

BIOLOGICAL THERAPIES FOR CANCER: TECHNOLOGIES AND GLOBAL MARKETS



BIO048C
January 2015

Usha Nagavarapu
Project Analyst

ISBN: 1-62296-026-2



BCC Research
49 Walnut Park, Building 2
Wellesley, MA 02481 USA
866-285-7215 (toll-free within the USA),
or (+1) 781-489-7301
www.bccresearch.com
information@bccresearch.com

TABLE OF CONTENTS

| TOPIC | PAGE NO. |
|---|-----------------|
| CHAPTER 1 INTRODUCTION | 2 |
| STUDY GOALS AND OBJECTIVES | 2 |
| REASONS FOR DOING THE STUDY | 2 |
| SCOPE AND FORMAT | 2 |
| INTENDED AUDIENCE | 3 |
| METHODOLOGY | 3 |
| RELATED BCC RESEARCH REPORTS | 4 |
| ANALYST'S CREDENTIALS | 4 |
| BCC RESEARCH WEBSITE | 4 |
| DISCLAIMER | 4 |
| CHAPTER 2 SUMMARY | 6 |
| <i>SUMMARY TABLE GLOBAL BIOLOGICAL CANCER TREATMENT MARKET BY SEGMENT, THROUGH 2019 (\$ MILLIONS)</i> | 7 |
| <i>SUMMARY FIGURE GLOBAL BIOLOGICAL CANCER TREATMENT MARKET BY SEGMENT, 2008-2019 (\$ MILLIONS)</i> | 7 |
| CHAPTER 3 BIOLOGICAL TREATMENTS FOR CANCER | 9 |
| DEFINING CANCER | 9 |
| CAUSES OF CANCER GROWTH | 10 |
| CANCER TREATMENT STRATEGIES | 11 |
| COMMON TREATMENTS AND PROBLEMS | 11 |
| Surgery | 11 |
| Chemotherapy | 11 |
| Radiation Treatment | 12 |
| Targeted Therapy | 13 |
| Hormone Therapy | 13 |
| BIOLOGICAL THERAPY OF CANCER | 13 |
| CHAPTER 4 CANCER DESCRIPTIONS | 16 |
| <i>TABLE 1 MAIN CANCER CATEGORIES</i> | 16 |
| LUNG CANCER | 17 |
| LUNG CANCER TREATMENT | 18 |
| BIOLOGIC USE | 19 |
| BLADDER CANCER | 20 |
| BREAST CANCER | 23 |
| HER2 EXPRESSION | 27 |
| Antiangiogenic and HER2 Agents | 30 |
| CERVICAL CANCER | 32 |
| VACCINES | 34 |
| DIAGNOSIS | 34 |
| TREATMENT | 35 |
| Avastin | 35 |
| COLORECTAL CANCER | 36 |
| SMALL INTESTINE CANCER | 41 |
| ESOPHAGEAL CANCER | 44 |

| TOPIC | PAGE NO. |
|--|-----------------|
| KIDNEY CANCER | 47 |
| TARGETED THERAPIES FOR KIDNEY CANCER | 51 |
| <i>TABLE 2 APPROVED RENAL CELL CANCER DRUGS</i> | 51 |
| Sorafenib | 52 |
| Sunitinib | 52 |
| Temsirolimus | 52 |
| Everolimus | 52 |
| Bevacizumab | 53 |
| Pazopanib | 53 |
| Axitinib | 53 |
| LEUKEMIA | 53 |
| SYMPTOMS AND TREATMENT | 55 |
| LYMPHOMA | 55 |
| NON-HODGKIN'S LYMPHOMA | 57 |
| <i>TABLE 3 MONOCLONAL ANTIBODIES FOR NON-HODGKIN'S LYMPHOMA TREATMENT</i> | 59 |
| Extranodal B-cell Lymphoma of Mucosa Associated Lymphoid Tissue | 61 |
| Mantle Cell Lymphoma | 61 |
| Mediastinal Diffuse Large B-Cell Lymphoma | 61 |
| Burkitt Lymphoma | 61 |
| LIVER CANCER | 61 |
| MELANOMA | 65 |
| METASTATIC MELANOMA | 71 |
| MULTIPLE MYELOMA | 74 |
| BRAIN CANCER | 78 |
| <i>TABLE 4 BRAIN TUMOR SPECIFIC STATISTICS</i> | 79 |
| GLIOMAS | 83 |
| <i>TABLE 5 ASTROCYTOMAS</i> | 83 |
| MENINGIOMAS | 85 |
| ACOUSTIC NEUROMAS AND SCHWANNOMAS | 85 |
| MEDULLOBLASTOMA | 85 |
| OVARIAN CANCER | 86 |
| DIAGNOSIS | 88 |
| PANCREATIC CANCER | 89 |
| PROSTATE CANCER | 94 |
| STOMACH CANCER | 99 |
| <i>TABLE 6 STOMACH CANCER TYPES</i> | 102 |
| <i>TABLE 7 ADENOCARCINOMA STOMACH CANCER STAGES</i> | 103 |
| CLINICAL TRIALS | 105 |
| HEAD AND NECK CANCERS | 105 |
| <i>TABLE 8 HEAD AND NECK CANCER TYPES</i> | 106 |
| CHAPTER 5 PRODUCT SEGMENTS AND TECHNOLOGY | 109 |
| <i>TABLE 9 GLOBAL BIOLOGICAL CANCER TREATMENT MARKET BY REGION, THROUGH 2019 (\$ MILLIONS)</i> | 109 |
| <i>FIGURE 1 GLOBAL BIOLOGICAL CANCER TREATMENT MARKET BY REGION, 2008-2019 (\$ MILLIONS)</i> | 109 |
| MONOCLONAL ANTIBODIES | 110 |
| <i>TABLE 10 MONOCLONAL ANTIBODIES FOR CANCER TREATMENT</i> | 111 |

