The Advent of Personalized Medicine

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“The use of biomarkers or molecular signatures to accelerate the development of new drugs targeted to specific subpopulations of patients.”

— Former Director, National Cancer Institute

Personalized medicine—a tailored approach that recognizes medical treatments do not affect all people the same way—has made monumental strides in the past several years. Advances are occurring at an exponential rate, paving the way for breakthroughs in a variety of medical conditions. From genome sequencing to CAR T-Cell therapy, scientific medical discoveries are having a significant impact on the human condition and their influence will continue to grow in the future.

**Driven by the Bioscience Industry**

New discoveries in the bioscience industry are occurring at a breathtaking pace. According to *The Value of Bioscience Innovation in Growing Jobs and Improving Quality of Life in 2016* report:

- There were more than 1.6 million people employed in the bioscience industry.
- The pace of venture capital investments has increased from $10 billion per year on average in 2012–2013 to almost $14.5 billion in 2014–2015.
- From 2012–2015, there were more than 100,000 U.S. bioscience patents issued, continuing an upward trend.
- As of 2014, there were more than 77,000 bioscience industry establishments.
- In 2016, there were 592 new experimental drugs and 100 biologics advancing through clinical trials for lung cancer alone.
An Introduction to Genomics

Historically, elucidating disease and inheritance patterns was performed through careful observation of conditions involving single gene mutations such as sickle cell anemia. The completion of the Human Genome Project in 2003 provided an enormous amount of information which is critical to the ongoing understanding of diseases, drug development, and the emergence of personalized medicine.

Genomics applies recombinant DNA, DNA sequencing, and bioinformatic techniques to sequence, assemble, and analyze the function and structure of genomes. Understanding our human DNA map is critical to understanding virtually every disease.

Lab testing coupled with genetic information and recent ground-breaking research into the impact of environmental factors on genetic mutations and disease etiology is driving current research and will undoubtedly shape the future of clinical medicine.

Diagnostics

The mapping of the human genome, all three billion base pairs that make up the complete set of DNA found in human cells, was revolutionary for the industry. This created a huge opportunity to understand not only how the sequences interact, but how to identify diseases. Since 2003, the project has fueled the discovery of 1,800 disease genes, 2,000 genetic tests for human conditions, and 350 biotechnology-based products in clinical trials.

What is Genome Sequencing?

A genome sequence can be thought of as a very long string of letters of an alphabet that make up a mysterious and highly complex language.

When you read a sentence, there is meaning not only in the sequence of letters that make up words, but also in how those words work together to create a phrase, a story, and provide context. Similarly, the human genome is more than just its sequence of letters—it is complex and layered. It creates the building blocks, good and bad, of the human body.

Imagine the genome as a book written without capitalization or punctuation; without breaks between words, sentences, or paragraphs; and with strings of nonsense letters scattered between, and even

The industry continues to add jobs and grow faster than other private sectors. To put this in perspective, Genentech, a leader in medical science-biotechnology and genomics, generated 466 total research publications in 2014, including 21 publications in industry-leading journals such as Nature, Science, and Cell. Each publication reflects the research efforts of dozens of scientists, encompassing years of work and discoveries that are changing the landscape of the industry. It would be nearly impossible to cover the broad range of dynamic discoveries of this industry within the scope of this report. Our focus will be on advancements in personalized medicine.

The global demand for drugs, both pharmaceuticals and biologics, has been growing steadily and is a significant contributing factor in the growth of personalized medicine. It is expected that by the year 2020, global pharma spending will reach $1.4 trillion, an increase of about 30% over 2015.

Specialty Medicines and Leading Therapy Areas in 2020

<table>
<thead>
<tr>
<th>SPECIALTY SHARE OF SPENDING 2020 (IN U.S. DOLLARS)</th>
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<tbody>
<tr>
<td>Global Spending $1.4 Trillion</td>
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<tr>
<td>Developed $850–880 Billion</td>
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<tr>
<td>Pharmerging $360–390 Billion</td>
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<td>28%</td>
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<td>36%</td>
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<td>12%</td>
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**LEADING SPECIALTY THERAPY AREAS**

