

INTRODUCTION .....	xix
STUDY GOALS AND OBJECTIVES.....	xix
REASONS FOR DOING THE STUDY .....	xix
AUDIENCE FOR THE REPORT .....	xx
SCOPE AND FORMAT .....	xx
METHODOLOGY AND INFORMATION SOURCES.....	xxi
ABOUT THE AUTHOR.....	xxi
BCC INFORMATION AND RELATED BCC STUDIES.....	xxi
DISCLAIMER .....	xxii
BCC RESEARCH ONLINE SERVICES .....	xxii
BCC ONLINE SERVICES.....	xxii
DISCLAIMER .....	xxiii
EXECUTIVE SUMMARY .....	xxiv
<i>SUMMARY TABLE GLOBAL MARKET FORECAST FOR BRANDED     MEDICATIONS FOR NEURODEGENERATIVE DISORDERS,     THROUGH 2012 (\$ MILLIONS).....</i>	<i>XXIV</i>
<i>SUMMARY FIGURE GLOBAL MARKET FORECAST FOR BRANDED     MEDICATIONS FOR NEURODEGENERATIVE DISORDERS, 2006-     2012 (\$ MILLIONS) .....</i>	<i>XXV</i>
OVERVIEW .....	1
GOVERNMENT REGULATIONS .....	1
INTRODUCTION.....	1
DRUG DISCOVERY.....	2
PRECLINICAL TESTING AND SUBMISSION OF AN IND .....	3
CLINICAL TRIALS.....	4
TIMELINE AND COSTS .....	5
SUBMISSION OF AN NDA OR BLA.....	5
POST-FDA APPROVAL.....	6
NEW DRUG APPROVALS .....	7
<i>TABLE 1 DRUGS APPROVED BY THE FDA, 1993–1999.....</i>	<i>7</i>
<i>TABLE 2 DRUGS APPROVED BY THE FDA, 2000–2006.....</i>	<i>7</i>
<i>TABLE 3 NEW MOLECULAR/BIOLOGICAL ENTITIES APPROVED BY     THE FDA, 1980–2006.....</i>	<i>8</i>
CONCLUSIONS .....	9
<i>TABLE 4 NME APPROVALS FOR NEUROLOGICAL DISORDERS,     2004–2006.....</i>	<i>9</i>
Conclusions (Continued) .....	10
THE U.S. MARKETS FOR ALZHEIMER’S DISEASE MEDICATIONS.....	11
ABOUT ALZHEIMER’S DISEASE .....	11
<i>TABLE 5 GLOBAL MARKET FORECAST FOR ALZHEIMER’S     DISEASE PHARMACEUTICALS, THROUGH 2012 (\$ MILLIONS).....</i>	<i>11</i>

<i>FIGURE 1 GLOBAL MARKET FORECAST FOR ALZHEIMER'S DISEASE PHARMACEUTICALS, 2005-2012 (\$ MILLIONS)</i> .....	11
ABOUT ALZHEIMER'S DISEASE (CONTINUED).....	12
CURRENT BRANDED PHARMACEUTICALS THAT TREAT ALZHEIMER'S DISEASE.....	13
ARICEPT (DONEPEZIL HCL).....	13
<i>TABLE 6 GLOBAL MARKET FORECAST FOR ARICEPT SALES, THROUGH 2012 (\$ MILLIONS)</i> .....	13
Acetylcholinesterase Inhibitors .....	13
Generic Competition.....	14
COGNEX (TACRINE HYDROCHLORIDE) .....	15
<i>TABLE 7 GLOBAL MARKET FORECAST FOR COGNEX SALES, THROUGH 2012 (\$ MILLIONS)</i> .....	15
EBIXA, NAMENDA, AND AXURA (MEMANTINE HYDROCHLORIDE) .....	16
<i>TABLE 8 GLOBAL MARKET FORECAST FOR MEMANTINE SALES, THROUGH 2012 (\$ MILLIONS)</i> .....	16
NMDA Antagonists .....	17
Patent Protection and Second-Generation NMDA Antagonists.....	17
<i>TABLE 9 NMDA ANTAGONISTS IN CLINICAL TRIALS</i> .....	18
EXELON (RIVASTIGMINE TARTRATE) .....	18
