

The Future of Monoclonal Antibodies Market – Market Forecasts to 2015, Competitive Benchmarking, Product Pipeline and Deals Analysis

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MABs are one of the fastest growing segments in the pharmaceutical industry. In 2008, MABs recorded sales worth \$27.4 billion indicating a growth rate of 23.9% over 2007.

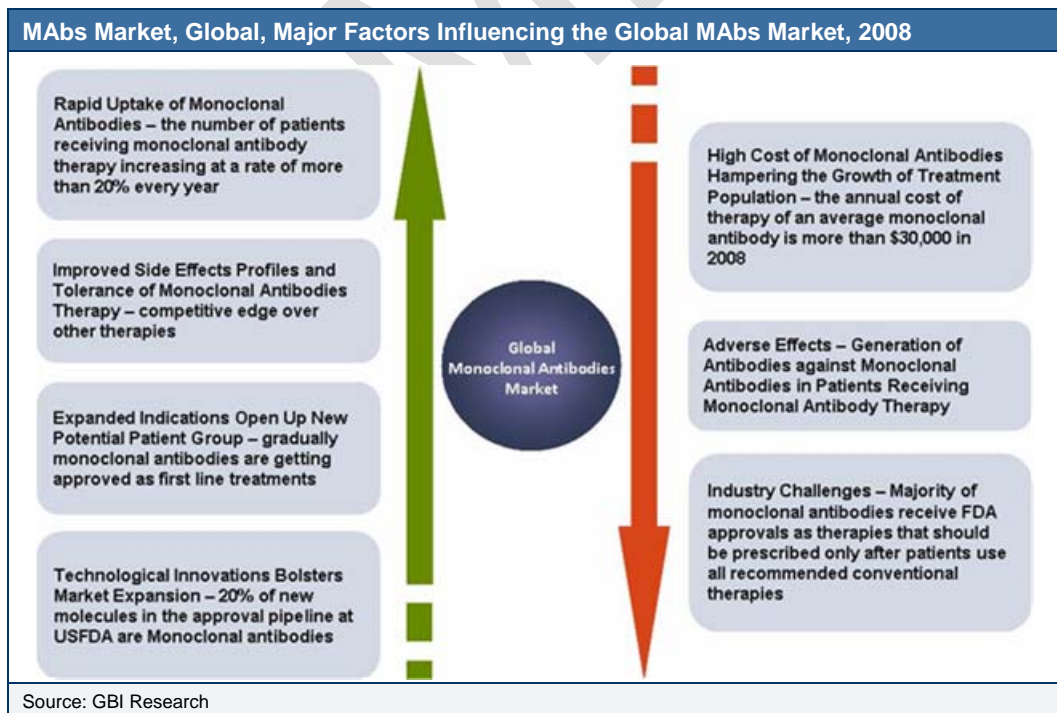
Global Monoclonal Antibodies Market: Executive Summary

Monoclonal Antibodies (MABs) was the fastest growing segment of the global pharmaceutical market in 2008. Application of MABs ranges from various oncology indications to autoimmune diseases. Gradually, MABs are beginning to pave their way into the treatment of Central Nervous System (CNS) disorders such as Alzheimer’s disease and metabolic disorders such as Diabetes. Since the launch of Orthoclone OKT3 in 1992, 23 MABs have been launched in the US market.

High unmet needs associated with the conventional therapies have compelled patients to switch over to the more effective and safer MABs.

GBI Research finds that conventional therapies such as chemotherapies, hormonal therapies and NSAIDs have a long history of poor safety profile due to their systemic-action characteristics. Further, due to their systemic action, they failed to impart the desired effect at the site of action. These unmet needs have propelled researchers to develop MABs, which specifically target the site of action. Due to this competitive advantage, MABs are preferred over conventional therapies in disease conditions, which require drug action at specific targets.

The utilization of MABs increased over the last few years due to increased awareness of these drugs among physicians and patients. In addition, successful MABs such as Rituxan, Avastin and Remicade have received regulatory approvals for multiple indications, which further increased the patient base. New MABs that have been launched into the market over the last couple of years such as Simponi and Ilaris have opened up new patient bases. Simponi is indicated for patients diagnosed with active psoriatic arthritis and active ankylosing spondylitis. Similarly, Ilaris is indicated for patient’s cryopyrin-associated periodic syndromes.



Therefore, GBI Research foresees huge market potential associated with MABs.

1 Table of Contents

1 Table of Contents 4

1.1 List of Tables 8

1.2 List of Figures 10

2 Global Monoclonal Antibodies Market: Introduction 13

2.1 GBI Research Report Guidance 14

3 Global Monoclonal Antibodies Market: Market Characterization 15

3.1 Introduction 15

3.2 Revenue Forecasts for the Global MABs Market Potential 15

3.2.1 MABs Treatment Potential 15

3.2.2 Drug Prices 17

3.2.3 Market Potential 18

3.2.4 Market Potential Segmentation 19

3.3 Revenue Forecasts of Global MABs Market – Actual Market 20

3.3.1 MABs Actual Treatment Population 20

3.3.2 Actual Sales 21

3.3.3 Actual Sales Segmentation 22

3.4 Treatment Usage Patterns 24

3.5 Global MABs Trends 25

3.5.1 Market Trends 25

3.5.2 Technology Trends 26

3.6 Product Trends 26

3.6.1 Research and Development Focus Shifted Towards Humanized and Fully Humanized MABs 26

3.7 Global MABs Market Drivers 27

3.7.1 Gradual Growth in the Uptake of MABs Have Driven the Monoclonal Antibody Sales Growth 27

3.7.2 Improved Side-effect Profiles and Tolerance of MABs Therapy 27

3.7.3 Lack of Effective Conventional Therapies Accelerates Utilization of MABs 27

3.7.4 Expanded Indications Opens up New Potential Patient Group 28

3.7.5 Lack of Generics Augmented the Sales Growth of MABs 28

3.8 Global MABs Market Restraints 28

3.8.1 High Cost of MABs Hampering the Growth of Treatment Population 28

3.8.2 Adverse Effects – Generation of Antibodies against MABs in Patients Receiving Monoclonal Antibody Therapy 28

3.8.3 Industry Challenges – Majority of MABs Receive Approvals as Last Option Therapies 29

3.9 Unmet Needs 29

3.9.1 The High Cost of MAb Therapies is the Major Unmet Need and it is Also Responsible for Low Utilization by Patients 29

