

Healthcare - Pharmaceuticals

September 2024

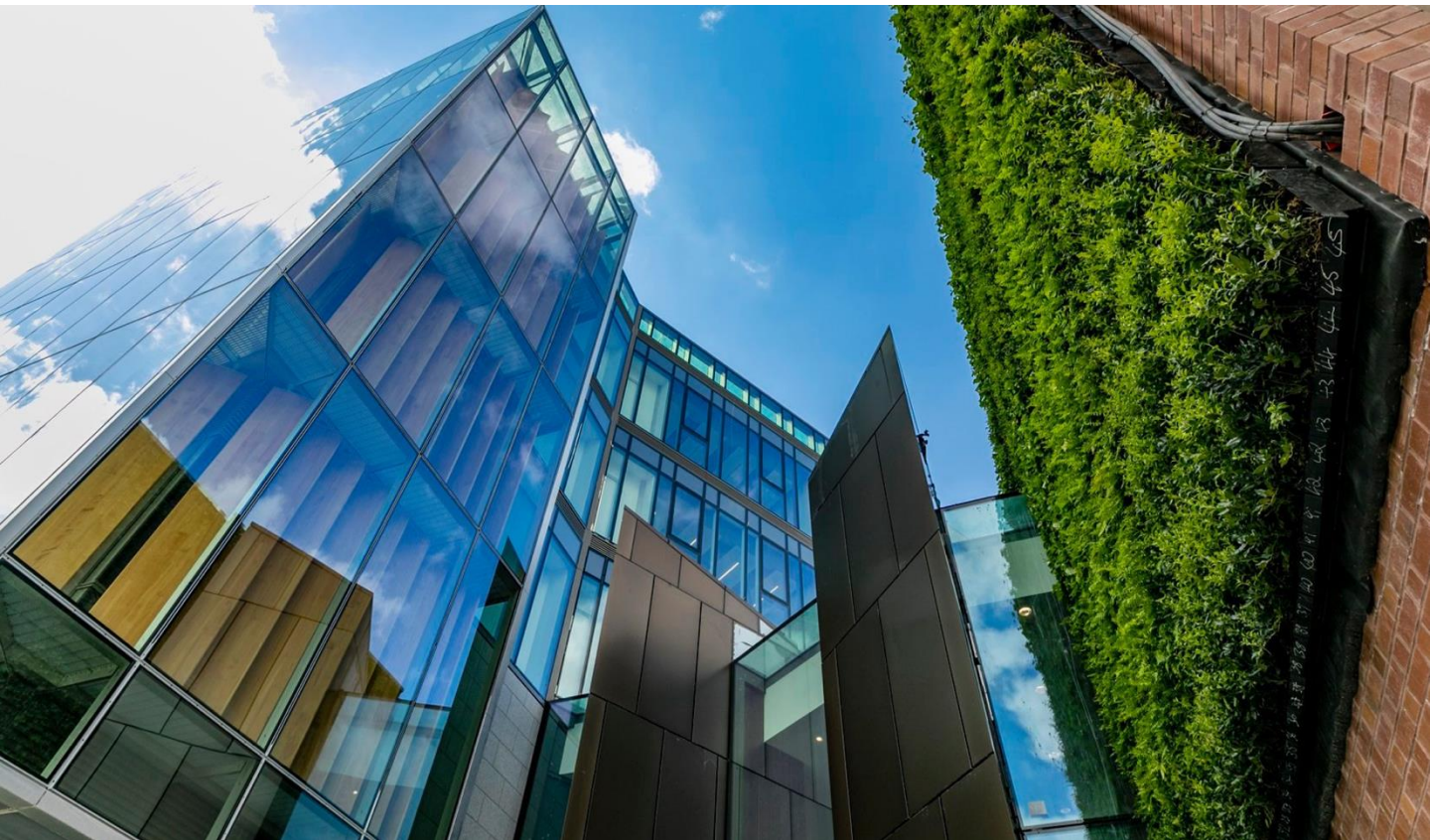


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Authors



Aoibhín Murdoch
Sector Manager



Adam McVerry
Senior Analyst

Sector Overview

Healthcare

The healthcare industry is a vital and complex sector characterised by its significant economic impact and diverse sub-sectors. The sector encompasses a wide range of businesses that are separated by several key areas: healthcare/medical services and providers, pharmaceuticals and biotechnology, health insurance, and medical equipment. The Healthcare sector can be divided primarily into Pharmaceuticals and Non-Pharmaceuticals; This report focuses on the Pharmaceutical side of the Healthcare sector.