<table>
<thead>
<tr>
<th>THERAPY AREA</th>
<th><strong>SALES IN 2020</strong></th>
<th><strong>CAGR 2016–2020</strong></th>
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<tbody>
<tr>
<td>Oncology</td>
<td>$100–120 Billion</td>
<td>9–12%</td>
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<tr>
<td>Autoimmune</td>
<td>$55–65 Billion</td>
<td>11–14%</td>
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<td>Viral Hepatitis</td>
<td>$45–55 Billion</td>
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<tr>
<td>Immunosuppressants</td>
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<td>11–14%</td>
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<tr>
<td>HIV Antivirals</td>
<td>$20–30 Billion</td>
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<tr>
<td>Immunostimulants</td>
<td>$15–18 Billion</td>
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<tr>
<td>Interferons</td>
<td>$7–9 Billion</td>
<td>1–4%</td>
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<tr>
<td>Erythropoietins</td>
<td>$7–9 Billion</td>
<td>0–3%</td>
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<tr>
<td>Macular Degeneration</td>
<td>$6–8 Billion</td>
<td>6–9%</td>
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*Sales represented in constant U.S. dollars.


CAGR stands for Compound Annual Growth Rate.
within, sentences. Sequencing the genome doesn't immediately reveal the genetic secrets of an entire species. Even with a rough draft of the human genome sequence in hand, much work remains to be done. Scientists still have to translate those strings of letters into an understanding of how the genome works: what the various genes that make up the genome do, how different genes are related, and how the various parts of the genome are coordinated. That is, they have to figure out what those letters of the genome sequence mean and which letters are simply noise.

Why is Genome Sequencing so Important?
Sequencing the genome is an important first step toward deciphering its meaning. At the very least, the genome sequence represents a valuable shortcut, helping scientists find targeted genes much more easily and quickly. A genome sequence contains clues about where genes are located and provides an invaluable starting point as to how to interpret the clues.

Scientists also hope that being able to study the entire genome sequence will help them understand how the whole genome functions. That is, how genes work together to direct the growth, development, and maintenance of an organism.

Finally, genes account for less than 25% of the DNA in the genome, and so knowing the entire genome sequence will help scientists study the parts of the genome outside the genes. The other parts include the regulatory regions that control how genes are turned on and off, as well as long stretches of “nonsense” or “junk” DNA—so called because we don’t yet know what, if anything, this DNA does now or did in the distant past.

Making History
The first human genome took a full decade to sequence and cost over $100 million to complete. Amazingly, sequencing kits today can sequence a genome in one day for around $1,000. The recent FDA approval of new sequencers promises to accelerate the use of genetic information for precision medicine and will lower the cost even further.

As the amount of information exploded with the sequencing of the human genome, so has the pace of discovery, creating the need for global collaboration across the scientific community.

In January 2017, Illumina released the NovaSeq, its fastest, cheapest, most high-throughput machine yet. Illumina hopes the NovaSeq will soon decode our genes for $100 or less.

Not to be outdone with a potentially significant breakthrough in sequencing costs, Illumina also announced it was adding IBM Watson to DNA tests for cancer patients. According to Steve Harvey, vice president of Watson Health, probably 2 million Americans could benefit from having their tumor DNA sequenced, only about 5% do. The goal of the new Illumina and IBM partnership is to make it simpler for a hospital to start doing DNA sequencing. “Illumina’s ability to bundle the Watson report along with the TruSeq 170 sequencer enables a cancer institute or a diagnostic lab to get up and running much quicker,” says Harvey. The IBM and Illumina partnership offers an elegant solution: The DNA sequencer analyzes the genes; within minutes Watson can provide data output that tells what genes are mutated and what drugs might help patients.²

These partnerships have shaped developments in a wide range of industries, from bioinformatics and chemical engineering to pharmaceuticals, medicine, and nutritional science. The opportunities that lie before us are extraordinary, and are quickly transforming the landscape of science and medicine.

Once the mapping of the human genome was complete, research emphasis began to shift from sequencing the genome to interpreting the genome to determine which genes and families of genes function and sometimes malfunction. The role of variation in individual genes, known as single nucleotide polymorphisms (SNPs), have now become a new frontier of investigation.

The sequenced human genome signaled the appearance of a long-awaited future for biology and medicine. Genomics showed that DNA is a readable text that has materially changed the world today, and will undoubtedly shape the future of science.

