Mu Sigma

DO THE MATH

Vertical Writeup

PHARMACEAUTICAL INDUSTRY

September 5 2024

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INTRODUCTION

Introduction to industry: One of the biggest and most intricate industries in the world economy, the pharmaceutical sector is devoted to the discovery, development, manufacturing, and distribution of drugs and treatments that enhance health and address a variety of illnesses. By delivering necessary medications that not only save lives but also improve the quality of life for billions of people globally, this industry plays a crucial role in modern healthcare. The development of modern medicine was made possible by advances in chemistry and biology throughout the late 19th and early 20th centuries, which is when the pharmaceutical business first emerged. Using innovative technology and creativity, the industry has progressed over decades from generating simple molecules to developing complex, life-saving therapies. Research and development (R&D), a crucial and resource-intensive step in the drug discovery process, lies at the core of the pharmaceutical industry.

Current market size: The global pharmaceutical industry is a major player in the healthcare sector, with a significant and growing market share. As of 2023, the industry is expected to be around 1.6 trillion U.S dollars, with projections to grow to $3.08 trillion dollars by 2032 at a compound annual growth rate (CAGR) of 6.8%. The growth of this market is driven by several factors, including increased healthcare awareness, advancements in drug development, and a rising prevalence of chronic and rare diseases. The increased incidence of chronic illnesses, biotechnology breakthroughs, and the growing need for tailored therapy are all contributing to the pharmaceutical industry's notable expansion.

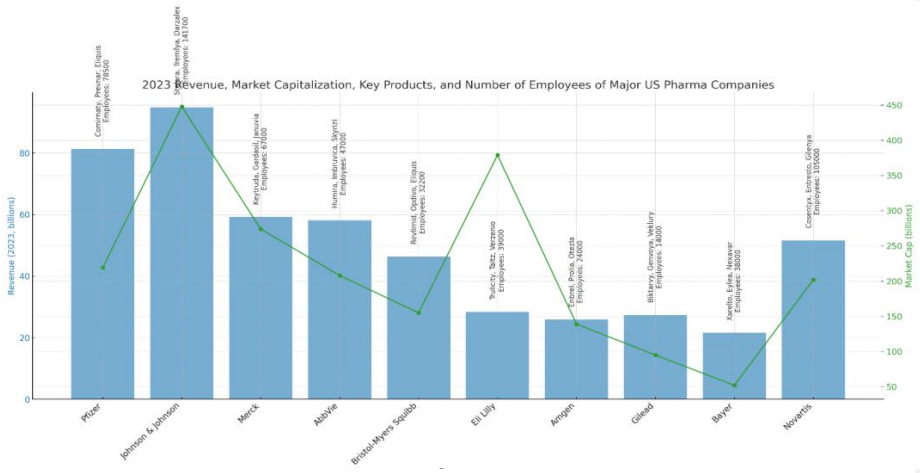
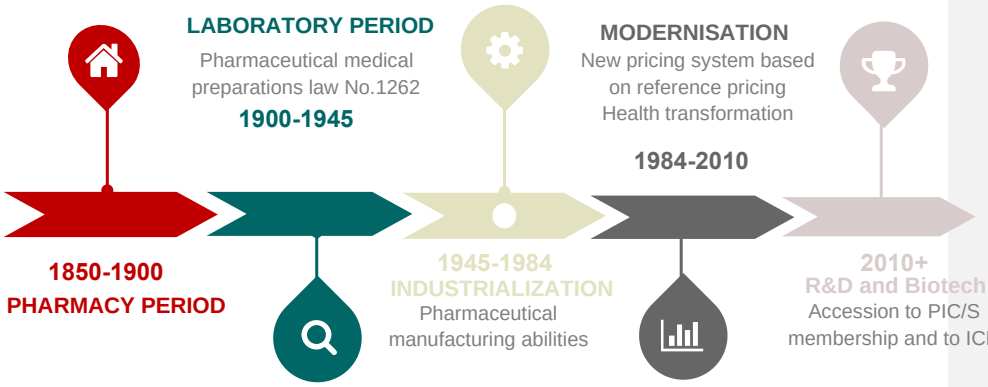


