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Pfizer

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"When Ian Read, an accountant and company lifer, took over as Pfizer's chief executive in December 2010, the drug firm was facing the impending patent expiration of Lipitor, the best-selling drug ever made, and the utter failure of one of the most lavishly funded research laboratories on the planet to develop much of anything. The stock was suffering, and Read's predecessor–Jeffrey Kindler, a bearlike lawyer hired from McDonald's–had just spent $68 billion to buy rival drug maker Wyeth in a Hail Mary strategy shift. Now Read had to make it work."[1]

COMPANY AND INDUSTRY BACKGROUND

Pfizer was established in 1849 in Brooklyn, New York by cousins Charles Pfizer and Charles Erhart with a loan of $2,500 from Pfizer's father.[2] Today, 167 years later, Pfizer Inc. has international revenues of $49 billion, which makes it the second-largest pharmaceutical manufacturer in the world.[3] Despite Pfizer's success, the company has faced many challenges over the last few decades. The pharmaceutical industry is heavily influenced by legal, political, and technological forces, and all indications are that the industry will continue to experience dramatic changes.

Since the passing of the Food and Drugs Act in 1906, the Food and Drug Administration (FDA) has had regulatory authority over drugs in the United States. The scope of its initial authority was limited and in 1938 President Roosevelt signed the Food, Drug and Cosmetic Act (FD&C) into law, which significantly expanded federal oversight of drug manufacturing and marketing.[4] In addition to granting the FDA authority to mandate pre-market review of drugs, the FD&C also allowed the FDA to regulate drug labeling and advertising. Then, in 1992, Congress passed the Prescription Drug User Fee Act, which enables the FDA to collect fees from drug manufacturers to aid in funding the pre-market review process for new drug approvals.[5] The effect of these reforms was significant increases in the time and cost for drug manufacturers to bring new drugs to market.

In 2006, a study estimated the cost of bringing a new drug to market was between $802 million and $2 billion, depending on the type of drug being developed and the number of drugs being developed simultaneously.[6] The study found that approximately 60% of the total cost of drugs was related to pre-market clinical trials required by the FDA. As inflation, increased regulation, and other factors have affected the pharmaceutical industry, a 2012 study indicated that the cost per drug for the largest manufacturers has increased to over $5.5 billion.[7] For Pfizer, the total Research & Development (R&D) cost for each drug that received FDA approval was $7.7 billion between 1997 and 2011.[8] The steep rise in development costs has forced many large drug manufacturers – including Pfizer – to cut R&D budgets in an attempt to control rising costs.[9]

The reduction in R&D funding in reaction to expanding costs has led to stifled innovation and revealed a crisis looming ahead for many large drug manufacturers in the industry. Not only have many drug companies' blockbuster drugs gone off patent in recent years, but the reductions in R&D spending have resulted in drug pipelines that have failed to produce anything of significant value.[10] The number of new drugs approved by the FDA per billion dollars of R&D expenditures has halved every nine years since 1950.[11] The rapid increase in the cost of drug development and the reduction in the approval frequency of blockbuster-level drugs has led many industry experts to largely consider the current, fully integrated business model of large pharmaceutical companies to be unsustainable.[12]

BUSINESS AND STRATEGIES

Like most large pharmaceutical manufacturers, Pfizer pursues a “blockbuster” business model that is heavily reliant on its R&D pipeline to consistently develop and launch high volume drugs – drugs with expected annual revenues of $1 billion or greater.[13] In 2012, Pfizer began restructuring its operations into a new commercial operating model. Pfizer divested its infant nutrition business for $11.9 billion and spun-off its animal health unit, Zoetis. Additionally, Pfizer restructured its operations into two primary business segments: Innovative Products and Established Products. Pfizer’s Innovative Products business is further divided into the Global Innovative Pharma (GIP) and Global Vaccines, Oncology, and Consumer Healthcare (VOC) businesses.[14] Ian Read commented regarding the restructuring: “This represents the next steps in Pfizer’s journey to further revitalize our innovative core. Our new commercial model will provide each business with an enhanced ability to respond to market dynamics, greater visibility and focus, and distinctive capabilities.”[15] Exhibit 1 contains some useful financial comparisons between Pfizer’s Innovative Products and its Established Products.

Innovative Products Business

Global Innovative Pharma (GIP) Business. This business focuses on developing, registering and commercializing novel, value-creating medicines that improve patients' lives. Therapeutic areas include inflammation, cardiovascular/metabolic, neuroscience and pain, rare diseases and women's/men's health, and include leading brands, such as Xeljanz®, Eliquis® and Lyrica®. GIP has a robust pipeline of medicines in inflammation, cardiovascular/metabolic disease, pain, and rare diseases.[16]

Global Vaccines, Oncology, and Consumer Healthcare Business. This segment consists of three businesses with the following key elements: 1) poised for high, organic growth; 2) distinct specialization and operating models in science, talent, and market approach; and 3) structured to ideally position Pfizer to be a market leader on a global basis.[17] Consumer products include Advil®, Centrum®, Robitussin®, Nexium® and ChapStick®.