Pharmaceuticals

Companies in the pharmaceutical industry focus on the discovery and deployment of drugs/medications. The discovery of drugs refers to the identification of novel compounds, and deployment includes the development and manufacturing of new drugs.

The healthcare sector is paramount, accounting for 14% of the S&P 500 in 2023 - falling short to only the information & technology sector. Pharmaceuticals account for 42% of healthcare; it is the largest healthcare sector by revenue, generating, as an industry, a staggering 1,600 billion USD in 2023. It's prone to rapid growth, exhibiting an annual growth rate of 4.71% - which is twice as fast as the global economy. Pharmaceuticals continue to trend upwards, with total sales revenue for the leading 20 pharmaceutical companies increasing by 9.6% from FY2021 to FY2022. The industry is expected to surpass 2,833 billion USD by 2033, expanding at a CAGR of 6.15% from 2024 to 2033.

Pharmaceuticals is a unique industry: its essentiality makes it non-cyclical in nature, and therefore not majorly influenced by broader economic conditions. In fact, during the COVID-19 pandemic, it delivered consistent sales growth of 5-10%. The broader healthcare sector also displayed the most positive change in earnings during recessionary periods of any industry over the past 40 years. Its resilience can also be attributed to its inelastic demand: consumers will seek medical care regardless of price changes, therefore pharmacies/medical institutions have pricing power. These characteristics can provide stability to pharmaceutical stocks during economic downturns, making it a defensive industry.

Sector Overview

Key Performance Indicators

Research and development (R&D) are the backbone of the pharmaceutical industry. Deloitte’s Annual Pharmaceutical Innovation Report shows that the leading 20 global pharmaceutical companies collectively spent \$145 billion on R&D in 2023, a 4.5% increase from 2022. However, the cost of failure represents a large portion of all R&D expenses: it is pertinent to not only assess the volume of R&D expenses, but the productivity of them. A major KPI for pharmaceutical companies is the Return on Research Capital (RORC), which reveals the revenue brought in from R&D expenditures.

For example: Eli Lilly & Co. has a competitive advantage in this industry as a leading firm with the highest industry market cap of 900.42 billion USD (MCSI World Healthcare Index). R&D have been identified as an advantageous positional choice of Lily, with expenditure reaching a whopping 9.3 billion U.S. dollars in 2023. Lilly’s RORC metric shows that the company is highly effective not only in investing, but in producing a return on its high R&D investments - generating a \$3.5 RORC which outperforms the industry benchmark of \$1.18. Accordingly, RORC is a strong indicator of performance in this industry.

Pharma KPIs	RORC
Industry Benchmark	\$1.18
Eli Lilly & Co	\$3.05

Healthcare is heavily regulated, with regulation compliance being paramount to the success of pharmaceutical companies. Most drugs never receive approval from the FDA, therefore large proportions of capital are burned by companies to achieve one profitable product. Significant challenges appear in interpreting and adapting to the evolving regulatory expectations in a timely and cost-efficient manner. A KPI related to regulatory compliance is the Regulatory Submission Success Rate: The percentage of products that achieve regulatory approval. The current success rate of drugs, from early stages of the pipeline to receiving marketing approval, is around 10-20% (16). In 2020, Pfizer achieved an industry high success rate of 21%, which helped to lay a foundation for the effective development of the COVID-19 vaccine (KMR Pharmaceutical Benchmarking Forum).

An important success indicator for the industry is the activity of mergers and acquisitions (M&A). M&A are the cornerstone of Pharmaceuticals: Large-cap pharmaceutical companies either merge with one another to share expertise and accelerate development or will take over small biotechs that have had scientific breakthroughs. The 30% rise in M&A activity from 2022 is indication of the industry’s strong performance and increasingly high market competition. The success indicator for the coming year is whether the recent rising trend in M&A activity can be sustained.

