

Department of Business and Management - MIKE B&E

MSc. in Economics (Innovation, Knowledge and Economic dynamics)

M&A as a disincentive to undertaking R&D in the U.S. pharmaceutical industry: Case studies of Pfizer and Bausch Health

Master's thesis

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Abstract: Contrary to what might be a popular belief, pharmaceutical corporations are not necessarily the primary source of innovative drugs. In fact, it is quite reasonable to expect large companies listed on the stock exchange to put a greater emphasis on profitable activities. This is especially true for the United States as it is not only the world's largest pharmaceutical industry, but also the most profitable. Pharmaceutical corporations have quickly realized how expensive and risky internal drug development is, and turned their attention towards M&A transactions as a mean to compensate for R&D gaps. Since smaller organizations are characterized by lack of operational constraints typical for larger companies, they are a breeding ground for brainstorming and innovation and may very well act as a substitute for the early phases of the drug development process when acquired. While it appears that M&A transactions may be some sort of a tool increasing the overall efficiency of the pharmaceutical industry by allowing large corporations to focus on their core capabilities (such as drug commercialization), the business environment is significantly more complicated. It stems from the fact that pharmaceutical executives are not necessarily required to introduce new drugs to the market as their primary purpose is to protect and manage shareholders' interests in the company. The thesis aims to explore the rationale behind utilizing M&A as a substitute for R&D in the pharmaceutical industry.

This thesis examines the following research questions: *1) Why do certain companies in the U.S. pharmaceutical industry find it more beneficial to base their strategies on increased M&A activity instead of more traditional in-house drug development? 2) Is the strategy sustainable enough that more companies can be expected to implement it as part of their long-term business model?* The research questions are addressed by reviewing all of the relevant literature and conducting case studies of Pfizer and Bausch Health. This research has found that potential factors contributing to the decision to substitute M&A for R&D in the U.S. are 1) regulatory requirements relating to the drug approval process in the U.S. and relatively short exclusivity period, 2) shareholders pressures on management to prioritize financial performance and 3) purely financial motives such as protecting drug licenses and limiting potential competition. Furthermore, it appears that the structure of the pharmaceutical industry and the regulatory environment in the United States incentivize large corporations to engage in M&A as a mean to stabilize their revenues and mitigate risk across the drug development process.

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Part I

1. Introduction

1.1 Background

The progress in discovery and development of new medications is likely one of the most significant achievements of humanity. The advances in medicine are easier to picture when one realizes that some of the earliest attempts to heal the sick included drilling a hole in their skull to release the disease from the body (Wadud et al., 2007). To put it into perspective, in the United States “life-expectancy at birth was 30.9 years in 1900, 46.7 in 1940, 61.13 in 1980” (Mishra, 2016, p.21) which, to a large extent, could be attributed to availability of new drugs (Mishra, 2016). Not so long ago, diseases such as tuberculosis, cancer or influenza seemed like a death sentence; today the sick can fully recover. There is still, however, a lot to be done to ensure smooth progress of humanity. In fact, there are currently more than 7000 diseases while the modern medicine is able to address only 500 of them (Upton and DeGette, 2015). Furthermore, as the recent outbreak of COVID-19 virus has shown, there is a constant need for improvement in this sector. For that reason, an interesting question regarding the pharmaceutical industry appears: How different would the modern world be without pharmaceutical firms prioritizing research and development?