| TOPIC | PAGE NO. |
|---|-----------------|
| MONOCLONAL ANTIBODIES: RECENT MARKET ACTIVITIES AND TRENDS | 113 |
| THE FUTURE OF CANCER MONOCLONALS | 114 |
| <i>TABLE 11 ANTIBODY-BASED DEVELOPMENTS WITH EPITHELIAL CELL-ADHESION MOLECULE</i> | 115 |
| MONOCLONALS ON THE MARKET | 116 |
| Rituxan | 116 |
| <i>TABLE 12 GLOBAL BEST-SELLING MONOCLONAL ANTIBODIES FOR CANCER, 2014 (\$ MILLIONS)</i> | 118 |
| <i>FIGURE 2 GLOBAL BEST-SELLING MONOCLONAL ANTIBODIES FOR CANCER, 2014 (\$ MILLIONS)</i> | 118 |
| <i>TABLE 13 U.S. BEST-SELLING MONOCLONAL ANTIBODIES FOR CANCER, 2007-2009 (\$ MILLIONS)</i> | 119 |
| <i>FIGURE 3 U.S. BEST-SELLING MONOCLONAL ANTIBODIES FOR CANCER, 2007-2009 (\$ MILLIONS)</i> | 119 |
| Avastin | 120 |
| Herceptin | 121 |
| Campath | 122 |
| Erbix | 124 |
| <i>TABLE 14 ERBITUX APPROVALS</i> | 125 |
| Approved for KRAS Wild-Type, Epidermal Growth Factor Receptor-Expressing Metastatic Colorectal Cancer | 126 |
| Approved for Recurrent or Metastatic Head and Neck Cancers | 127 |
| Head and Neck Cancers | 127 |
| Colorectal Cancer | 127 |
| Mylotarg | 128 |
| Vectibix | 128 |
| Bexxar | 129 |
| Zevalin | 130 |
| INTERFERONS | 130 |
| <i>TABLE 15 GLOBAL BEST-SELLING INTERFERONS FOR CANCER, 2013 AND 2014 (\$ MILLIONS)</i> | 131 |
| <i>FIGURE 4 GLOBAL BEST-SELLING INTERFERONS FOR CANCER, 2013 AND 2014 (\$ MILLIONS)</i> | 131 |
| ALDESLEUKIN | 132 |
| INTERFERON ALPHA | 132 |
| VACCINES | 135 |
| THERAPEUTIC AND PREVENTATIVE CANCER VACCINES | 135 |
| PREVENTIVE CANCER VACCINES | 138 |
| <i>TABLE 16 GLOBAL BEST-SELLING PREVENTATIVE VACCINES FOR CANCER, 2013 AND 2014 (\$ MILLIONS)</i> | 138 |
| <i>FIGURE 5 GLOBAL BEST-SELLING PREVENTATIVE VACCINES FOR CANCER, 2013 AND 2014 (\$ MILLIONS)</i> | 139 |
| Gardasil | 139 |
| GRANULOCYTE COLONY STIMULATING FACTOR | 141 |
| <i>TABLE 17 GLOBAL BEST-SELLING SUPPORTIVE CARE DRUGS, 2013 AND 2014 (\$ MILLIONS)</i> | 142 |
| <i>FIGURE 6 GLOBAL BEST-SELLING SUPPORTIVE CARE DRUGS, 2013 AND 2014 (\$ MILLIONS)</i> | 142 |
| ARANESP | 144 |
| PROCRIT AND EPOGEN | 146 |

| TOPIC | PAGE NO. |
|--|-----------------|
| OMONTYS | 146 |
| NEULASTA | 147 |
| NEUPOGEN | 147 |
| LEUKINE/SARGRAMOSTIM | 148 |
| NEUMEGA | 148 |
| BIOSIMILARS | 149 |
| BIOCON | 150 |
| OTHER BIOTHERAPY AND GENE THERAPY | 152 |
| CHAPTER 6 MARKET DYNAMICS AND OVERVIEW | 154 |
| TABLE 18 GLOBAL BIOLOGICS SALES, 2013 (\$ MILLIONS) | 154 |
| PIPELINE BIOLOGICS | 155 |
| STANDARD TREATMENTS | 155 |
| GLOBAL CANCER MARKET TRENDS | 155 |
| TABLE 19 GLOBAL CANCER INCIDENCE AND FORECAST BY REGION, 2007-2030 (MILLIONS) | 156 |
| FIGURE 7 GLOBAL CANCER INCIDENCE AND FORECAST BY REGION, 2007-2030 (MILLIONS) | 156 |
| TABLE 20 GLOBAL CANCER-RELATED DEATHS AND FORECAST BY REGION, 2007-2030 (MILLIONS) | 157 |
| FIGURE 8 GLOBAL CANCER-RELATED DEATHS AND FORECAST BY REGION, 2007-2030 (MILLIONS) | 158 |
| TABLE 21 APPROVED ONCOLOGY DRUGS, 2013-2014 | 158 |
| GLOBAL ONCOLOGY MARKET | 160 |
| TABLE 22 GLOBAL ONCOLOGY MARKET BY REGION, THROUGH 2019 (\$ MILLIONS) | 161 |
| FIGURE 9 GLOBAL ONCOLOGY MARKET BY REGION, 2008-2019 (\$ MILLIONS) | 161 |
| PAST PERFORMANCE OF CANCER DRUGS | 162 |
| TABLE 23 GLOBAL ONCOLOGY SALES, 2012 AND 2013 (\$ MILLIONS/%) | 164 |
| EMERGING MARKETS | 165 |
| TABLE 24 ASIA-PACIFIC SOLID TUMOR MARKET, THROUGH 2019 (\$ MILLIONS) | 165 |
| TABLE 25 ASIA-PACIFIC ONCOLOGY MARKET, 2008 (\$ MILLIONS) | 168 |
| FIGURE 10 ASIA-PACIFIC ONCOLOGY MARKET, 2008 (\$ MILLIONS) | 168 |
| GLOBAL CANCER BIOLOGICAL THERAPEUTIC MARKET | 169 |
| TABLE 26 GLOBAL BIOTHERAPEUTIC SALES COMPARED TO TOTAL PRESCRIPTION DRUG SALES, THROUGH 2019 (\$ MILLIONS) | 170 |
| FIGURE 11 GLOBAL BIOTHERAPEUTIC SALES COMPARED TO TOTAL PRESCRIPTION DRUG SALES, 2008-2019 (\$ MILLIONS) | 170 |
| TABLE 27 U.S. BIOLOGIC DRUG SALES, 2011 AND 2012 (\$ BILLIONS) | 171 |
| CANCER BIOTHERAPEUTIC MARKET SIZE AND GROWTH | 171 |
| TABLE 28 GLOBAL BIOLOGICAL MONOCLONAL, ANTIBODY CANCER TREATMENT MARKET, THROUGH 2019 (\$ MILLIONS) | 172 |
| FIGURE 12 GLOBAL BIOLOGICAL MONOCLONAL ANTIBODY MARKET, 2009-2019 (\$ MILLIONS) | 173 |
| TABLE 29 CANCER MONOCLONAL ANTIBODY THERAPIES | 173 |
| NEW DEVELOPMENTS | 174 |
| ARZERRA | 174 |
| NIVOLUMAB | 174 |
| TABLE 30 GLOBAL BIOLOGICAL INTERFERON/INTERLEUKIN CANCER TREATMENT MARKET, THROUGH 2019 (\$ MILLIONS) | 174 |

