WELLINGTON MANAGEMENT®

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Investable innovation: Tracking remarkable biopharmaceutical advances

Despite recent volatility, opportunities in health care remain abundant, and we believe the long-term outlook for the sector is positive. Powerful demographic trends, a record-setting pace of innovation, and structural changes in health care delivery systems continue to drive growth and expand the investment opportunity set. Wellington Management's Health Care team currently manages over US$60 billion in assets for clients globally.[1] Several team members recently shared their views on advances in the biopharmaceutical industry around the world.

KEY POINTS

- The pace of drug discovery is at an all-time high. New tools and modalities are enabling scientists to develop innovative treatments for diseases with major unmet needs.
- Team members aim to leverage their diverse academic, industry, scientific, and clinical backgrounds to identify opportunities and risks — including which drugs are likely to succeed or fail — ahead of the market.
- The team's knowledge of the biopharmaceutical industry, perspectives on incremental scientific discoveries, and fluency with the drug development process are central to their investment approach.
- Emerging markets can be opportunity-rich for health care investors. A fast-growing market centered in Asia features innovative companies serving large local markets and competing on a global scale.

Q: What is the key to investing in biotechnology?

BOB: An investor needs to understand the inefficiencies of the markets in which he or she invests. If one's skills and experience map well to those inefficiencies, one should be able to exploit them successfully on behalf of clients. In biotech, the principal inefficiency stems from the opacity of scientific data, and the resultant inability of market participants to agree on the merits of a given drug development program.

[1]As of 30 June 2017

Consider the risks

All investors should consider the risks that may impact their capital, before investing. The value of your investment may become worth more or less than at the time of the original investment. Please refer to the risk section for a full list of risk factors to consider.

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In our view, the key is to try to identify — ahead of the market, and based on rigorous scientific evaluation — which programs are likely to yield important new drugs, and which are not.

— Bob Deresiewicz, MD

This causes substantial volatility in valuations — independent of scientific progress or lack thereof — potentially enabling patient, discerning investors to build investment positions before the true value of a drug development program is reflected in a stock's price.

In our view, the key is to try to identify — ahead of the market, and based on rigorous scientific evaluation — which programs are likely to yield important new drugs, and which are not. The repeated ability to do this increases the probability that one can profit in the sector while also mitigating risk. We draw upon our diverse academic, scientific, and clinical backgrounds, which include professional careers in science and medicine, to make our investment decisions. The combination of our scientific fluency, business acumen, and long investment experience enables us to analyze drug development programs thoroughly and holistically, both at the company and industry level.

We aim to consider all relevant factors, including basic scientific mechanisms of disease, reasons why toxicity may emerge, the best biochemical nodes at which to intervene, the chemical and biochemical properties of drug candidates, and their preclinical and clinical profiles. We also deliberate nonscientific factors, such as ease of manufacturing, intellectual property protection, commercial market dynamics, and payer mix. Our goal is to reach accurate conclusions about the value of drug programs and the companies that develop them.

Q: The world has benefitted from amazing advances in biotechnology. What is driving the field today?

JEAN: Incredible new tools are enabling scientists to understand human biology at a much more profound level than ever before, greatly improving comprehension of the specific causes of disease and allowing them to identify molecules to treat them. Prior to about 1975, drugs were developed by screening animal models of disease — a slow, cumbersome, and moderately informative approach. The 1980s saw a big leap forward, as modern biochemical analyses that revealed results faster and more accurately replaced much of the animal work. This led to a raft of new drugs for major indications, including high blood pressure, high cholesterol, and depression — biochemical targets that are relatively easy to address. During that decade, the industry began to use proteins as therapeutic agents, building on advances in cloning and molecular genetics that had originated 20 years earlier.

Progress continued in the 1990s, as monoclonal antibodies entered the therapeutic tool kit. But momentum slowed somewhat thereafter, as very specific scientific advances were needed to crack the next layer of difficulty. By the early 2000s, the full DNA sequence of the human genome was in hand, as were new tools in microfluidics, bioinformatics, subcellular pathway analysis, and genetic manipulation. In addition, fundamental discoveries about the pathophysiology of certain diseases allowed drug developers to tackle a whole new set of drug targets that were much more complicated and elusive than those targeted in the 1980s. Since then, entirely new treatment paradigms have been developed, setting the stage for where we are today. In the coming decade, we should witness the arrival of a host of wonderful new drugs and novel treatment modalities.

