

CHAPTER ONE: INTRODUCTION.....	1
STUDY GOALS AND OBJECTIVES.....	1
REASONS FOR DOING THE STUDY	1
SCOPE OF REPORT	2
INTENDED AUDIENCE.....	2
INFORMATION SOURCES.....	2
ANALYST’S CREDENTIALS.....	2
RELATED BCC REPORTS	3
BCC ONLINE SERVICES.....	3
DISCLAIMER	3
 CHAPTER TWO: SUMMARY.....	 4
<i>SUMMARY TABLE GLOBAL CNS BIOMARKER MARKET, BY</i> <i>APPLICATION, THROUGH 2015 (\$ MILLIONS)</i>	 4
<i>SUMMARY FIGURE GLOBAL CNS BIOMARKER MARKET, BY</i> <i>APPLICATION, 2008–2015 (\$ MILLIONS)</i>	 5
 CHAPTER THREE: OVERVIEW	 6
BIOMARKER DEFINITION	6
TYPES OF BIOMARKERS.....	6
WHY USE BIOMARKERS?.....	7
WHY USE BIOMARKERS? (CONTINUED)	8
HISTORY	9
BIOMARKER DISCOVERY PROCESS.....	10
BIOMARKER IDENTIFICATION	10
BIOMARKER VALIDATION	11
BIOMARKER VERIFICATION.....	11
Sensitivity and Specificity.....	12
Biomarker Assay Validation	12
Qualification of Biomarker Assay.....	12
Utilization Analysis.....	12
REGULATORY APPROVAL	13
Analytical Validation.....	13
Clinical Validation.....	14
Clinical Utility	14
REGULATORY APPROVAL FOR MOLECULAR IMAGING AGENTS.....	 14
 CHAPTER FOUR: TECHNOLOGIES.....	 15
GENOMICS.....	15
GENETIC BIOMARKERS.....	15
SNP Examples in Neurology.....	16
Limitations of SNPs	17
TRANSCRIPTIONAL BIOMARKERS.....	18
TECHNOLOGY ADVANCEMENT IN GENOMICS	19

EMERGING TECHNOLOGIES IN THE FIELD OF	
GENOMICS.....	20
RNA Interference (RNAi)	20
MicroRNA (miRNA).....	20
Epigenetics.....	20
PROTEINS AND PROTEOMICS.....	20
PROTEIN ARRAYS AND OTHER PROTEIN TECHNOLOGIES.....	21
FUNCTIONAL PROTEIN ARRAY.....	21
ANALYTICAL CAPTURE ARRAY	22
LYSATE ARRAYS.....	22
PROTEOMICS FOR NEUROLOGICAL DISEASES	22
METABOLOMICS.....	23
<i>TABLE 1 ADVANTAGES AND DISADVANTAGES OF EACH</i>	
<i>TECHNOLOGY FOR BIOMARKER STUDY.....</i>	<i>24</i>
TECHNOLOGIES FOR BIOMARKER ANALYSIS:	
BIOINFORMATIONS AND SUPERCOMPUTING	25
MOLECULAR IMAGING.....	26
MAGNETIC RESONANCE IMAGING (MRI)	26
MRI FOR ALZHEIMER'S DISEASE	27
DIFFUSION TENSOR MRI (DTI).....	27
FUNCTIONAL MRI (fMRI).....	27
POSITRON EMISSION TOMOGRAPHY	28
SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY	
(SPECT).....	29
Single Photon Emission ...(Continued)	30
CHAPTER FIVE: FACTORS INFLUENCING DEMAND OF BIOMARKERS.....	31
CHALLENGES IN FINDING EFFECTIVE TREATMENTS TO CNS	
DISORDERS.....	31
SINGLE TARGET APPROACH	31
GENETIC ASSOCIATIONS	31
ANIMAL MODELS	31
CNS DISEASES ARE COMPLEX.....	32
INCREASED IN CHRONIC DISEASE AND INCREASED ACCESS	
TO HEALTH INSURANCE IN THE U.S.....	33
LOW R&D PRODUCTIVITY IN THE BIOPHARMACEUTICAL	
INDUSTRY AND INCREASING COSTS OF CLINICAL TRIAL.....	34
UNMET NEEDS	35
GROWTH IN PUBLIC-PRIVATE PARTNERSHIPS.....	35
FNIH BIOMARKER CONSORTIUM.....	35
PREDICTIVE SAFETY CONSORTIUM.....	36
ALZHEIMER'S DISEASE NEUROIMAGING INITIATIVE	
(ADNI)	36
NEWMEDS CONSORTIUM.....	36
FDA SUPPORT	37