Established Products Business

Global Established Pharma (GEP) Business. This area consists of three primary product segments: 1) Peri-LOE products which are losing or approaching a losing position in market exclusivity; 2) legacy established products in developed markets that have lost market exclusivity and those with growth opportunities; and 3) emerging market products with growth opportunities such as organic initiatives, partnerships, product enhancements, sterile injectables, and biosimilars.[18] Examples of established products include Celebrex®, EpiPen®, Zoloft®, and Lypitor®.

Pricing Strategy

Pfizer’s and other large drug companies’ revenue growth has been largely dependent on raising the price of older drugs, particularly those nearing patent expirations. Approximately

34% of Pfizer's revenue growth over the past three years has come from increasing prices on existing drugs.[19] Over this period, Pfizer has increased the price of Viagra by 57%, of Lyrica by 51%, and of Premarin by 41%. A 2013 study by the AARP found that the price of Lipitor rose by 9.3% in the year preceding patent expiration, and by 17.5% in 2011, the year of expiration.[20] Pfizer is not alone in these practices. AbbVie and Bristol-Myers Squibb have both been reported as generating a very significant amount of their revenue growth from price increases. Drug pricing scandals and increased media and societal attention on drug pricing in general makes Pfizer's reliance on pricing strategy to drive top-line revenue growth unsustainable. This is evident in the drug industry's flat net pricing in 2015.[21]

Growth Strategy

Pfizer has become one of the largest pharmaceutical companies in the world primarily as a result of aggressive mergers and acquisitions (M&A). Pfizer's acquisitions have been focused on two main strategies: expanding its capabilities and acquiring brands with strong revenues. Many of Pfizer's acquisitions have provided new capabilities for the organization, such as biologics with the acquisition of Warner-Lambert in 2000 and biosimilar drugs with the acquisition of Hospira in 2015. Additionally, Pfizer acquired the rights to the best-selling drug Lipitor in its 2000 acquisition of Warner-Lambert and the rights to Celebrex and Bextra in its 2003 acquisition of Pharmacia Corporation. From Pfizer's press releases and company history, a brief timeline of Pfizer's major acquisitions (and divestitures) is outlined below:[22]

- 2000: Pfizer acquires Warner-Lambert for $90 billion for their biologics and consumer products portfolio, along with the rights to Lipitor.
- 2003: Pfizer acquires Pharmacia Corporation for $60 billion and acquires the rights to Celebrex, Bextra, Detrol and Xalatan.
- 2005: Pfizer acquires Vicuron Pharmaceuticals for $1.9 billion for their antibiotic research and development.
- 2006: Pfizer sells its consumer products division to Johnson & Johnson for $16.6 billion.
- 2007: Pfizer acquires Coley Pharmaceutical for $164 million for their portfolio of biotechnology, cancer, and vaccine drugs.
- 2009: Pfizer acquires Wyeth for $68 billion for their portfolio of biotech drugs.
- 2010: Pfizer acquires King Pharmaceuticals for $3.6 billion and acquires the rights to EpiPen.
- 2015: Pfizer Acquires Hospira for $16 billion for their biosimilar and injectable drugs portfolio, as well as infusion technologies.[23]
- 2016: Pfizer acquires Anacor Pharmaceuticals for $5.1 billion for their topical anti-inflammatory drugs and acquires the rights to Crisaborole.[24]
- 2016: Pfizer acquires Medivation for $14 billion for its prostate cancer drug Xtandi.[25]

Pfizer has attempted unsuccessfully to acquire a foreign drug company and relocate its headquarters overseas. CEO Ian Read has said numerous times that the company faces a competitive disadvantage with foreign rivals that have significantly lower tax bills.[26] These sorts of deals are called corporate inversions – transactions undergone by a U.S. company that moves its tax residence to a foreign country in order to reduce U.S. taxes.[27] In 2014, Pfizer attempted a merger with rival AstraZeneca, which faced fierce opposition from lawmakers on either side. In the end, Pfizer walked away from the $118 million deal after rejection by AstraZeneca's board.[28]

In 2016 Pfizer entered into an agreement to merge with Allergan. The $160 billion deal would have created the largest pharmaceutical company in the world and would have allowed Pfizer to relocate its headquarters to Allergan's home country of Ireland in order to take advantage of their lower corporate tax rate.[29] However, on April 4, 2016, the U.S. Department of Treasury took measures to limit corporate inversions.[30] Previously, a company realized tax benefits for inversions only when the foreign company would contribute 20% or greater of the combined company's assets. The new ruling disregards the last three years of U.S. acquisitions by the foreign entity when determining the foreign company's relative size under the combined entity. The new rule was the predominant factor that caused Pfizer to pay $150 million to walk away the Allergan deal.[31] Pfizer would not have realized the full tax benefit of the inversion because Allergan's relative size would have fallen below the 20% threshold under the new tax rules.