> Among the most exciting and investable new modalities are gene therapy, gene editing, and cellular therapy.
>
> — Wen Shi, PhD, CFA

Q: What are some of those new modalities?

WEN: Among the most exciting and investable new modalities are gene therapy, gene editing, and cellular therapy. Gene therapy delivers genetic instructions into a patient's cells to reverse the harmful effects of a missing or defective gene. This technology is already being used to treat several lifelong crippling diseases.

With hemophilia, for example, deficient blood clotting can lead to catastrophic bleeding, with attendant tissue and organ damage and a degraded quality of life. Hemophilia occurs in patients born without the gene that directs production of a certain blood-clotting factor. Traditional treatments involve frequent infusions of a replacement factor, a cumbersome and expensive method that is only partially effective and exposes the patient to the risk of infection. In contrast, gene therapy may be a one-time treatment that induces the body to produce enough of the missing factor on an ongoing basis to correct the bleeding problem and allow hemophiliacs to lead normal lives. The approach is being studied in other blood diseases such as sickle cell anemia and thalassemia, and it has proven effective in treating certain retinal diseases.

Gene therapy is currently limited in its ability to target only diseases of tissues or organs that are easily accessible to the intervention, including the eyes, blood, and liver. There are other challenges, which several companies in our coverage universe are actively seeking to overcome.

Q: What is gene editing, and "CRISPR" in particular?

WEN: Gene editing, using the CRISPR system, is a new technology that can make extremely precise changes in a patient's genetic material. CRISPR (clustered regularly interspaced short palindromic repeats), builds on the astonishing discovery of a bacterial defense system that protects the bacteria from viruses, which has been adapted for genome editing. Because it is more flexible and potentially less disruptive than gene therapy, CRISPR introduces the possibility of correcting an inborn genetic error regardless of type, as opposed to replacing a defective gene in parallel. It can be used to either completely replace a missing gene or to deactivate a harmful gene that is causing disease. Because of this, it has potentially broader applications than gene therapy. Clinical use of CRISPR is in its infancy but could advance rapidly.

Q: Can you talk a bit about cell therapy?

BOB: Cellular therapy is being studied as a cancer treatment. Healthy, living cells that normally function to protect the body from infectious agents or tumors are harvested from the patient or a healthy blood donor, and reengineered by changing their genetic code to turn them into cancer-fighting machines. To date, this strategy has been most productively applied with T-cells, one of the primary cells of the body's immune system. Engineered chimeric antigen receptor T-cells, or "CAR-Ts", have produced amazing clinical results, particularly in children with late-stage leukemia, for whom other hopes for a cure have been exhausted. CAR-Ts have also been shown to be active in the treatment of lymphoma. The first CAR-T therapy should come to market soon.

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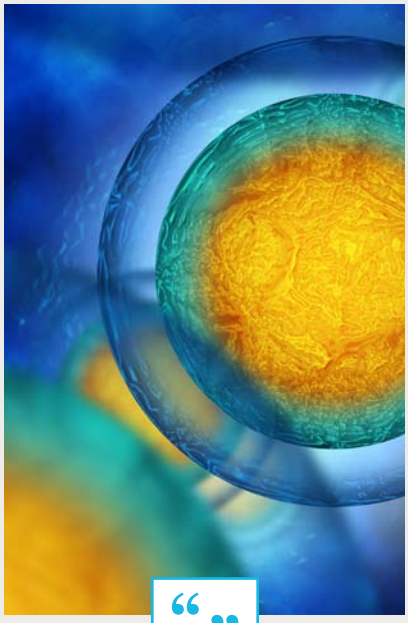

> Immuno-oncology accounts for more than 50% of spending in the biopharmaceutical industry, and new discoveries are happening all the time. The science is enabling IO to be used far more broadly than the market realizes.
>
> — Catherine Arnold

Q: What is the opportunity set for these new modalities?

