

# Stratanalysis Document

## *Novartis Launches New Multiple Sclerosis Drug*

Stratanalysis  
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# Novartis Launches New MS Drug

## FDA Approves Extavia For Relapsing MS

Novartis'  
Extavia  
Approved for  
Relapsing MS

- FDA has approved Extavia (interferon  $\beta$ -1b), the first in a new planned portfolio of multiple sclerosis (MS) medicines from Novartis
  - The drug has been approved for the treatment of relapsing forms of MS to reduce the frequency of clinical exacerbations
  - It is also indicated for patients who have experienced a first clinical episode of MS and have features consistent with the disease as shown by MRI
- Novartis gained the rights to seek approval for its own branded version of interferon  $\beta$ -1b through agreements with Bayer Schering, the company that markets Betaseron
- Extavia will be available to patients in the US by September 2009
- Novartis plans to provide Extavia patients access to a support program including a nurse helpline, one-on-one injection training and reimbursement support services, as well as an auto-injector for drug application

Extavia  
(Interferon  $\beta$ -1b)

- Extavia is a first-line disease-modifying therapy similar to Betaseron, a branded version of interferon  $\beta$ -1b
- Efficacy data from IFNB Multiple Sclerosis Study Group:
  - Interferon  $\beta$ -1b has been shown to reduce annualized relapse rates by 34%, with patients nearly twice as likely to remain relapse-free for more than two years compared to those receiving placebo. In addition, treatment with interferon  $\beta$ -1b may slow disease progression
  - After two years, almost three-quarters of patients who experienced a single episode of neurological disease lasting 24 hours or more did not progress to clinically definite MS

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## Market Analysis for MS – Market Potential

### Market Potential

#### ➤ **Global Market:**

- The MS market is expected to increase from the present global prevalence of 2.5 MM (World Health Organization estimates)
  - The prevalence and onset of MS in children and adults is expected to rise steadily
  - Global sales for MS therapies will rise accordingly, because of epidemiological, healthcare and commercial drivers
- Growth opportunity due to predicted rise in treated patient percentage from 36% in June 2009 to 56% by 2014
  - Launch of new oral MS therapies is expected to boost the treated patient percentage. The injectables market is big but their side effects could boost the potential of the oral drugs to succeed

➤ **Growth Rate:** The market for MS treatments has grown 15% globally since 2004 and continued double-digit growth is expected in the near term

➤ **Value of Market:** The MS market had total global revenues of over USD 6BN in 2008. Global annual revenues for MS are expected to exceed USD 9BN during the latter half of the coming decade