Sector Overview

Sub-Sectors

MSCI and S&P Dow Jones Indices developed the Global Industry Classification Standard (GICS), which separates the pharmaceuticals industry into the following sub-sectors: Biotechnology, Life Sciences Tools & Services, & Pharmaceuticals.

Biotechnology

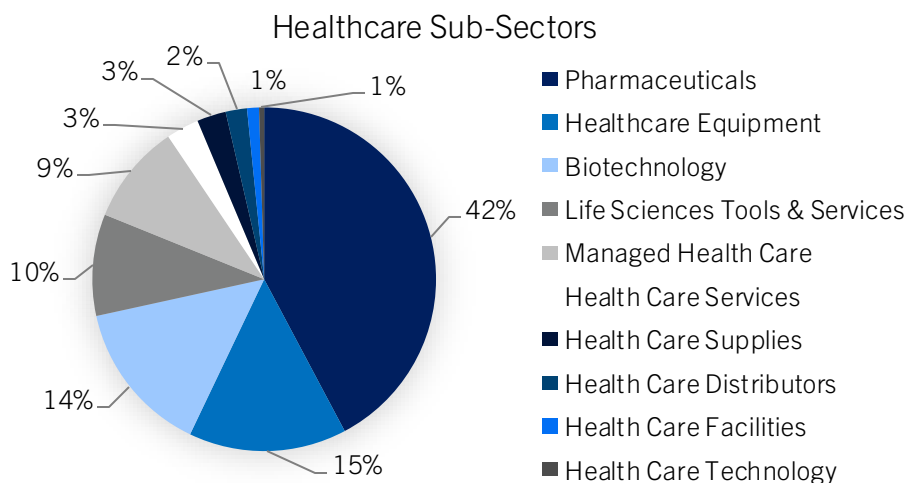
The biotechnology sector consists of companies that focus on the research, development, and manufacturing and marketing of products derived from genetic analysis and genetic engineering. This sector includes firms that specialize in protein-based therapeutics designed to treat human diseases. However, it does not encompass companies that utilise biotechnology for manufacturing products that lack a healthcare application.

Life Sciences Tools & Services

The life sciences and tools sub-sector of the pharmaceutical industry encompasses companies that enable the continuum of drug discovery and deployment. These firms provide essential products and services to support the pharmaceutical and biotechnology industries, from instruments to clinical trial and research services. Their products and services span the entire drug development pipeline, from early-stage discovery to late-stage clinical trials and manufacturing. By providing these resources, life sciences and tools companies facilitate the work of pharmaceutical and biotech firms.

Pharmaceuticals

The pharmaceuticals sub-sector within the broader pharmaceuticals industry comprises companies involved in the research, development, and production of various pharmaceutical products. This includes the creation of active pharmaceutical ingredients (APIs), which are the essential components used in formulating medications, as well as the development of veterinary drugs. These companies play a crucial role in advancing healthcare by bringing innovative therapies and treatments to market.



Investment Themes

Obesity & GLP-1 Drugs

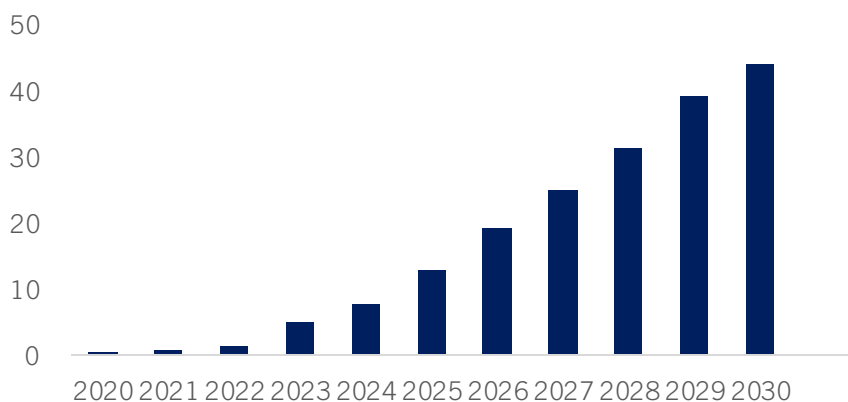
The weight-loss industry has astronomical potential, with a projected market value of \$105 billion by 2030. Obesity affects over 40% of U.S. adults, making weight-loss drugs a highly coveted product - it is estimated that more than 25% of obese Americans will receive GLP-1 treatment in ten years time.