Fig: Revenue, market capitalization of major US pharma companies

HISTORY



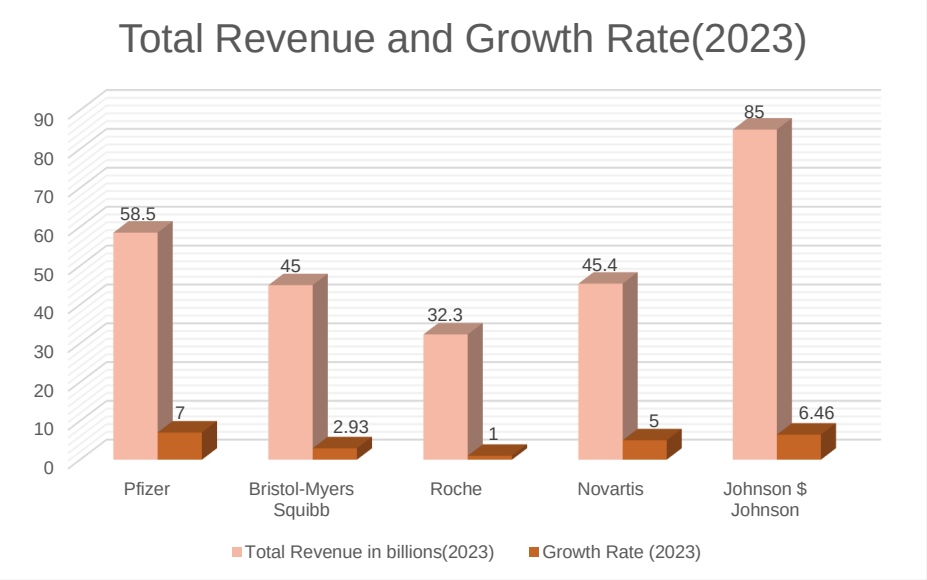
MARKET ANALYSIS

The pharmaceuticals market is set to reach US$1,155 billion in 2024, showcasing its vast scale and importance in global healthcare. Within this market, oncology drugs are projected to dominate, with a significant market volume of US$194.10 billion for the same year. This sector's growth is expected to continue robustly, with an annual compound growth rate (CAGR) of 4.71% from 2024 to 2029, leading to a market volume of US$1,454 billion by 2029.

The United States is anticipated to lead globally in pharmaceutical revenue, with an estimated US$630.30 billion in 2024. This dominance is largely due to the country's advanced healthcare infrastructure and leading position in research and development. As a result, the U.S. remains a pivotal player in pharmaceutical innovation and market dynamics worldwide.

Other Regions with Pharma dominance includes China, Germany, Japan, Europe.

Companies invest more than 20% or more of their sales revenue in R&D projects.



Johnson & Johnson (J&J)

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Strengths: J&J is highly diversified, with strong positions in pharmaceuticals, medical devices, and consumer health products. It is rated as one of the strongest companies in the biopharma industry by S&P Global.

Market Position: Diversified across pharmaceuticals, medical devices, and consumer health products. Reported sales growth of 6.5% to $85.2 billion in 2023. Robust R&D pipeline across multiple therapeutic areas, including oncology and immunology. Stock price around $164.35, market cap $395.63 billion, dividend yield 3.03%Recognized for its diversified portfolio and strong market presence.

Drug	Sales in Billions ($)(2023)	US Patent Expiration
Stelara	10.8	2023
Imbruvica	3.2	2024
Erleada	2.3	2028
Darzalex	9.7	2030 or beyond

Roche

Strengths: Roche is a leader in oncology and diagnostics, with a strong focus on personalized healthcare. It also ranks highly in S&P Global' s ratings for both business and financial risk.

Market Position: A leader in oncology and diagnostics, with significant sales in both pharmaceuticals and diagnostics Invested CHF 13.2 billion in R&D, focusing on personalized healthcare and diagnostics.

Strong reputation in oncology and diagnostics.