3 The Advent of Personalized Medicine
In 2015, President Obama launched the Precision Medicine Initiative, with a contribution of $215 million and the goal of pioneering a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which patients. Treating a person by taking into account the genetic information of the disease and individual patient characteristics will enable doctors to provide more efficacious treatment alternatives with a reduction in deleterious side effects. Genome sequencing will likely become more commonplace. In fact, many experts believe that testing at birth will become routine.

Advances in technology and data will undoubtedly revolutionize the industry and our approach to medicine. However, the path to widespread use of personalized medical techniques is a long one. Significant investments will need to be made to build the appropriate infrastructure (data storage, analytics) and research capabilities, then clinically integrate these discoveries to ultimately transform the healthcare industry.

The commitment to genomics and biotechnology extends beyond U.S. borders. For example, in January 2016, China announced government support to target personalized medicine, which will include substantial investment in genome sequencing.3

Moore’s Law is a computing term which originated around 1970. The simplified version of this law states that computer processor speeds, or overall processing power, will double every two years, thus resulting in cheaper computing power. Genomic sequencing costs have fallen at a pace far exceeding Moore’s Law.

Cost of Genome Sequencing

Source: National Human Genome Research Institute.

Moore’s Law

Genomics and Personalized Medicine

Developments in genetics and genomics over the last several decades have led to the emergence of “personalized medicine” which recognizes the need for tailored treatments. Efficacy and tolerability of cancer drugs, for example, have improved in recent years, along with our understanding of the specific characteristics of each disease variant. According to the National Cancer Institute, there are about 200 types of cancer, each containing a number of subtypes or variants. This highlights the incredible differences in how cancer is expressed and underscores the importance of developing more precise treatments, since all cancers cannot and should not be treated the same way. Although expanding this approach to cancer therapy will take a tremendous amount of work, it will ultimately lead to a reduction in toxic side effects, an increase in survival rates, and potentially reduced costs in the future.
Ongoing Focus of Immunotherapy

Advances in cancer immunotherapy are the result of long-term investments in basic research underway to:

• Understand why immunotherapy is effective in some patients but not others who have the same type of cancer.

• Expand immunotherapy to more types of cancer.

• Increase the effectiveness of immunotherapy by combining it with other types of cancer treatment, such as targeted therapy, chemotherapy, or radiation therapy.

In the past few years, the rapidly advancing field of immune-oncology has produced several new methods of treating cancer that increase the strength of immune responses against tumors. Immunotherapies either stimulate the activities of specific components of the immune system or counteract signals produced by cancer cells that suppress immune responses.

On the next page, we explore two types of immunotherapy—adoptive cell transfer and CAR T-Cell therapy—which exhibit promise in the treatment of cancer. Research efforts are led by Steven Rosenberg’s lab at the National Cancer Institute, as well as several public and private healthcare companies.
Adoptive Cell Transfer

Progress is being made with an experimental form of immunotherapy called adoptive cell transfer (ACT). In several small clinical trials testing ACT, some patients with very advanced cancer have had their disease completely eradicated. In some cases, these treatments have lasted for years.

In one form of ACT, T-Cells that have infiltrated a patient’s tumor, called tumor-infiltrating lymphocytes (TILs), are collected from samples of the tumor. TILs that show the greatest recognition of the patient’s tumor cells in laboratory tests are selected, and large populations of these cells are grown in the laboratory. The cells are then activated by treatment with immune-signaling proteins called cytokines and infused into the patient’s blood stream.

The idea behind this approach is that the TILs have already shown an ability to target tumor cells, but there may not be enough of them within the tumor microenvironment to eradicate the tumor or overcome the immune suppressive signals that are being released there. According to the NIH/National Cancer Institute, introducing massive amounts of activated TILs can help to overcome these barriers and shrink or destroy tumors.

CAR T-Cell Therapy

What are T-Cells and how do CAR T-Cells work? Simply put, T-Cells play a key role in ensuring that our immune systems work and respond appropriately to foreign invaders or pathogens. T-Cells can be removed from a patient and modified with a flag that can seek out and help destroy specific cancers. In theory, this targeted approach should be much more effective as it harnesses the power of an individual’s immune system (immunotherapy), while avoiding the toxic side effects of traditional chemotherapies.