Innovation Strategy

Pfizer has a long history of investing in R&D for the development of blockbuster drugs. However, many industry experts believe the age of blockbuster drugs has come to an end and that new blockbusters will be rare.[32] They argue that the opportunities for revolutionary drugs have been mostly exploited, with very few areas of medicine in which breakthrough drugs can have a huge impact. In light of industry trends, Pfizer has shifted its strategy of maintaining an industry-leading drug pipeline from in-house development to being more reliant on strategic partnerships and mergers and acquisitions.

To support its interest in strategic partnerships, in 2004 Pfizer founded Pfizer Venture Investments (PVI). Its goal is to identify and invest in strategic areas and businesses at the leading edge of healthcare science and technologies. PVI started with a $50 million annual budget and was Pfizer's way of staying ahead of industry trends and investing in companies which are developing compounds and technologies that will enhance Pfizer's drug pipeline and help drive the future of the pharmaceutical industry.[33] In January 2016, Pfizer announced that it would be expanding its investment strategy to include investments in early-stage scientific innovations in immuno-oncology, gene therapy, and other cutting-edge fields. Pfizer invested nearly $46 million in four companies in these fields: BioAtla, NextCure Inc., Cortexyme Inc., and 4D Molecular Therapists, Inc. Pfizer's strategic partnership with these and other firms provides a world-class resource in start-up organizations to accelerate the pace of scientific innovation and to help develop their pipeline of drugs.[34]

INSIDE PFIZER

Management Team

CEO, Ian C. Read

Ian C. Read was elected CEO of Pfizer in December of 2010 and Chairman of the Board in 2011, taking over from Jeffrey Kindler. Read has spent his entire career at Pfizer, starting as an operational auditor. Read's B.S. in chemical engineering and accounting experience set the groundwork for a successful career in pharmaceuticals. Some of his previous roles included CFO of Pfizer Mexico, Country Manager of Pfizer Brazil, President of Pfizer's International Pharmaceuticals Group, Executive Vice President of Europe, and Corporate Vice President. Read also serves on the boards of Pharmaceutical Research Manufacturers of America (PhRMA), which represents the leading innovative biopharmaceutical research companies.[35]

Executive VP Strategy Portfolio and Commercial Operations, Laurie J. Olso

Laurie Oslo oversees long-term strategy, execution of commercial objectives, and advises portfolio functions for R&D investment strategies. She started working for Pfizer in 1987 in Marketing Research. As a economics graduate from the State University of New York at Stony Brook and with a MBA from Hofstra University, her experiences span across domestic and global leadership positions in marketing, commercial development, strategy, analytics corporate responsibility and operations. Her most recent role was Senior Vice President of Portfolio Management and Analytics, and within that role she was part of the task force that "redesigned Pfizer's R&D organization to strengthen its pipeline and improve efficiency."[36]

Executive VP Chief Development Officer, Rod MacKenzie, PhD

Rod MacKenzie received his PhD from Imperial College, London after getting his chemistry degree from the University of Glasgow. As the co-inventor of Darifenacin, which was sold in 2003 due to regulatory issues, MacKenzie held various positions within Pfizer before assuming his current position.[37] His role oversees "the development and advancement of Pfizer's pipeline of medicines in several therapeutic areas." He serves on the Portfolio Strategy and Investment Committee and sits on the Board of Directors for ViiV Healthcare.[38]

Executive VP Business Operations and CFO, Frank D'Amelio

Frank D'Amelio joined the company in September 2007 and oversees finance, business development and business operations. He has been ranked as a top CFO for various years by Institutional Investor magazine. He has led the organization in many mergers, spin offs, and sales, such as: Pfizer and Wyeth merger, sale of their nutrition business, and the spin-off of Zoetis. His experience comes from his many leadership roles at Alcatel-Lucent, including Senior Executive Vice President of Integration and Chief Administrative Officer, and his experience as COO of Lucent Technologies. "Frank earned his MBA in Finance from St. John's University and his bachelor's degree in Accounting from St. Peter's College." Representing Pfizer, he currently serves on the Board of Directors for many organizations. They include, Humana, Inc., Zoetis, Inc., the Independent College Fund of New Jersey, and the Gillen-Brewer School. [39]

Major Shareholders

Pfizer is a publicly traded company with approximately 6.2 billion shares outstanding at December 31, 2015.[40] According to Yahoo Finance, among Pfizer's primary shareholders are institutional investment companies Vanguard Group, Inc., BlackRock Institutional Trust Company, and JPMorgan Chase & Co., who own 6.32%, 4.95%, and 1.89% of total outstanding shares, respectively. Additionally, Pfizer's only major non-institutional shareholders are all executive-level leadership within the organization.

