receptor

MAO-A: Monoamine Oxidase-A

MAO-B: Monoamine Oxidase-B

MRI: Magnetic Resonance Imaging

MS: Multiple Sclerosis

nAChR: Nicotinic Acetylcholine Receptor

PD: Parkinson's Disease

PDE: Phosphodiesterase

PET: Positron Emission Tomography

SNCA: Alpha Synuclein

SOD: Superoxide Dimutase

TNF-α: Tumor Necrosis Factor alpha

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7.4 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 Society of 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.

7.4.1 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.
- 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).

7.4.2 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
- News articles, press releases and web-casts specific to the companies operating in the market.

7.4.3 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:

- Provides first-hand information on the market size, market trends, growth trends, competitive landscape and future outlook
- Helps in validating and strengthening the secondary research findings
- 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
- 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

7.5 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, treatment-seeking 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.

7.5.1 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 therapy 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.

7.5.2 Market Size by Geography

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

Forecasting Model for Therapeutic Areas

Figure 109: 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.

7.6 Geographical Landscape

GBI Research analyzes seven major geographies: the US, the top five European countries (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.

7.7 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.

7.8 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.

7.8.1 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.

7.10 Disclaimer