Research related to engineered T-Cells, or specifically Chimeric Antigen Receptors (CAR) T-Cell therapy, has exploded in recent years, leading to significant developments in cancer treatment.

T-Cells can best be understood as they relate to Human Immunodeficiency Virus (HIV). T-Cells represent a type of white blood cell that fights infection. CD4 T-Cells are important to the body—the higher the CD4 T-Cell count, the stronger the immune system. The HIV virus attaches itself to a CD4 T-Cell, takes over the cell, and uses it to create more of the HIV virus destroying the CD4 T-Cell in the process. This depletion of CD4 T-Cells weakens the immune system’s ability to fight and leaves it highly susceptible to infections.

Another type of T-Cell is called the “killer” CD8 T-Cell. These cells produce antibodies that kill off foreign invaders. They are found in our blood and lymph nodes and are produced by the thymus.

(Continued on next page)
As you age, T-Cells help build an “immune memory.” Think of the vaccine you received as a child for chickenpox. You receive a weakened version of a virus that stimulates an immune response. Your body generates antibodies that basically protect you for life. This highly effective and long-term protection is what makes the concept of engineered T-Cells so attractive. The end goal is to create or engineer very specific treatments that can potentially last a lifetime. To administer engineered or CAR T-Cells, doctors remove immune cells from patients, tagging them with molecules that target a specific cancer.

The beauty of engineered T-Cells lies in the “memory” produced in the immune system. Recent promising studies have produced high success rates in some cancers, but with some potentially dangerous side effects, like overloading the immune system (called cytokine release syndrome). Scientists are making progress in overcoming this effect. CAR T-Cell technology has significant promise to become a central pillar of cancer therapy in the coming years.

Source: www.cancer.gov

The Promise of Immunotherapy

Immunotherapy refers to treatments that use the body’s own immune system to combat disease. Immune-oncology specifically refers to immunotherapy directed at cancer. The immune system—a collection of organs, specialized cells, and substances that respond to threats from infectious organisms—can theoretically be “trained” to help protect against cancer. Cancer however is highly variable and has evolved an array of escape mechanisms. Cancer evades our immune system through three primary mechanisms. First, cancer cells are remarkably good at “impersonating” regular body cells. Second, cancer is highly skilled at suppressing the immune system. Finally, cancer makes use of natural proteins called “immune checkpoint inhibitors” that act as brakes to prevent an attack on the cancer by killer T-Cells (a sub-type of white blood cells).

Discovering HER2: An Important Immunotherapy Start

Breast cancer is diagnosed in over 1.6 million women annually, far surpassing any other cancer incidence for women. The discovery and FDA approval of Herceptin 17 years ago marked a small but ground-breaking positive turn in the fight against breast cancer.

The story of Herceptin’s discovery goes back to the early- to mid-1980s when the research community was abuzz with the discovery that a mutated gene could stimulate excessive cell growth and division. Subsequent research identified the growth factor receptor gene, HER2.

“HER2-positive breast cancer” is a type of breast cancer that tests positive for a protein called human epidermal growth factor receptor 2 (HER2). Normally, HER2 proteins play a part in normal cell development. However, when HER2 is overexpressed, it leads to overproduction of the HER2 protein, causing the cells to become cancerous. Approximately 25% of women who develop breast cancer have this mutation, which can lead to an extremely aggressive form of the disease. Understanding the genetics of the HER2 gene and its mechanism of action were key factors in the development of Herceptin in the late 90s. The development of Herceptin, a monoclonal antibody which targets the HER2 receptor, has significantly improved survival rates over the last two decades. In a nutshell, Herceptin works by attaching to HER2 receptors to stop the signals that make tumor cells grow and divide, and by also signaling the body’s immune system to destroy the cells, according to Genentech.

It was quite a discovery. Herceptin has now treated over 1.5 million women, leading to the common practice of making this type of diagnostic testing a standard in treating cancer. In fact, over 95% of all women diagnosed with breast cancer are now tested for the HER2 trait.