3.9.2 MABs Do Not Cure the Disease; They either Treat Signs and Symptoms or Decelerate Cell Proliferation 29

4 Global MABs Market Potential: Therapeutic Distribution 30

4.1 MABs Market Potential in HER2 Breast Cancer (Adjuvant and Metastatic) 30

4.1.1 Introduction 30

4.1.2 Prescription Population 32

4.1.3 Annual Cost of Therapy 33

4.1.4 Market Potential 34

4.2 MABs Market Potential in Bone Metastases and Bone Loss Due to Cancer Therapy 35

4.2.1 Introduction 35

4.2.2 Prescription Population 36

4.2.3 Annual Cost of Therapy 37

4.2.4 Market Potential 38

4.3 MABs Market Potential in Relapsing-remitting Multiple Sclerosis (RRMS) 39

4.3.1 Introduction 39

4.3.2	Prescription Population.....	41
4.3.3	Annual Cost of Therapy.....	42
4.3.4	Market Potential	43
4.4	MAbs Market Potential in Metastatic Non-Small Cell Lung Cancer (NSCLC)	44
4.4.1	Introduction.....	44
4.4.2	Prescription Population.....	46
4.4.3	Annual Cost of Therapy.....	46
4.4.4	Market Potential	47
4.5	MAbs Market Potential in Rheumatoid Arthritis	48
4.5.1	Introduction.....	48
4.5.2	Prescription Population.....	50
4.5.3	Annual Cost of Therapy.....	51
4.5.4	Market Potential	52
5	Global MAbs Market: Pipeline Analysis	54
5.1	Introduction	54
5.2	MAbs Nomenclature.....	54
5.3	Monoclonal Antibody Technology	55
5.4	Applications of MAbs.....	56
5.4.1	Detection Assays.....	56
5.4.2	Purification Techniques	56
5.4.3	Gene Identification	56
5.4.4	Applied Chemistry	56
5.4.5	Disease Therapy	57
5.5	Therapeutic Applications in Oncology	57
5.5.1	Introduction.....	57
5.5.2	Marketed Therapies.....	57
5.5.3	Therapies in Late Stage Pipeline.....	63
5.6	Therapeutic Applications in Autoimmune and Inflammatory Diseases	67
5.6.1	Introduction.....	67
5.6.2	Marketed Therapies.....	67
5.6.3	Therapies in Late Stage Pipeline.....	72
5.7	Therapeutic Applications in Respiratory Diseases	75
5.7.1	Introduction.....	75
5.7.2	Marketed Therapies.....	75
5.7.3	Therapies in Late Stage Pipeline.....	76
5.8	Therapeutic Applications in Infectious Diseases	76
5.8.1	Introduction.....	76
5.8.2	Marketed Therapies.....	77
5.8.3	Therapies in Pipeline	77
5.9	Therapeutic Applications in Organ Transplantation.....	78
5.9.1	Introduction.....	78
5.9.2	Marketed Therapies.....	79
5.10	Therapeutic Applications in Cardiovascular Diseases.....	80
5.10.1	Introduction.....	80
5.10.2	Marketed Therapies.....	81
5.10.3	Therapies in Pipeline	82
5.11	New Indications.....	82
5.11.1	Central Nervous System.....	83
5.11.2	Diabetes	84
5.12	Insights into Most Promising Drugs	84
5.12.1	Denosumab	84
6	Global MAbs Market: M&A Landscape	87
6.1	Overview	87
6.1.1	Emergent BioSolutions acquires Avanir Pharmaceuticals.....	87

6.1.2	MacroGenics acquires Raven Biotechnologies	87
6.1.3	Thermo Fisher acquires Affinity BioReagents	88
6.2	R&D Licensing Agreements	88
6.2.1	Deals by Phase	88
6.2.2	Deals by Geography.....	88
6.2.3	Deals by Licensing Type	89
6.2.4	Deals by Value (\$).....	89
6.2.5	Preclinical.....	90
6.2.6	Phase I	91
6.2.7	Phase II	92
6.2.8	Phase III	93
6.2.9	Approved.....	93
7	Global MAb Market: Competitive Landscape	95
7.1	Evolving competitive landscape	95
7.1.1	Major players.....	95
7.1.2	Key MAbs in the Market	96
7.2	Company Benchmarking Analysis.....	97
7.3	Roche/Genentech	99
7.3.1	Key Monoclonal Antibody Drugs	101
7.3.2	Key Indications of Interest	103
7.3.3	Pipeline Analysis	104
7.4	Abbott.....	105
7.4.1	Key MAbs.....	106
7.4.2	Key Indications of Interests	107
7.4.3	Pipeline Analysis	107
7.5	Johnson & Johnson.....	107
7.5.1	Key MAbs.....	108
7.5.2	Key Indications of Interest.....	109
7.5.3	Pipeline Analysis	109
7.6	Biogen Idec	110
7.6.1	Key MAbs.....	111
7.6.2	Key Indications of Interest.....	112
7.6.3	Pipeline Analysis	112
7.7	Merck/Schering Plough	113
7.7.1	Key MAbs.....	114
7.7.2	Key Indications of Interest.....	114
7.7.3	Pipeline Analysis	115
7.8	AstraZeneca.....	116
7.8.1	Key MAbs.....	116
7.8.2	Key Indications of Interest.....	117
7.8.3	Pipeline Analysis	117
7.9	Bristol-Myers Squibb	118
7.9.1	Key MAbs.....	119
7.9.2	Key Indications of Interest.....	119
7.10	Elan.....	120
7.10.1	Key MAbs	121
7.10.2	Key Indications of Interest	121
7.10.3	Pipeline Analysis.....	122
7.11	Eli Lilly	123
7.11.1	Key Monoclonal Antibody Drugs.....	124
7.11.2	Key Indications of Interests.....	124
7.11.3	Pipeline Analysis.....	125
7.12	Amgen.....	125
7.12.1	Key Monoclonal Antibody Drugs.....	126

