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CANCER THERAPEUTICS MARKETS *(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers

TABLE OF CONTENTS

1.	Overview	5	
1.1	Introduction	5	
1.2	Goals and Objectives	6	
1.3	Study, Scope and Format	6	
1.4	Methodology	6	
1.5	Summary of Major Findings	8	
2.	Introduction to the Cancer Therapeutic Market	10	
3.	Cancer Therapeutics Market Overview	18	
3.1	Cancer Therapeutics in the Pharmaceutical and Biotech Industry	18	
3.2	Business Analysis of the Cancer Market	25	
3.2.1	Growth Potential	25	
3.2.2	Demographics of Cancer	26	
3.2.3	The Global Market for Cancer Therapies	26	
3.2.3.1	European Cancer Market	28	
3.2.3.2	The Environment in the U.K. for Clinical Research into New Anti-Cancer Therapies	30	
3.2.3.3	The Suitability of Current U.K. and E.U. Regulatory Regimes	30	
3.2.3.4	Comments on the Current E.U. Regulatory Environment	31	
3.3	The Pharmaceutical Industry	32	
3.4	Cancer Therapies	33	
3.4.1	Market Size	33	
3.5	New Product Trends	35	
3.5.1	Chemotherapy	35	
3.5.2	Hormone Therapy	40	
3.5.3	Photodynamic Therapy and Photosensitizers	41	
3.5.4	Gene Therapy	41	
3.5.4.1	Tumor-Suppressor Gene Therapy	42	
3.5.4.2	Immunomodulatory Gene Therapy	42	
3.5.4.3	Suicide Gene Therapy	42	
3.5.5	Radiation Therapy	43	
3.5.6	Farnesyl Transferase Inhibitors (FTIs)	44	
3.5.7	Genetic Screening	44	
3.5.8	Biological Therapies	45	
3.5.9	Interferons	46	
3.5.10	Interleukins	46	
3.5.11	Tumor Necrosis Factor (TNF)	46	
3.5.12	Colony-Stimulating Factors (CSFs)	46	
3.5.13	Monoclonal Antibodies (MAbs)	47	
3.5.14	Cancer Vaccines	48	
3.5.15	Anti-Sense Therapy	50	
3.5.16	Adjuvants	50	
3.5.17	Angiogenesis Inhibitors	51	
3.5.18	Hyperthermia	53	
3.5.19	Transplants	53	
3.5.19.1	Bone Marrow Transplants	53	
3.5.19.2	Stem Cell Transplants	53	
4.	The Disease of Cancer	56	
4.1	Incidence of Cancer	56	
4.1.1	U.S. Statistics	56	
4.1.2	Global Statistics	58	

4.2	Causes of Cancer	61
4.3	Risk Factors	62
4.3.1	Smoking	63
4.3.2	Diet	63
4.3.3	Radiation	63
4.3.4	Occupational Risks	64
4.3.5	Medicine and Infection	65
4.3.6	Environmental Pollution	65
4.3.7	Reproductive Factors	65
4.3.8	Socio-Economic Factors	65
4.4	Cancer Costs	66
5.	Specific Cancers	67
5.1	Bladder Cancer	67
5.1.1	Overview of the Disease	67
5.1.2	Diagnosis and Staging	68
5.1.3	Therapy	68
5.1.4	Test for Bladder Cancer Analyzes DNA in Urine	70
5.1.5	Drugs in Development	71
5.2	Brain Cancer	71
5.2.1	Overview of the Disease	71
5.2.2	Treatment Options	72
5.3	Breast Cancer	73
5.3.1	Overview of the Disease	73
5.3.2	Therapeutic Drugs	74
5.3.3	Market Overview for Breast Cancer Therapeutics	89
5.4	Cervical Cancer	91
5.4.1	Overview of the Disease	91
5.4.2	Treatment Options	92
5.5	Colon Cancer	94
5.5.1	Overview of the Disease	94
5.5.2	Treatment Options	94
5.5.3	Market Overview for Colon Cancer Therapeutics	100
5.6	Leukemia	101
5.6.1	Overview of the Disease	101
5.6.2	Treatment Options	102
5.7	Lymphoma	108
5.7.1	Overview of the Disease	108
5.7.2	Treatment Options	108
5.8	Lung Cancer	112
5.8.1	Overview of the Disease	113
5.8.2	Treatment Options	113
5.8.3	Breakthrough Treatments for Lung Cancer	114
5.8.4	Market Overview for Lung Cancer Therapeutics	123
5.9	Ovarian Cancer	123
5.9.1	Overview of the Disease	124
5.9.2	Treatment Options	124
5.10	Prostate Cancer	132
5.10.1	Overview of the Disease	132
5.10.2	Treatment Options	132
6.	Corporate Profiles	137
6.1	AstraZeneca Plc	137
6.2	Biogen Idec, Inc.	138
6.3	Bristol-Myers Squibb	139