The aforementioned question is undoubtedly a difficult to imagine scenario; however, it is crucial to recognize that the pharmaceutical industry has become an incredibly profitable business with a projected global worth of 1.5 trillion dollars in 2023 (“Global pharma spending”, 2019). For that reason, it is not unreasonable to expect large corporations listed on the stock exchange to put a greater emphasis on profits which, in fact, is clearly visible on the pharmaceutical drug market. Quite frankly, unethical situations in this sector are not uncommon and one of the most glaring examples of this is the case of Mylan. In short, the

company based its growth primarily on questionable acquisitions (Wieczner, 2016) and abused its monopoly power by increasing the price of a life-saving drug, EpiPen, by 500% in less than 10 years (Johnson and Ho, 2016). Another example, at the extreme end of scale, is Turing Pharmaceuticals. The company increased the price of Daraprim, a drug used in HIV-positive patients, by around 5000% soon after it was acquired (Pollack, 2015). While this business strategy is not necessarily illegal, the cases of these American firms suggest that the pharmaceutical industry has taken notice of new business opportunities and corporations are not afraid to act upon them, even if they are ethically questionable. Thus, the fact that the profit margin for companies in this industry is often as high as that of banks (DeAngelis, 2016), is not necessarily surprising. Perhaps it is no longer the matter of investigating whether pharmaceutical companies indeed put greater emphasis on profits, but rather how they obtain new sources of revenue and what the externalities are.

As is commonly known, the pharmaceutical research and development (R&D) not only requires substantial investments, but also is viewed as a risky undertaking. For that very reason, pharmaceutical companies have turned towards large acquisitions to counteract failing revenues of major drugs as well as expiring patents (Nisen, 2019). In fact, the mergers and acquisitions (M&A) pharmaceutical deals in 2019 added up to 342 billion dollars in the United States alone which was the highest amount ever recorded (Lee, 2019). According to John L. LaMattina, the former president of Pfizer Global Research, while this strategy may be a desirable path from a business perspective, it has had a disastrous effect on the R&D of companies involved (LaMattina, 2011). As an example of post-merger reality, Pfizer, the third largest pharmaceutical company by revenue (Aspa, 2019), closed several research centers, decreased R&D spending and experienced a lower rate of progress of its drugs in developments (LaMattina, 2011). Furthermore, ensuring that an acquired company is properly integrated in the current structures is also likely to significantly hamper R&D efforts for a

substantial period of time (LaMattina, 2011). Given the aforementioned externalities of M&A, it becomes clear that certain pharmaceutical companies, such as Pfizer, may find value added in this strategy and potential benefits exceed the final product of traditional in-house drug development.

It is not, however, a coincidence that the above-mentioned cases concern primarily the pharmaceutical industry in the United States. Not only is its M&A activity unmatched by any other country, but also four of the top 10 pharmaceutical companies in the world are currently based there (Aspa, 2019). Its undeniable significance to the world economy as well as the fact that profit-driven companies, such as previously mentioned Mylan and Turing Pharmaceuticals, originated there, makes it an ideal candidate to analyze the trend. Of course, the cases cannot be used as an indicator of the overall direction of the industry, even in United States. In fact, certain pharmaceutical companies such as Merck and Lilly openly express their commitment to investing in drug development (LaMattina, 2011). Nonetheless, it cannot be ignored that Pfizer, as well as other firms that have caused large public outcry in the recent years, use M&A as a substitute for R&D to a certain extent. Thus, the aim of the thesis is to explore why increased M&A activity is the strategy of choice for certain companies in the United States overshadowing the more traditional focus on in-house drug development.

1.2 Purpose and research question

While it is not a secret that M&A has been an essential part of the pharmaceutical industry for decades, there are certain areas that may have not been fully explored. Although studies analyzing the impact of M&A on R&D exist, researchers take a more general approach and tend to investigate whether industry-wide trends are in fact visible (Richman et al., 2017; Comanor and Scherer, 2013; Sheperd, 2018). The purpose of this thesis is quite different as it is not focused on confirming any industry-wide trends, but rather exploring the factors contributing to the aforementioned phenomenon. The potential findings may prove to

be a valuable insight into what drives pharmaceutical companies utilizing this strategy as the rationale for addressing the R&D productivity gaps with the use of M&A has been a widely discussed topic in the recent years in both business and academic literature (DeAngelis, 2016; Amir-Aslani and Chanel, 2016; Fisher, 2015; Herper, 2015). Thus, this thesis may potentially contribute to the literature in three ways by exploring (i) why certain large American pharmaceutical companies may find it beneficial to base their strategy on M&A to a large extent, (ii) how sustainable this strategy is, and (iii) whether more companies in the United States are to be expected to follow this business model. The final product of this research will be a thorough overview of the phenomenon which may serve as a starting point for further research.