Over the last few decades, discoveries in genomics have not only expanded our understanding of the human body, but have led to a stunning number of advances in cancer therapies.
**Telomeres and Telomerase Research**

To better understand telomeres and telomerase, let’s first review some basic principles of biology and genetics. The human body is an organism formed by adding many organ systems together. Examples include cardiovascular, nervous, and endocrine systems. Those organ systems are made of individual organs. Each organ contains tissues designed for specific functions like absorption and secretion. Tissues are made of cells that have joined together to perform those special functions. Each cell is then made of smaller components called organelles, one of which is called the nucleus. The nucleus contains structures called chromosomes that are actually “packages” of all the genetic information that is passed from parents to their children. The genetic information, or “genes,” is really just a series of bases called Adenine (A), Guanine (G), Cytosine (C), and Thymine (T). These bases are like letters of an alphabet which link together to create “pairs,” and ultimately our cellular alphabet. In order to grow and age, our bodies must duplicate their cells. This process is called mitosis. Mitosis is a process that allows one “parent” cell to divide into two new “daughter” cells. During mitosis, cells make copies of their genetic material. Half of the genetic material goes to each new daughter cell. To make sure that information is successfully passed from one generation to the next, each chromosome has a special protective cap called a telomere located at the end of its “arms.” Telomeres are controlled by the presence of the enzyme telomerase.

A telomere is a repeating DNA sequence (for example, TTAGGG) at the end of the body’s chromosomes. The telomere can reach a length of 15,000 base pairs. Telomeres function by preventing chromosomes from losing base pair sequences at their ends. They also stop chromosomes from fusing to each other. However, each time a cell divides, some of the telomere is lost (usually 25-200 base pairs per division). When the telomere becomes too short, the chromosome reaches a “critical length” and can no longer replicate. This means that a cell becomes “old” and dies by a process called apoptosis. Telomere activity is controlled by two mechanisms: erosion and addition. Erosion, as mentioned, occurs each time a cell divides.

Telomerase, also called telomere terminal transferase, is an enzyme made of protein and RNA subunits that elongates chromosomes by adding TTAGGG sequences to the end of existing chromosomes.

Telomerase is found in fetal tissue, adult germ cells, and also tumor cells. Telomerase activity is regulated during development and has a very low, almost undetectable activity in somatic (body) cells. Because these somatic cells do not regularly use telomerase, they age. The result of aging cells is an aging body. If telomerase is activated in a cell, the cell will continue to grow and divide. This “immortal cell” theory is important in two areas of research: aging and cancer.

Cellular aging, or senescence, is the process by which a cell becomes old and dies. It is due to the shortening of chromosomal telomeres to the point that the chromosome reaches a critical length. Cellular aging is analogous to a wind-up clock. If the clock stays wound, a cell becomes immortal and constantly produces new cells. If the clock winds down, the cell stops producing new cells and dies. Our cells are constantly aging. Being able to make the body’s cells live forever certainly creates some exciting possibilities. Telomerase research could therefore yield important discoveries related to the aging process.

Cancer cells are a type of malignant cell. The malignant cells multiply until they form a tumor that grows uncontrollably. Telomerase has been detected in human cancer cells and is found to be 10-20 times more active than in normal body cells. This provides a selective growth advantage to many types of tumors. If telomerase activity was to be turned off, then telomeres in cancer cells would shorten, just like they do in normal body cells. This would prevent the cancer cells from dividing uncontrollably in their early stages of development. In the event that a tumor has already thoroughly developed, it may be removed and anti-telomerase therapy could be administered to prevent relapse. In essence, preventing telomerase from performing its function would change cancer cells from “immortal” to “mortal.”

It can be said that scientists are on the verge of discovering many of telomerase’s secrets. In the future, their research in the area of telomerase could uncover valuable information to combat aging, fight cancer, and even improve the quality of medical treatment in other areas such as skin grafts for burn victims, bone marrow transplants, and heart disease. Who knows how far this could go?

The Future “WOW”—Emerging Tech

With the continuing study of our genetic blueprint, many biotech companies, small and large, are furiously working toward significant advances in cancer therapy. Illumina, a global biotech company, is considered by many to be the “Google of genetic testing.” A start-up company called Grail, backed by Illumina, has the goal of catching cancer in its nascent stage, pursuing the thought that cancer can be stopped or contained well before it overwhelms our system. Its goal is to develop a diagnostic blood test that can detect all cancers in their early stages. Many teams have attempted this, but Grail is both well capitalized and has the resources of a world-renowned scientific team. The company has set an ambitious goal of having the blood test available by 2019. This test, which could be easily administered at an annual physical, has potentially ground-breaking implications. The basis of the test involves the ability to detect what is known as circulating tumor DNA, or ctDNA. Bits of ctDNA, byproducts of dying tumor cells, can be detected and counted, thanks to advances in gene sequencing which detect somatic mutations. Somatic mutations are only present in tumor cells. Unlike hereditary mutations that are present in every cell in the body, somatic ctDNA is a specific cancer biomarker that can be detected, measured, and tracked.