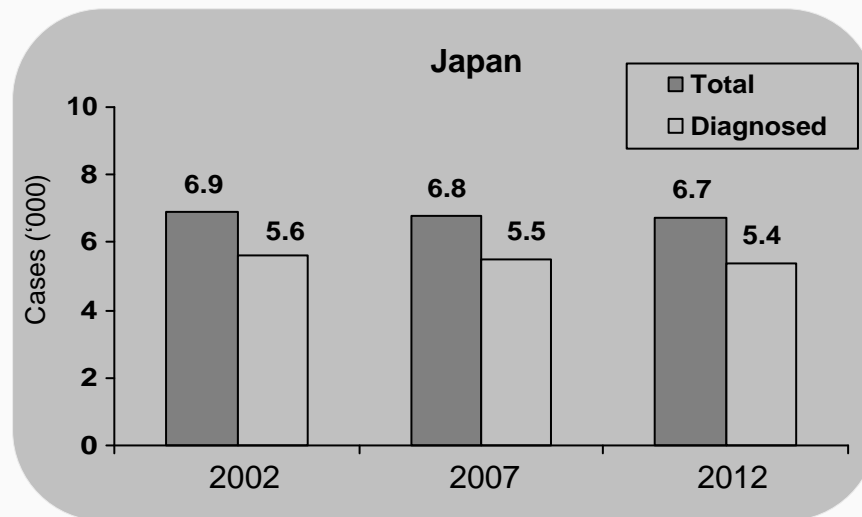
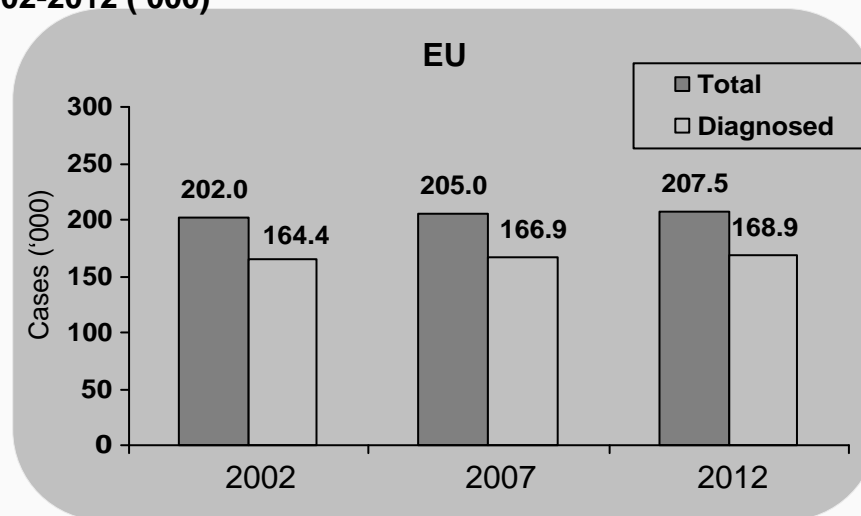
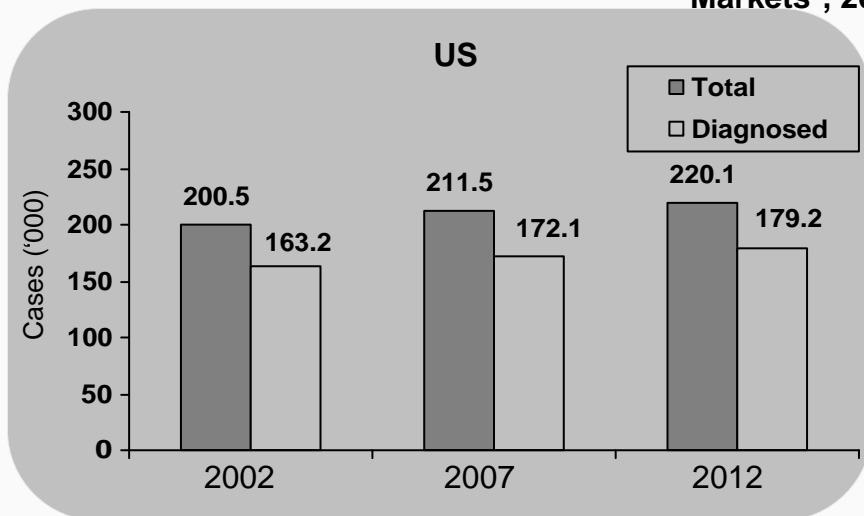
➤ **US Market:** Approximately 250,000-350,000 patients in the US are affected by MS, of whom more than 65% have relapsing-remitting MS. It is one of the most common causes of neurological disability in young adults in the region

Source: Novartis Press Release, Pharma Licensing, News Wire Today, National Institute of Neurological Disorders and Strokes, Decision Resources Pharmacor Report: Cognos May 2002

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## Market Analysis for RRMS – Regional Diagnosed and Total Cases

Total and Diagnosed Prevalent Cases of Relapsing-Remitting Multiple Sclerosis in Major Pharmaceutical Markets<sup>1</sup>, 2002-2012 ('000)