6.4	Genentech, Inc.	140
6.5	Genta, Inc.	142
6.6	Genzyme Oncology	142
6.7	GlaxoSmithKline Plc	143
6.8	ImClone Systems, Inc.	144
6.9	Medarex	146
6.10	Millennium Pharmaceuticals, Inc.	148
6.11	Novartis AG	150
6.12	Onyx Pharmaceuticals, Inc.	153
6.13	OSI Pharmaceuticals, Inc.	154
6.14	Pfizer	155
6.15	Regeneron Pharmaceuticals, Inc.	156
6.16	Roche	157
6.17	Sanofi-Aventis	161
7.	References	164
7.1	Online References for Cancer	164
7.2	Print Sources	165
7.3	Product Approvals for Cancer Indications	173

INDEX OF TABLES

Table 2.1:	The 646 Medicines in Development for Cancer, 2006	10
Table 2.2:	Drug Approvals for Cancer Indications, 1996-2007	11
Table 3.1:	Opportunities for Molecular-Targeting Therapeutics for Cancer	20
Table 3.2:	Top U.S. Biotechnology Companies by Market Capitalization	21
Table 3.3:	Top Pharmaceutical Companies by Market Capitalization	21
Table 3.4:	Clinical Development for some of Hoffman-La Roche Products	22
Table 3.5:	Global Pharmaceutical Industry R&D Spending, 1995-2006	28
Table 3.6:	U.S. Government NIH Research Budget, 1995-2007	28
Table 3.7:	Health Spending as Percentage of GDP by Country	29
Table 3.8:	Spending on Health by Country	29
Table 3.9:	Annual Spending on Cancer Drugs Per Person	29
Table 3.10:	Patients Per Cancer Specialist	30
Table 3.11:	World Healthcare Cancer Therapeutics Markets by Region	33
Table 3.12:	U.S. Market for Cancer Therapeutics, 1998-2006	34
Table 3.13:	European Market for Cancer Therapeutics, 1998-2006	34
Table 3.14:	Japanese Market for Cancer Therapeutics, 1998-2006	34
Table 3.15:	Cancer Vaccines Approved or in Phase III Clinical Trials	49
Table 3.16:	Anti-Angiogenic Drugs in Clinical Trial for Cancer	51
Table 4.1:	New Cancer Cases and Deaths in the U.S. by Sex for all Cancer Sites, 2007	56
Table 4.2:	New Cancer Cases and Deaths for Ten Leading Cancer Sites in the U.S., by Sex, 2007	57
Table 4.3:	Worldwide Number of New Cancer Cases and Deaths by Leading Cancer Sites and by Level of Economic Development, 2007	58
Table 4.4:	Estimated Number of New Cancer Cases and Deaths by World Area, 2007	60
Table 4.5:	Cancer Death Rates per 100,000 Population (and Rank) for all Cancer Sites by Country, 2006	61
Table 4.6:	Genes and Cancer Risk	62
Table 4.7:	Carcinogens in the Workplace	64
Table 5.1:	Drugs Used in Bladder Cancer Therapy	69
Table 5.2:	Drugs in Development for Bladder Cancer	71
Table 5.3:	Medicines in Development for Brain Cancer	72
Table 5.4:	Classes of Chemotherapy Drugs Used to Treat Breast Cancer	74
Table 5.5:	U.S. Sales of Doxorubicin, 2001-2009	76
Table 5.6:	New Therapeutics for Breast Cancer	78