Drug	Sales in Billions ($)(2023)	US Patent Expiration
Perjeta	4.4	2024
Tecentriq	4.4	2032
Avastin	1.8	2019
ocrevus	7.5	2029

Pfizer

Strengths: Pfizer is a global leader in pharmaceuticals, with a strong focus on vaccines, oncology, and rare diseases. It has a robust pipeline and significant R&D investments.

Market Position: Held 9% of the global pharmaceutical market in 2022. Known for its strong portfolio in vaccines, oncology, and rare diseases. Significant investments in R&D, particularly in vaccines and oncology.

Stock price around $28.70, market cap $162.61 billion, dividend yield 5.84%.

Known for its patient-centric approach and collaboration with healthcare professionals.

Drug	Sales In Billions ($)(2023)	US Patent Expiration
Comirnaty	1.1	2024
Xeljanz	1.7	2034
Ibrance	4.7	2027
Prevnar family	6.4	2033

Novartis

Strengths: Novartis is known for its strong R&D capabilities and diverse product portfolio, including innovative therapies in oncology, immunology, and neuroscience.

Market Position: Ranked highly for its commitment to patient engagement and innovation in cardiovascular drugs.Strong R&D capabilities with a focus on innovative therapies in oncology and cardiovascular diseases.

Strong in innovative therapies, particularly in oncology and cardiovascular diseases. Full-year sales up 10%, core operating income up 18% in 2023.

Drug	Sales In Billions($)(2023)	US Patent Expiration
Entresto	1.6	2025
Promacta/Revolade	0.5	2038
Kesimpta	0.6	2025
Cosentyx	1.3	2026

Bristol-Myers Squibb (BMS)

Strengths: BMS has a strong focus on oncology, immunology, and cardiovascular diseases. Its acquisition of Celgene has bolstered its pipeline and market position.

Market Position: Focuses on oncology, hematology, and immunology. Reported revenues of $45.0 billion in 2023. Focused on expanding its pipeline in oncology and immunology.

Stock price around $49.69, market cap $100.73 billion, dividend yield 4.89%.

Drug	Sales in Billions ($)(2023)	US Patent Expiration
Opdivo	9	2025
Eliquis	12.2	2026
Orencia	3.6	2026
Pomalyst/Imnvoid	3.4	2024

TRENDS AND INSIGHTS

Pharmaceutical companies are increasingly focusing on personalized medicine, a trend where drugs are tailored to individual genetic profiles to enhance treatment effectiveness. This approach provides valuable insights, as it has been shown to improve patient outcomes by increasing the efficacy of treatments and reducing side effects. By leveraging personalized medicine, companies can deliver more targeted and success.

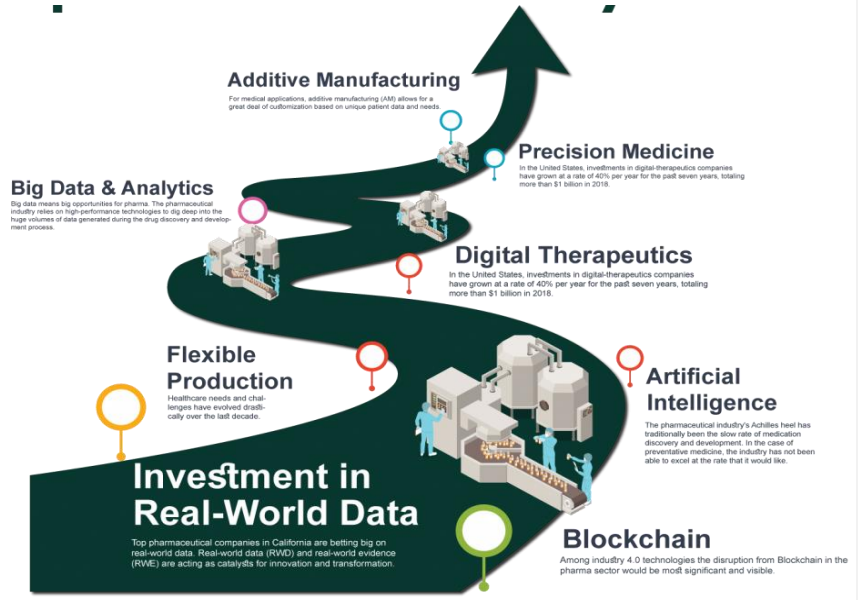
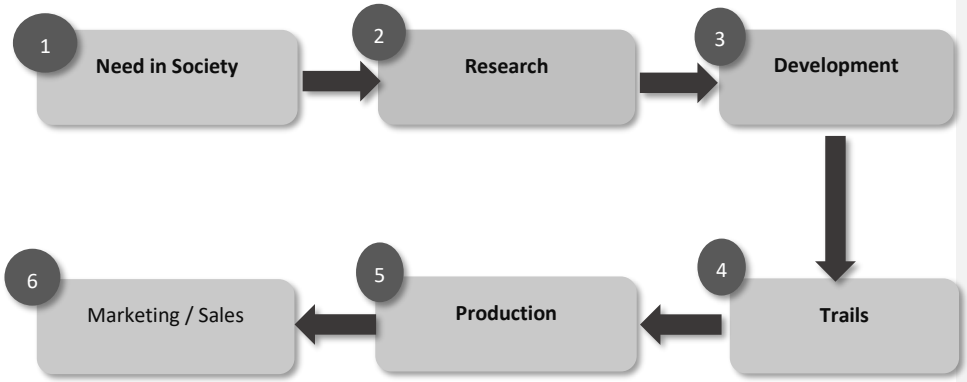