7.12.2	<i>Key Indications of Interest</i>	127
7.12.3	<i>Pipeline Analysis</i>	128
8	Global MAb Market: Appendix	129
8.1	Related Reports	129
8.2	Research Methodology	129
8.3	Geographical Scope.....	129
8.4	Coverage.....	129
8.5	Secondary Research.....	130
8.6	Primary Research	130
8.7	Models.....	131
8.8	Forecasts	131
8.9	Expert Panels.....	131
8.10	GBI Research Consulting.....	131
8.11	Contact Us	131
8.12	Disclaimer	132

SAMPLE

1.1 List of Tables

Table 1: MAbs Market, Global, MAbs Treatment Potential, 2000-2008 16

Table 2: MAbs Market, Global, MAbs Treatment Potential, 2008-2015 16

Table 3: MAbs Market, Global, Annual Cost of Therapy (\$), 2000-2008 17

Table 4: MAbs Market, Global, Annual Cost of Therapy (\$), 2008-2015 18

Table 5: MAbs Market, Global, MAbs Market Potential (\$ bn), 2000-2008 19

Table 6: MAbs Market, Global, MAbs Market Potential (\$ bn), 2008-2015 19

Table 7: MAbs Market, Global, MAbs Actual Treatment Population, 2000-2008 21

Table 8: MAbs Market, Global, MAbs Actual Treatment Population, 2008-2015 21

Table 9: MAbs Market, Global, Actual Sales (\$ bn), 2000-2008 22

Table 10: MAbs Market, Global, Actual Sales (\$ bn), 2008-2015 22

Table 11: MAbs Market, Global, Actual Sales Segmentation (\$ bn), 2000-2008 24

Table 12: MAbs Market, Global, Actual Sales Segmentation (\$ bn), 2008-2015 24

Table 13: MAbs Market, Global, HER2+ Breast Cancer, Prescription Population, 2000-2008 32

Table 14: MAbs Market, Global, HER2+ Breast Cancer, Prescription Population, 2008-2015 33

Table 15: MAbs Market, Global, HER2+ Breast Cancer, Annual Cost of Therapy (\$), 2000-2008 33

Table 16: MAbs Market, Global, HER2+ Breast Cancer, Annual Cost of Therapy (\$), 2008-2015 33

Table 17: MAbs Market, Global, HER2+ Breast Cancer, Market Potential (\$ bn), 2000-2008 34

Table 18: MAbs Market, Global, HER2+ Breast Cancer, Market Potential (\$ bn), 2008-2015 34

Table 19: MAbs Market, Global, Bone Metastasis and Bone Loss, Prescription Population, 2009-2015 37

Table 20: MAbs Market, Global, Bone Metastasis and Bone Loss, Annual Cost of Therapy (\$), 2009-2015 38

Table 21: MAbs Market, Global, Bone Metastasis and Bone Loss, Market Potential (\$ bn), 2009-2015 39

Table 22: MAbs Market, Global, RRMS, Treatment Options, 2008 41

Table 23: MAbs Market, Global, RRMS, Prescription Population, 2000-2008 42

Table 24: MAbs Market, Global, RRMS, Prescription Population, 2008-2015 42

Table 25: MAbs Market, Global, RRMS, Annual Cost of Therapy (\$), 2000-2008 43

Table 26: MAbs Market, Global, RRMS, Annual Cost of Therapy (\$), 2008-2015 43

Table 27: MAbs Market, Global, RRMS, Market Potential (\$ bn), 2000-2008 43

Table 28: MAbs Market, Global, RRMS, Market Potential (\$ bn), 2008-2015 44

Table 29: MAbs Market, Global, Metastatic NSCLC, Treatment Options, 2008 45

Table 30: MAbs Market, Global, Metastatic NSCLC, Prescription Population, 2000-2008 46

Table 31: MAbs Market, Global, Metastatic NSCLC, Prescription Population, 2008-2015 46

Table 32: MAbs Market, Global, Metastatic NSCLC, Annual Cost of Therapy (\$), 2000-2008 47

Table 33: MAbs Market, Global, Metastatic NSCLC, Annual Cost of Therapy (\$), 2008-2015 47

Table 34: MAbs Market, Global, Metastatic NSCLC, Market Potential (\$ bn), 2000-2008 48

Table 35: MAbs Market, Global, Metastatic NSCLC, Market Potential (\$ bn), 2008-2015 48

Table 36: MAbs Market, Global, Rheumatoid Arthritis, Prescription Population, 2000-2008 51

Table 37: MAbs Market, Global, Rheumatoid Arthritis, Prescription Population, 2008-2015 51