Table 5.7: Other Classes of Drugs Used to Treat Breast Cancer	80	
Table 5.8: Worldwide AstraZeneca's Nolvadex Sales, 2000-2005	82	
Table 5.9: Aromatase Inhibitors	83	
Table 5.10: Worldwide Sales Estimates for Arimidex, 2000-2008	84	
Table 5.11: Worldwide Herceptin Sales, 1999-2005	86	
Table 5.12: Innovative Drug Therapies applied to the Breast Cancer Market Sector	89	
Table 5.13: Treatment Regimens for Advanced Breast Cancer	89	
Table 5.14: Medicines in Development for Cervical Cancer	93	
Table 5.15: New Therapies for Colon Cancer	94	
Table 5.16: Worldwide Sales for Xeloda, 2001-2005	97	
Table 5.17: Worldwide Sales of Tomudex, 1998-2005	97	
Table 5.18: Medicines in Development for Leukemia	103	
Table 5.19: Pricing of Novartis' Gleevec in Various Strengths in the U.S.	106	
Table 5.20: Medicines in Development for Lymphoma	109	
Table 5.21: U.S. Sales of Rituxan, 1999-2005	111	
Table 5.22: Cytotoxics for Lung Cancer Therapy	115	
Table 5.23: Anti-Angiogenics for Lung Cancer	115	
Table 5.24: Drugs in Development for Lung Cancer	120	
Table 5.25: Current Therapies for Ovarian Cancer	124	
Table 5.26: Emerging Therapies for Ovarian Cancer	125	
Table 5.27: New Development Therapies for Ovarian Cancer	126	
Table 5.28: New Drug Types for Ovarian Cancer	127	
Table 5.29: Medicines in Development for Prostate Cancer	133	
Table 6.1: Potential Therapeutic Indications and Development Stages	146	
Table 6.2: Products in Clinical Development in Phase II and III (Including Additional Indications)	161	
Table 7.1: Drugs Currently Approved for the Treatment of Cancer	166	

1. Overview

1.1 Introduction

Cancer is the second leading cause of death by disease in the United States, exceeded only by heart disease. Currently, [REDACTED] out of every [REDACTED] deaths in the U.S. is from cancer. In [REDACTED], cancer claimed an estimated [REDACTED] American lives, or more than [REDACTED] people a day. Moreover, an estimated [REDACTED] new cases of cancer were diagnosed. Approximately, [REDACTED] Americans, now living, have a history of cancer. Although cancer occurs in all age groups, the incidence increases as people grow older. Nearly [REDACTED]% of all cancers occur in people [REDACTED] years and older. However, pediatric cancer—though rare—is the nation's leading cause of death by disease in children under the age of [REDACTED]. An estimated [REDACTED] children in the U.S. were diagnosed with cancer in [REDACTED] and [REDACTED] have died.

An estimated [REDACTED] new cancer cases occurred worldwide in [REDACTED], of which approximately [REDACTED] cases occurred in economically developed countries and [REDACTED] in economically developing countries. The corresponding total cancer deaths in [REDACTED] were an estimated [REDACTED] (about [REDACTED] cancer deaths a day), [REDACTED] in economically developed countries and [REDACTED] in economically developing countries.

However, cancer research has made remarkable progress, with several innovative therapies coming into the market in the past decade. There have been notable improvements over time in the relative five-year survival rates for many cancer sites and for all sites combined. In the U.S., death rates for [REDACTED] of the top [REDACTED] cancers remained level or declined during the [REDACTED], according to the *Journal of National Cancer Institute* report. The most notable decreases are in the death rates for breast cancer, prostate cancer, lung cancer, colon cancer and leukemia. This is, in no small measure, due to early detection and improved treatments, including more effective prescription drugs.