The GLP-1 market is extremely competitive: both large pharmaceutical companies and small biotechs are jockeying to capitalise on the boom created originally by Novo Nordisk’s Wegovy and Ozempic in 2023. For the past year, Novo’ Nordisk’s Ozempic & Wegovy have been undisputed leaders along with Eli Lilly’s Tirzepatide (branded as Zepbound and Mounjaro) among the GLP-1 hormone-mimicking drugs. The next focus for pharmaceutical companies is to create a weight-loss drug that can be taken orally (in pill form), while being convenient, effective, and affordable. This race is lead by Eli Lilly, Novo Nordisk, and Pfizer, who are all in late-stages of oral GLP-1 development.

Other competitive advantages could be found in new drugs that reduce side effects, or target fat loss while maintaining muscle mass. Roche’s CT-388 (purchased from Californian biotech) is still in early stages of development, but shows promising results of 19% weight loss over 24 weeks, compared to Eli Lilly’s 21% weight loss over 72 weeks. Amgen’s MariTide, which is in phase 2 trials, also poses a threat: it may only need to be taken on a monthly basis, and has been found to maintain weight-loss effect past completion of the treatment.

Obesity drugs also have the potential to treat associated diseases: obesity is responsible for over 50% of diabetes cases and is linked to more than 200 chronic diseases. If drug-makers can keep pace with demand while battling rising health costs, the obesity market will achieve its promising potential.

Obesity Market, Billion USD



Investment Themes

Artificial Intelligence & Machine Learning

Drug R&D

The effects of recent developments in technology are evident across all sectors, and pharmaceuticals is no exception. In the pharmaceutical industry, Artificial Intelligence and Machine Learning has the potential to revolutionise drug discovery and disease treatment.

In terms of drug deployment, AI is streamlining and expediting development and manufacturing processes. Generative AI aids in target identification and compound design processes, making them more efficient. AstraZeneca, for instance, worked with deep learning algorithms, using a process called ‘digital pathology,’ to reduce the steps of cell imaging in drug screening. There is exciting clinical potential of AI-discovered molecules. AI appears to be highly capable of identifying molecules with drug-like properties, with the number of small molecules that were discovered using AI techniques in 2023 amounting to 24. Utilising AI with these methods to accelerate drug development reduces the costs of R&D, which in turn improves companies’ RORC. If AI-assisted drug development isn't hindered by barriers such as overregulation, it has the potential to revolutionise the pharmaceutical industry.

Personalised Medicine

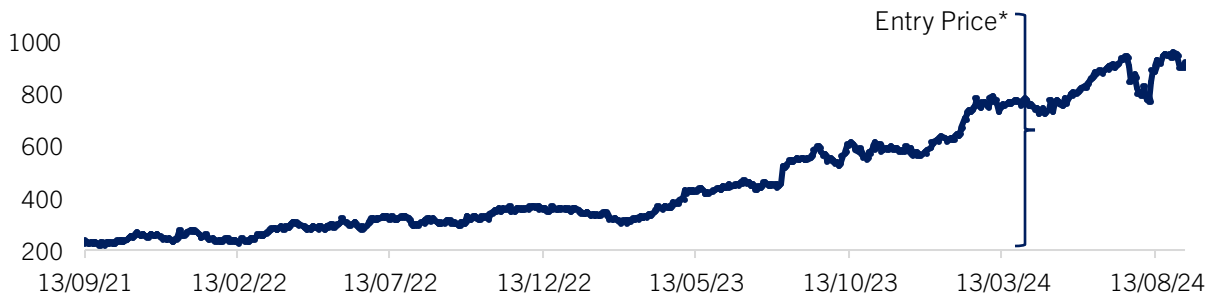
In terms of AI-facilitated drug discovery, the process of novel therapeutic discovery is enhanced by leveraging AI for the identification of novel compounds - especially for the purpose of the personalisation of medicine. Personalised medicine uses genetic and other personal information to tailor disease treatment; it is currently gaining more investment as attention shifts away from broad-spectrum therapies. Personalised medicine appears to be the long-term direction of healthcare – and it is an approach that goes hand-in-hand with AI. With personalised diagnostic medicine, there is evidence of machine learning outperforming clinicians in screening visual imaging data in fields such as pathology and dermatology. Personalised medicine has the potential to revolutionise disease treatment, and AI has the potential to fuel its ascendancy.