| TOPIC | PAGE NO. |
|--|-----------------|
| <i>FIGURE 13 GLOBAL BIOLOGICAL INTERFERON/INTERLEUKIN CANCER TREATMENT MARKET, 2013-2019 (\$ MILLIONS)</i> | 175 |
| BEXXAR | 175 |
| ZEVALIN | 175 |
| SANOFI/GENZYME WITHDRAWS CAMPATH | 176 |
| PROMETHEUS ACQUIRES EXCLUSIVE RIGHTS TO PROLEUKIN IN THE U.S. | 176 |
| <i>TABLE 31 SELECTED INTERFERON DRUG SALES, 2009 (\$ MILLIONS)</i> | 176 |
| ROCHE | 176 |
| <i>TABLE 32 PATENT EXPIRIES</i> | 177 |
| Gazyva | 179 |
| JOHNSON AND JOHNSON | 179 |
| <i>TABLE 33 REMICADE SALES, 2012-2014 (\$ MILLIONS)</i> | 180 |
| Procrit | 180 |
| <i>TABLE 34 PROCRIIT SALES, 2009 AND 2012 (\$ MILLIONS)</i> | 181 |
| MERCK AND BRISTOL-MYERS SQUIBB | 181 |
| CANCER VACCINES | 182 |
| <i>TABLE 35 GLOBAL BIOLOGICAL CANCER VACCINE MARKET, THROUGH 2019 (\$ MILLIONS)</i> | 182 |
| <i>FIGURE 14 GLOBAL BIOLOGICAL CANCER VACCINE MARKET, 2009-2019 (\$ MILLIONS)</i> | 182 |
| <i>TABLE 36 GARDASIL SALES, 2012 AND 2013 (\$ MILLIONS)</i> | 183 |
| PFIZER | 183 |
| <i>TABLE 37 MYLOTARG SALES, 2009 (\$ MILLIONS)</i> | 183 |
| <i>TABLE 38 GLOBAL IMMUNOSTIMULANT MARKET, THROUGH 2019 (\$ MILLIONS)</i> | 184 |
| <i>FIGURE 15 GLOBAL IMMUNOSTIMULANT MARKET, 2009-2019 (\$ MILLIONS)</i> | 184 |
| <i>TABLE 39 AMGEN SALES, 2012-2013 (\$ MILLIONS)</i> | 186 |
| ISSUES AND TRENDS AFFECTING THE MARKET | 186 |
| CHAPTER 7 PRODUCTS IN DEVELOPMENT | 188 |
| RECENT DEVELOPMENTS AND APPROVALS | 188 |
| <i>TABLE 40 APPROVED BIOLOGICS CANCER DRUGS, 2013-2014</i> | 189 |
| 2013 APPROVALS | 189 |
| NEW DRUGS AND COMPANIES IN DEVELOPMENT | 190 |
| ROCHE'S GAZYVA | 190 |
| AMGEN'S PROLIA | 191 |
| PFIZER'S TANEZUMAB | 191 |
| PEREGRINE'S COTARA | 192 |
| DENDREON'S PROVENGE | 193 |
| <i>TABLE 41 PROVENGE'S KEY FEATURES</i> | 194 |
| CEL-SCI'S MULTIKINE | 195 |
| NORTHWEST BIOTHERAPEUTICS | 195 |
| GERON | 197 |
| <i>TABLE 42 GERON-SPONSORED CLINICAL TRIALS</i> | 198 |
| ADVAXIS | 198 |
| <i>TABLE 43 ADVAXIS DRUG CANDIDATES</i> | 198 |
| AGENUS | 199 |
| ONCOPTHYREON | 199 |
| IMMUNOCELLULAR THERAPEUTICS | 201 |