<i>TABLE 10 GLOBAL MARKET FORECAST FOR AD-RELATED EXELON SALES, THROUGH 2012 (\$ MILLIONS)</i> .....	19
RAZADYNE (GALANTAMINE HYDROBROMIDE) .....	19
<i>TABLE 11 GLOBAL MARKET FORECAST FOR RAZADYNE SALES, THROUGH 2012 (\$ MILLIONS)</i> .....	20
COMPOUNDS IN CLINICAL TRIALS FOR AD.....	20
<i>TABLE 12 POTENTIAL AD AGENTS IN PHASE III CLINICAL TRIALS</i> .....	21
Alzhemed.....	21
Flurizan.....	22
Neramexane.....	22
Phenserine .....	22
Failed AD Candidate Drugs.....	23
COMPANY PROFILES .....	23
FOREST LABORATORIES .....	23
MEDIVATION.....	24
MERZ PHARMA GMBH & CO. KGAA.....	24
NEUROCHEM, INC. ....	25
SCIELE PHARMA, INC. ....	26
THE U.S. MARKETS FOR MEDICATIONS DIRECTED AT AMYOTROPHIC LATERAL SCLEROSIS .....	27
<i>TABLE 13 GLOBAL MARKET FORECAST FOR ALS THERAPEUTICS, THROUGH 2012 (\$ MILLIONS)</i> .....	27

<i>FIGURE 2 GLOBAL MARKET FORECAST FOR ALS THERAPEUTICS, 2005-2012 (\$ MILLIONS)</i> .....	27
THE U.S. MARKETS (CONTINUED) .....	28
ALS: BACKGROUND INFORMATION .....	29
ALS: BACKGROUND ... (CONTINUED).....	30
RILUTEK: THE SOLE FDA-APPROVED DRUG FOR ALS.....	30
<i>TABLE 14 U.S. MARKET FORECAST FOR RILUTEK, THROUGH 2012 (\$ MILLIONS)</i> .....	31
ANIMAL MODELS OF ALS AND PRECLINICAL STUDIES.....	32
STRENGTHS OF RODENT ALS MODELS .....	32
LIMITATIONS OF RODENT ALS MODELS.....	33
<i>TABLE 15 ALS/SOD1 RODENT MODELS</i> .....	33
ALS DRUG CANDIDATES IN CLINICAL TRIALS .....	34
SURVIVAL .....	35
<i>TABLE 16 A SAMPLE OF ALS DRUG CANDIDATES IN CLINICAL TRIALS</i> .....	36
<i>TABLE 17 ALS DRUG CANDIDATES FOR WHICH NDAS HAVE BEEN FILED WITH THE FDA</i> .....	37
<i>TABLE 18 ALS DRUG CANDIDATES THAT PEFORMED WELL IN CLINICAL TRIALS</i> .....	37
<i>TABLE 19 A SAMPLE OF RECENT ALS DRUG CANDIDATES THAT DID NOT PEFORM WELL IN CLINICAL TRIALS</i> .....	38
<i>TABLE 19 (CONTINUED)</i> .....	39
CURRENT COLLABORATIONS AND DRUG DISCOVERY PROGRAMS IN ALS DRUG DISCOVERY OR DEVELOPMENT .....	39
<i>TABLE 20 ALS DRUG CANDIDATES IN PRECLINICAL DEVELOPMENT</i> .....	40
AEOLUS PHARMACEUTICALS .....	40
BIOGEN IDEC AND AMORFIX LIFE SCIENCES .....	40
ISIS PHARMACEUTICALS .....	41
METABOLON .....	41
POWER3 MEDICAL PRODUCTS.....	41
DIAGNOSTIC PRODUCTS FOR ALS.....	42
<i>TABLE 21 U.S. MARKETFORECAST FOR ALS DIAGNOSTIC PRODUCTS, THROUGH 2012 (\$ MILLIONS)</i> .....	42
<i>TABLE 22 RESEARCH EFFORTS AIMED AT BIOMARKERS FOR ALS</i> .....	43
COMPANY PROFILES .....	43
AEOLUS PHARMACEUTICALS .....	43
AMORFIX LIFE SCIENCES .....	44
AVICENA GROUP, INC. ....	44
CYTRX CORP.....	45
ISIS PHARMACEUTICALS, INC. ....	46