The potential benefits of this technology are vast. Testing for ctDNA is less invasive than biopsy, requires no radiation exposure, is relatively inexpensive, and allows near real-time monitoring of response to treatment. Illumina CEO Jay Flatley estimates that if ctDNA can accurately identify Stage 1 cancers, market opportunity could exceed $100 billion. At least half of all U.S. cancers are diagnosed at Stage III and IV, so an early detection test could significantly impact treatment efficacy at a curable stage.

Investment Opportunities

Given robust, ongoing growth in personalized medicine, how is Abbot Downing incorporating these ideas into investment portfolios? Here are three primary vehicles used in portfolio construction:

- **EDGEWOOD GROWTH FUND**
  Edgewood is a concentrated large cap growth stock manager typically looking for high quality positions with a consistent earnings record. Positions are typically held for a three-to-five year holding period. Biotechnology is usually represented in its top fund holdings.

- **DRIEHAUS MICROCAP GROWTH FUND**
  This particular fund focuses on smaller, faster growing companies with a weighted average market capitalization usually more than $1 billion. The fund typically has a significant focus on healthcare.

- **ORBIMED**
  Our offering in the private equity space is ORBIMED partners. ORBIMED is a Tel Aviv/New York City-based life sciences venture capital fund with a 22-year highly successful track record of investing in public and private healthcare investments. ORBIMED sees the “biotech industry coming of age” and “massive interest in cancer immunotherapy.”
Fast Facts

• U.S. prescription drug spending was greater than 11.7% in 2015 ($419.4 billion total). Generic drugs accounted for approximately 88% of all prescriptions written.6

• In 2015, the Center for Drug Evaluation and Research (CDER) approved 22 novel drugs. From 2007 through 2015, CDER averaged about 30 novel drug approvals per year.7

• Worldwide spending on pharma products is expected to shoot up to $1.4 trillion by 2020, an increase of almost one-third over 2015 levels.8

• Global drug spending will take a major leap forward according to the IMS Institute of Healthcare Informatics.

• IMS is also predicting a “surge of innovation” with 225 new medicines hitting the market by 2020. About one-third will treat cancer.

• The Generic Pharmaceutical Association (GPhA) estimates the U.S. healthcare system saved $254 billion in 2014 by using generic drugs, and $1.64 trillion over the 2004 to 2014 timeframe.

Research and Development, Patent Protection, and Regulatory Issues

Drug development is a highly lucrative business. The discovery and introduction of new products is crucial to the health and wellbeing of not only individuals, but to businesses and the biotechnology industry. Continued innovation and success comes from scientific tools and discoveries, as well as from the ability to successfully navigate the changing regulatory environment, capitalizing on the right incentives and protecting intellectual property.

Biopharmaceutical companies operate under a challenging business model. For every 5,000 to 10,000 experimental compounds, only one will make it to the finish line and become approved.9 It typically takes up to 10 years of research and development and an average cost of $2.6 billion for a drug to reach the market and consumer (Tufts Center for Study of Drug Development, March 10, 2016). It is estimated that only two out of 10 medicines will recoup the money spent on their development.9 Patents expire 20 years from the date of filing; however, many factors can affect the duration of a patent, which is frequently litigated.

As new drug development became increasingly complex and expensive over time, drug prices began to escalate, further straining health care budgets. The Hatch-Waxman Act (AKA Drug Price Competition and Patent Term Restoration Act of 1984) was passed to set guidelines to expedite and streamline the manufacture of generic drugs by the pharmaceutical industry while protecting incentives for innovation.

According to Statista 2017, there could be as much as $192 billion in worldwide prescription drug revenue at risk from patent expiration from 2017 to 2022.

In the five years ending in 2015 there was more than $1.5 trillion in healthcare merger and acquisition activity.10


The Burden of Cancer in the U.S.