| TOPIC | PAGE NO. |
|--|-----------------|
| INOVIO BIOMEDICAL | 202 |
| BIOVEST | 203 |
| OMNIMMUNE | 204 |
| CELLDEX THERAPEUTICS | 205 |
| CDX-1127 | 207 |
| ONCOLYTICS BIOTECH | 208 |
| <i>TABLE 44 ONCOLYTICS BIOTECH CLINICAL TRIALS</i> | 209 |
| CLINICAL TRIALS | 209 |
| VICAL | 210 |
| PIPELINE DRUGS IN DEVELOPMENT | 211 |
| ABT-199/GDC-0199 | 211 |
| <i>TABLE 45 ABBVIE ONCOLOGY PIPELINE</i> | 212 |
| ELOTUZUMAB | 213 |
| ABT-414 | 213 |
| ABT-700 | 214 |
| XBIOTECH | 214 |
| <i>TABLE 46 ENROLLING OR COMPLETED CLINICAL STUDIES*</i> | 215 |
| PFIZER ONCOLOGY | 215 |
| <i>TABLE 47 PFIZER ONCOLOGY PIPELINE</i> | 216 |
| CLINICAL TRIALS IN ONCOLOGY | 217 |
| <i>TABLE 48 ONCOLOGY CLINICAL TRIALS, 2009 (NUMBER)</i> | 217 |
| <i>FIGURE 16 ONCOLOGY CLINICAL TRIALS, 2009 (NUMBER)</i> | 217 |
| <i>TABLE 49 APPROVED BIOLOGICS FOR CANCER, 2009</i> | 218 |
| CONCLUSIONS | 220 |
| CHAPTER 8 ONCOLOGY DRUG MARKET | 222 |
| MARKET SIZE AND GROWTH | 222 |
| MARKET BY PRODUCT TYPE | 224 |
| Roche | 224 |
| Kadcyla (ado-trastuzumab emtansine) | 224 |
| Perjeta | 225 |
| Rituxan | 225 |
| <i>TABLE 50 RITUXAN TREATMENT INDICATIONS</i> | 225 |
| Avastin | 226 |
| Herceptin | 226 |
| Neulasta | 226 |
| Amgen | 226 |
| Xgeva | 226 |
| <i>TABLE 51 DENOSUMAB MARKET, THROUGH 2019 (\$ MILLIONS)</i> | 227 |
| Aranesp | 227 |
| ONCOLOGY MARKET AND GROWTH | 227 |
| <i>TABLE 52 TOP CANCER BIOLOGICS, 2007-2009 (\$ MILLIONS)</i> | 227 |
| <i>FIGURE 17 TOP CANCER BIOLOGICS, 2007-2009 (\$ MILLIONS)</i> | 228 |
| MARKET BY REGION | 228 |
| <i>TABLE 53 ONCOLOGY TREATMENT BY REGION, 2013</i> | 230 |
| Oncology Pipeline | 231 |
| U.S. Cancer Market | 231 |

| TOPIC | PAGE NO. |
|---|-----------------|
| <i>TABLE 54 U.S. BIOLOGICAL CANCER TREATMENT MARKET BY DRUG CLASS, THROUGH 2019 (\$ MILLIONS)</i> | 232 |
| <i>FIGURE 18 U.S. BIOLOGICAL CANCER TREATMENT MARKET BY DRUG CLASS, 2008-2019 (\$ MILLIONS)</i> | 232 |
| <i>TABLE 55 U.S. BIOLOGICAL CANCER TREATMENT MARKET BY PRODUCT, 2007-2009</i> | 233 |
| <i>TABLE 56 CAMPATH SALES, 2007 AND 2008 (\$ MILLIONS)</i> | 234 |
| Japanese Cancer Market | 234 |
| <i>TABLE 57 JAPANESE BIOLOGICAL CANCER TREATMENT MARKET BY DRUG CLASS, THROUGH 2019 (\$ MILLIONS)</i> | 234 |
| <i>FIGURE 19 JAPANESE BIOLOGICAL CANCER TREATMENT MARKET BY DRUG CLASS, 2008-2019 (\$ MILLIONS)</i> | 235 |
| <i>TABLE 58 JAPANESE BIOLOGICAL CANCER TREATMENT MARKET BY PRODUCT, 2008 AND 2009 (\$ MILLIONS)</i> | 235 |
| <i>FIGURE 20 JAPANESE BIOLOGICAL CANCER TREATMENT MARKET BY PRODUCT, 2008 AND 2009 (\$ MILLIONS)</i> | 235 |
| European Cancer Market | 236 |
| <i>TABLE 59 EUROPEAN BIOLOGICAL CANCER TREATMENT MARKET BY DRUG CLASS, THROUGH 2019 (\$ MILLIONS)</i> | 237 |
| <i>FIGURE 21 EUROPEAN BIOLOGICAL CANCER TREATMENT MARKET BY DRUG CLASS, 2008-2019 (\$ MILLIONS)</i> | 237 |
| <i>TABLE 60 EUROPEAN BIOLOGICAL CANCER TREATMENT MARKET BY PRODUCT, 2008 AND 2009 (\$ MILLIONS)</i> | 238 |
| Asia-Pacific Cancer Market | 238 |
| Australian Cancer Market | 239 |
| South Korean Cancer Market | 239 |
| Chinese Cancer Market | 239 |
| Indian Cancer Market | 240 |
| Singapore Cancer Market | 240 |
| Taiwanese Cancer Market | 241 |
| BIOMAB-EGFR | 241 |
| <i>TABLE 61 ASIA-PACIFIC ONCOLOGY COMPANIES</i> | 241 |
| MARKET DATA BY TOP-SELLING BIOLOGIC DRUGS | 242 |
| <i>TABLE 62 GLOBAL TOP-SELLING BIOLOGIC DRUGS, 2007-2009 (\$ MILLIONS)</i> | 242 |
| <i>FIGURE 22 GLOBAL TOP-SELLING BIOLOGIC DRUGS, 2007-2009 (\$ MILLIONS)</i> | 242 |
| <i>TABLE 63 U.S. TOP-SELLING BIOLOGIC DRUGS, 2007-2009 (\$ MILLIONS)</i> | 243 |
| <i>FIGURE 23 U.S. TOP-SELLING BIOLOGIC DRUGS, 2007-2009 (\$ MILLIONS)</i> | 243 |
| CHAPTER 9 GLOBAL CANCER STATISTICS | 246 |
| GLOBAL CANCER INCIDENCE | 246 |
| CANCER TRENDS | 246 |
| <i>TABLE 64 CANCER ESTIMATES, 2012 (MILLIONS)</i> | 247 |
| <i>TABLE 65 NEW CANCER CASES DIAGNOSED, 2012* (NUMBER/%)</i> | 247 |
| <i>TABLE 66 GLOBAL COMMONLY DIAGNOSED CANCERS, 2012 (MILLIONS/%)</i> | 248 |
| <i>TABLE 67 AGE-STANDARDIZED CANCER RATES, 2012 (PER 100,000)</i> | 250 |
| TRENDS OVER TIME | 251 |
| GLOBAL CANCER INCIDENCE, 2008 | 251 |
| <i>TABLE 68 GLOBAL CANCER INCIDENCE BY TYPE, 2008 (MILLIONS)</i> | 252 |
| <i>TABLE 69 GLOBAL CANCER DEATHS BY TYPE, 2008 (MILLIONS)</i> | 253 |