METABOLON .....	47
POWER3 MEDICAL PRODUCTS.....	48

MARKETS FOR MEDICATIONS DIRECTED AT HUNTINGTON'S DISEASE .....	49
<i>TABLE 23 GLOBAL MARKET FORECAST FOR HUNTINGTON'S DISEASE THERAPEUTIC AGENTS, THROUGH 2012 (\$ MILLIONS)</i> .....	49
<i>FIGURE 3 GLOBAL MARKET FORECAST FOR HUNTINGTON'S DISEASE THERAPEUTIC AGENTS, 2006-2012 (\$ MILLIONS)</i> .....	50
HUNTINGTON'S DISEASE: BACKGROUND INFORMATION .....	51
TETRABENAZINE LIKELY THE FIRST PRODUCT TO GAIN FDA APPROVAL FOR HUNTINGTON'S DISEASE .....	52
<i>TABLE 24 GLOBAL MARKET FORECAST FOR THE U.S. AND WORLDWIDE SALES FOR TETRABENAZINE, THROUGH 2012 (\$ MILLIONS)</i> .....	53
HD DRUG CANDIDATES IN CLINICAL TRIALS .....	53
<i>TABLE 25 HD DRUG CANDIDATES IN CLINICAL TRIALS</i> .....	54
MIRAXION .....	54
DIMEBON .....	54
CREATINE/HD-02 .....	55
MINOCYCLINE .....	55
OTHER AGENTS IN CLINICAL TRIALS FOR HD .....	56
COMPANY PROFILES .....	56
AMARIN CORP., PLC.....	56
AVICENA GROUP, INC. ....	57
MEDIVATION.....	57
PRESTWICK PHARMACEUTICALS .....	58
Prestwick Pharmaceuticals (Continued) .....	59
MARKETS FOR MEDICATIONS DIRECTED AT MULTIPLE SCLEROSIS .....	60
<i>TABLE 26 GLOBAL MARKET FORECAST FOR MULTIPLE SCLEROSIS THERAPEUTICS, THROUGH 2012 (\$ MILLIONS)</i> .....	60
<i>FIGURE 4 GLOBAL MARKET FORECAST FOR MULTIPLE SCLEROSIS THERAPEUTICS, 2005-2012 (\$ MILLIONS)</i> .....	60
ABOUT MS.....	61
<i>TABLE 27 OVERALL MARKET LEADERS IN MS THERAPEUTIC AGENTS, 2005 AND 2006 (\$ MILLIONS)</i> .....	62
<i>TABLE 28 U.S. MARKET LEADERS IN MS THERAPEUTICS, 2006 AND 2006 (\$ MILLIONS)</i> .....	63
CURRENT PHARMACEUTICAL AGENTS THAT TREAT MULTIPLE SCLEROSIS .....	64
AVONEX.....	64
<i>TABLE 29 GLOBAL MARKET FORECAST FOR AVONEX SALES, THROUGH 2012 (\$ MILLIONS)</i> .....	64
<i>TABLE 30 U.S. AVONEX SALES AS A PERCENTAGE OF TOTAL SALES, 2003-2012 (PERCENT (%)) ROUNDED TO THE NEAREST WHOLE VALUE)</i> .....	65
Factors Affecting Avonex Sales.....	65

BETASERON .....	66
<i>TABLE 31 GLOBAL MARKET FORECAST FOR BETASERON, THROUGH 2012 (\$ MILLIONS)</i> .....	67
<i>TABLE 32 U.S. BETASERON SALES AS A PERCENTAGE OF TOTAL SALES, 2003–2012 (ROUNDED TO THE NEAREST WHOLE VALUE)</i> .....	68
Factors Affecting Sales of Betaseron .....	68
Generic competition .....	68
Cross-Border Sales in the European Union.....	69
Tysabri.....	69
COPAXONE.....	69
<i>TABLE 33 GLOBAL MARKET FORECAST FOR COPAXONE, THROUGH 2012 (\$ MILLIONS)</i> .....	70
<i>TABLE 34 U.S. COPAXONE SALES AS A PERCENTAGE OF TOTAL SALES, 2003–2012 (PERCENT (%) ROUNDED TO THE NEAREST WHOLE VALUE)</i> .....	71