CRITICAL PATH INITIATIVE (CPI)	38
VOLUNTARY GENOMIC DATA SUBMISSIONS.....	38
IMPACT OF VOLUNTARY EXPLORATORY DATA SUBMISSION (VXDS).....	39
CHAPTER SIX: GLOBAL REGULATORY ENVIRONMENT AND RECENT ECONOMIC CONDITIONS	
INTRODUCTION	40
U.S. REQUIREMENTS	41
REIMBURSEMENT IN THE U.S.	41
Reimbursement in the U.S. (Continued)	42
EUROPE'S REGULATORY ENVIRONMENT	43
RECENT ECONOMIC CONDITIONS AND THEIR AFFECT ON BIOMARKER DEVELOPMENT	43
<i>FIGURE 1 NASDAQ BIOTECHNOLOGY INDEX FROM JULY 2006 TO JULY 2010.....</i>	44
<i>FIGURE 2 STOCK PERFORMANCE OF TOP SUPPLIERS FOR BIOMARKER DISCOVERY.....</i>	45
<i>TABLE 2 REVENUES AND MARKET SHARE OF BIOMARKER DISCOVERY AND DRUG DEVELOPMENT SUPPLIERS, THROUGH Q1 2010 (\$ MILLIONS/%).....</i>	45
<i>TABLE 2 (CONTINUED).....</i>	46
CHAPTER SEVEN: CNS DISEASE SEGMENTS, PREVALENCE, AND GAPS IN TREATMENT.....	
INTRODUCTION	47
<i>TABLE 3 NUMBER OF CASES OF CNS DISEASES FROM WHO, 2004 (THOUSANDS).....</i>	47
<i>TABLE 3 (CONTINUED).....</i>	48
<i>TABLE 4 NUMBER OF CASES OF CNS DISEASE, 2004 (THOUSANDS).....</i>	48
<i>TABLE 5 ESTIMATED NUMBER OF CASES OF CNS DISEASE, 2008 (THOUSANDS).....</i>	48
<i>TABLE 5 (CONTINUED).....</i>	49
<i>TABLE 6 ESTIMATED NUMBER OF CASES OF CNS DISEASE, 2008 (THOUSANDS).....</i>	49
NEURODEGENERATION AND NEUROLOGICAL DISORDERS.....	49
ALZHEIMER'S DISEASE.....	49
Alzheimer's Disease (Continued)	50
Alzheimer's Disease (Continued)	51
AD Treatment Gaps	52
Gaps in Diagnosing AD	52
PARKINSON'S DISEASE (PD)	52
Gaps in Treatment.....	52
Gaps in Diagnosis	53

MULTIPLE SCLEROSIS (MS).....	53
Number of Cases and Cost of Treatment	53
Gaps in Treatment.....	54
Gaps in Diagnosing Multiple Sclerosis.....	54
AMYOTROPHIC LATERAL SCLEROSIS (ALS)	55
Gaps in Treatment and Diagnosis	55
HUNTINGTON'S DISEASE.....	55
Gaps in Treatment and Diagnosis	56
NEUROPSYCHIATRIC DISORDERS	56
ANXIETY DISORDERS (PTSD, PANIC DISORDER, OCD, SAD, GAD)	56
Panic Disorder	56
Obsessive Compulsive Disorder	56
Social Anxiety Disorder (SAD).....	57
Generalized Anxiety Disorder (GAD)	57
Depression.....	57
Treatment Gaps for Anxiety Disorders and Depression.....	58
Gaps in Diagnosis	59
Serotonin 2A Receptor Gene (HTR2A).....	60
B-cell Lymphoma 2 Gene (Bcl-2).....	60
Glutamate Receptor, Ionotropic Kainate 2 Gene (GRIK2).....	60
SCHIZOPHRENIA.....	60
Gaps in Treatment.....	61
Gaps in Diagnosis	61
BIPOLAR.....	61
Bipolar I Disorder	62
Bipolar II Disorder	62
Cyclothymic Disorder	62
Gaps in Treatment and Diagnosis	62
ADHD.....	62
Gaps in Treatment and Diagnosis	63
AUTISM.....	63
Gaps in Treatment and Diagnosis	63
CHAPTER EIGHT: GLOBAL CNS MARKET AND GROWTH	64
OVERVIEW.....	64
<i>TABLE 7 MAJOR CNS COMPANIES, TREATMENTS, TOTAL MARKET, AND MARKET SHARE 2008 (\$ MILLIONS/%)</i>	65
CHAPTER NINE: MARKETS BY APPLICATION.....	66
INTRODUCTION	66
<i>TABLE 8 GLOBAL CNS BIOMARKER MARKET BY APPLICATION, THROUGH 2015 (\$ MILLIONS)</i>	66
DISCOVERY	66

