Rheumatology Therapeutics Market to 2018
Increasing Uptake of Benlysta, Uloric, Krystexxa, and the Launch of Oral Tofacitinib to Spur Growth

GBI Research
Global Business Intelligence
GBI Research Report Guidance

- Chapter 3 provides an overview of the global rheumatologic disorders market, including the estimated market size of the global rheumatology market, and the market forecast until 2018. This section also deals with the Annual Cost of Treatment (ACT) for Musculoskeletal Disorders (MSDs).

- Chapter 4 describes the geographical landscape of the rheumatologic disorders therapeutics market. This section includes a revenue analysis of the major geographies in the market, such as the US, the top five countries of Europe and Japan, and a brief overview of the MSD market in the Asia-Pacific region.

- Chapter 5 deals with the therapeutic landscape for rheumatoid arthritis, osteoarthritis, gout and SLE. This section provides data on the revenues, annual cost of treatment, treatment usage patterns and growth drivers and restraints for each respective indication.

- Chapter 6 provides a detailed product pipeline analysis of the molecules at various stages of clinical development. It also contains detailed analysis of the key pipeline products and most promising drugs in the pipeline.

- Chapter 7 details the competitive landscape with an examination of the top companies in the market.

- Chapter 8 on strategic consolidations and partnerships, analyzes recent M&A deals, licensing deals and co-development deals that took place in the rheumatologic disorders therapeutics market.
Rheumatology Therapeutics Market to 2018 - Executive Summary

Rheumatology Therapeutics Market Set to Witness Modest Growth in the Forecast Period

The rheumatology therapeutics market is expected to increase at a modest Compound Annual Growth Rate (CAGR) of XX% during the forecast period, primarily due to the patent expiries of Celebrex (celecoxib) and Uloric (febuxostat) in 2014. While the entry of biosimilars after the patent expiry of key drug Remicade (infliximab) in 2016 could act as a barrier to the growth of the market, the expected launch of tofacitinib in 2013 for the treatment of Rheumatoid Arthritis (RA) will have a positive impact on the growth of the market. Tofacitinib is a first-in-class oral Disease-Modifying Antirheumatic Drug (DMARD) intended for RA, and has received a positive recommendation from the FDA (Food and Drug Administration) advisory committee in May 2012. The drug is expected to be reviewed by the FDA in November 2012. Benlysta (belimumab) is expected to be another blockbuster drug in the rheumatology therapeutics market. Krystexxa (pegloticase), approved for the treatment of refractory gout, is expected to reach peak sales of $XXm by 2015. Increasing market acceptance of Benlysta, Uloric and Krystexxa, and the expected launch of oral Tofacitinib, will drive the market growth. The entry of biologics such as Arcalyst (rilonacept) is expected in the gout market, and will act as a key driver of the market.

### Rheumatology Therapeutics Market, Global, Revenue Forecasts ($bn), 2005, 2011 & 2018

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2 Rheumatology Therapeutics Market to 2018 - Introduction

2.1 Introduction

Many individuals will experience musculoskeletal pain during their lifetime. The disorder may be mild, moderate of chronic. Some rheumatologic disorders can cause long-term disability, while most will have some influence on the quality of life of individuals. Rheumatologic disorders account for a major share of healthcare expenditure, which involves direct and indirect costs. Indirect costs involve loss of employment/pay/revenues due to rheumatologic disorders. Chronic rheumatologic disorders such as osteoarthritis are more prevalent in elderly patient groups. Some of the most common types of disorder within rheumatology include osteoarthritis, rheumatoid arthritis and low back pain. Rheumatologic disorders are the second most common reason for a patient to visit a physician, and constitute about XX-XX% of visits to primary care centers. Rheumatologic disorders are known to be associated with long-term disability.

Rheumatology disorders are common chronic diseases in the US, with more than XX% of the US population is affected by some form of arthritis (Naguib, 2003). The rheumatoid arthritis market accounted for XX% of the market share in the rheumatology therapeutics market in 2011, while the osteoarthritis market accounted for XX% and gout therapeutics accounted for XX% of the market. The SLE market holds about XX% of the market share in the total rheumatology therapeutics market. The rheumatology therapeutics market is expected to witness a moderate growth rate of XX% during the forecast period.