While the death rate from cancer is declining, the number of actual deaths is increasing because of an increasing population and longer life expectancy. Lifetime risk is the probability that an individual will develop cancer or die from it over the course of a lifetime. In the U.S., men have a one in two lifetime risk of developing cancer and women have a one in three risk.

Cancer is caused by both external (chemicals, radiation, viruses) and internal (hormones, immune conditions, inherited mutations) factors. These factors can act together or in sequence to initiate or promote abnormal cell growth and spread. Ten years or more may pass before exposures or mutations and detectable cancer.

Some cancers can be prevented. All cancers caused by cigarette smoking and the excessive use of alcohol can be completely prevented. In the U.S., in [REDACTED], about [REDACTED] cancer deaths were due to tobacco use and nearly [REDACTED] were related to excessive use of alcohol, which frequently occurs in connection with cigarette smoking. Many other cancers that are related to diet can also be prevented. Scientific research suggests that as many as one-third of all cancer deaths may be related to obesity, physical inactivity, and nutrition, and can also be prevented. Certain cancers are related to infectious agents, such as hepatitis B virus (HBV), human papillomavirus (HPV), *Helicobacter pylori*, and others, and can be prevented through behavioral changes, vaccines, or antibiotics. In addition, many of the more than a million cases of skin cancers that were estimated to be diagnosed in [REDACTED] could have been prevented by the use of proper protection from the sun.

Screening examinations administered by healthcare professionals can result in the early detection of some cancers—cancer of the breast, colon, rectum, cervix, prostate, oral cavity and skin. Treatment is more likely to be effective when the cancer is detected in its early stages. Self-examinations for cancer of the breast and skin also detect cancer early on. The cancers listed above, that can be prevented or detected earlier by screening, account for approximately half of all new cancer cases. The [REDACTED]-year survival rate for those cancers is now about [REDACTED]%. If everyone in the U.S. were regularly screened for cancer, the survival rate would be over [REDACTED]%.

A simple cure for cancer does not seem likely. Cancer is not a single disease. Each type of cancer is complex. The causes and progress of each type of cancer is different. Tumors are composed of both normal cells and cancerous cells. Within a single tumor, the cells are in different stages of development.

Traditionally cancer has been treated with surgery, chemotherapy, hormones and radiation therapy, alone or in combination. Emerging technologies include photodynamic therapy, gene therapy, biological therapy (immunotherapy) and angiogenesis inhibitors. Pharmaceutical and biotechnology companies are investing billions of dollars to search out and develop weapons for the arsenal in the war against cancer. This report provides an overview of the global market for cancer therapeutics.

1.2 Goals and Objectives

The aim of this report is to provide in-depth information on the developing market for anti-cancer products and services. It includes detailed market analyses and discussions of industry trends in order to assess the impact on the current and emerging anti-cancer product markets. Forecasts and trends were developed from interviews with industry sources, as well as from assessment of available and emerging technologies. The study also focuses on the efforts of biotechnology companies and pharmaceutical firms to incorporate new technologies for developing anti-cancer drugs into their corporate strategies.

This review examines cancer therapeutic products now on the market, as well as those currently under development, that might be commercialized in the near future. It also profiles a number of firms that are actively involved in the marketing and development of products to be used in the treatment of cancer—both large multinational corporations, such as Bristol-Myers Squibb, GlaxoSmithKline, Roche/Genentech, and the smaller emerging biotechnology firms.

The report also provides an overview of the disease and data on cancers by site or type. It provides incidence and mortality data for different types of the disease. In addition, it provides a summary of each of the therapies that are being used to treat cancer. Industry influences on the cancer therapeutic market are also discussed.