MARKET ASSESSMENT AND FORECASTING METHOD.....	67
RECENT ADVANCES AND DEVELOPMENTS IN DISCOVERY	67
GROWTH DRIVERS.....	68
Growth in Chronic Diseases.....	68
Favorable Funding Environment.....	68
Public-Private Partnerships.....	69
GROWTH INHIBITORS.....	69
Lack of Short-Term Returns	69
Potential for Loss in Market Share	70
Lack of Standardized Methods.....	70
High Cost	70
DRUG DEVELOPMENT	70
MARKET ASSESSMENT AND FORECASTING METHOD.....	71
MOLECULAR DIAGNOSTICS	72
MARKET ASSESSMENT AND FORECASTING METHOD.....	72
GROWTH DRIVERS.....	73
GROWTH INHIBITORS.....	74
<i>TABLE 9 CNS DIAGNOSTIC COMPANIES AND DISEASE INDICATION</i>	<i>75</i>
<i>TABLE 9 (CONTINUED).....</i>	<i>76</i>
ALZHEIMERS DISEASE	76
Applied NeuroSolutions	76
Satoris	76
Diagenic	76
Solvay	77
Proteome Sciences	77
ExonHit.....	77
OTHER CNS DISEASES.....	77
Psynova Neurotech Ltd.....	77
Glycominds, Ltd.....	78
<i>TABLE 10 NUMBER OF CNS DIAGNOSTIC BIOMARKERS IN DEVELOPMENT, BY INDICATION.....</i>	<i>78</i>
<i>TABLE 11 GLOBAL CNS BIOMARKER DISCOVERY MARKET BY TECHNOLOGY, THROUGH 2015 (\$ MILLIONS).....</i>	<i>79</i>
<i>TABLE 12 GLOBAL CNS BIOMARKER DEVELOPMENT MARKET BY TECHNOLOGY, THROUGH 2015 (\$ MILLIONS).....</i>	<i>80</i>
<i>TABLE 13 GLOBAL CNS BIOMARKER MOLECULAR DIAGNOSTIC MARKET BY TECHNOLOGY, THROUGH 2015 (\$ MILLIONS).....</i>	<i>80</i>
<i>TABLE 14 GLOBAL CNS BIOMARKER DISCOVERY MARKET BY REGION, THROUGH 2015 (\$ MILLIONS)</i>	<i>81</i>
<i>TABLE 15 GLOBAL CNS BIOMARKER DEVELOPMENT MARKET BY REGION, THROUGH 2015 (\$ MILLIONS)</i>	<i>82</i>