Human Resources

Human resource efforts are led by Charles H. Hill III, who has been the Executive Vice President of Worldwide Human Resources since December 2010. Prior to that assignment, Hill was Senior Vice President of Human Resources for the Worldwide Biopharmaceuticals Businesses from 2008 through December 2010. On December 31st, 2015, Pfizer employed approximately 97,900 employees across the globe.[41]

In 2007, Pfizer Global Manufacturing, a global manufacturing site in the U.K., was recognized for their Explorer training program. The Explorer program was a year long and covered team dynamics that included purpose, leadership, motivation, meetings, and the environment, among other topics. For each of the four training segments, there were pre-workshop activities, two-day workshops, post-workshop assignments, and a follow-up workshop.[42]

Pfizer utilizes also uses traditional techniques to develop their personnel. Employees are expected to collaborate with their direct leaders to create individual development plans. They have also implemented a tool called Mentor Match. It is designed to allow employees to volunteer as a mentor or search for mentors with certain characteristics. Managers are encouraged to give frequent and in-depth performance appraisals in lieu of the standard annual review process. Pfizer also uses short and medium-term job rotations or projects to help further the development of their employees.[43]

Organizational Culture

Upon taking charge of Pfizer in 2010, Read soon discovered that many of the processes in place at Pfizer were broken. The process for FDA drug applications was so bad that the FDA sometimes refused to even review submitted applications. Read demanded answers, and the only answer he received was that everyone knew the application didn't meet the required quality standards, but nobody was willing to speak out about it. Read's response was to hand every employee a gold coin with the words "Straight Talk" on one side and "OWNIT!" on the other side. It was Read's way of empowering his employees to speak up to their boss when they believe they are wrong, but above all, to create accountability.[44] Since then, OWNIT! has become ingrained in Pfizer's culture.[45]

Mission, Purpose and Values[46]

Pfizer's mission is: "To be the premier, innovative biopharmaceutical company."

Pfizer's purpose is: "Innovate to bring therapies to patients that significantly improve their lives."

Pfizer's core values are: "Customer focus; Community; Respect for people; Performance; Collaboration; Leadership; Integrity; Quality; Innovation."

Operations & Supply Chain

Each of the Innovative Products and Established Products businesses is led by a single manager responsible for both commercial productivity as well as research and development activities that meet proof-of-concept requirements. The Innovative Products Business is tasked with development and commercialization of new medicines and vaccines. The Established Products Business focuses on branded generic medicines and legacy brands that have lost or will lose market exclusivity in the short-term. Both businesses have geographic footprints that span developed and emerging markets.[47]

Pfizer has a truly global supply chain network with 64 internal manufacturing facilities, over 200 supply chain partners, and 134 logistics centers in 2015. Pfizer claims to have over 850 major product groups. Due to the high demands for traceability, Pfizer employs a serialization program across its supply chain. Pfizer also uses their Highly Orchestrated Supply Network (HOSuN) to connect inventory, transportation, logistics and its associated security, compliance, environmental health and safety, and other functions into a truly integrated system. They also use HoSuN for business continuity risk assessment and resolution.[48]

Manufacturing pharmaceuticals can be extremely complex. For example, the vaccine known as Prevenar 13 was produced for the one-billionth-time in 2015. According to Pfizer, manufacturing Prevenar 13 includes the participation of 1700 employees, 678 quality tests, 400 different raw materials, 580 steps in manufacturing, and over 2 years.[49]

Pfizer earned 56% of its 2015 revenue from operations outside the United States, which represented $27.1 billion. Japan is the second largest market, behind the United States.[50]

Marketing and Distribution

Pfizer promotes its products within the global biopharmaceutical business to healthcare providers and patients. Pfizer's marketing organization is responsible for educating a wealth of stakeholders regarding product approved uses, benefits, and risks. Pfizer employs a direct-to-consumer advertising campaign in the U.S.; this provides similar information and suggests that interested customers have discussions with their doctor. Pfizer's "Global Consumer Healthcare business uses its own sales and marketing organizations to promote its products and occasionally uses distributors in smaller markets." Television, digital, print, and in-store media are all used to advertise to consumers.[51]