Table 38: MAbs Market, Global, Rheumatoid Arthritis, Annual Cost of Therapy (\$), 2000-2008.... 52

Table 39: MAbs Market, Global, Rheumatoid Arthritis, Annual Cost of Therapy (\$), 2008-2015.... 52

Table 40: MAbs Market, Global, Rheumatoid Arthritis, Market Potential (\$ bn), 2000-2008 53

Table 41: MAbs Market, Global, Rheumatoid Arthritis, Market Potential (\$ bn), 2008-2015 53

Table 42: MAbs Market, Global, Monoclonal Antibody Nomenclature..... 55

Table 43: MAbs Market, Global, Licensing Agreements for Drugs in the Preclinical Stage, 2008-2009 91

Table 44: MAbs Market, Global, Licensing Agreements for Drugs in the Phase I, 2008-2009 92

Table 45: MAbs Market, Global, Licensing Agreements for Drugs in the Phase II, 2008-2009 93

Table 46: MAbs Market, Global, Licensing Agreements for Drugs in the Phase III, 2008-2009 93

Table 47: MAbs Market, Global, Licensing Agreements for Approved Drugs, 2008-2009..... 94

Table 48: MAbs Market, Global, Top 5 Companies Sales (\$m), 2006-2008 96

Table 49: MAbs Market, Global, Top 10 MAbs (\$m), 2006-2008 99

Table 50: MAbs Market, Global, Roche/Genentech Revenue (\$ m), 2006-2015 101

Table 51: MAbs Market, Global, Abbott Revenue (\$ m), 2006-2015 106

Table 52: MAbs Market, Global, Johnson & Johnson Revenue (\$ m), 2006-2015 108

Table 53: MAbs Market, Global, Biogen Idec Revenue (\$ m), 2006-2015 111

Table 54: MAbs Market, Global, Merck/Schering Plough Revenues (\$ m), 2006-2015..... 114

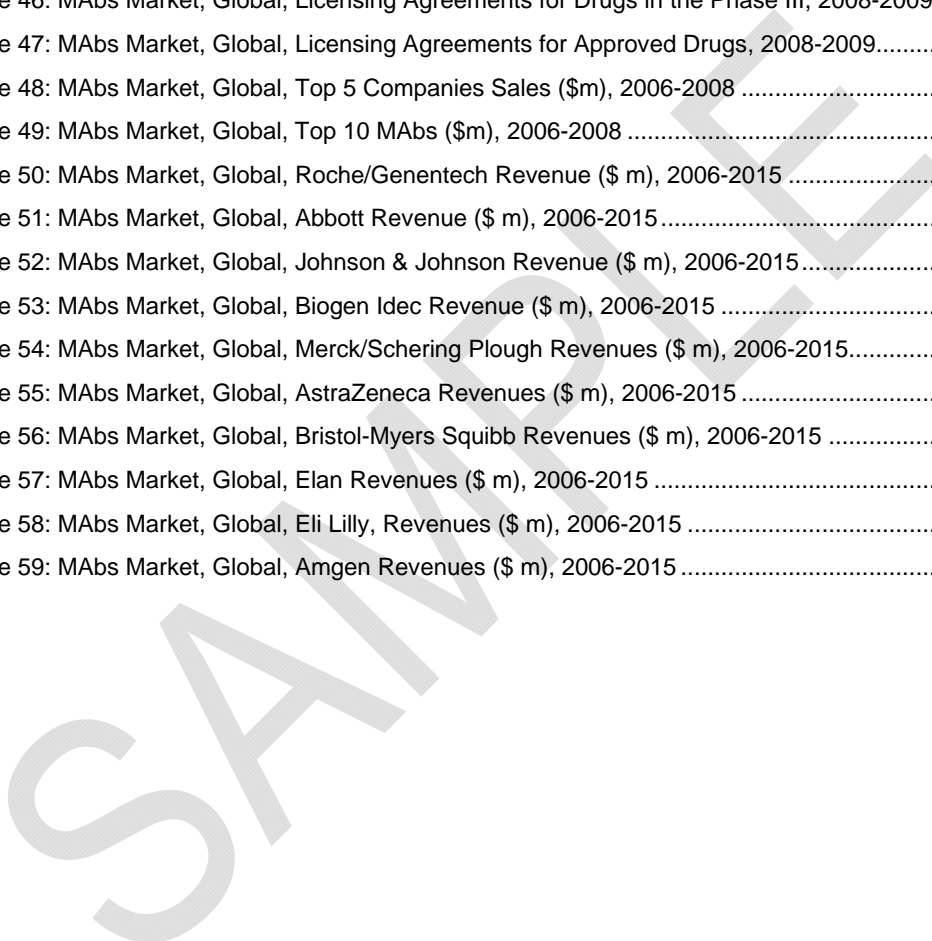
Table 55: MAbs Market, Global, AstraZeneca Revenues (\$ m), 2006-2015 116

Table 56: MAbs Market, Global, Bristol-Myers Squibb Revenues (\$ m), 2006-2015 119

Table 57: MAbs Market, Global, Elan Revenues (\$ m), 2006-2015 121

Table 58: MAbs Market, Global, Eli Lilly, Revenues (\$ m), 2006-2015 123

Table 59: MAbs Market, Global, Amgen Revenues (\$ m), 2006-2015 126



1.2 List of Figures

Figure 1: MAbs Market, Global, Major Factors Influencing the Global MAbs Market, 2008 15