WEN: There are several dozen publicly listed biotechnology companies that specialize in the development of gene therapy, gene editing, and cellular therapy approaches for the treatment of human diseases; nearly all of them are small- or mid-cap companies under US$5 billion in market capitalization, and this number is growing every year. Additionally, more traditional biopharmaceutical companies are adopting these new modalities in their pipelines.

Q: What are some of the risks of genetic engineering?

BOB: The biggest risk, regardless of approach, is the inadvertent creation of harmful mutations in the target DNA. This could occur in a number of ways, and could potentially cause abnormal cellular growth, leading to cancer. Cancer is a theoretical risk here, but not a trivial one; when one alters the blueprint of life, one may unintentionally introduce problematic changes to the genome.

Q: What is happening with immuno-oncology?

CATHERINE: Immuno-oncology (IO) is still in very early stages of growth. With IO, drugs are given to enable a patient's immune system to fight cancer, either by removing obstacles or optimizing immune actions. The goal is for the body to recognize cancer cells as foreign and produce quality "fighter cells" in optimal proportion. These fighter cells then travel to the right location with sufficient power to eliminate the cancer and prevent recurrence. Immuno-oncology accounts for more than 50% of spending in the biopharmaceutical industry, and new discoveries are happening all the time. The science is enabling IO to be used far more broadly than the market realizes. Our models reveal an opportunity set upwards of US$70 billion, about three times what is discounted in current market valuations.

Several market inefficiencies provide investment opportunities in IO. For example, while most IO successes to date have been in late-stage cancer, I expect the most significant uses going forward to be in the earlier-stage treatment population, which is much larger. So far, the investment community has not embraced this idea, continuing to debate the merits of early-treatment clinical-trial data and potential survival benefits. But IO responses have already translated into higher survival rates than traditional chemotherapy, with multiple trials corroborating early progression metrics. Overall, the durability and depth of response for IO should be even better in earlier disease stages, when patients have stronger baseline health and relatively uncompromised immune systems.

The power of combinations — stacking several IO treatment agents with different mechanisms — is another opportunity driver that has the potential to increase the number of patients who respond. IO uses are proliferating, including approaches that apply IO to treat hundreds of types of cancer. Today, many of these are in human trials using first- and subsequent-generation IO agents. There is rapid progress in predictive techniques to determine where IO agents may be most effective. And finally, the structures for delivering immune therapies are improving, potentially leading to more effective treatment outcomes.

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Successful companies are studying their oncology portfolios with an eye on multiple strategies for each different tumor, quickly learning to identify markers that predict which patients will respond to treatment.

— Jean Hynes, CFA

JEAN: In this growing investable universe, the key is to identify potential "winners" and "losers." Cancer is a highly heterogeneous disease; each tumor type likely has many different recipes for treatment. Successful companies are studying their oncology portfolios with an eye on multiple strategies for each different tumor, quickly learning to identify markers that predict which patients will respond to treatment. This knowledge will likely lead to even better mapping of patients to these different therapies. We believe that, ultimately, a broad arsenal of mechanisms will prove the best strategy, so owning the rights to a range of IO and complementary mechanisms should afford good companies more flexibility on their clinical-trial strategy and pricing upon approval.

Q: What are some other areas that are particularly intriguing?

MARK: There are many, but I will discuss two. The first area is a class of underappreciated oncology drugs that I call "smart chemos." Used alone, these agents don't have much effect on a tumor, nor do they make a patient sick the way traditional chemotherapy does. When carefully paired with another agent, however, the two-drug combination produces remarkable anti-tumor activity with little additional toxicity. I think of it as two beams of light focused on a single point.

An example of smart chemos is the group of drugs used to target the poly-(ADP-ribose) polymerase (PARP) family of proteins involved in cellular processes like DNA repair and programmed cell death. These have shown phenomenal activity in ovarian cancer when given immediately after a course of conventional DNA-damaging chemotherapy. Another example is cyclin-dependent kinase (CDK) 4/6 inhibitors, which have had great efficacy in the treatment of breast cancer when combined with an anti-hormonal agent. These smart chemos may well have far greater clinical use than what is priced into stocks today. There is no reason to believe, for example, that PARP inhibitors will only be useful in ovarian cancer, or that they can only be paired with certain chemotherapeutic agents. In fact, they will more likely be broadly useful as long as amenable patients can be identified in advance. I believe that biopharmaceutical companies developing these treatments are not being given credit for their potential.