Current Holdings



Eli Lilly & Company (NASDAQ:LLY)

Entry Price*: \$759.59 Performance to date: + 26.39%



Eli Lilly and Company is an American pharmaceutical company headquartered in Indianapolis, Indiana. The company discovers, develops, manufactures, and markets products in the human pharmaceutical products segment. The company offers a wide range of treatments across segments such as diabetes, oncology and immunology.

Hold at \$960 for the following reasons:

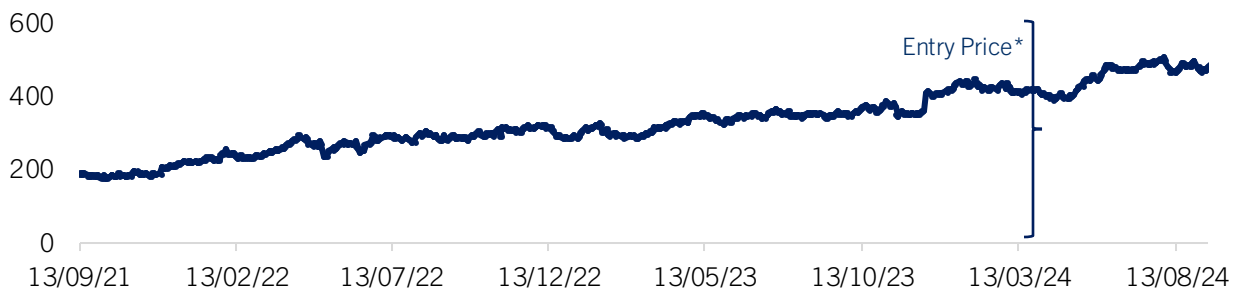
- 1. GS raises obesity market forecast from \$100bn to \$130bn:** After having projected a \$100bn obesity market only 10 months ago, recent approval of Lilly’s Zepbound and label expansions of Novo Nordisk’s Wegovy have brought an increased projection to \$130bn. Goldman sees Lilly and Novo retaining about 80% of the global market by 2030, with Lilly having a slight advantage over Novo in market share(20).
- 2. \$9bn commitment to Tirzepatide manufacturing site:** Sales of Lilly’s GLP-1 medicines continue to grow rapidly. The launch of Tirzepatide, the active ingredient in Zepbound and Mounjaro has been incredibly successful, but sales would be much higher if Lilly could keep up with intense demand. Lilly have recently raised their commitment to manufacturing Tirzepatide in Indiana from \$3.7bn to \$9bn. This significant investment is expected to combat the shortage of Zepbound, which has been predicted to bring sales of \$50bn annually at its peak (21).
- 3. Tipped to take control of \$13bn Alzheimer’s market:** While Eisai and Biogen’s Alzheimer’s drug Leqembi, the only FDA approved drug of its kind, was seen as a major step forward for treating Alzheimer’s, it has only recently gained a positive growth trajectory after a sluggish start due to safety concerns. Lilly’s Donanemab, approved by the FDA in July, could exceed sales of Leqembi in 12 months, due to more convenient dosing and because patients can stop receiving the drug once amyloid levels reach a clearance threshold. Analysts predict that Lilly will be the dominant force in Alzheimer’s in 2030, forecasting Donanemab sales of \$6.5bn a year (22).

Vertex Pharmaceuticals (NASDAQ:VRTX)



Entry Price*: \$400.23 Performance to date: + 23.90%

Vertex Pharmaceuticals Incorporated is an American biotechnology company based in Boston, Massachusetts. The company is the market leader in treatments for Cystic Fibrosis (CF), with marketed medicines Trikafta, Symdeko, Orkambi and Kalydeco. Vertex has a pipeline of therapies in other serious diseases, including sickle cell disease, type 1 diabetes, and beta thalassemia.