Chart: Trends and Innovations

Challenges and Opportunities

Challenges	Opportunities
High R&D Costs: Developing new drugs is expensive and time-consuming.	**Innovation in Drug Development:** Advancements in technology (AI, personalized medicine) can reduce R&D costs and speed up drug discovery.
Regulatory Hurdles: Strict regulations make it difficult to get approvals.	**Regulatory Flexibility for Innovative Therapies**: Growing flexibility for new treatments, like gene therapies, can streamline the approval process.
Patent Expirations: Loss of exclusivity leads to revenue drop due to generic competition.	**Focus on Biologics:** Investing in biologics, which are harder to replicate, can provide longer-lasting patent protection and revenue streams.
Complex Supply Chains: Ensuring the supply chain operates efficiently across global markets is challenging.	**Supply Chain Optimization with Technology**: Digital solutions like blockchain can improve transparency and reduce inefficiencies in the supply chain.
Drug Pricing Pressure: Governments and patients demand lower drug prices, affecting profitability.	**Value-Based Pricing:** Opportunity to align pricing with outcomes, gaining support from healthcare providers and payers.
Slow Market Penetration in Emerging Markets: Complex regulations and infrastructure limitations slow growth in emerging markets.	**Emerging Market Expansion**: Expanding into high-growth regions with increasing healthcare access can provide significant revenue opportunities.

Pharma value chain



Key Opinion Leaders:

- **Ways to Identify KOL's**

- Speakers at national conferences and local events
- Authors of Published research in professional journals
- Top Rated Physicians by their peers

- **Importance of KOL's in Pharma**

- KOL's are consulted by Pharma Industries in phases of development and testing
- They have power to influence product perceptions and often have a broad influential reach across medical community

How Rules Affect Medicines:

1.Getting Medicines Approved

- Approval Agencies

2.Medicine Costs

- Price Limits
- Insurance

3.Protecting New Ideas

- Patents

4.Advertising Medicines

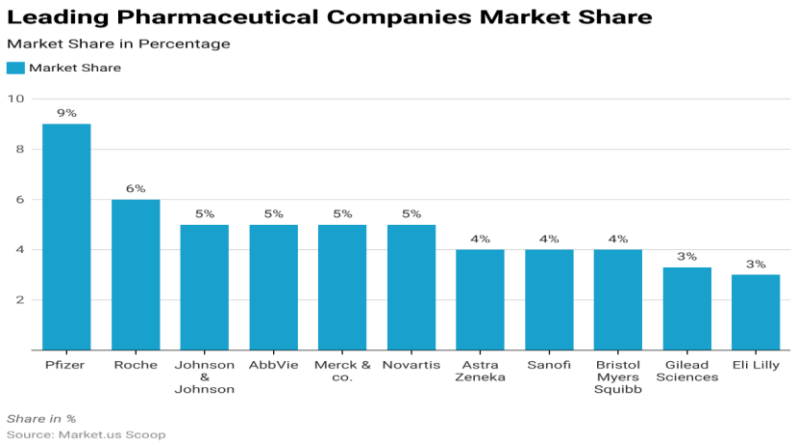
- Ads Rules

5.Safety Checks

- Ongoing Monitoring
- Testing

KEY SUCCESS METRICS AND KPI's

1.Market Share: It refers to the percentage of total sales or revenue that a specific company or product commands within the overall market. It indicates a company's position relative to its competitors in the pharmaceutical market. Increasing market share is a key goal for most pharmaceutical companies.



2.Cost of Drug Development: This metric measures the total cost incurred from drug discovery through to the final approval. The pharmaceutical industry is characterized by high R&D costs, so managing these effectively is critical to maintaining profitability. Companies often compare this metric against industry benchmarks to evaluate their R&D efficiency.

3.R&D development productivity: R&D is crucial in the pharmaceutical industry because the development of new drugs is fundamental to a company's success. Key metrics in this area include:

- **Time to market**: The time it takes for a drug to go from initial discovery through to market launch. Shortening this period is critical to gaining a competitive advantage and maximizing the patent-protected sales period and maximizing revenue potential
- **Cost per Clinical Trial**: The average expenditure required to conduct a clinical trial. Controlling these costs while maintaining high standards is vital for profitability

4.Audit Pass Rate: This KPI tracks the percentage of successful audits conducted by regulatory bodies, such as the FDA, EMA, or other relevant authorities. The Audit Pass Rate directly measures how well a pharmaceutical company complies with stringent regulatory standards, which is crucial in this highly regulated industry. A high pass rate reflects the effectiveness of the company's quality management systems, manufacturing processes, and overall adherence to Good Manufacturing Practices (GMP).

5.Post-Market Surveillance Metrics: Post-market surveillance ensures ongoing safety and effectiveness of drugs. Key metrics include:

- **Adverse Event Reporting Rate**: The frequency of adverse event reports for a drug. Lower rates can indicate better safety profiles or more effective patient education

6.Product recall rate, defect rate:

- **Defect rate:** It measures the percentage of products produced that fail to meet the required quality standards. Essentially, the Defect Rate provides insights into the quality control and effectiveness of a manufacturing process
- **Product recall rate**: Frequency of product recalls due to quality issues. Product recalls can have significant financial implications, including costs associated with the recall process, legal liabilities, and damage to the company's reputation. A lower recall rate helps minimize these impacts

7.Customer acquisition cost (CA): Customer Acquisition Cost (CAC) is the total expense incurred to acquire healthcare professionals (HCPs) and other key stakeholders, including costs for marketing, sales efforts, promotional activities, regulatory compliance, and distribution. It reflects the investment needed to convince HCPs to prescribe or recommend a drug or treatment.

STRATEGIC RECOMMENDATION

Strategic recommendations for the pharmaceutical industry typically focus on addressing industry challenges and leveraging opportunities to enhance growth and competitive advantage. Here are some key areas to consider:

- **Putting the patient at the center with decentralized trials**
  Putting the patient at the center with decentralized trials means designing and conducting clinical studies that prioritize patient convenience and accessibility. This approach reduces the need for travel and in-person visits by leveraging home-based care, virtual consultations, and local health providers. It aims to lower participant burden, increase engagement, and include a more diverse population, ultimately leading to more relevant and effective research outcomes
- **Adopting human-machine technologies at scale is a game-changer**
  Adopting human-machine technologies at scale is a game-changer because it significantly enhances efficiency, accuracy, and productivity across industries. By integrating advanced technologies like artificial intelligence, robotics, and automation with human expertise, organizations can streamline complex processes, reduce errors, and handle large volumes of data more effectively
  This synergy not only accelerates innovation and decision-making but also optimizes resource use and drives cost savings, ultimately transforming operational capabilities and creating competitive advantages
- **Capitalizing on digital innovation in the value proposition**