| TOPIC | PAGE NO. |
|--|-----------------|
| <i>TABLE 70 GLOBAL CANCER DISTRIBUTION BY TYPE, 2009 (MILLIONS)</i> | 254 |
| <i>TABLE 71 GLOBAL NEW CANCER CASES BY TYPE AND REGION, 2009 (MILLIONS)</i> | 255 |
| FUTURE TRENDS, 2020 | 257 |
| <i>TABLE 72 NEW CANCER CASES BY TYPE, 2020 (MILLIONS)</i> | 257 |
| <i>TABLE 73 GLOBAL NEW CANCER CASES BY TYPE AND REGION, 2020 (MILLIONS)</i> | 258 |
| CANCER CURE AND COSTS | 260 |
| RISE IN CANCER: CAUSES | 260 |
| <i>TABLE 74 AMERICAN CANCER SOCIETY RECOMMENDATIONS FOR CANCER PREVENTION</i> | 261 |
| PROJECTIONS TO 2030 | 261 |
| <i>TABLE 75 GLOBAL CANCER INCIDENCE, 2008-2030 (\$ MILLIONS)</i> | 262 |
| <i>FIGURE 24 GLOBAL CANCER INCIDENCE, 2008-2030 (MILLIONS)</i> | 262 |
| <i>TABLE 76 GLOBAL DISTRIBUTION OF NEW CANCER CASES BY REGION, 2009 (MILLIONS/%)</i> | 263 |
| <i>FIGURE 25 GLOBAL DISTRIBUTION OF NEW CANCER CASES BY REGION, 2009 (%)</i> | 264 |
| CURRENT CANCER TRENDS AND ECONOMIC BURDEN | 264 |
| <i>TABLE 77 GLOBAL CANCER INCIDENCE AND DEATH BY REGION AND GENDER, 2008 (MILLIONS)</i> | 265 |
| <i>FIGURE 26 GLOBAL CANCER INCIDENCE AND DEATH BY REGION AND GENDER, 2008 (MILLIONS)</i> | 265 |
| <i>TABLE 78 GLOBAL CANCER INCIDENCE BY TYPE, 2007-2012</i> | 267 |
| <i>FIGURE 27 GLOBAL CANCER INCIDENCE BY TYPE, 2007-2012 (MILLIONS)</i> | 268 |
| <i>TABLE 79 GLOBAL MORTALITY BY CANCER TYPE, 2012 (MILLIONS)</i> | 268 |
| CANCER PREVALENCE AND MARKET | 269 |
| EMERGING MARKETS | 270 |
| Africa | 270 |
| Asia | 272 |
| China | 274 |
| Malaysia | 276 |
| India | 277 |
| Europe | 278 |
| Americas | 279 |
| <i>TABLE 80 AMERICAS: CANCER FACTS</i> | 279 |
| North America | 281 |
| <i>TABLE 81 U.S. LEADING NEW CANCER CASES, 2014 (NUMBER/%)</i> | 281 |
| <i>TABLE 82 U.S. LEADING NEW CANCER CASES, 2014 (NUMBER/%)</i> | 282 |
| <i>TABLE 83 U.S. CANCER INCIDENCE BY TYPE, 2007-2009</i> | 283 |
| <i>FIGURE 28 U.S. CANCER INCIDENCE BY TYPE, 2007-2009 (MILLIONS)</i> | 283 |
| <i>TABLE 84 U.S. CANCER DEATHS BY TYPE, 2007-2009 (MILLIONS)</i> | 284 |
| <i>FIGURE 29 U.S. CANCER DEATHS BY CANCER TYPE, 2007-2009 (MILLIONS)</i> | 284 |
| Canada | 285 |
| CHAPTER 10 BIOLOGIC CANCER MARKET ISSUES AND TRENDS | 287 |
| MEDICARE AND HEALTHCARE POLICIES | 287 |
| CANCER COSTS | 290 |
| CANCER DRUG COSTS | 292 |
| PERSONALIZED MEDICINE | 293 |
| PRICING STRATEGIES FOR CANCER BIOLOGICS | 294 |

| TOPIC | PAGE NO. |
|---|-----------------|
| PERSONALIZED MEDICINE: USING PHARMACOGENOMICS | 297 |
| PHARMACOGENOMICS | 301 |
| TARGETED CANCER THERAPY | 302 |
| LIFESTYLES AND CANCER PREVENTION | 304 |
| MARKETING AND DISTRIBUTION TRENDS | 305 |
| GLOBAL TRENDS | 306 |
| BIOSIMILARS | 307 |
| PATENT EXPIRIES AND BIOSIMILARS | 309 |
| <i>TABLE 85 MAJOR BIOPHARMACEUTICAL PATENT DATES (\$ MILLIONS)</i> | 309 |
| BIOSIMILARS AND COSTS OF CANCER DRUGS | 311 |
| BIOGENERICS, BIOSIMILARS AND FOLLOW-ON BIOLOGICS | 313 |
| BIOSIMILAR MANUFACTURERS | 314 |
| BIOSIMILARS IN INDIA AND CHINA | 316 |
| HURDLES FOR BIOSIMILARS | 318 |
| DATA EXCLUSIVITY PERIODS | 319 |
| DIFFERENCES BETWEEN BIOPHARMACEUTICALS AND BIOGENERICS | 320 |
| BIOSIMILARS IN EUROPE | 322 |
| ISSUES WITH BIOSIMILARS | 323 |
| ERYTHROPOIESIS-STIMULATING AGENTS OR ERYTHROPOIETINS (ESAS) BIOSIMILARS | 324 |
| BIOSIMILARS AND PATIENT SAFETY | 324 |
| CURRENT BIOSIMILARS | 325 |
| SUMMARY | 327 |
| CONCLUSIONS | 329 |
| VENTURE CAPITAL AND RESEARCH INVESTMENT | 332 |
| FUNDING CANCER RESEARCH | 332 |
| <i>TABLE 86 GLOBAL CANCER RESEARCH INVESTMENT, 2009 (MILLIONS/%)</i> | 333 |
| CONCLUSION | 333 |
| CHAPTER 11 COMPANY PROFILES | 336 |
| BIOLOGIC COMPANIES | 336 |
| <i>TABLE 87 GLOBAL BIOLOGIC DRUG PRESCRIPTION SALES, THROUGH 2014 (\$ MILLIONS)</i> | 336 |
| SELECTED COMPANIES AND PROFILES | 338 |
| ABBVIE INC. | 338 |
| AMGEN INC. | 338 |
| ASTELLAS PHARMA U.S. LLC | 339 |
| BIOGEN IDEC | 340 |
| BIOSERVICES | 341 |
| BRISTOL MYERS SQUIBB | 341 |
| CELLDEX THERAPEUTICS | 342 |
| CEL-SCI CORP. | 342 |
| DENDREON | 342 |
| ELI LILLY AND COMPANY | 343 |
| GENENTECH INC. | 343 |
| HOFFMANN-LA ROCHE INC. | 343 |
| GENMAB A/S | 344 |
| GENZYME CORP. | 345 |