In the U.S., all products must be approved by the FDA prior to any marketing campaigns. The FDA oversight includes "regulations that govern the testing, manufacturing, safety, efficacy, labeling and storage of our products, record keeping, advertising, and promotion."[52] There are also several federal and state laws that were enacted to prevent fraud and abuse, including false claim and anti-kickback laws. Pfizer encounters "similar regulatory and legislative issues in most other countries."[53]

Pfizer has been criticized in the past regarding some of its foreign marketing practices. In August 2012, the U.S. Securities and Exchange Commission fined Pfizer $45 million dollars for violating the US Foreign Corrupt Practices Act. In order to secure regulatory approval, sales, and increased prescriptions, several subsidiaries of Pfizer had been bribing foreign officials. The bribes had been concealed under marketing and promotion expenses in the accounting records. Pfizer reported the violations voluntarily in 2004 and subsequently implemented anti-corruption training.[54]

From a distribution perspective, prescription pharmaceutical products primarily are sold primarily to wholesalers. In 2015, the "top three biopharmaceutical wholesalers accounted for approximately 34% of our total revenues (and 74% of total U.S. revenues)."[55] Pfizer also does some direct shipments to retailers, hospitals, pharmacies, and clinics. For its vaccines, Pfizer "primarily sell[s] directly to individual provider offices, the Centers for Disease Control and Prevention and wholesalers".[56]

Financial Condition

Over the past five years, Pfizer's revenues have been steadily decreasing, reducing net income to a five-year low of $6.96 billion. A decrease in revenue from continuing operations is the primary cause of the decrease in revenues. The spin-off of Zoetis had a compounding effect on both the decrease in revenues and cost of sales post 2013. Current assets were steady over the past three years; however, there was a recent dip in short-term investments. Goodwill is increasing, reflecting the premiums paid for acquisitions in recent years. Pfizer's short-term borrowing has increased almost twofold in the past five years. Overall, Pfizer's balance sheet has been fairly steady the past two years, but Pfizer's total liabilities are slightly higher and its total equity slightly lower in 2015 compared to 2014. Both of these years are lower compared to pre-Zoetis spin-off levels.[57] Exhibits 2 and 3 contain detailed Pfizer financial information.

COMPETITIVE LANDSCAPE

Major Competitors

The pharmaceutical industry invests heavily in research and clinical trials and relies on obtaining FDA approval and patent protection for its products to ensure prolonged profits while the next "miracle" drug is under research. There are high payoffs when a drug is successfully brought to market; but there also great costs, in the form of massive time and monetary investments for failures, if it is not. Among Pfizer's largest competitors are Merck, Novartis, Bristol-Myers and Johnson & Johnson.[58] Exhibit 4 contains some comparative financial ratios for these competitors.

Merck & Co. (MRK)

Merck & Co. was founded in 1891 and had $39.5B in 2015 revenues, making it one of the largest pharmaceuticals companies in the world today. The cholesterol-lowering drug branded Zetia, which is Merck's 2nd largest revenue generator, is a direct competitor to Pfizer's drug Lipitor (patent expired in 2011). Zetia is selling at a rate of nearly $3 billion a year whereas Lipitor is generating $1.86B.[59]

Major Acquisitions:[60]

1993: Merck acquired Medco Containment Services, Inc. ($6B)
2009: Schering-Plough merged with Merck & Co. ($41B merger)

2014: Merck acquired Cubist Pharmaceuticals ($8.4B)

Novartis AG (NVS)

Founded in 1996 in Switzerland, Novartis AG is the pharmaceutical industry's world leader in sales, generating $50.4B in 2015 revenues. Novartis has several oncology products in the pipeline that will directly compete with Pfizer pharmaceuticals. Currently its best sellers are prescription treatments for cancer, multiple sclerosis and macular degeneration.[61]

Major Acquisitions:[62]

1999: Formed by merger with Ciba-Geigy and Sandoz Laboratories
2005: Acquired Hexal and Eon Labs ($8.29B)
2006: Acquired Chiron Corp. ($5.1B)
2010: Acquired Alcon ($39.3B)
2012: Acquired Fougera Pharmaceuticals ($1.5B)

Bristol-Myers Squibb (BMY)

Bristol-Myers Squibb was founded in New York in 1887 and had $18.8B in 2015 revenues. They produce the market leading antipsychotic drug, Abilify, which is widely used for treating schizophrenia. Bristol-Myers Squibb, like the majority of pharmaceuticals companies, derives the bulk of its profits from a limited number of expensive specialty drugs or much wider market spread of cheaper drugs.[63]

Major Acquisitions:[64]