In this report, GBI Research has studied Rheumatoid Arthritis (RA), Osteoarthritis (OA), Systemic Lupus Erythematosus (SLE) and gout, as these diseases are the most prevalent forms of rheumatologic diseases.
3.1.1 Revenue

GBI research estimates that the overall rheumatology therapeutics market was worth $XX billion in 2011.

Figure 1: Rheumatology Therapeutics Market, Global, Revenue Forecasts ($bn), 2005-2018

<table>
<thead>
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<th>Year</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
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GBI Research has covered RA, OA, SLE and gout as these are the most prevalent rheumatologic diseases. GBI Research estimates that the overall rheumatology therapeutics market was worth $XX billion in 2011, representing a Compound Annual Growth Rate (CAGR) of XX% between 2005 and 2011. The global rheumatology therapeutics market is expected to grow at a CAGR of XX% between 2011 and 2018, to reach $XX billion by 2018.

The rheumatoid arthritis market accounted for XX% of the market share in the total rheumatology therapeutics market in 2011, while the OA market accounted for XX% and gout therapeutics accounted for XX% of the total market share. The SLE market holds about XX% of the market share in the total rheumatology therapeutics market.

The rheumatology therapeutics market is going to witness a moderate growth rate of XX% in the forecast period. It is expected that the launch of tofacitinib in 2013 for the treatment of RA will have a positive impact on the growth of the market. Benlysta is considered to be another blockbuster drug in the rheumatology therapeutic market. The launch of Benlysta in 2011 in the US and Europe will drive the rheumatology market. Krystexxa is approved for the treatment of refractory gout, and is expected to reach peak sales of $XXm by 2015. An increase in the global geriatric population will act as a driver for the rheumatology market. The patent expiries of Celebrex and Uloric in 2014 will have a negative impact on the growth of the market. The entry of biosimilars after the patent expiry of key drugs Enbrel and Remicade in around 2016-2017 will act as a barrier to the growth of the market.
Licensing agreements and acquisitions were the most common type of deal agreements that occurred between 2007 and April 2012. Licensing agreements formed about XX% of total deals, while acquisitions accounted for XX% of total deals. Some of the major licensing agreements which occurred during 2007-2012 were AstraZeneca’s licensing agreement with Rigel Pharma, Alder Biopharmaceuticals’ agreement with Bristol-Myers Squibb, and Incyte’s agreement with Eli Lilly. Some of major acquisitions in the rheumatology therapeutics market were the acquisition of Ardea Biosciences by AstraZeneca for $XX billion and the acquisition of URL by Takeda for $XXm.

### Figure 44: Rheumatology Therapeutics Market, Global, Deals by Type of Agreement (%), 2007-2012

![Pie Chart: Deals by Type of Agreement](chart.png)

Source: GBI Research’s Proprietary Deals Database [Accessed on: June 18, 2012]

### Table 59: Rheumatology Therapeutics Market, Global, Deals by Type of Agreement (%), 2007-2012

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<td>Partnership Agreements</td>
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Source: GBI Research’s Proprietary Deals Database [Accessed on: June 18, 2012]
9  Rheumatology Therapeutics Market - Appendix

9.1  Market Definitions

- Prevalence population: the prevalence population is the estimated number of people at any given point in time who are affected by musculoskeletal disorders.
- Diagnosis rate and population: the diagnosis rate is the percentage of the prevalence population that is diagnosed with musculoskeletal disorders; the diagnosis population refers to the number of people that are diagnosed with musculoskeletal disorders.
- Prescription rate and population: the prescription rate is the percentage of the diagnosed population that is prescribed medication for musculoskeletal disorders; the prescription population refers to the number of people that are on medication for musculoskeletal disorders.