• In 2016, an estimated 1.68 million new cases of cancer were diagnosed in the U.S. with as many as 595,000 deaths occurring from the disease.

• Cancer mortality is higher among men than women (207.9 per 100,000 men and 145.4 per 100,000 women). It is highest among African-American men (261.5 per 100,000) and lowest in Asian/Pacific Islander women (91.2 per 100,000), based on 2008 to 2012 death rates.

• The number of people living beyond a cancer diagnosis reached nearly 14.5 million in 2014 and is expected to rise to almost 19 million by 2024.

• Approximately 39.6% of Americans will be diagnosed with cancer at some point during their lifetimes based on 2010 to 2012 data.

• According to the American Cancer Society, expenditures for cancer care in the U.S. totaled nearly $125 billion in 2010 and could reach $156 billion by 2020.

The Advent of Personalized Medicine
Predictions by Illumina – A Leading Gene Sequencing Company (ILMN)

- Sequences are already available in medical records and are beginning to save lives.
- By the end of the next decade, it is anticipated that at least 10 countries will be engaged in sequencing their own populations.
- Infants will be routinely sequenced at birth by the early 2020s.
- It is not inconceivable that many cancers will be managed as a chronic disease by the end of the next decade.


Additional sources for research on personalized medicine and immunology

  Juno and Kite are two emerging “pure play” companies that focus on immunotherapy. Their websites offer a wealth of information on related topics.
- Clinicaltrials.gov
  Find clinical trials focusing on specific conditions or therapies. For example, if you search for “adoptive t-cell therapy,” it will list the global clinical sites focused on this particular therapy.
  Find biomedical literature and clinical trial information.
  Find cancer-related information.

Conclusion

A combination one-two punch of early cancer detection through a simple blood diagnostic test followed by CAR T-Cell therapy may produce a potential outcome previously unthinkable—curing, and/or keeping cancer at bay.

Advancements in biotechnology have dramatically changed the scientific landscape, ushering in a new era of discovery in diagnostics and medicine. The emergence of genomics has paved the way for changes across the continuum of health and disease management, giving rise to changes in preventive medicine and personalized treatment. Discoveries and ground-breaking advances across all specialties are a daily occurrence, lending power to the notion that medicine will be far more effective and cost efficient in the years and decades to come.

Imagine a world where babies are routinely sequenced at birth, where tumor samples are routinely sequenced, and cancer is managed as a chronic disease. Genomic sequencing will undoubtedly shape the future of personalized treatments and preventive care. Despite the rapid pace of discovery, much more work needs to be done. For example, understanding the impact of environmental factors on genetic variations, referred to as epigenetics, is one example of the variables that must be considered as medicine and science evolve.

The depth and breadth of current and future opportunities, both known and unknown, support the fact that biotechnology should be a core piece of an investment portfolio. How the future takes shape remains to be seen; however, the excitement, growth, and emerging discoveries to come are undeniable.

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DEFINITIONS

**Biotechnology:** Integration of natural science and organisms, cells, parts thereof, and molecular analogues for products and services (European Federation of Biotechnology).

**Genomics/Genetics:** Genomics is defined as the study of genes and their functions, and related techniques. The main difference between genomics and genetics is that genetics scrutinizes the functioning and composition of the single gene whereas genomics addresses all genes and their interrelationships in order to identify their combined influence on the growth and development of the organism.

**Genomes:** Complete set of DNA within a single cell of an organism.

**Molecular biology:** Investigation of the roles and functions of single genes.

**Monoclonal antibody:** A type of protein made in the laboratory that can bind to substances in the body, including cancer cells. There are many kinds of monoclonal antibodies. A monoclonal antibody is made so that it binds to only one substance. Monoclonal antibodies are being used to treat some types of cancer. They can be used alone or to carry drugs, toxins, or radioactive substances directly to cancer cells (National Cancer Institute).

**Somatic mutations:** An alteration in DNA that occurs after conception. Somatic mutations can occur in any of the cells of the body except the germ cells (sperm and egg) and therefore are not passed on to children. These alterations can (but do not always) cause cancer or other diseases (National Cancer Institute).

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1 BusinessWire. IMS Health Forecasts. November 18, 2015.
5 Ibid.
7 U.S. Food and Drug Administration.

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