2009: Acquired Medarex
2010: Acquired ZymoGenetics
2015: Acquired Flexus Biosciences ($1.25B) and Cardioxyl ($2B)
2016: Acquired Padlock Therapeutics ($600M) & Cormorant Pharmaceuticals ($520M)

Johnson & Johnson (JNJ)

Founded in 1886, Johnson & Johnson is an American multinational medical devices, pharmaceutical (40% by revenues) and consumer packaged goods manufacturer. Besides over-the-counter products for self-treatment and at-home medication, Johnson & Johnson produces high-priced specialty drugs used in the treatment of autoimmune diseases, prostate cancer, and HIV/AIDS.[65]

Major Acquisitions:[66]

2006: Acquired consumer healthcare business of Pfizer ($16.6B)
2013: Acquired Aragon Pharma ($1B)
2014: Alios BioPharma, Inc ($1.75B)

EXTERNAL ENVIRONMENT

The pharmaceutical industry is heavily influenced by legal, political, and technological forces. Societal views on issues such as drug pricing and tax evasion have created demand for increased government regulation.

Regulation

In the U.S., pharmaceutical companies are under the regulation granted to the Food and Drug Administration. The FDA has primarily provided oversight over pharmaceutical product quality through two actions: reviewing drug applications and inspecting factories for compliance with good manufacturing practices. In an effort to reduce recognized shortcomings, such as high levels of product recalls, shortages of critical drugs, and limited inspection efforts, the FDA created an Office of Pharmaceutical Quality (OPQ) in January 2015. The OPQ was created to enhance oversight of drug quality for all pharmaceuticals.[67] Its mission is to assure supply of quality drugs to the American market, use enhanced science and risk-based methods, leverage quantitative and expert assessments for product oversight, encourage development and adoption of new technologies, and "provide seamless integration of review inspection, surveillance, policy, and research across the product life cycle."[68]

FDA oversight impacts several areas of the value chain. For example, the FDA increased the importance of audit trails of information in manufacturing when 21 CFR part 11 came into effect. The update requires anyone designing, manufacturing, or testing pharmaceuticals to follow the guidelines. This encouraged manufacturers to keep better electronic records to include timestamps, validation, and signatures. 21 CFR part 11 was built unto the National Drug Code (NDC), which was passed in 2007. The NDC required manufacturers to use a serialized code on the product to improve traceability throughout the supply chain post-manufacturer.[69]

Affordable Care Act

In 2014, the Internal Revenue Service issued final regulations for the Branded Prescription Drug Fee (BPD), an annual non-tax deductible fee imposed on branded prescription drug manufacturers, which was included in the Patient Protection and Affordable Care Act (ACA). The new legislation requires government-funded drug programs to report yearly prescription drug sales data to the Department of Treasury. The reporting programs include: Medicare, Medicaid, TRICARE, and the Department of Veterans Affairs. The branded prescription drug fee is allocated to manufacturers based on their relative percentage of total reported prescription drug sales.[70] The total 2014 BPD fee, according to the IRS fee schedule, was $3 billion – Pfizer's portion was approximately $220 million, which was paid in 2015.[71]

The ACA also amended the Public Health Service Act (PHS) to expedite FDA approval of biosimilars – drugs that are generic versions of FDA-approved biologic products. A manufacturer must show clinical evidence that a new product is "highly similar" in effectiveness to an FDA-approved reference biologic. Once the FDA receives the trial data for a biosimilar, the ACA allows the FDA to pursue a fast-track approval process. Prior to 2010, no biosimilar products had been approved by the FDA.[72] As of August 2016, three biosimilar products had been approved.[73]

Drug Pricing Concerns

Public outrage over increasing drug prices came to a head recently, with many scandals receiving national headline attention. One such incident occurred when Turing Pharmaceuticals raised the price of Daraprim - a drug used predominantly by AIDS patients and pregnant women – from $13.50 to $750 per pill, over a 5,000% increase.[74] Another such incident involved Mylan, the company that manufacturers the injector EpiPen, which contains a drug used to treat life-threatening allergy attacks (a drug Pfizer manufacturers). Mylan increased the price of EpiPen from $265 to over $600 in less than three years.[75] Many believe the increase was in response to a settlement agreement in 2012 under which Mylan agreed to allow a generic competitor to enter the market in 2015.