A second fascinating area is neurology. Tremendous progress in the basic understanding of neuroscience is widening the opportunity set in neurology drug development. Encouraging new treatments for everything from headaches to depression to neurodegenerative conditions like Alzheimer's disease are being developed. A new class of agents called CGRP (calcitonin gene-related peptide) antagonists that have shown impressive benefits in treating migraines is expected to enter markets in 2018, for example. Progress is ongoing; while the first generation of CGRP antagonists is effective, patients must undergo regular intravenous infusions. We believe that a second generation of CGRP antagonists, which can be taken orally, presents an even greater opportunity. These are now entering late-stage clinical trials.

Several companies in our coverage universe are in late-stage trials with promising new drugs to combat forms of depression that have thus far been resistant to almost anything doctors have prescribed. And finally, advances in the treatment of Alzheimer's disease remain an enormous opportunity set, with current data suggesting that meaningful disease-modifying therapies are only a few years away. Because the nervous system is the most complex system in the body, neuroscience arguably stands to benefit most from increased scientific understanding of disease mechanisms and pathways.

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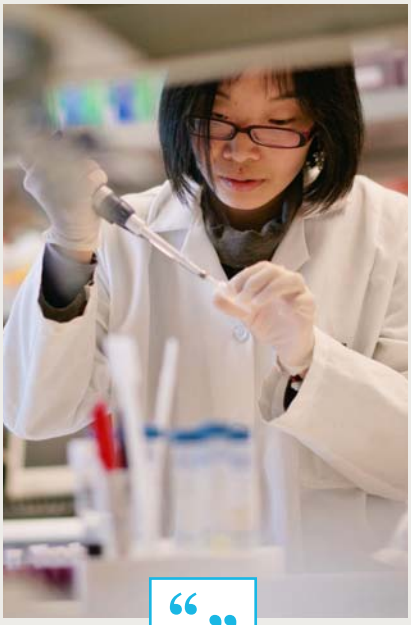

The rise of innovation in certain emerging markets is a very recent development that presents new investment opportunities. In China, biomedical innovation is flourishing thanks to increased investment, an influx of skilled labor, and loosened government regulations.

— Rebecca Sykes, CFA

Q: Shifting gears, why have emerging markets become such an important part of the global health care arena?

REBECCA: Demand for health care is growing fast in emerging markets. Aging populations, increased personal wealth, government health care reform, and a rise in chronic disease are all contributing to increased spending on health care. In many developing countries, health care spending has grown significantly faster than the overall economy for many years. Governments increasingly need to turn to the private sector to help build a more robust health care infrastructure. In addition, developing a strong local biopharmaceutical industry becomes a strategic priority over time, reducing a developing country's dependence on imported medicines and showcasing its research and innovation capabilities.

The rise of innovation in certain emerging markets is a very recent development that presents new investment opportunities. In China, biomedical innovation is flourishing thanks to increased investment, an influx of skilled labor, and loosened government regulations. A 2008 government initiative called the Thousand Talents Program encouraged many Chinese-born, US-trained scientists to return to China, with the promise of research funding and tax incentives.

In terms of regulations, reforms at the China Food and Drug Administration have helped streamline the drug approval process and level the playing field for local and multinational companies. Anticorruption measures are beginning to help as well. In addition, modifications to the drug pricing and reimbursement system are positive for the industry's long-term growth. Increasingly, novel drugs will be priced for the value they deliver, while older, off-patent drugs will face stiffer price cuts and increased competition. We think this creates attractive incentives for companies investing in innovation.