Hold at \$496 for the following reasons:

- 1. Dominating a rapidly growing market:** The global cystic fibrosis market is expected to reach \$37.04bn by 2030, with a CAGR of 24.3%. This is due to both a rise in the incidence of cystic fibrosis and advancements in therapeutics for treatment. VRTX is the dominant player in the market, due to a diverse product portfolio and a strong presence in CF treatment globally. VRTX’s Trikafta continues to perform both inside and outside the US, with Q1 sales worth \$2.48bn, up 18.5% YoY (23).
- 2. New Casgevy data makes case for blockbuster sales:** Casgevy is the world’s first gene therapy that aims to cure sickle cell disease. Having gained FDA approval in December 23, the latest data is groundbreaking, suggesting that Casgevy is a ‘one and done’ permanent cure for a disease that causes lifelong health issues for over 80,000 US patients, and often reduces duration of life. Partnered with CRISPR, VRTX only take 60% of profits, however with an expensive treatment at \$2.2mn, the total market opportunity, considering 36k patients, is over \$80bn. While this is unlikely, if VRTX were to achieve 25% market penetration over a period of 10 years, the company would earn an average of over \$1bn revenues per annum (24).
- 3. Strong Pipeline for Non-Opioid Pain Medication:** A significant opportunity arises with VX-548, VRTX’s non-opioid pain medication. Given the opioid crisis, a non-opioid pain management alternative has huge potential in healthcare. It has produced promising results in mid-stage clinical trials, and if approved, is expected to produce \$5 billion in sales at its peak (25).

Potential Buy



AstraZeneca PLC (LSE:AZN)

AstraZeneca is a British-Swedish biopharmaceutical company with medicine sales in more than 130 countries, making it one of the largest drug companies in the world. AstraZeneca's main R&D areas include oncology, rare diseases, and biopharmaceutical intervention, and it has numerous ongoing projects.



Buy at £133 for the following reasons:

- 1. Recent FDA approval of high-flying cancer therapy:** AstraZeneca's Imfinzi has been shown in studies treating non-small cell lung cancer to reduce the risk of recurrence, progression or death by 32% when compared to chemotherapy alone. The treatment is expected to become a backbone in treating this form of cancer, which has high rates of recurrence even after surgery and chemotherapy. The approval is a boost to the drugmaker's ambitions for its medication to be a treatment option for more than half of lung cancer patients by 2030 (26).
- 2. Significant investment in oncology pipeline:** AstraZeneca is set to open its first manufacturing presence in Singapore with the buildout of a \$1.5bn chemotherapy drug manufacturing facility. The manufacturing site will add to their industry-leading portfolio of cancer medicines which have shown enormous potential to replace traditional chemotherapy for patients. With ADC's having an estimated market size of \$10 bn, and a CAGR of 15%, AstraZeneca are in a prime position to capitalise on this rapid growth and technological advancement (27).
- 3. Potential major player in obesity market:** Having secured the right to acquire Swiss biotech company SixPeaks Bio, AstraZeneca have an innovative pipeline of weight loss therapies at their disposal. The treatments are expected to overcome the common side-effect of muscle loss that occurs in the GLP-1 therapies which dominate the market. If the pipeline proves successful, AstraZeneca will have the opportunity to flourish in a market expected to reach \$125 trillion by 2033 (28).

Risks

US Biosecure Act

Introduced in January 2024, the Biosecure Act intends to prevent Chinese biotechs and manufacturers from accessing US funding and collaborating with pharma companies. The legislation, which is intended to protect US national security, causes high concern about the impact of R&D and manufacturing for medicines. Several major Chinese biotech companies were named as US national security concerns, including WuXi, which helps produce the active ingredient in Eli Lilly's key obesity treatment Zepbound and sister diabetes drug Mounjaro. Though the bill is not law, it has gathered momentum and caused significant concern in the pharma community. The Biosecure Act could raise drug prices higher due to the pharma companies not having access to cheap manufacturing sources within their supply chain, along with the costs of transitioning to different manufacturing partners (29).