Figure 2: MAbs Market, Global, MAbs Treatment Potential, 2000-15 16

Figure 3: MAbs Market, Global, Annual Cost of Therapy (\$), 2000-2015..... 17

Figure 4: MAbs Market, Global, MAbs Market Potential (\$ bn), 2000-2015 18

Figure 5: MAbs Market, Global, Market Segmentation by Disease, 2008 and 2015 20

Figure 6: MAbs Market, Global, MAbs Actual Treatment Population, 2000-2015 21

Figure 7: MAbs Market, Global, Actual Sales (\$ bn), 2000-2015 22

Figure 8: MAbs Market, Global, Actual Sales Segmentation (\$ bn), 2008 and 2015..... 23

Figure 9: MAbs Market, Global, Actual Sales Segmentation (\$ bn), 2000-2015 24

Figure 10: MAbs Market, Global, Treatment Population Trends, 2000-2015 25

Figure 11: MAbs Market, Global, MAbs Segmented by Origin, 1992-2009 26

Figure 12: MAbs Market, Global, Market Share of Key Indications, 2008 30

Figure 13: MAbs Market, Global, HER2+ Breast Cancer, Prescription Population, 2000-2015..... 32

Figure 14: MAbs Market, Global, HER2+ Breast Cancer, Annual Cost of Therapy (\$), 2000-2015 33

Figure 15: MAbs Market, Global, HER2+ Breast Cancer, Market Potential (\$ bn), 2000-2015 34

Figure 16: MAbs Market, Global, Bone Metastasis and Bone Loss, Prescription Population, 2009-2015 37

Figure 17: MAbs Market, Global, Bone Metastasis and Bone Loss, Annual Cost of Therapy (\$), 2009-2015 38

Figure 18: MAbs Market, Global, Bone Metastasis and Bone Loss, Market Potential (\$ bn), 2009-2015 39

Figure 19: MAbs Market, Global, Multiple Sclerosis, Diseased Population, 2008 40

Figure 20: MAbs Market, Global, RRMS, Prescription Population, 2000-2015 41

Figure 21: MAbs Market, Global, RRMS, Annual Cost of Therapy (\$), 2000-2015 42

Figure 22: MAbs Market, Global, RRMS, Market Potential (\$ bn), 2000-2015 43

Figure 23: MAbs Market, Global, Metastatic NSCLC, Prescription Population, 2000-2015..... 46

Figure 24: MAbs Market, Global, Metastatic NSCLC, Annual Cost of Therapy (\$), 2000-2015 47

Figure 25: MAbs Market, Global, Metastatic NSCLC, Market Potential (\$ bn), 2000-2015 48

Figure 26: MAbs Market, Global, Rheumatoid Arthritis, Prescription Population, 2000-2015..... 51

Figure 27: MAbs Market, Global, Rheumatoid Arthritis, Annual Cost of Therapy (\$), 2000-2015 ..52

Figure 28: MAbs Market, Global, Rheumatoid Arthritis, Market Potential (\$ bn), 2000-2015 53

Figure 29: MAbs Market, Global, Pipeline Segmentation by Disease, 2009 54

Figure 30: MAbs Market, Global, Oncology Pipeline, 2009 57

Figure 31: MAbs Market, Global, Autoimmune Diseases Pipeline, 2009 67

Figure 32: MAbs Market, Global, Respiratory Diseases Pipeline by Phase of Development, 2009 75

Figure 33: MAbs Market, Global, Infectious Diseases Pipeline by Phase of Development, 2009 ... 77

Figure 34: MAbs Market, Global, Organ Transplantation Pipeline by Phase of Development, 2009... 79

Figure 35: MAbs Market, Global, Cardiovascular Pipeline by Phase of Development, 2009 81

Figure 36: MAbs Market, Global, Other New Indications in Pipeline, 2009 83

Figure 37: MAbs Market, Global Major M&A Deals, 2008-2009..... 87

Figure 38: MAbs Market, Global, Major Licensing Agreements by Phase, 2008-2009..... 88

Figure 39: MAbs Market, Global, Major Licensing Agreements By Geography, 2008-2009..... 89

Figure 40: MAbs Market, Global, Major Licensing Agreements By Deal Value, 2008-2009..... 89

Figure 41: MAbs Market, Global, Top Three Companies, 2008 95

Figure 42: MAbs Market, Global, Top 5 Companies Sales Trend, 2006-2008 96

Figure 43: MAbs Market, Global, Key Target Therapies Launched, 1997-2009..... 97

Figure 44: MAbs Market, Global, Company Market Share Analysis, 2008..... 97

Figure 45: MAbs Market, Global, Company Benchmarking Analysis, 2008 98

Figure 46: MAbs Market, Global, Top 10 MAbs, 2006-2008 99

Figure 47: MAbs Market, Global, Roche/Genentech Revenue Segmentation, 2008..... 100

Figure 48: MAbs Market, Global, Roche/Genentech Revenue (\$ m), 2006-2015 101

Figure 49: MAbs Market, Global, Roche/Genentech R&D Pipeline by Therapeutic Area, June 2009. 104

Figure 50: MAbs Market, Global, Roche/Genentech Pipeline Analysis by Phase, June 2009 105

Figure 51: MAbs Market, Global, Abbott Revenue Segmentation, 2008 105

Figure 52: MAbs Market, Global, Abbott Revenue (\$ m), 2006-2015..... 106

Figure 53: MAbs Market, Global, Abbott Pipeline Analysis by Phase, June 2009..... 107

Figure 54: MAbs Market, Global, Johnson & Johnson Revenue (\$ m), 2006-2015..... 108

Figure 55: MAbs Market, Global, Johnson & Johnson R&D Pipeline by Therapeutic Area, June 2009..... 109

Figure 56: MAbs Market, Global, Johnson & Johnson Pipeline Analysis by Phase, June 2009..... 110