Factors Affecting Copaxone’s Future Revenues.....	71
NOVANTRONE (MITOXANTRONE) .....	72
<i>TABLE 35 MARKET FORECAST FOR BRAND-NAME NOVANTRONE, THROUGH 2012 (\$ MILLIONS)</i> .....	72
REBIF .....	73
<i>TABLE 36 GLOBAL MARKET FORECAST FOR REBIF, THROUGH 2012 (\$ MILLIONS)</i> .....	73
<i>TABLE 37 U.S. REBIF SALES AS A PERCENTAGE OF TOTAL SALES, 2003–2012 (PERCENT (%) ROUNDED TO THE NEAREST WHOLE VALUE)</i> .....	74
Factors Affecting Rebif’s Future Revenues .....	74
TYSABRI .....	75
<i>TABLE 38 GLOBAL MARKET FORECAST FOR TYSABRI, THROUGH 2012 (\$ MILLIONS)</i> .....	76
Tysabri (Continued).....	77
MS DRUG CANDIDATES IN CLINICAL TRIALS.....	78
<i>TABLE 39 A SAMPLE OF MS DRUG CANDIDATES IN CLINICAL TRIALS</i> .....	78
EARLY STAGE COLLABORATIONS IN MS.....	79
Early Stage Collaborations ... (Continued) .....	80
COMPANY PROFILES .....	81
BIOGEN IDEC .....	81
CHEMOCENTRYX, INC. ....	82
PARATEK PHARMACEUTICALS.....	82
PDL BIOPHARMA, INC.....	83
SERONO INTERNATIONAL SA .....	84
Serono, Inc. ....	84
SYNTONIX PHARMACEUTICALS, INC.....	85
TEVA PHARMACEUTICALS .....	86

Teva North America .....	86
Teva ... (Continued) .....	87
MARKETS FOR MEDICATIONS DIRECTED AT PARKINSON'S DISEASE .....	88
TABLE 40 GLOBAL MARKET FORECAST FOR PARKINSON'S DISEASE THERAPEUTICS, THROUGH 2012 (\$ MILLIONS) .....	88
FIGURE 5 GLOBAL MARKET FORECAST FOR PARKINSON'S DISEASE THERAPEUTICS, 2005-2012 (\$ MILLIONS) .....	88
CHARACTERISTICS OF THE PARKINSON'S DISEASE THERAPEUTICS INDUSTRY .....	89
ABOUT PARKINSON'S DISEASE .....	90
SHORTCOMINGS OF LEVODOPA THERAPY AND NEW MEDICATIONS .....	91
IMPROVEMENTS TO LEVODOPA MONOTHERAPY .....	91
Dopamine Agonists .....	92
Anticholinergics .....	92
MAO-B inhibitors .....	92
COMT Inhibitors .....	93
CURRENT BRANDED PHARMACEUTICAL AGENTS THAT TREAT PD .....	93
APOKYN/APOMORPHINE .....	93
TABLE 41 GLOBAL MARKET FORECAST FOR APOKYN/APOMORPHINE, THROUGH 2012 (\$ MILLIONS) .....	94
INJECTABLE APOMORPHINE: BARRIERS TO MARKET PENETRATION .....	95
AZILECT (RASAGILINE) .....	96
TABLE 42 GLOBAL MARKET FORECAST FOR AZILECT, THROUGH 2012 (\$ MILLIONS) .....	96
MIRAPEX (PRAMIPEXOLE) .....	97
TABLE 43 GLOBAL MARKET FORECAST FOR MIRAPEX, THROUGH 2012 (\$ MILLIONS) .....	97
MIRAPEX AND COMPULSIVE BEHAVIORS .....	98
MIRAPEX AND RESTLESS LEGS SYNDROME .....	98
REQUIP (ROPINIROLE HYDROCHLORIDE) .....	99
TABLE 44 GLOBAL MARKET FORECAST FOR REQUIP FOR PARKINSON'S DISEASE, THROUGH 2012 (\$ MILLIONS) .....	99