9.2  Abbreviations

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<th>Acronym</th>
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<tr>
<td>ACT</td>
<td>Annual Cost of Treatment</td>
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<td>CAGR</td>
<td>Compound Annual Growth Rate</td>
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<td>EULAR</td>
<td>European League Against Rheumatism</td>
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<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>GUAES</td>
<td>The Gout and Uric Acid Education Society</td>
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<tr>
<td>IND</td>
<td>Investigational New Drug</td>
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<tr>
<td>MSU</td>
<td>Monosodium Urate</td>
</tr>
<tr>
<td>M&amp;A</td>
<td>Mergers and Acquisitions</td>
</tr>
<tr>
<td>NCBI</td>
<td>National Centre for Biotechnology Information</td>
</tr>
<tr>
<td>NIBR</td>
<td>Novartis Institutes for Biomedical Research</td>
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<tr>
<td>NSAID</td>
<td>Non-Steroidal Anti-Inflammatory Drugs</td>
</tr>
<tr>
<td>OA</td>
<td>Osteoarthritis</td>
</tr>
<tr>
<td>RA</td>
<td>Rheumatoid Arthritis</td>
</tr>
<tr>
<td>S-UA</td>
<td>Serum Uric Acid</td>
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<tr>
<td>ULD</td>
<td>Urate Lowering Drug</td>
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9.3  Bibliography


9.4 Research Methodology

GBI Research's dedicated research and analysis teams consist of experienced professionals with a pedigree in marketing, market research and consulting, with backgrounds in the pharmaceutical 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 group (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 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).

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 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
- Procedure registries
- 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 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, 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 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
- 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

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, 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.
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.

\[
\text{Sales} = \text{Volume of units sold} \times \text{Price per unit}
\]

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 percentage of the population diagnosed with a disease (the diagnosis population). The diagnosis population is the population diagnosed with a disease expressed as a percentage of the prevalence. The prevalence of a disease (diseased population) is the percentage of the total population who suffer from a disease/condition.

Data on treatment seeking rates, diagnosis rates and prescription rates, 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.

The ACT 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, 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.

**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, the technology available, patient access to these diagnostic tests, and the 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. The 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 the cost of drug treatment.

9.5.2 Market Size by Geography

The treatment usage pattern and ACT in each country has been factored in while deriving the individual country market size.

**Forecasting Model for Therapeutic Areas**

**Figure 47: GBI Research Market Forecasting Model**

<table>
<thead>
<tr>
<th>Disease Population</th>
<th>GBI Research Market Sizing Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Population</td>
<td></td>
</tr>
<tr>
<td>Qualifying condition 1 (Age/Sex/Occupation etc)</td>
<td>743,535,048</td>
</tr>
<tr>
<td>Qualifying condition 2 (Age/Sex/Occupation etc)</td>
<td></td>
</tr>
<tr>
<td>Prevalence tissue valve disease 0.2%</td>
<td>1,784,484</td>
</tr>
<tr>
<td>Qualifying condition (complication, severity)</td>
<td></td>
</tr>
<tr>
<td>Diseased Population</td>
<td>1,784,484</td>
</tr>
</tbody>
</table>

**Treatment Flow Patterns**

| Treatment Seeking Rate (Symptoms/Disease 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 liability) |                                   |
| ASP for Cost of Therapy |                                   |

**TOTAL PATIENT VOLUMES**

| Product Purchase Frequency | 1 |
| TOTAL UNIT VOLUMES |                                   |

**Pricing per Unit**

| $ 1,800 |

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 percentage of general population, and the diagnosed population as a percentage 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.

Articles are used from research journals and agency publications, such as the American Academy of Pain Medicine, American Pain Society, American Chronic Pain Association, British Medical Journal, New England Journal of Medicine, Cancer Association, Fibromyalgia Association, Arthritis Association, National Institute of Health and clinicaltrials.gov. The marketed drugs section is constructed from company websites and internal databases.

9.6 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.

Articles are used from research journals and agency publications, such as the American Academy of Pain Medicine, American Pain Society, American Chronic Pain Association, British Medical Journal, New England Journal of Medicine, Fibromyalgia Association, Arthritis Association, National Institute of Health and clinicaltrials.gov. The marketed drugs section is constructed from company websites and internal databases.

9.7 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.

9.8 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 M&A, licensing deals and co-development deals related to the market. This section is sourced from the companies’ websites 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 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.
9.10  Disclaimer

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