Capitalizing on digital innovation in the value proposition means leveraging advanced digital technologies to enhance the overall appeal and effectiveness of a product or service. By integrating digital tools such as artificial intelligence, big data analytics, and automation, companies can offer more personalized, efficient, and responsive solutions to meet customer needs. This approach not only differentiates the product or service in the marketplace but also adds value by improving user experiences, optimizing processes, and unlocking new revenue opportunities

- **Reimagining customer engagement with analytics and technology**
  Reimagining customer engagement with analytics and technology involves using data-driven insights and advanced digital tools to create more personalized and interactive experiences. By analyzing customer behaviors, preferences, and feedback, companies can tailor their interactions and offers to better meet individual needs and preferences. Technologies such as artificial intelligence, machine learning, and automation enable real-time responses and more dynamic engagement strategies. This approach enhances customer satisfaction, fosters stronger relationships, and drives loyalty by ensuring that interactions are relevant, timely, and value driven
- **Taking real-world evidence to the next level**
  Taking real-world evidence (RWE) to the next level involves leveraging advanced data analytics, technology, and larger, more diverse datasets to enhance the depth and applicability of insights derived from real-world data. This approach goes beyond traditional observational studies by integrating sources like electronic health records, patient registries, wearable devices, and mobile health apps. The goal is to generate more accurate, actionable insights into how treatments perform in everyday settings, improve patient outcomes, and inform better healthcare decisions and policymaking. Enhanced RWE can drive innovation, optimize treatment strategies, and support more personalized and effective healthcare solutions

SCOPE OF ANALYSIS

Scope	Description
Market analysis Entails evaluating the pharmaceutical industry's overall size, growth trends, and competitive environment to pinpoint opportunities and obstacles.	**Market size:** is an evaluation of the overall volume and value of the market, broken down by product type, application, and geography **Growth Rate**: Examining past and anticipated growth rates, determining the main forces behind and impeding them **Competitive Landscape**: Assessment of market share, competitive tactics, market positioning, and main competitors
Research and Development Analysis of investments, innovation trends, development pipelines, and the effectiveness of R&D procedures in bringing	**R & D Investment**: Analysis of R&D spending patterns, including distribution according to therapeutic area and development stage, is included in R&D investment

novel medications to market are the main topics of research and development (R&D).	**Pipeline Analysis:** An assessment of drug development pipelines that considers success rates and various stages (preclinical, clinical, and approval) **Collaboration and Partnerships:** Synopsis of strategic alliances, licensing contracts, and R&D collaborations
Financial Performance: This assesses pharmaceutical businesses' liquidity by looking at their income, profitability, sources of funding, and market value.	**Revenue Analysis**: Evaluating revenue streams from product sales, licensing, and royalties. **Profitability**: Analyzing profit margins, cost structures, and key financial ratios. **Investment and Funding**: Reviewing investment sources, such as venture capital, public funding, and private equity. **Market Valuation**: Analyzing market capitalization, stock performance, and valuation metrics.
Risk management: Involves Identifying and addressing various risks—such as operational, financial, regulatory, market, and strategic risks—to ensure business continuity and maintain resilience.	**Operational Risks**: Identifying and mitigating risks related to production, supply chain management, and logistics operations.

INDIA	US
Market Size: India's pharmaceutical market is the third largest by volume and the thirteenth-largest by value, estimated to be around $50 billion.	**Market Size:** The US pharmaceutical industry is one of the largest in the world, with a market size exceeding $600 billion.
Growth Rate: India's pharmaceutical industry is growing rapidly, CAGR of around 10-15%.	**Growth Rate:** The industry has a stable growth rate, driven by high healthcare spending, innovation, and an aging population.
Challenges: Regulatory compliance can vary, and there is a need for better enforcement of quality standards.	**Challenges:** High costs of drug development and compliance with extensive regulations.
Investment: Increasing investment in biotechnology and pharmaceutical research, but still catching up with the US in terms of overall R&D expenditure.	**Investment:** High levels of investment in biotechnology, and personalized medicine.

The US market is characterized by its size, innovation, and stringent regulations, while India's market is marked by rapid growth, a strong generic sector, and evolving regulatory standards.

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