TABLE 45 U.S. PD-RELATED REQUIP SALES AS A PERCENTAGE OF TOTAL SALES, 2004-2012 (PERCENT (%) ROUNDED TO THE NEAREST WHOLE VALUE) .....	100
REQUIP AND COMPULSIVE BEHAVIORS .....	100
STALEVO AND COMTAN .....	100
TABLE 46 GLOBAL MARKET FORECAST FOR COMTAN/STALEVO, THROUGH 2012 (\$ MILLIONS) .....	101
TASMAR (TOLCAPONE) .....	102

TABLE 47 GLOBAL MARKET FORECAST FOR TASMAR, THROUGH 2012 (\$ MILLIONS).....	102
ZELAPAR (SELEGILINE HCL).....	103
TABLE 48 GLOBAL MARKET FORECAST FOR ZELAPAR, THROUGH 2012 (\$ MILLIONS).....	104
PD DRUG CANDIDATES IN CLINICAL TRIALS.....	104
TABLE 49 A SAMPLE OF PD DRUG CANDIDATES IN CLINICAL TRIALS.....	105
E2007.....	105
Direct-to-the-Brain Drug Delivery.....	106
COMPANY PROFILES.....	106
ORION PHARMACEUTICALS.....	106
TEVA PHARMACEUTICALS.....	107
Teva North America.....	107
VALEANT PHARMACEUTICALS.....	108
VERNALIS, PLC.....	109
MARKETS FOR MEDICATIONS DIRECTED AT MUSCULAR DYSTROPHY AND RARE NEURODEGENERATIVE DISORDERS.....	110
TABLE 50 GLOBAL MARKET FORECAST FOR MUSCULAR DYSTROPHY-RELATED THERAPEUTIC AGENTS, THROUGH 2011 (\$ MILLIONS).....	110
FIGURE 6 GLOBAL MARKET FORECAST FOR MUSCULAR DYSTROPHY-RELATED THERAPEUTIC AGENTS, 2005- 2021 (\$ MILLIONS).....	111
THE MUSCULAR DYSTROPHIES.....	112
BACKGROUND INFORMATION.....	112
MD DRUG CANDIDATES IN CLINICAL TRIALS.....	113
TABLE 51 MD DRUG CANDIDATES IN CLINICAL TRIALS.....	114
PTC124.....	114
Stamulumab.....	115
Other Agents in Clinical Trials for MD.....	116
RARE NEURODEGENERATIVE DISORDERS.....	116
TABLE 52 GLOBAL MARKET FORECAST FOR RARE NEURODEGENERATIVE DISORDERS, THROUGH 2012 (\$ MILLIONS).....	117
FIGURE 7 GLOBAL MARKET FORECAST FOR RARE NEURODEGENERATIVE DISORDERS, 2005-2012 (\$ MILLIONS).....	117
CANDIDATES FOR RARE NEURODEGENERATIVE DISORDERS IN CLINICAL TRIALS.....	118
TABLE 53 CANDIDATES IN CLINICAL TRIALS FOR RARE DISORDERS.....	118
Batten Disease.....	118
Niemann-Pick Disease.....	119
Adrenoleukodystrophy.....	120

Lorenzo's Oil .....	120
COMPANY PROFILES .....	120
GENZYME.....	120
Genzyme (Continued).....	121
PTC THERAPEUTICS.....	122
STEM CELLS, INC.....	123
WYETH PHARMACEUTICALS.....	123
Wyeth Pharmaceuticals (Continued).....	124
U.S. PATENT ANALYSIS.....	125
INTRODUCTION .....	125
AMYOTROPHIC LATERAL SCLEROSIS (ALS).....	125
<i>TABLE 54 ALS-RELATED TECHNOLOGY: U.S. PATENT TRENDS,</i>	
<i>1997-2007*</i> .....	126
<i>TABLE 55 ALS-RELATED PATENTS BY USE CATEGORY</i> .....	126
GENERAL TRENDS.....	127
TRENDS BY ASSIGNEE.....	127
<i>TABLE 56 ALS-RELATED PATENTS BY ASSIGNEE CATEGORY</i> .....	127
<i>TABLE 56 (CONTINUED)</i> .....	128