<i>TABLE 16 GLOBAL CNS BIOMARKER MOLECULAR DIAGNOSTIC MARKET BY REGION, THROUGH 2015 (\$ MILLIONS)</i>	82
CHAPTER TEN: MARKET BY REGIONS.....	83
MARKET ASSESSMENT AND FORECASTING	83
<i>TABLE 17 GLOBAL CNS BIOMARKER MARKET BY REGION, THROUGH 2015 (\$ MILLIONS)</i>	83
<i>FIGURE 3 GLOBAL CNS BIOMARKER MARKET BY REGION, 2008-2015 (\$ MILLIONS)</i>	84
<i>TABLE 18 U.S. CNS BIOMARKER MARKET BY APPLICATION, THROUGH 2015 (\$ MILLIONS)</i>	85
<i>TABLE 19 CANADA CNS BIOMARKER MARKET BY APPLICATION, THROUGH 2015 (\$ MILLIONS)</i>	86
<i>TABLE 20 EUROPEAN CNS BIOMARKER MARKET BY APPLICATION, THROUGH 2015 (\$ MILLIONS)</i>	86
<i>TABLE 21 U.S. CNS BIOMARKER MARKET BY TECHNOLOGY, THROUGH 2015 (\$ MILLIONS)</i>	86
<i>TABLE 22 CANADIAN CNS BIOMARKER MARKET BY TECHNOLOGY, THROUGH 2015 (\$ MILLIONS)</i>	87
<i>TABLE 23 EUROPEAN CNS BIOMARKER MARKET BY TECHNOLOGY, THROUGH 2015 (\$ MILLIONS)</i>	87
JAPAN	87
Japan (Continued)	88
<i>TABLE 24 JAPAN CNS BIOMARKER MARKET BY APPLICATION, THROUGH 2015 (\$ MILLIONS)</i>	89
<i>TABLE 25 JAPAN CNS BIOMARKER MARKET BY TECHNOLOGY, THROUGH 2015 (\$ MILLIONS)</i>	89
EMERGING COUNTRIES	89
<i>TABLE 26 CHINA CNS BIOMARKER MARKET BY APPLICATION, THROUGH 2015 (\$ MILLIONS)</i>	90
<i>TABLE 27 INDIA CNS BIOMARKER MARKET BY APPLICATION, THROUGH 2015 (\$ MILLIONS)</i>	91
<i>TABLE 28 CHINA CNS BIOMARKER MARKET BY TECHNOLOGY, THROUGH 2015 (\$ MILLIONS)</i>	91
<i>TABLE 29 INDIA CNS BIOMARKER MARKET BY TECHNOLOGY, THROUGH 2015 (\$ MILLIONS)</i>	91
CHAPTER ELEVEN: MARKETS BY TECHNOLOGY	92
<i>TABLE 30 GLOBAL CNS BIOMARKER MARKET BY TECHNOLOGY, THROUGH 2015 (\$ MILLIONS)</i>	92
<i>TABLE 31 GENOMIC CNS BIOMARKER MARKET BY APPLICATION, THROUGH 2015 (\$ MILLIONS)</i>	92
<i>TABLE 32 PROTEOMIC CNS BIOMARKER MARKET BY APPLICATION, THROUGH 2015 (\$ MILLIONS)</i>	93

TABLE 33 MOLECULAR IMAGING CNS BIOMARKER MARKET BY APPLICATION, THROUGH 2015 (\$ MILLIONS).....	93
TABLE 34 GENOMIC CNS BIOMARKER MARKET BY REGION, THROUGH 2015 (\$ MILLIONS).....	93
TABLE 35 PROTEOMIC CNS BIOMARKER MARKET BY REGION, THROUGH 2015 (\$ MILLIONS).....	94
TABLE 36 MOLECULAR IMAGING CNS BIOMARKER MARKET BY REGION, THROUGH 2015 (\$ MILLIONS)	94
CHAPTER TWELVE: MARKET BY CONDITION.....	95
TABLE 37 GLOBAL CNS BIOMARKER MARKET BY CONDITION, THROUGH 2015 (\$ MILLIONS).....	95
FIGURE 4 GLOBAL CNS BIOMARKER MARKET BY CONDITION, 2008-2015 (\$ MILLIONS).....	96
CHAPTER THIRTEEN: INDUSTRY STRUCTURE AND COMPETITIVE ANALYSIS	97
INTRODUCTION	97
TECHNOLOGY AS DRIVING FORCE	98
BUYERS AS DRIVING FORCE.....	98
THIRD-PARTY PAYERS AS DRIVING FORCE	98
COMPETITION	99
STRATEGIES FOR A DIAGNOSTIC TO REMAIN COMPETITIVE	100
SIGNIFICANT IMPACT OF BIOMARKERS.....	101
SIGNIFICANT IMPACT OF BIOMARKERS (CONTINUED)	102
FIGURE 5 PORTER MODEL.....	103
STRENGTHS, WEAKNESSES, OPPORTUNITIES AND THREATS (SWOT) ANALYSIS.....	103
FIGURE 6 SWOT ANALYSIS	104
MOVING TOWARD PERSONALIZED MEDICINE	104
Moving Toward Personalized ...(Continued).....	105
Moving Toward Personalized ...(Continued).....	106
CHAPTER FOURTEEN: PATENT INFORMATION	107
TABLE 38 PATENT APPLICATIONS FOR CNS BIOMARKERS, 2009.....	107
TABLE 38 (CONTINUED).....	108
TABLE 38 (CONTINUED).....	109
TABLE 38 (CONTINUED).....	110
TABLE 38 (CONTINUED).....	111
TABLE 39 PATENT APPLICATIONS FOR CNS BIOMARKERS, 2008.....	111
TABLE 39 (CONTINUED).....	112
TABLE 40 ALSERES PHARMACEUTICALS, INC. PATENT APPLICATIONS	113
TABLE 41 APOSENSE LTD. PATENT APPLICATIONS.....	113
TABLE 42 APPLIED NEUROSOLUTIONS PATENT APPLICATIONS	113