1.3 Study, Scope and Format

The scope of the study is worldwide. The overview section provides extended definitions of the anti-cancer drugs to provide the reader with a clear understanding of the technology involved. It also provides an analysis of how drugs that combat cancer will transform the healthcare industry. The company profiles section includes a detailed discussion of the companies that have pioneered anti-cancer drug development and examines how their available products and services are transforming the practice of medicine.

1.4 Methodology

This study is based on interviews with sales and marketing professionals of companies in the cancer therapeutics market. They were queried, some several times, about their companies' products and marketing strategies as well as their overall thoughts about their industry segment. Information was also obtained from interviews with founders, CEOs and vice presidents of some of the companies discussed in the report.

Sources of information for the study were trade association publications and meetings, product brochures and catalogs, and company literature. For all publicly held companies under discussion, an examination of the annual reports and financial reports were used as the basis of the data reported. Important data sources include reports by the Pharmaceutical Research and Manufacturers of America (PhRMA), the American Cancer Society, the Health for All Database of the World Health Organization (WHO), data published by the Canadian Cancer Society, as well as various health data from the Organization for Economic Cooperation and Development (OECD) and the U.S. Food and Drug Administration (FDA). Where possible and practicable, the most recent data available have been used.

The author of this report is a PhD in biochemistry with decades of experience in science writing and as a medical industry analyst. He has been a senior director of several large regional and national clinical testing laboratories. The senior editor is a doctoral level clinical scientist. He has over 30 years of experience in laboratory testing and instrument and reagent development technology, as well as extensive experience in senior level positions in biotech and medical service companies.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information set forth in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information, omission or for the results obtained by the use of such information.

Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals with regard to commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this study.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects and Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark's research of the past three years as part of this data collection. We also extract qualified data feeds from e-questionnaire responses and primary research responses for this compilation.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government-affiliated trade releases, and other published information as part of our secondary research materials. The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations. The report conclusions are verified through intensive interviewing of top-ranking companies in the industry.

TriMark Publications Report Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly-available databases, proprietary databases, direct meetings and personal interviews with key personnel.
- Formulating a study outline with the assigned writer, including important items:
 - Market and product segment grouping and evaluating their relative significance.
 - Key competitors' evaluations including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
 - End-user research to evaluate analytical significance in market estimation.
 - Supply chain research and analysis to identify any factors affecting the market.
 - New technology platforms and cutting-edge applications.
- Identifying the key technology and market trends that drive or affect these markets. Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.
- Launching a combination of primary research activities including two levels of questionnaires, executive-direct focused, company-specific, and region-specific communications to qualified and experienced senior executives worldwide.
- Completing a confirmatory primary research assessment of the report's findings with the assistance of Expert Panel Partners from the industry being analyzed.

1.5 Summary of Major Findings

The worldwide cancer-therapy market produced revenues of \$ [REDACTED] in [REDACTED]. Treatment for cancer is estimated to become the largest sales value area at \$ [REDACTED] by [REDACTED], from the current \$ [REDACTED]. New treatments are emerging all the time and could dramatically alter the cancer therapeutics market. Currently, there are more than [REDACTED] new medicines approved for the treatment of cancer. Researchers are constantly looking for safer and more efficacious therapies. Therapies are also being sought that will mitigate the side effects of other cancer therapies and/or improve the quality of life of the cancer survivor.

The biotechnology industry will play an ever-increasing role in cancer therapeutics. Basic research projects by these firms have already done much in characterizing the disease. Treatments are now focusing more on the molecular and cellular levels of the disease. With the advent of these new treatments, combination therapy is becoming increasingly important. One of the major challenges for oncologists is to provide the cancer patient with the proper combination of therapies. There is also a strong emphasis on the cost-effectiveness of each therapy, not only as regards to the price of the product, but also its side effects and toxicity, route of administration and treatment regimen.