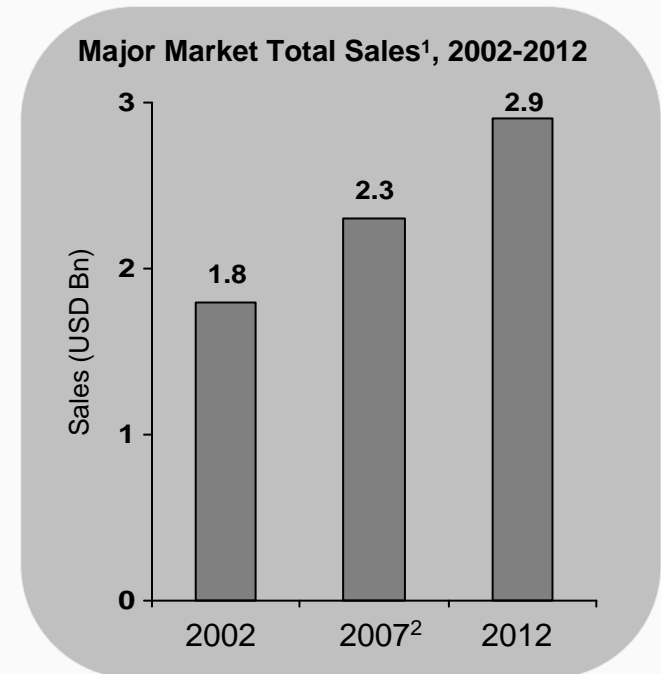
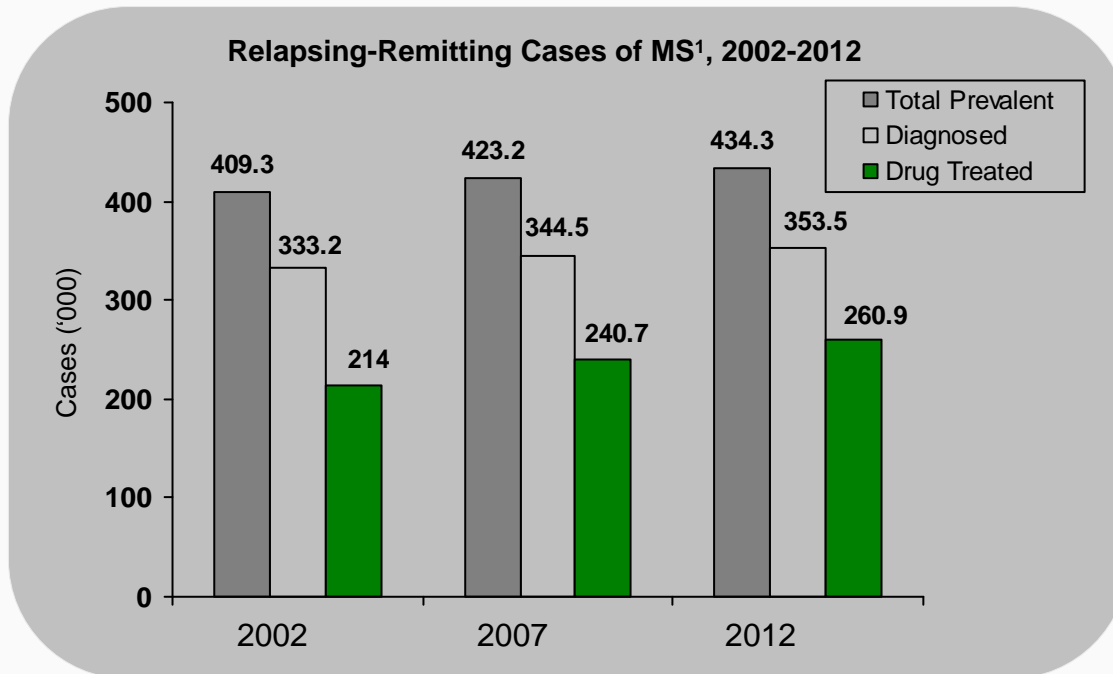


Note: <sup>1</sup>As predicted in 2004

Source: Decision Resources Report: Multiple Sclerosis March 2004

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## Market Analysis for MS – Relapsing-Remitting Type (RRMS)



- About 85% of people have RRMS at the time of diagnosis, which comprises a USD 2.9 Bn market as of 2012
- Current drugs for MS cater mostly to the relapsing-remitting type of MS (Avonex, Betaseron, Copaxone) and in some cases of progressive relapsing types (Betaseron)
  - **Novartis' drug, Extavia, has been approved by the FDA for RRMS**

Note: <sup>1</sup>As predicted in 2004; <sup>2</sup>Actual Global Revenue in 2008 was USD 8 BN and Stratanalysis is of the view that USD 2.3 BN was an underestimated figure for major markets

Source: Decision Resources Report: Multiple Sclerosis Relapsing-Remitting March 2004

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## Market Analysis for MS – US Epidemiology