Inflation Reduction Act (IRA)

The IRA, introduced in 2022 to curb inflation by allowing Medicare to negotiate prices for certain drugs, is expected to have a knock-on effect on R&D. Currently the act has two different timelines for large and small molecule therapies. The law gives small molecule drugs a shorter timeline before their 'fair prices' are implemented. As a result, pharma companies might rethink their pipelines to contain fewer small molecule drugs. Such drugs are used to address many types of cancer and occupy 40% of Eli Lilly's portfolio. Such measures brought Lilly to discontinue their development of a treatment for certain blood cancers after an assessment of the impact of the law. With Vertex currently investigating small molecule medicines for sickle cell disease, the act might come into play as a major headwind (30).

Patent Cliff

In what is one of the most important elements of the pharmaceutical sector, loss of exclusivity on drugs allows competitors to enter the market, significantly reducing the drug's revenue. US Senate lawmakers have recently imposed a bill to limit the number of patents drugmakers can assert in litigation on individual biological products. The affordable prescriptions for patients act aims to fight 'patent thickening', a tactic used to thwart competition. With patents playing a huge role in innovation, there is concern that the legislation would allow lawmakers to prohibit innovative companies from enforcing lawfully awarded patents (31).

Strategy For The Year Ahead

As the obesity market booms and market capitalisations surge, we are optimistic about the pharmaceutical sector’s trajectory for the coming year. Despite many products losing exclusivity and Medicare’s new negotiating power, the pharmaceutical sector has grown at a healthy rate.

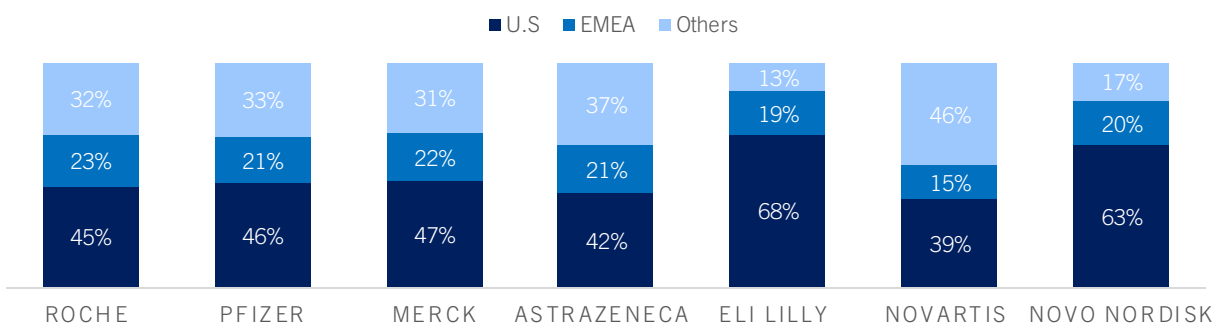
For the coming year low- to mid- single digit growth is expected for big pharma companies. Furthermore, therapeutic areas of oncology, immunology, CNS and obesity are expected to grow by 8-10%, reinforcing our current holdings. As such, we are bullish on the performance of pharmaceuticals (32).

Obesity Market Competitive Landscape

With the obesity market expected to reach \$130 bn by 2030, there are several players waiting to enter. As several obesity drugs are already approved for diabetes, they proceed rapidly through the early stages of the pipeline. With AstraZeneca, Bristol Myers Squibb, Novartis and Amgen all trying their hand in the space, attention must be paid to how well Novo and Lilly can keep their grip on the market (33).

Geographic Diversification

Given industry pressures and risks of drug price reforms in the U.S, geographic in the U.S is seen as more of a risk than in the past. With Harris and Trump both promising pharmaceutical reforms, it could be wise to look at companies with less U.S exposure.



September Watchlist Review

Alynlyam (NASDAQ: ALNY) – Shares up 28% after heart disease drug hails positive results in late-stage trials – cut risk of death/ cardiovascular events by >29%.

Amgen (NASDAQ: AMGN) – Targeting booming GLP-1 market with MariTide in stage 2 clinical trials. Data suggests faster weight loss than both Wegovy and Zepbound.

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