The field of cancer drug research is one of the most active areas of research by the pharmaceutical industry. At the end of [REDACTED], some [REDACTED] drugs were in development for all diseases and over [REDACTED] of these were targeted to treat cancer. Many of the [REDACTED] drugs in development in [REDACTED] will be used to treat more than one type of cancer. For example, there were [REDACTED] drugs under development for breast cancer, the [REDACTED] leading cause of cancer deaths for women in the U.S.; [REDACTED] for lung cancer, the leading cause of cancer deaths for both American men and women; and [REDACTED] for skin cancer. Over [REDACTED] new oncology products will be launched in the next [REDACTED] years with new players entering the market. About [REDACTED]% of all launches by [REDACTED] will be in oncology.

The worth of the worldwide pharmaceutical market in [REDACTED] was \$ [REDACTED]. This represented a [REDACTED]% increase over the previous year. The North American market, which accounts for [REDACTED]% of global pharmaceutical sales, continued to drive the growth with a [REDACTED]% increase to \$ [REDACTED], up from [REDACTED]% the previous year. This strong growth was due to the impact in the U.S. of the first year of the Medicare Part D benefit and the resulting increase in prescribing volume, as well as due to solid [REDACTED]% growth in Canada. The five major European markets (France, Germany, Italy, Spain and the United Kingdom) grew at [REDACTED]% to \$ [REDACTED], down from [REDACTED]% growth in [REDACTED], the [REDACTED] year of slowing performance. Sales in Latin America grew [REDACTED]% to \$ [REDACTED], while Africa and Asia-Pacific (outside of Japan) grew [REDACTED]% to \$ [REDACTED]. The performances in individual countries varied widely. Japan, at \$ [REDACTED], experienced a decline of [REDACTED]% in [REDACTED], a result of the government's biennial price cuts. Pharmaceutical sales in China grew [REDACTED]% to \$ [REDACTED] in [REDACTED], compared with a [REDACTED]% increase the previous year. India was one of the fastest growing markets in [REDACTED], with pharmaceutical sales increasing [REDACTED]% to \$ [REDACTED].

The [REDACTED] worldwide pharmaceutical market is predicted to grow to nearly \$ [REDACTED] to \$ [REDACTED]. According to Murray Aitken, senior vice president, *Healthcare Insight, IMS*, “[REDACTED] marks an important inflection point for the global pharmaceutical market. For the first time, the seven largest markets will contribute just half of overall pharmaceutical growth, while the seven emerging markets will contribute nearly [REDACTED]% of growth worldwide.” The seven “pharmemerging” markets (of China, Brazil, Mexico, South Korea, India, Turkey and Russia) are expected to grow [REDACTED]% to [REDACTED]% in [REDACTED], to \$ [REDACTED] to \$ [REDACTED]. Driving this growth will be the flood of new drug targets identified through genomics technology.

The estimated worldwide market size for cancer therapeutics in [REDACTED] was \$ [REDACTED], with an increase of [REDACTED]% since [REDACTED]. This significant growth, the highest among the top [REDACTED] therapeutic classes, was fueled by strong acceptance of innovative and effective therapies that are reshaping the approach to cancer treatments and outcomes. Today, [REDACTED] of the oncology products in late-stage development are targeted therapies, directed at specific molecules involved with carcinogenesis and tumor growth. *IMS Health* anticipates that up to [REDACTED] innovative new medicines will be launched in [REDACTED], including four new oncology drugs for treating melanoma, prostate cancer and acute myeloid leukemia (AML). Products used in the treatment of cancer are expected to exceed \$ [REDACTED] in value in [REDACTED], contributing nearly [REDACTED]% of audited market growth.

The rapidly emerging science of genomics is about to revolutionize various aspects of oncology practice, including how anti-cancer drugs are discovered and developed, how cancers are detected and classified and finally how patients are treated and monitored. Since the discovery of oncogenes and tumor suppressor genes, cancer has become one of the most important diseases in the design of therapeutic approaches based on genetics and genomics research and technologies.

