

## Breaking Eroom's Law: Biopharma in Transition

August 2020

Prior to the COVID-19 pandemic, the pharmaceutical industry was suffering from market apathy due to poor research and development (R&D) productivity, negative publicity regarding high drug costs and a lack of innovation from mature biotech and biopharma companies – and valuations suffered. Despite these struggles, we believe the industry is reentering a golden age of discovery and productivity, and companies that are prepared to refocus on high-value drugs and innovative research stand to benefit long term. Here, we describe our investment framework to identify companies that are well-positioned to break Eroom's law.<sup>1</sup>

### The Current Paradigm

Eroom's law is Moore's law spelled in reverse. In contrast to Moore's law, which describes the doubling of the number of transistors that can fit in an integrated circuit every two years, Eroom's law describes the steady decline in biopharma R&D productivity since the 1950s, when drug approvals fell by 50% per inflation-adjusted billion dollars spent on R&D every nine years; essentially, R&D productivity has slowed and become more expensive. Internal rate of return (IRR) declined from 10% in 2010 and was trending towards 0% IRR in 2019.<sup>2</sup> If this trend line is extended, we should expect terminal decline in the near future. Four broad theories have been proposed to explain this decline.

1. The most value-added drugs that help the greatest number of patients, including cardiovascular drugs, chemotherapy, antibiotics, and pain medications have already been discovered. Newer drugs have a higher bar to clear in order to add value in the marketplace.
2. Regulations are becoming stricter. Authorities have continuously raised the bar for safety and efficacy since the 1960s, leading to more expensive paperwork and clinical trials.



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3. Biopharma's tendency to fund research for less-promising or copycat drugs.
4. The lack of industry productivity despite advances in clinical R&D and highly efficient drug discovery methodologies.

Because of declining productivity, the industry gradually moved away from its core strength –the discovery, development and commercialization of innovative new drugs. Many companies diversified by adding adjacent verticals, such as consumer health care, generic drugs and medical devices. Some companies resorted to R&D cuts and increased prices of older drugs. Share buybacks and dividends became preferred ways to boost financial performance instead of internal investment.

Given the uncertainty of long-term returns, valuations of mature biopharma companies pulled back sharply compared to other subsectors, including medical tool and device companies and services companies. Related subsectors require fewer product overhauls due to patent expiries and instead rely on incremental innovation to existing products to maintain a competitive edge. We believe this valuation disparity presents opportunities to invest in mature biopharma companies with compelling fundamentals that can overcome shortcomings highlighted by Eroom's law.

### Biopharma Industry Outlook

Our view of the innovation cycle is rooted in the facts that disease will remain an intractable problem for the next 50 to 100 years and that there are significant areas

of unmet medical need globally. We believe the market underestimates the paradigm shift that has occurred since genetics and molecular biology technologies that are revolutionizing our understanding of the human body, became affordable and scalable. The first draft of the human genome was published in 2003 and it took over a decade for sequencing and molecular biology costs to reach a point where widespread projects became feasible. Since then, our capability to understand biology at the system's levels has increased exponentially.

Globally, drug spending per capita remains very low and quality health care remains underpenetrated. As primary care needs are satisfied, markets like India and China are moving up the value chain and are focusing on developing or procuring next-generation, high-value drugs. We believe Eroom's law is also rooted in the observation that peak growth has passed in developed markets. With over 3 billion people globally emerging economically and health care becoming a top priority, we believe international markets will be key growth areas long term.

### Breaking Eroom's Law

Roche, a major Swiss-based global biopharma and diagnostics company, is in our view, at the forefront of companies making changes to break Eroom's law. From the 1960s-1980s, Roche was a large, diversified company with businesses that encompassed dyes, chemicals, cosmetics, primary-care pharmaceuticals and diagnostics. It was one of the first global pharma companies to recognize the immense potential of cloning and the burgeoning field of biologics. Instead of incorporating biologics as another line of business, the company sold non-core assets (cosmetics, chemicals and oral drugs) and jumped into the biologics revolution.

Later, Roche transformed into an oncology and immunology company with one of the most successful oncology franchises of all time while retaining a leading diagnostics business. However, Roche did not stop there. It recognized the need to improve the safety and efficacy of its leading drugs and sought to create new products that added significant value to patients who were already on their oncology drugs. In other words, it sought to break theory one of Eroom's law by discovering, and eventually marketing, drugs that beat the high bar set by their own drugs. Roche's oncology drugs are facing considerable generics pressure, but the company continues to see top-line growth thanks to its next-generation drugs and continued research and innovation.

Roche also understands the global regulatory environment. Over the years, the company has secured numerous breakthrough designations (BTD) from the FDA. BTDs are one of five initiatives undertaken by the FDA to incentivize and improve R&D productivity by awarding priority review or accelerated approval for drugs that substantially improve efficacy in serious diseases, pediatric conditions or for conditions where there is no cure. Roche is one of the leaders in breakthrough drugs and has secured 31 BTD designations since the program was introduced in 2012. Subsequently, Roche's BTD drugs that eventually gained market approval account for roughly 50% of market share in their respective categories.

Roche is one of the largest investors into R&D among pharmaceutical companies, spending on average \$10 billion per year over the past five years. Undisciplined companies with similar R&D budgets have done a poor job allocating capital, and in many cases, have fallen into the trap of theories three and four – throwing good money after bad into unproductive projects and cutting corners on drug development processes, including poor clinical trial design. Over the past five years, Roche altered its clinical development strategy to focus on personalized health care and precision medicine and implemented several changes we believe will drive innovation.

### Our Portfolio

Our investment framework has helped us uncover undervalued biopharma companies that possess key characteristics to break Eroom's law. In general, these companies are prepared to shed non-core assets, take advantage of paradigm shifts in science and technology, identify areas of unmet medical need, attract quality talent and are long term in their commitment to innovative medicine and patient wellness.

A key consideration when evaluating health care companies is recognizing that the success or failure of yesterday's medicine does not foretell the future of tomorrow's medicine in a linear fashion. Our goal is to identify companies with strong scientific and commercial fundamentals that trade at relatively cheap valuations. Today, our health care exposure is weighted more towards mature biopharma companies, reflecting our view that current biopharma holdings Roche, Novartis, GlaxoSmithKline and Astellas are in various stages of transition to counter the trend described by Eroom's law.

<sup>1</sup> Diagnosing the decline in pharmaceutical R&D efficiency. Nature Reviews Drug Discovery volume 11, 2012.

<sup>2</sup> Source: Deloitte. Unlocking R&D productivity. Measuring the return from pharmaceutical innovation 2018.

As of 7/31/20, Diamond Hill owned Roche Holdings AG (equity), Novartis AG (equity), GlaxoSmithKline PLC (equity) and Astellas Pharma, Inc. (equity).

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