Figure 57: MAbs Market, Global, Biogen Idec Revenue Segmentation, 2008..... 110

Figure 58: MAbs Market, Global, Biogen Idec Revenue (\$ m), 2006-2015 111

Figure 59: MAbs Market, Global, Biogen Idec R&D Pipeline by Therapeutic Area, June 2009..... 112

Figure 60: MAbs Market, Global, Biogen Idec Pipeline Analysis by Phase, June 2009 113

Figure 61: MAbs Market, Global, Merck/Schering Plough Revenues (\$ m), 2006-2015 114

Figure 62: MAbs Market, Global, Merck/Schering-Plough R&D Pipeline by Therapeutic Area, June 2009..... 115

Figure 63: MAbs Market, Global, Merck/Schering-Plough Pipeline Analysis by Phase, June 2009..... 115

Figure 64: MAbs Market, Global, AstraZeneca Revenues (\$ m), 2006-2015 116

Figure 65: MAbs Market, Global, AstraZeneca R&D Pipeline by Therapeutic Area, June 2009 ... 117

Figure 66: MAbs Market, Global, AstraZeneca Pipeline Analysis by Phase, June 2009 118

Figure 67: MAbs Market, Global, Bristol-Myers Squibb Revenues (\$ m), 2006-2015 119

Figure 68: MAbs Market, Global, Bristol-Myers Squibb R&D Pipeline by Phase, June 2009 120

Figure 69: MAbs Market, Global, Elan Revenues (\$ m), 2006-2015 121

Figure 70: MAbs Market, Global, Elan R&D Pipeline by Therapeutic Area, June 2009..... 122

Figure 71: MAbs Market, Global, Elan Pipeline Analysis by Phase, June 2009 122

Figure 72: MAbs Market, Global, Eli Lilly, Revenues (\$ m), 2006-2015 123

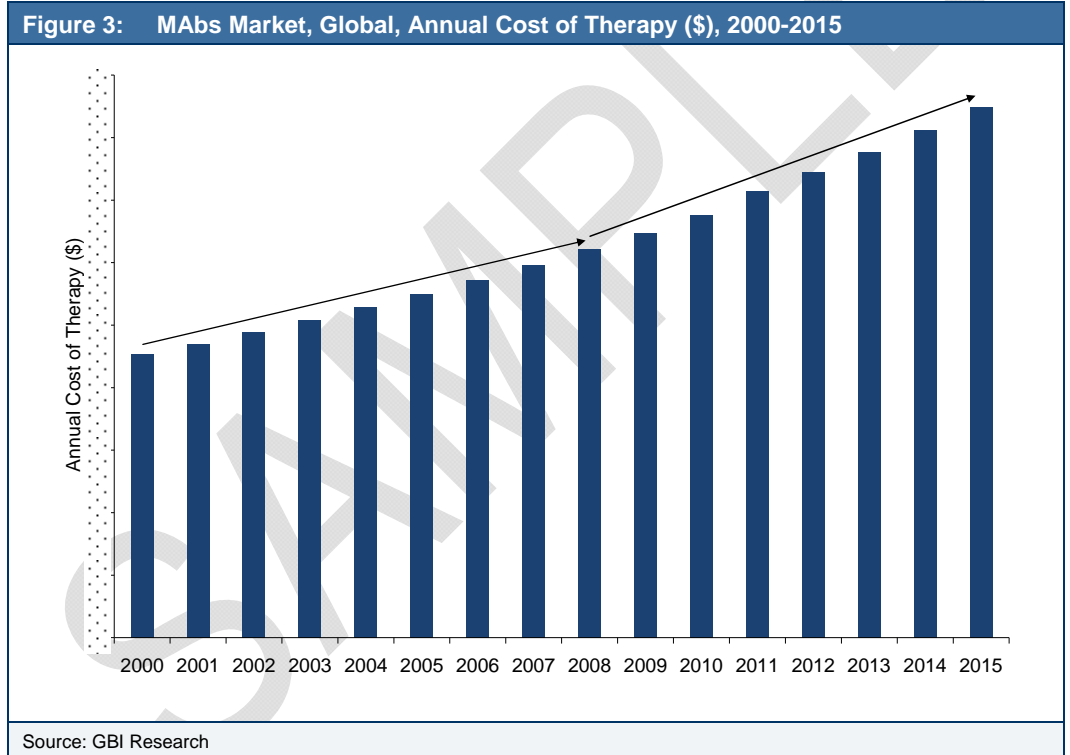
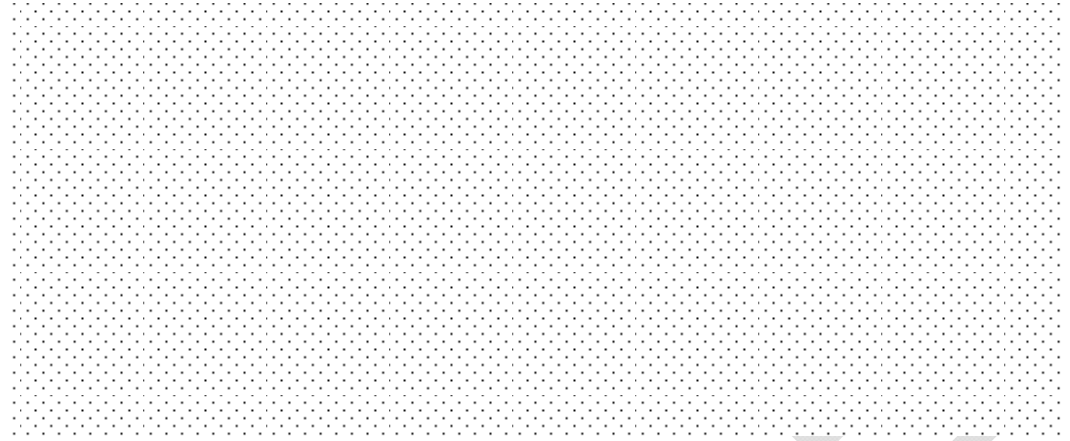
Figure 73: MAbs Market, Global, Eli Lilly R&D Pipeline by Therapeutic Area, June 2009..... 124