The rising cost of healthcare in the United States is a growing concern among voters, and societal pressures are seeing health care reform and regulation on drug prices reaching political platforms and ballots across the country. Political lobbyists on both sides are spending millions of dollars to influence the outcome of such initiatives. One such initiative, Proposition 61 in California, would limit the amount that state agencies pay for prescription drugs to that of the U.S. Department of Veterans Affairs, which normally receives a 20 to 25% discount on its prescription drug prices. Pfizer donated more than $9.4 million to political action groups in opposition to Prop 61, and in total pharmaceutical companies contributed $109 million (Merck & Co. $9.4 million and Johnson & Johnson $9.3 million).[76]

LOOKING FORWARD

Ian Read has been at Pfizer's helm for the past six years. With the patent expiration for Lipitor behind him, the best-selling drug in history is no longer contributing as much to Pfizer's bottom line. Is the firm still capable of delivering a sustainable pipeline of profitable drugs, or are major changes to strategy and operations necessary? And is Pfizer's opportunity for significant inversions over with the failed takeover attempts of both AstraZeneca and Allergan? To add to these issues, drug pricing scandals and healthcare reform have created an environment of active political reform. How can Pfizer navigate the upcoming challenges that growing societal discontent with "big pharma" and the rising cost of healthcare present? Do these threats also provide opportunities? How can Pfizer best be positioned for growth and profitability in this challenging business environment?

EXHIBIT 1: PFIZER BUSINESS SEGMENT COMPARISONS

Business Segment Financials
Innovative vs Established Segments

	2015		2014		2013	
	Innovative	Established	Innovative	Established	Innovative	Established
Revenues	$26,758	$21,587	$24,005	$25,149	$23,602	$27,619
Cost of Sales	3,650	4,486	3,848	4,570	3,675	4,732
% of revenue	13.60%	20.80%	16.00%	18.20%	15.60%	17.10%
Selling, informational and administrative expenses	6,807	3,572	6,162	3,903	5,520	4,714
R&D Expenses	3,030	758	2,549	657	2,154	737
Amortization of intangible assets	94	36	69	85	58	100
Restructuring charges and certain acquisition-related costs	-	-	-	-	6	-
Other (income)/deductions—net	(1,087	(150)	(1,096)	(265)	(576)	(216)
Income from continuing operations before provision for taxes on income	$14,264	$12,885	$12,472	$16,199	$12,765	$17,552

Source: 2015 Pfizer Annual Report

EXHIBIT 2: PFIZER INCOME STATEMENTS

Consolidated Statements of Income - USD ($) shares in Millions, $ in Millions					
	2015	2014	2013	2012	2011
Income Statement [Abstract]					
Revenues	$ 48,851	$ 49,605	$ 51,584	$ 58,986	$ 65,259
Costs and expenses:					
Cost of sales	9,648	9,577	9,586	11,334	14,076
Selling, informational and administrative expenses	14,809	14,097	14,355	16,616	18,832
Research and development expenses	7,690	8,393	6,678	7,870	9,074
Amortization of intangible assets	3,728	4,039	4,599	5,175	5,544
Restructuring charges and certain acquisition-related costs	1,152	250	1,182	1,880	2,930
Other (income)/deductions––net	2,860	1,009	(532)	4,031	2,499
Income from continuing operations before provision for taxes on income	8,965	12,240	15,716	12,080	12,304
Provision for taxes on income	1,990	3,120	4,306	2,562	3,909
Income from continuing operations	6,975	9,119	11,410	9,518	8,395
Discontinued operations:					
Income from discontinued operations––net of tax	17	(6)	308	297	350
Gain/(loss) on disposal of discontinued operations––net of tax	(6)	55	10,354	4,783	1,304
Discontinued operations––net of tax	11	48	10,662	5,080	1,654
Net income before allocation to noncontrolling interests	6,986	9,168	22,072	14,598	10,049
Less: Net income attributable to noncontrolling interests	26	32	69	28	40
Net income attributable to Pfizer Inc.	$ 6,960	$ 9,135	$ 22,003	$ 14,570	$ 10,009

Source: Pfizer Annual Reports

EXHIBIT 3: PFIZER BALANCE SHEETS

Consolidated Balance Sheets - USD ($) $ in Millions	2015	2014	2013	2012	2011
Assets					
Cash and cash equivalents	$ 3,641	$ 3,343	$ 2,183	$ 10,081	$ 3,182
Short-term investments	19,649	32,779	30,225	22,318	23,270
Trade accounts receivable, less allowance for doubtful accounts	8,176	8,401	9,357	10,675	13,058
Inventories	7,513	5,663	6,166	6,076	6,610
Current tax assets	2,662	2,566	4,624	6,170	9,380
Other current assets	2,163	2,843	3,613	3,567	5,317
Assets of discontinued operations and other assets held for sale	-	-	76	5,944	-
Total current assets	43,804	55,595	56,244	64,831	60,817
Long-term investments	15,999	17,518	16,406	14,149	9,814
Property, plant and equipment, less accumulated depreciation	13,766	11,762	12,397	13,213	15,921
Identifiable intangible assets, less accumulated amortization	40,356	35,166	39,385	45,146	51,184
Goodwill	48,242	42,069	42,519	43,661	44,569
Noncurrent deferred tax assets and other noncurrent tax assets	1,794	1,944	1,554	1,565	5,697
Other noncurrent assets	3,499	3,513	3,596	3,233	-
Total assets	$167,460	$167,566	$172,101	$185,798	$188,002