- **Prevalence:** There is estimated to be 250,000-350,000 cases of MS in the US. There is no definitive evidence that the rate of MS is generally on the increase
- **Age:** Most people are diagnosed between the ages of 20 and 50, although MS can occur in young children and significantly older adults
- **Genetic factors:** The average person in the US has about a one in 750 chance of developing MS. But first-degree relatives of people with MS, such as children, siblings or non-identical twins, have a higher chance — ranging from one in 100 to one in 40. The identical twin of someone with MS, who shares all the same genes, has a one in 4 chance of developing the disease
- **Gender:** MS prevalence rate is higher in women than men (MS is at least two to three times more common in women than in men) but the cause of the disease has not been found. MS is the fourth leading cause of disability among American women
- **Ethnicity:** MS is more common among Caucasians (particularly those of northern European ancestry) than other ethnic groups, but people of African, Asian, and Hispanic ancestry also develop the disease
- **Clusters:** Certain outbreaks or “clusters” of MS have been identified, but the cause and significance of these outbreaks is not known

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## Current Drugs Evaluation

Drug	Avonex	Betaseron	Copaxone
Approval Year	1996	1993	1996
Company	Biogen	Schering	Teva
Functionality	<ul style="list-style-type: none"> <li>- Avonex (interferon <math>\beta</math>-1a) is a copy of interferon-<math>\beta</math>, which is a protein component that your body makes</li> <li>- It works by reducing the immune response that can attack nerve cells in your body</li> </ul>	<ul style="list-style-type: none"> <li>- Betaseron (interferon <math>\beta</math>-1b) is a medication made from interferon <math>\beta</math>, which is a protein component that your body makes</li> <li>- It works by reducing the immune response that can attack nerve cells</li> </ul>	<ul style="list-style-type: none"> <li>- Copaxone (glatiramer acetate) is a compound made up of amino acids</li> <li>- Amino acids are thought to help switch the immune system from causing inflammation around lesions to reducing inflammation</li> </ul>
Type of MS	Relapsing-remitting MS and sometimes for people suspected to have MS	Relapsing-remitting and progressive-relapsing	Relapsing-remitting
Effectiveness	Reduces the relapse rate by 30%	Reduces the relapse rate by 30%	Reduces the relapse rate by 30%
Application (Mode and Frequency)	Intramuscular injection once a week	Subcutaneous injection every day	Subcutaneous injection every day
Co-morbidities	Cannot be used in pregnancy, depression, anxiety, trouble sleeping, thyroid problems, blood problems seizures, heart problems or liver disease	Cannot be used in pregnancy. Routine blood tests may be used to monitor liver, thyroid and blood counts	Cannot be used in pregnancy
Side Effects	<ul style="list-style-type: none"> <li>- Flu-like symptoms during the initial weeks. These symptoms may continue longer</li> <li>- Less common are depression and liver dysfunction</li> </ul>	<ul style="list-style-type: none"> <li>-Flu-like symptoms during the initial weeks</li> <li>-Injection site reactions including swelling, redness, and pain</li> <li>- Can also cause depression</li> </ul>	<ul style="list-style-type: none"> <li>- Injection site reactions may occur, including swelling, redness and pain. Injection sites must be rotated</li> </ul>

Source: Company websites, BNET news

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## Stratanalysis Viewpoints and Analysis

### Advantage Novartis

- The aim of the deal for Novartis is to gain experience in the MS marketplace for the **future launch of the MS drug FTY720** (currently in Phase III trials) and build a sales force and start meeting MS doctors and nurses before the anticipated launch
  - Results of an ongoing Phase II study extension of the drug demonstrate sustained benefits in patients with relapsing MS – 68-73% of patients in the study remained free from relapses after three years of continuous treatment
- *“It’s a way to build a strong commercial organization and a strong medical organization ahead of FTY”* - Novartis pharmaceuticals chief Joe Jimenez

### Drug Differentiation

- Novartis hopes to differentiate Extavia by offering patients extra support, including one-on-one training on how to use a self-injector, and some financial assistance if a patient can’t get insurance to cover Extavia

### Bayer Schering’s Benefit

- Novartis is paying Bayer royalties on the sales of Extavia, the rights of which it got through a deal stemming from its 2006 acquisition of Chiron

### Market Impact

- Novartis aims for at least USD 1 BN in annual sales for its multiple sclerosis franchise (Betaseron generated USD 426 MM in sales for Bayer in the first quarter of 2009)
- The deal would lay the foundations for companies such as Novartis providing innovative and more effective approaches to MS care in this rapidly growing market

Website: [www.stratanalysis.com](http://www.stratanalysis.com)

Phone:  
+44 7950 324483

EMAIL:  
[hari@stratanalysis.com](mailto:hari@stratanalysis.com)

SKYPE ID: harithrividramji

**Thank You**