<i>TABLE 57 ALS-RELATED PATENTS BY COMPANY</i> .....	129
PATENT APPLICATION TRENDS .....	129
<i>TABLE 58 ALS-RELATED PATENT APPLICATIONS BY USE</i>	
<i>CATEGORY</i> .....	130
<i>TABLE 59 ALS-RELATED TECHNOLOGY: U.S. PATENT</i>	
<i>APPLICATION TRENDS, 2001-2006</i> .....	131
TRENDS BY COUNTRY .....	131
HUNTINGTON'S DISEASE (HD) .....	132
<i>TABLE 60 HUNTINGTON'S DISEASE-RELATED TECHNOLOGY: U.S.</i>	
<i>PATENT TRENDS, 1997-2007</i> .....	132
<i>TABLE 61 HD-RELATED PATENTS BY USE CATEGORY</i> .....	133
TRENDS BY ASSIGNEE.....	133
<i>TABLE 62 HD-RELATED PATENTS BY ASSIGNEE CATEGORY</i> .....	134
<i>TABLE 63 HD-RELATED PATENTS BY COMPANY</i> .....	135
ALZHEIMER'S DISEASE (AD).....	135
<i>TABLE 64 ALZHEIMER'S DISEASE-RELATED TECHNOLOGY: U.S.</i>	
<i>PATENT TRENDS, 1997-2007</i> .....	135
<i>TABLE 65 AD-RELATED PATENTS BY USE CATEGORY</i> .....	136
TRENDS BY ASSIGNEE.....	137
<i>TABLE 66 AD-RELATED PATENTS BY ASSIGNEE CATEGORY</i> .....	137
<i>TABLE 67 AD-RELATED PATENTS BY COMPANY</i> .....	138
PARKINSON'S DISEASE (PD).....	138
<i>TABLE 68 PARKINSON'S DISEASE-RELATED TECHNOLOGY: U.S.</i>	
<i>PATENT TRENDS, 1997-2007</i> .....	139
<i>TABLE 69 PD-RELATED PATENTS BY USE CATEGORY</i> .....	140
TRENDS BY ASSIGNEE.....	140



<i>TABLE 70 PD-RELATED PATENTS BY ASSIGNEE CATEGORY</i> .....	141
<i>TABLE 71 PD-RELATED PATENTS BY COMPANY</i> .....	142
MULTIPLE SCLEROSIS (MS) .....	142
<i>TABLE 72 MULTIPLE SCLEROSIS-RELATED TECHNOLOGY: U.S.</i>	
<i>PATENT TRENDS, 1997–2007</i> .....	143
<i>TABLE 73 MS-RELATED PATENTS BY USE CATEGORY</i> .....	143
TRENDS BY ASSIGNEE.....	144
<i>TABLE 74 MS-RELATED PATENTS BY ASSIGNEE CATEGORY</i> .....	144
<i>TABLE 75 MS-RELATED PATENTS BY COMPANY</i> .....	145
MUSCULAR DYSTROPHY (MD) .....	146
<i>TABLE 76 MUSCULAR DYSTROPHY-RELATED TECHNOLOGY: U.S.</i>	
<i>PATENT TRENDS, 1997–2007</i> .....	146
<i>TABLE 77 MD-RELATED PATENTS BY USE CATEGORY</i> .....	147
TRENDS BY ASSIGNEE.....	147
<i>TABLE 78 MD-RELATED PATENTS BY ASSIGNEE CATEGORY</i> .....	148
<i>TABLE 79 MD-RELATED PATENTS BY ORGANIZATION</i> .....	149
MD-RELATED PATENT APPLICATIONS .....	149
<i>TABLE 80 MUSCULAR DYSTROPHY-RELATED TECHNOLOGY: U.S.</i>	
<i>PATENT APPLICATION TRENDS, 2001–2007</i> .....	149
<i>TABLE 81 MD-RELATED PATENT APPLICATIONS BY USE</i>	
<i>CATEGORY</i> .....	150
A RARE DISORDER: ATAXIA-TELANGIECTASIA.....	150
<i>TABLE 82 RARE DISORDER PATENT APPLICATIONS BY DISEASE</i> .....	150
<i>TABLE 83 ATAXIA-TELANGIECTASIA-RELATED PATENTS BY USE</i>	
<i>CATEGORY</i> .....	151