| TOPIC | PAGE NO. |
|---------------------------|-----------------|
| GERON CORP. | 345 |
| GLAXOSMITHKLINE | 346 |
| IMMUNOGEN | 347 |
| INOVIO | 350 |
| JOHNSON AND JOHNSON | 350 |
| MERCK & COMPANY | 351 |
| NORTHWEST BIOTHERAPEUTICS | 352 |
| NOVARTIS | 352 |
| NOVARX CORP. | 354 |
| PFIZER | 354 |
| ROCHE/GENENTECH | 355 |
| VICAL INCORPORATED | 355 |
| | |
| CHAPTER 12 REFERENCES | 357 |

LIST OF TABLES

| TABLE HEADING | PAGE NO. |
|--|-----------------|
| SUMMARY TABLE GLOBAL BIOLOGICAL CANCER TREATMENT MARKET BY SEGMENT, THROUGH 2019 (\$ MILLIONS) | 7 |
| TABLE 1 MAIN CANCER CATEGORIES | 16 |
| TABLE 2 APPROVED RENAL CELL CANCER DRUGS | 51 |
| TABLE 3 MONOCLONAL ANTIBODIES FOR NON-HODGKIN'S LYMPHOMA TREATMENT | 59 |
| TABLE 4 BRAIN TUMOR SPECIFIC STATISTICS | 79 |
| TABLE 5 ASTROCYTOMAS | 83 |
| TABLE 6 STOMACH CANCER TYPES | 102 |
| TABLE 7 ADENOCARCINOMA STOMACH CANCER STAGES | 103 |
| TABLE 8 HEAD AND NECK CANCER TYPES | 106 |
| TABLE 9 GLOBAL BIOLOGICAL CANCER TREATMENT MARKET BY REGION, THROUGH 2019 (\$ MILLIONS) | 109 |
| TABLE 10 MONOCLONAL ANTIBODIES FOR CANCER TREATMENT | 111 |
| TABLE 11 ANTIBODY-BASED DEVELOPMENTS WITH EPITHELIAL CELL-ADHESION MOLECULE | 115 |
| TABLE 12 GLOBAL BEST-SELLING MONOCLONAL ANTIBODIES FOR CANCER, 2014 (\$ MILLIONS) | 118 |
| TABLE 13 U.S. BEST-SELLING MONOCLONAL ANTIBODIES FOR CANCER, 2007-2009 (\$ MILLIONS) | 119 |
| TABLE 14 ERBITUX APPROVALS | 125 |
| TABLE 15 GLOBAL BEST-SELLING INTERFERONS FOR CANCER, 2013 AND 2014 (\$ MILLIONS) | 131 |
| TABLE 16 GLOBAL BEST-SELLING PREVENTATIVE VACCINES FOR CANCER, 2013 AND 2014 (\$ MILLIONS) | 138 |
| TABLE 17 GLOBAL BEST-SELLING SUPPORTIVE CARE DRUGS, 2013 AND 2014 (\$ MILLIONS) | 142 |
| TABLE 18 GLOBAL BIOLOGICS SALES, 2013 (\$ MILLIONS) | 154 |
| TABLE 19 GLOBAL CANCER INCIDENCE AND FORECAST BY REGION, 2007-2030 (MILLIONS) | 156 |
| TABLE 20 GLOBAL CANCER-RELATED DEATHS AND FORECAST BY REGION, 2007-2030 (MILLIONS) | 157 |
| TABLE 21 APPROVED ONCOLOGY DRUGS, 2013-2014 | 158 |
| TABLE 22 GLOBAL ONCOLOGY MARKET BY REGION, THROUGH 2019 (\$ MILLIONS) | 161 |
| TABLE 23 GLOBAL ONCOLOGY SALES, 2012 AND 2013 (\$ MILLIONS/%) | 164 |
| TABLE 24 ASIA-PACIFIC SOLID TUMOR MARKET, THROUGH 2019 (\$ MILLIONS) | 165 |
| TABLE 25 ASIA-PACIFIC ONCOLOGY MARKET, 2008 (\$ MILLIONS) | 168 |
| TABLE 26 GLOBAL BIOTHERAPEUTIC SALES COMPARED TO TOTAL PRESCRIPTION DRUG SALES, THROUGH 2019 (\$ MILLIONS) | 170 |
| TABLE 27 U.S. BIOLOGIC DRUG SALES, 2011 AND 2012 (\$ BILLIONS) | 171 |
| TABLE 28 GLOBAL BIOLOGICAL MONOCLONAL, ANTIBODY CANCER TREATMENT MARKET, THROUGH 2019 (\$ MILLIONS) | 172 |
| TABLE 29 CANCER MONOCLONAL ANTIBODY THERAPIES | 173 |
| TABLE 30 GLOBAL BIOLOGICAL INTERFERON/INTERLEUKIN CANCER TREATMENT MARKET, THROUGH 2019 (\$ MILLIONS) | 174 |
| TABLE 31 SELECTED INTERFERON DRUG SALES, 2009 (\$ MILLIONS) | 176 |
| TABLE 32 PATENT EXPIRIES | 177 |
| TABLE 33 REMICADE SALES, 2012-2014 (\$ MILLIONS) | 180 |
| TABLE 34 PROCRT SALES, 2009 AND 2012 (\$ MILLIONS) | 181 |