Figure 74: MAbs Market, Global, Eli Lilly Pipeline Analysis by Phase, June 2009 125
Figure 75: MAbs Market, Global, Amgen Revenues (\$ m), 2006-2015 126
Figure 76: MAbs Market, Global, Amgen R&D Pipeline by Therapeutic Area, June 2009 128
Figure 77: MAbs Market, Global, Amgen Pipeline Analysis by Phase, June 2009 128
Figure 78: GBI Research Methodology 129

SAMPLE

3.2.2 Drug Prices

Mabs prices are fixed at a very high level. For example, the annual cost of therapy for Soliris for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) is \$XXX. Similarly, Raptiva, which is indicated for plaque psoriasis, has an annual cost of therapy of around \$XXX. Further,



In 2008, MABs annual of cost of therapy was estimated at \$XXX indicating a CAGR of approximately XX% between 2000 and 2008. By 2015, the cost is forecast to reach \$XXX.

Table 3: MABs Market, Global, Annual Cost of Therapy (\$), 2000-2008

Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	CAGR (2000-2008)
Annual Cost of Therapy (\$)										

Source: GBI Research

3.7 Global MAb Market Drivers

3.7.1 Gradual Growth in the Uptake of MAb Have Driven the Monoclonal Antibody Sales Growth

MAbs uptake has been rapid in cancer indications such as HER over-expressing breast cancer, B-cell non-Hodgkin's lymphoma, metastatic NSCLC and metastatic colorectal cancer. In these indications, systemic therapies such as chemotherapies are also available as treatment options.

3.7.2 Improved Side-effect Profiles and Tolerance of MAb Therapy

Murine MAb were the first antibodies developed through hybridoma technology. However,

3.7.3 Lack of Effective Conventional Therapies Accelerates Utilization of MAb

Chemotherapy drugs are cytotoxic in nature. They are given either orally or through intravenous infusion. One of the serious side effects

5 Global MAb Market: Pipeline Analysis

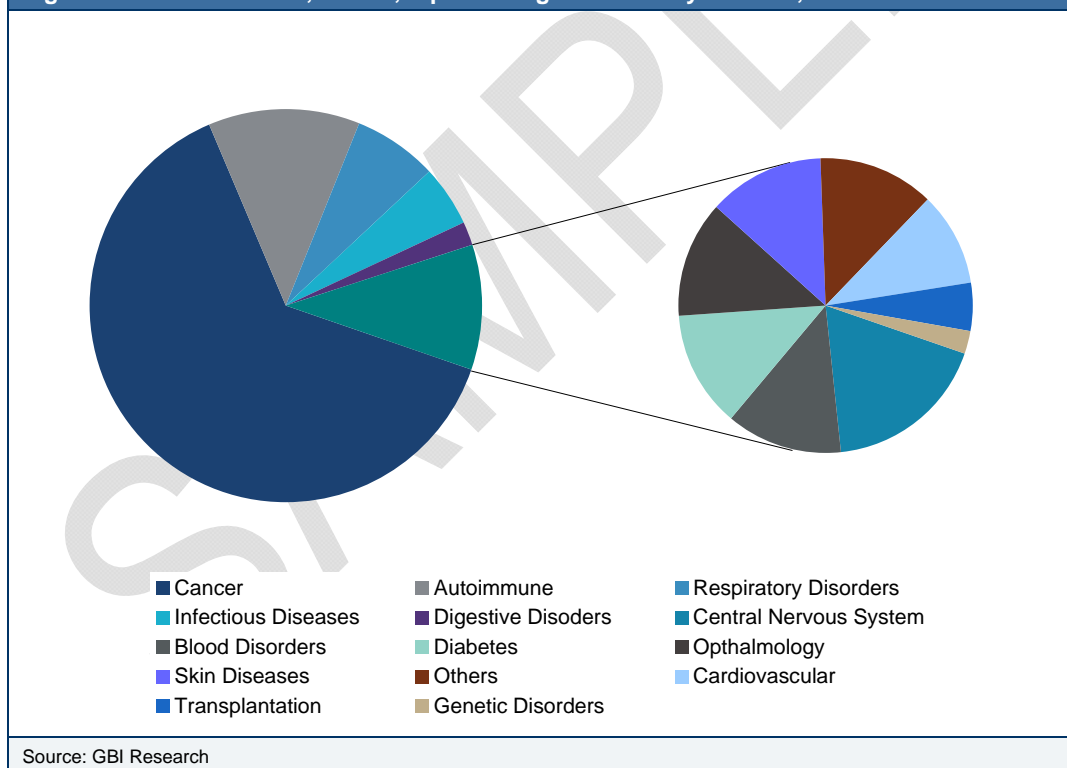
5.1 Introduction

In 2008-09, 193 Mabs are under research and development for various indications such as cancer, autoimmune diseases, and CNS and metabolic disorders.

Recent developments of MAb in immunology are paving the way for a wide range of new therapies. MABs are under clinical studies for various new indications including genetic, blood and central nervous system disorders.

In 2008-2009, approximately 193 MABs were under research and development. Approximately, 375 clinical trials are under process for these 193 MABs.