Another notable topic is biosimilars. Biosimilars are cheaper generic copies of complex injectable drugs called biologics. Making biosimilars is a capital-intensive process, and successful clinical development requires scientific and regulatory skill. A few companies in emerging markets have the ability to compete effectively here, and they enjoy cost advantages not always shared by counterparts in developed markets. Two South Korean companies sell biosimilars into developed markets today, for example. In addition, pharmaceutical companies in China, India, and Eastern Europe have developed biosimilars for their local markets, helping to broaden access to many highly effective therapies. ■

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ABOUT THE AUTHORS

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Portfolio Manager

The team leader for Wellington's Health Care team, Jean has spent nearly all of her 26-year career specializing in the pharmaceutical and biotechnology industries. She is also one of the firm's three Managing Partners, a group responsible for the governance of the Wellington Management partnership. Jean joined Wellington Management upon her graduation from Wellesley College (1991), where she was awarded a BA in economics.

Robert Deresiewicz, MD
Portfolio Manager

Prior to joining Wellington in 2000, Bob was assistant professor of medicine at Harvard Medical School and associate physician in the Division of Infectious Diseases at Brigham and Women's Hospital, where he conducted biomedical research, treated patients, and taught medical students (1990 – 1998). He trained in infectious diseases at Harvard Medical School (1987 – 1990), in tropical medicine at Hadassah Medical School in Jerusalem (1986 – 1987), and in internal medicine at Columbia-Presbyterian Medical Center in New York (1983 – 1986). Bob received his MBA from Harvard Business School (2000), his MD from the Mount Sinai School of Medicine (1983), and his BA in biochemistry, summa cum laude, from Columbia University (1979). He is board certified in internal medicine and infectious diseases, and was an elected fellow of the American College of Physicians and of the Infectious Diseases Society of America.

Catherine Arnold
Global Industry Analyst

Catherine specializes in pharmaceuticals. Prior to joining the firm in 2013, Catherine spent nine years at Credit Suisse as a managing director and senior analyst covering the US pharmaceutical industry and served as the global head of pharmaceutical research for the investment bank (2004 – 2013). She joined Credit Suisse from Sanford C. Bernstein, where she was a senior analyst covering European pharmaceutical stocks (1999 – 2004). Before her financial services roles, Catherine worked in the drug industry in strategic and marketing areas at Hoffmann-La Roche (1995 – 1999), as a consultant with Booz Allen Hamilton (1992 – 1995) and Ernst & Young (1990 – 1992), and as a registered nurse at the University of Pittsburgh Medical Center (1985 – 1990). Catherine earned her MBA (1990), MHA (1990), and bachelor of science in nursing (1987) from the University of Pittsburgh.

Mark Sevecka, PhD
Research Associate

Mark conducts fundamental research on global pharmaceutical companies. Prior to joining the firm in 2016, Mark worked as a research associate at Leerink Partners (2015 – 2016), where he followed a number of biotechnology and major pharmaceutical firms. Before transitioning into financial services, Mark spent four years in preclinical drug development at Merrimack Pharmaceuticals (2011 – 2015), most recently as a principal scientist, after conducting post-doctoral work at the Whitehead Institute for Biomedical Research (2009 – 2010). He earned his PhD (2008) and master of arts (2004) in chemistry from Harvard University, following undergraduate studies in chemistry at the Technical University of Munich in Germany (1999 – 2002).

Wen Shi, PhD, CFA
Global Industry Analyst

Wen conducts fundamental research on public and private global biotechnology companies. Prior to joining Wellington Management in 2015, Wen worked as a senior research associate on the global biotechnology team at Sanford C. Bernstein (2013 – 2014). Before Bernstein, he was a consultant to biotech and pharmaceutical companies at Campbell Alliance (2011 – 2013), Navigant Consulting (2009 – 2011), and McKinsey & Company (2007 – 2009). Wen earned his DPhil (PhD) in medical oncology from Oxford University, where he was a Rhodes Scholar (2007), and his BS in biology from Johns Hopkins University (2004).

Rebecca Sykes, CFA
Global Industry Analyst

Rebecca conducts fundamental research on medical technology companies worldwide, as well as pharmaceutical companies in the emerging markets. Rebecca joined Wellington Management in 2007 from Goldman Sachs & Co. where she was an analyst in the health care investment banking group. Rebecca earned both her MBA (2016) and her BS (2005) in economics, magna cum laude, from the University of Pennsylvania (Wharton).

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