| TABLE HEADING | PAGE NO. |
|--|-----------------|
| TABLE 35 GLOBAL BIOLOGICAL CANCER VACCINE MARKET, THROUGH 2019 (\$ MILLIONS) | 182 |
| TABLE 36 GARDASIL SALES, 2012 AND 2013 (\$ MILLIONS) | 183 |
| TABLE 37 MYLOTARG SALES, 2009 (\$ MILLIONS) | 183 |
| TABLE 38 GLOBAL IMMUNOSTIMULANT MARKET, THROUGH 2019 (\$ MILLIONS) | 184 |
| TABLE 39 AMGEN SALES, 2012-2013 (\$ MILLIONS) | 186 |
| TABLE 40 APPROVED BIOLOGICS CANCER DRUGS, 2013-2014 | 189 |
| TABLE 41 PROVENGE'S KEY FEATURES | 194 |
| TABLE 42 GERON-SPONSORED CLINICAL TRIALS | 198 |
| TABLE 43 ADVAXIS DRUG CANDIDATES | 198 |
| TABLE 44 ONCOLYTICS BIOTECH CLINICAL TRIALS | 209 |
| TABLE 45 ABBVIE ONCOLOGY PIPELINE | 212 |
| TABLE 46 ENROLLING OR COMPLETED CLINICAL STUDIES* | 215 |
| TABLE 47 PFIZER ONCOLOGY PIPELINE | 216 |
| TABLE 48 ONCOLOGY CLINICAL TRIALS, 2009 (NUMBER) | 217 |
| TABLE 49 APPROVED BIOLOGICS FOR CANCER, 2009 | 218 |
| TABLE 50 RITUXAN TREATMENT INDICATIONS | 225 |
| TABLE 51 DENOSUMAB MARKET, THROUGH 2019 (\$ MILLIONS) | 227 |
| TABLE 52 TOP CANCER BIOLOGICS, 2007-2009 (\$ MILLIONS) | 227 |
| TABLE 53 ONCOLOGY TREATMENT BY REGION, 2013 | 230 |
| TABLE 54 U.S. BIOLOGICAL CANCER TREATMENT MARKET BY DRUG CLASS, THROUGH 2019 (\$ MILLIONS) | 232 |
| TABLE 55 U.S. BIOLOGICAL CANCER TREATMENT MARKET BY PRODUCT, 2007-2009 | 233 |
| TABLE 56 CAMPATH SALES, 2007 AND 2008 (\$ MILLIONS) | 234 |
| TABLE 57 JAPANESE BIOLOGICAL CANCER TREATMENT MARKET BY DRUG CLASS, THROUGH 2019 (\$ MILLIONS) | 234 |
| TABLE 58 JAPANESE BIOLOGICAL CANCER TREATMENT MARKET BY PRODUCT, 2008 AND 2009 (\$ MILLIONS) | 235 |
| TABLE 59 EUROPEAN BIOLOGICAL CANCER TREATMENT MARKET BY DRUG CLASS, THROUGH 2019 (\$ MILLIONS) | 237 |
| TABLE 60 EUROPEAN BIOLOGICAL CANCER TREATMENT MARKET BY PRODUCT, 2008 AND 2009 (\$ MILLIONS) | 238 |
| TABLE 61 ASIA-PACIFIC ONCOLOGY COMPANIES | 241 |
| TABLE 62 GLOBAL TOP-SELLING BIOLOGIC DRUGS, 2007-2009 (\$ MILLIONS) | 242 |
| TABLE 63 U.S. TOP-SELLING BIOLOGIC DRUGS, 2007-2009 (\$ MILLIONS) | 243 |
| TABLE 64 CANCER ESTIMATES, 2012 (MILLIONS) | 247 |
| TABLE 65 NEW CANCER CASES DIAGNOSED, 2012* (NUMBER/%) | 247 |
| TABLE 66 GLOBAL COMMONLY DIAGNOSED CANCERS, 2012 (MILLIONS/%) | 248 |
| TABLE 67 AGE-STANDARDIZED CANCER RATES, 2012 (PER 100,000) | 250 |
| TABLE 68 GLOBAL CANCER INCIDENCE BY TYPE, 2008 (MILLIONS) | 252 |
| TABLE 69 GLOBAL CANCER DEATHS BY TYPE, 2008 (MILLIONS) | 253 |
| TABLE 70 GLOBAL CANCER DISTRIBUTION BY TYPE, 2009 (MILLIONS) | 254 |
| TABLE 71 GLOBAL NEW CANCER CASES BY TYPE AND REGION, 2009 (MILLIONS) | 255 |
| TABLE 72 NEW CANCER CASES BY TYPE, 2020 (MILLIONS) | 257 |
| TABLE 73 GLOBAL NEW CANCER CASES BY TYPE AND REGION, 2020 (MILLIONS) | 258 |
| TABLE 74 AMERICAN CANCER SOCIETY RECOMMENDATIONS FOR CANCER PREVENTION | 261 |
| TABLE 75 GLOBAL CANCER INCIDENCE, 2008-2030 (\$ MILLIONS) | 262 |