Unlike the markets for monogenic diseases, most of which are caused by inherited mutations in a single gene, the market for cancer is enormous, and the commercial sector is expressing significant interest in clinical applications of genomics research. We estimate that the potential market for cancer therapeutics based on genomic solutions will be worth of \$ [redacted] by [redacted]. Ranking with the computer industry, the biotechnology industry is positioned for substantial growth in this century. The amount of money invested in the U.S. biotechnology industry, increased [redacted]% in [redacted] years, soaring from \$ [redacted] in [redacted] to \$ [redacted] in [redacted]. With \$ [redacted] raised in [redacted], this was the best year on record for biotech financing, excluding the bubble year of [redacted]. In fact, this industry has the promise to be the next high growth industry in the early years of the 21st century as it moves to become the foundation of a \$ [redacted] medical care industry in the U.S. According to *Beyond Borders, Global Biotechnology Report* [redacted], the accounting firm Ernst & Young estimates that in [redacted] there were [redacted] biotechnology companies in the U.S., out of which [redacted] were publicly held.

The main focus of the cancer drug market is to provide treatment for the four most common types of cancer—lung (small-cell and non-small-cell), breast, colorectal and prostate. These cancers have the greatest incidence of new cases and are responsible for the highest combined mortality—approximately [redacted]% of all cancer deaths worldwide. The treatment of these cancers provides a significant growth market potential for emerging therapeutics. These cancer segments have attracted the attention of pharmaceutical and biotechnology companies, which are developing a large and diverse array of investigational agents.

Competitor pipelines face significant changes in cancer treatment as it shifts toward molecular-based therapies. Ten of the top pharmaceutical and biotechnology companies have significant programs in oncology: Roche/Genentech, AstraZeneca, Bristol-Myers Squibb, Sanofi-Aventis, Merck, Eli Lilly, GlaxoSmithKline, Novartis, Johnson & Johnson and Genzyme. These ten companies sell [redacted]% of current U.S. FDA-approved and marketed oncology drugs in the U.S., Europe and Asia. New additions to the drug development pipelines of these companies will represent large opportunities in the oncology market over the next few years.

Examples of how new therapeutic drugs can explode the top line are illustrated by a number of examples in this report. Among them, MabThera/Rituxan (rituximab) and Herceptin (trastuzumab) are the first such treatments to become available. They have generated encouraging sales in their first few years on the market, particularly U.S. Genentech's Rituxan (developed by Biogen-Idec Pharmaceuticals), a treatment for non-Hodgkin's lymphoma (NHL), launched in the U.S. at the end of [redacted], that recorded sales of \$ [redacted] in [redacted], an increase of [redacted]% over \$ [redacted] in [redacted]. The product generated worldwide sales of \$ [redacted] in [redacted], a growth of [redacted]% since the previous year for Genentech (majority-owned by Roche, in [redacted]), and has become one of the leading cancer therapies in the world in terms of sales. Herceptin, a treatment for breast cancer launched in the fourth quarter of [redacted], looks on course to be just as successful, with worldwide sales of \$ [redacted] for Genentech/Roche in [redacted], an [redacted]% increase on sales since the previous year on the market, making it one of the most successful cancer products ever launched.

Currently, the important regional markets for cancer therapeutics are the U.S. and Canada, the European Union (E.U.) and Japan. Europe remains the largest importer of U.S. pharmaceuticals, accounting for [redacted]% of all U.S. pharmaceutical exports. Mexico and Canada account for [redacted]%. The North American Free Trade Agreement (NAFTA) is expected to increase U.S. exports of pharmaceuticals to these two nations.

Approximately, [redacted]% of pharmaceutical R&D conducted worldwide is performed by U.S. firms. Japan follows with [redacted]%. Of [redacted] major global drugs developed between [redacted] and [redacted], [redacted]% originated in the U.S., [redacted]% in the U.K. and [redacted]% in Switzerland. U.S. firms dominate cancer R&D. Japan is currently investing heavily in R&D in an attempt to catch up with its foreign competitors.