Source: Pfizer Annual Reports

EXHIBIT 3 (CONTINUED)

Consolidated Balance Sheets - USD ($) $ in Millions	2015	2014	2013	2012	2011
Liabilities and Equity					
Short-term borrowings, including current portion of long-term debt	$10,160	$5,141	$6,027	$6,424	$4,016
Trade accounts payable	3,620	3,210	3,234	2,921	3,678
Dividends payable	1,852	1,711	1,663	1,733	1,796
Income taxes payable	418	531	678	979	1,009
Accrued compensation and related items	2,359	1,841	1,792	1,875	2,120
Other current liabilities	10,990	9,153	9,951	13,812	15,066
Liabilities of discontinued operations	-	-	21	1,442	1,224
Total current liabilities	29,399	21,587	23,366	29,186	28,909
Long-term debt	28,818	31,541	30,462	31,036	34,926
Pension benefit obligations, net	6,310	7,885	4,635	7,782	6,355
Postretirement benefit obligations, net	1,809	2,379	2,668	3,491	3,344
Noncurrent deferred tax liabilities	26,877	23,317	25,590	21,193	18,861
Other taxes payable	3,992	4,353	3,993	6,581	6,886
Other noncurrent liabilities	5,257	4,883	4,767	4,851	6,100
Total liabilities	102,463	95,944	95,481	104,120	105,381
Commitments and Contingencies					
Preferred stock, no par value, at stated value	$ 26	$ 29	$ 33	$ 39	$ 45
Common stock	459	455	453	448	445
Additional paid-in capital	81,016	78,977	77,283	72,608	71,423
Employee benefit trusts	-	-	-	-	(3)
Treasury stock, shares at cost	(79,252)	(73,021)	(67,923)	(40,122)	(31,801)
Retained earnings	71,993	72,176	69,732	54,240	46,210
Accumulated other comprehensive loss	(9,522)	(7,316)	(3,271)	(5,953)	(4,129)
Total Pfizer Inc. shareholders' equity	64,720	71,301	76,307	81,260	82,190
Equity attributable to noncontrolling interests	278	321	313	418	431
Total equity	64,998	71,622	76,620	81,678	82,621
Total liabilities and equity	$ 167,460	$ 167,566	$ 172,101	$ 185,798	$ 188,002

Source: Pfizer Annual Reports

EXHIBIT 4: COMPARATIVE FINANCIAL RATIOS

	Pfizer	Merck	Novartis	Bristol-Myers Squibb	Johnson & Johnson
Research over Revenue %	15.74	16.97	17.73	35.79	12.91
Revenue INR Mil	48,851	39,498	50,387	16,560	70,074
Gross Margin %	80.3	62.2	65.5	76.4	69.3
Operating Income INR Mil	11,824	6,928	8,977	1,890	18,065
Operating Margin %	24.2	17.5	17.8	11.4	25.8
Net Income INR Mil	6,960	4,442	17,783	1,565	15,409
Earnings Per Share INR	1.11	1.56	7.29	0.93	5.48
Dividends INR	1.12	1.81	2.67	1.49	2.95
*Payout Ratio % **	82.7	48.4	77.7	139.6	55.6
Shares Mil	6,257	2,841	2,403	1,679	2,813
*Book Value Per Share * INR*	10.82	16.39	32.31	9.08	25.86
Operating Cash Flow INR Mil	14,512	12,421	11,897	1,832	19,279
Cap Spending INR Mil	-1,496	-1,283	-3,505	-820	-3,463
Free Cash Flow INR Mil	13,016	11,138	8,392	1,012	15,816
*Free Cash Flow Per Share * INR*	2.22	1.65	3.97	0.64	5.3
Working Capital INR Mil	14,405	10,561	-863	2,398	32,463
Tax Rate %	22.2	17.44	13.6	21.47	19.73
Net Margin %	14.25	11.25	35.29	9.45	21.99
Asset Turnover (Average)	0.29	0.39	0.39	0.51	0.53
Return on Assets %	4.13	4.44	13.84	4.78	11.65
Financial Leverage (Average)	2.59	2.28	1.71	2.23	1.88
Return on Equity %	10.24	9.52	24.06	10.75	21.87
Return on Invested Capital %	7.11	6.74	19.28	7.83	17.55
Interest Coverage	8.48	9.04	13.16	12.29	35.78

Source: Morningstar.com

FOOTNOTES

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