| TABLE HEADING | PAGE NO. |
|--|-----------------|
| TABLE 76 GLOBAL DISTRIBUTION OF NEW CANCER CASES BY REGION, 2009 (MILLIONS/%) | 263 |
| TABLE 77 GLOBAL CANCER INCIDENCE AND DEATH BY REGION AND GENDER, 2008 (MILLIONS) | 265 |
| TABLE 78 GLOBAL CANCER INCIDENCE BY TYPE, 2007-2012 | 267 |
| TABLE 79 GLOBAL MORTALITY BY CANCER TYPE, 2012 (MILLIONS) | 268 |
| TABLE 80 AMERICAS: CANCER FACTS | 279 |
| TABLE 81 U.S. LEADING NEW CANCER CASES, 2014 (NUMBER/%) | 281 |
| TABLE 82 U.S. LEADING NEW CANCER CASES, 2014 (NUMBER/%) | 282 |
| TABLE 83 U.S. CANCER INCIDENCE BY TYPE, 2007-2009 | 283 |
| TABLE 84 U.S. CANCER DEATHS BY TYPE, 2007-2009 (MILLIONS) | 284 |
| TABLE 85 MAJOR BIOPHARMACEUTICAL PATENT DATES (\$ MILLIONS) | 309 |
| TABLE 86 GLOBAL CANCER RESEARCH INVESTMENT, 2009 (MILLIONS/%) | 333 |
| TABLE 87 GLOBAL BIOLOGIC DRUG PRESCRIPTION SALES, THROUGH 2014 (\$ MILLIONS) | 336 |

LIST OF FIGURES

| FIGURE TITLE | PAGE NO. |
|--|-----------------|
| SUMMARY FIGURE GLOBAL BIOLOGICAL CANCER TREATMENT MARKET BY SEGMENT, 2008-2019 (\$ MILLIONS) | 7 |
| FIGURE 1 GLOBAL BIOLOGICAL CANCER TREATMENT MARKET BY REGION, 2008-2019 (\$ MILLIONS) | 109 |
| FIGURE 2 GLOBAL BEST-SELLING MONOCLONAL ANTIBODIES FOR CANCER, 2014 (\$ MILLIONS) | 118 |
| FIGURE 3 U.S. BEST-SELLING MONOCLONAL ANTIBODIES FOR CANCER, 2007-2009 (\$ MILLIONS) | 119 |
| FIGURE 4 GLOBAL BEST-SELLING INTERFERONS FOR CANCER, 2013 AND 2014 (\$ MILLIONS) | 131 |
| FIGURE 5 GLOBAL BEST-SELLING PREVENTATIVE VACCINES FOR CANCER, 2013 AND 2014 (\$ MILLIONS) | 139 |
| FIGURE 6 GLOBAL BEST-SELLING SUPPORTIVE CARE DRUGS, 2013 AND 2014 (\$ MILLIONS) | 142 |
| FIGURE 7 GLOBAL CANCER INCIDENCE AND FORECAST BY REGION, 2007-2030 (MILLIONS) | 156 |
| FIGURE 8 GLOBAL CANCER-RELATED DEATHS AND FORECAST BY REGION, 2007-2030 (MILLIONS) | 158 |
| FIGURE 9 GLOBAL ONCOLOGY MARKET BY REGION, 2008-2019 (\$ MILLIONS) | 161 |
| FIGURE 10 ASIA-PACIFIC ONCOLOGY MARKET, 2008 (\$ MILLIONS) | 168 |
| FIGURE 11 GLOBAL BIOTHERAPEUTIC SALES COMPARED TO TOTAL PRESCRIPTION DRUG SALES, 2008-2019 (\$ MILLIONS) | 170 |
| FIGURE 12 GLOBAL BIOLOGICAL MONOCLONAL ANTIBODY MARKET, 2009-2019 (\$ MILLIONS) | 173 |
| FIGURE 13 GLOBAL BIOLOGICAL INTERFERON/INTERLEUKIN CANCER TREATMENT MARKET, 2013-2019 (\$ MILLIONS) | 175 |
| FIGURE 14 GLOBAL BIOLOGICAL CANCER VACCINE MARKET, 2009-2019 (\$ MILLIONS) | 182 |
| FIGURE 15 GLOBAL IMMUNOSTIMULANT MARKET, 2009-2019 (\$ MILLIONS) | 184 |
| FIGURE 16 ONCOLOGY CLINICAL TRIALS, 2009 (NUMBER) | 217 |
| FIGURE 17 TOP CANCER BIOLOGICS, 2007-2009 (\$ MILLIONS) | 228 |
| FIGURE 18 U.S. BIOLOGICAL CANCER TREATMENT MARKET BY DRUG CLASS, 2008-2019 (\$ MILLIONS) | 232 |
| FIGURE 19 JAPANESE BIOLOGICAL CANCER TREATMENT MARKET BY DRUG CLASS, 2008-2019 (\$ MILLIONS) | 235 |
| FIGURE 20 JAPANESE BIOLOGICAL CANCER TREATMENT MARKET BY PRODUCT, 2008 AND 2009 (\$ MILLIONS) | 235 |
| FIGURE 21 EUROPEAN BIOLOGICAL CANCER TREATMENT MARKET BY DRUG CLASS, 2008-2019 (\$ MILLIONS) | 237 |
| FIGURE 22 GLOBAL TOP-SELLING BIOLOGIC DRUGS, 2007-2009 (\$ MILLIONS) | 242 |
| FIGURE 23 U.S. TOP-SELLING BIOLOGIC DRUGS, 2007-2009 (\$ MILLIONS) | 243 |
| FIGURE 24 GLOBAL CANCER INCIDENCE, 2008-2030 (MILLIONS) | 262 |
| FIGURE 25 GLOBAL DISTRIBUTION OF NEW CANCER CASES BY REGION, 2009 (%) | 264 |
| FIGURE 26 GLOBAL CANCER INCIDENCE AND DEATH BY REGION AND GENDER, 2008 (MILLIONS) | 265 |
| FIGURE 27 GLOBAL CANCER INCIDENCE BY TYPE, 2007-2012 (MILLIONS) | 268 |
| FIGURE 28 U.S. CANCER INCIDENCE BY TYPE, 2007-2009 (MILLIONS) | 283 |
| FIGURE 29 U.S. CANCER DEATHS BY CANCER TYPE, 2007-2009 (MILLIONS) | 284 |