Figure 29: MABs Market, Global, Pipeline Segmentation by Disease, 2009



5.2 MABs Nomenclature

The nomenclature of MABs is the name given to identify the generic, or nonproprietary, names to MABs. This is widely used by all pharmaceutical and biotechnology companies as well as World Health Organization’s International Nonproprietary Names and the United States Adopted Names.

Affix for origin: The affix preceding -mab suffix is the animal origin of the monoclonal antibody. For human MABs, the affix -u- and for humanized monoclonal antibody the affix is -zu-

8 Global MABs Market: Appendix

8.1 Related Reports

The Future of the Biosimilars - Market Forecasts to 2015 Key and Trends

RNA Therapeutics - Strong Potential for Unmet Needs in Pharma

The Future of the Oncology Therapeutics - Market Forecasts to 2015 and Key Trends

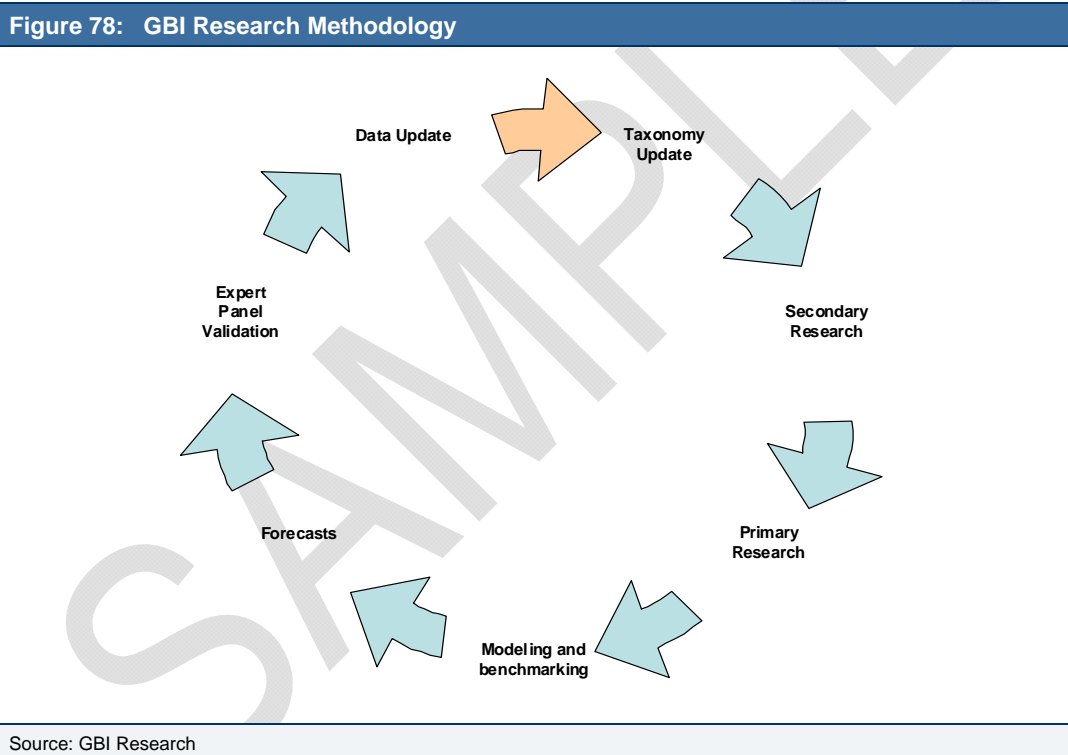
The Future of the Autoimmune Diseases Therapeutics - Market Forecasts to 2015 and Key Trends

8.2 Research Methodology

GBI Research's dedicated Research and Analysis Teams consists of experienced professionals with a pedigree in marketing, market research, consulting background 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 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.



8.3 Geographical Scope

The report covers markets across the seven major geographies the US, the UK, Germany, France, Spain, Italy and Japan. In the report, wherever "global" is mentioned it refers to these seven geographies.

8.4 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 based on 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, updated on a daily basis.

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

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

8.6 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:

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 E-mail interactions, telephonic 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 para-medics;
- 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.

8.7 Models

Where no hard data is available GBI Research uses modeling and estimates in order to produce comprehensive data sets. The following rigorous methodology is adopted:

Available hard data is cross referenced with the following data types to produce estimates:

- Demographic data: Population, split by segment;
- Macro-economic Indicators: GDP, Inflation Rate etc;
- Healthcare Indicators: Health expenditure, Physicians Base, healthcare infrastructure and facilities; and
- Selected epidemiological and procedure statistics.

Data is then cross checked by the expert panel. All data and assumptions relating to modeling are stored and are available to clients on request.

8.8 Forecasts

GBI Research uses proprietary forecast models. The following four factors are utilized in the forecast models:

- Historic growth rates;
- Macro indicators such as population trends and healthcare spending;
- Forecast epidemiological data; and
- Qualitative trend information and assumptions.

Data is then cross checked by the Expert Panel.

8.9 Expert Panels

GBI Research uses a panel of experts to cross verify its databases and forecasts.

GBI Research expert panel comprises of marketing managers, product specialists, international sales managers from medical device companies; academics from research universities, KOLs from hospitals, consultants from venture capital funds and distributors/suppliers of medical equipment and supplies etc.

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

Details of the make up of the expert panel can be viewed through GBI Research.com, and are available to clients on request.

8.10 GBI Research Consulting

We hope that the data and analysis in this brief will help you make informed and imaginative business decisions. If you have further requirements, GBI Research's consulting team may be able to help you. GBI Research offers Tailor made analytical and advisory services to drive your key strategic decisions. For more information about GBI Research's Consulting capabilities, please contact us directly at GBI Research: +1 646 395 5460 or email us at info@gbiresearch.com

8.11 Contact Us

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8.12 Disclaimer

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