<i>TABLE 43 AVID RADIOPHARMACEUTICALS PATENT APPLICATIONS</i>	114
<i>TABLE 44 DIAGENIC PATENTS AND PATENT APPLICATIONS</i>	114
<i>TABLE 45 EXONHIT ASSOCIATED PATENTS AND PATENT APPLICATIONS</i>	114
<i>TABLE 45 (CONTINUED)</i>	115
<i>TABLE 46 INNOGENETICS PATENTS AND PATENT APPLICATIONS</i>	115
<i>TABLE 47 OLIGOMERIX, INC. PATENT APPLICATIONS</i>	115
<i>TABLE 48 PROTEOME SCIENCES, PLC PATENT APPLICATIONS</i>	116
<i>TABLE 49 RIDGE DIAGNOSTICS PATENTS</i>	116
<i>TABLE 50 PSYNOVA NEUROTECH LTD. PATENTS</i>	117
<i>TABLE 51 NUMBER OF PATENT APPLICATIONS AND ASSOCIATED INDICATION, 2008-2009</i>	118
CHAPTER FIFTEEN: COMPANY PROFILES	119
ABASTAR MDX INC.	119
ABIANT, INC.	120
ACUMEN PHARMACEUTICALS, INC.	120
ADLYFE INC.	121
ALSERES PHARMACEUTICALS, INC.	122
APITOPE.....	122
APITOPE TECHNOLOGY (BRISTOL) LTD.	122
APOSENSE.....	123
APPLIED NEUROSOLUTIONS, INC.	124
AVID RADIOPHARMACEUTICALS, INC.....	124
BANYAN BIOMARKERS.....	125
BRAHMS GMBH	126
THERMO FISHER SCIENTIFIC BRAHMS BIOMARKERS.....	126
CURIDIUM LTD.....	126
DIAGENIC ASA.....	127
PXBIOVISION GMBH.....	128
EXONHIT THERAPEUTICS	128
EXONHIT THERAPEUTICS INC.....	128
GENE SOLUTIONS, LLC	129
GENENEWS LTD.....	130
GENIZON BIOSCIENCES INC.....	130
GLYCOMINDS LTD.....	131
GLYCOMINDS INC.....	131
INNOVATIVE NEUROTECHNOLOGIES, INC.	132
METABOLON, INC.	132
OLIGOMERIX, INC.....	133
OPKO HEALTH INC.....	134
OSTA BIOTECHNOLOGIES INC.	134
POWER3 MEDICAL PRODUCTS, INC.	135
PROTEOME SCIENCES PLC	135

PROVISTA LIFE SCIENCES	136
PSYNOVA NEUROTECH LIMITED.....	136
RULES-BASED MEDICINE, INC. (RBM)	137
SATORIS, INC.	137
SOLVAY S.A.	138
INNOGENETICS BIOLOGICALS	138
RIDGE DIAGNOSTICS	139
APPENDIX A.....	140
<i>TABLE 52 CNS BIOMARKER ALLIANCES, 2008–2010</i>	140
<i>TABLE 52 (CONTINUED)</i>	141
<i>TABLE 53 RECENT TECHNOLOGY DEVELOPMENTS</i>	141
<i>TABLE 53 (CONTINUED)</i>	142
<i>TABLE 53 (CONTINUED)</i>	143
APPENDIX B.....	144
BIBLIOGRAPHY	144
BIBLIOGRAPHY (CONTINUED)	145
BIBLIOGRAPHY (CONTINUED)	146
BIBLIOGRAPHY (CONTINUED)	147