Accordingly, the thesis will explore the following research questions:

1) Why do certain companies in the U.S. pharmaceutical industry find it more beneficial to base their strategies on increased M&A activity instead of more traditional in-house drug development?

2) Is the strategy sustainable enough that more companies can be expected to implement it as part of their long-term business model?

1.3 Thesis outline

Firstly, the methodological approach utilized in this thesis is described which covers areas such as research approach, case selection and data collection. In addition, validity and reliability as well as research limitations are also described (Chapter 2). The chapter is followed by the literature review which (i) introduces the concept of M&A in relation to the U.S. pharmaceutical industry, (ii) describes the drug approval process in the United States and (iii) explores to what extent the debate shareholder wealth maximization theory vs. stakeholder theory as well as the agency theory can be applied to the cases (Chapter 3).

Subsequently, the case companies, Pfizer and Bausch Health, are analyzed in terms of their M&A activity and internal R&D (Chapters 4-6). Lastly, the findings are addressed in Chapter 7 followed by a conclusion in relation to research questions (Chapter 8) and discussion on potential implications for future research (Chapter 9).

2. Methodology

The goal of the methodology chapter is to introduce the primary research methods utilized in the thesis as well as provide the rationale for choosing this particular design. Firstly, the research methodological fit and method of analysis are described (2.1). Subsequently, the rationale for choosing Pfizer and Bausch Health as the case companies is provided (2.2) followed by an introduction of data selection and collection methods utilized during the writing process (2.3). Lastly, the validity and reliability of the research (2.4) and research limitations (2.5) are addressed.

2.1 Methodological fit and method of analysis

For the purpose of the thesis, an exploratory multiple-case design was chosen to address the research questions. The decision to utilize this research method was supported by a well-known case study book *Case Study Research: Design and Methods* by Robert K. Yin. According to Yin (2009), three types of case studies prevail which are exploratory, explanatory and descriptive. In terms of the thesis, the exploratory case study is the most suitable method as it addresses questions “what” and “how” and there is not one answer that would explain a particular social phenomenon (Yin, 2009). Furthermore, exploratory case designs address relationships between variables that are simply too complex for methods such as surveys to provide any meaningful data (Yin, 2009). In terms of the multiple-case design, Yin (2009) suggests that it is a preferred method over the single-case design as it allows researchers to more fully understand a social phenomenon.

2.2 Rationale for case selection

The cases were selected based on a careful analysis of the U.S. pharmaceutical industry and filtered for a specific tendency relating to corporations substituting internal R&D for drugs acquired through M&A transactions. It stems from the fact that the selected cases are meant to be literal replications, which, according to Yin (2009), serve as an example of a social phenomenon addressed through the research questions. The outcome of the cases was known prior to the research and the primary purpose of the thesis is to understand what motivated them to pursue this particular strategy. In terms of the rationale for picking this particular country, the United States is the biggest pharmaceutical market in relation to M&A transactions in the world (Lee, 2019) representing as much as 64% of global pharmaceutical profits (Goldman and Lakdawalla, 2018). Thus, it was clearly the most optimal decision to analyze this specific industry.

2.2.1 Pfizer

The first case studied is Pfizer, one the largest pharmaceutical companies in the world, which was repeatedly mentioned in the first chapter. This firm is an interesting illustration of how M&A can be an efficient substitute for R&D as even a quick look at its annual reports shows how essential this strategy was in retaining its competitive strategy over the past 20 years. In terms of the research questions, Pfizer is an excellent candidate as it appears that this strategy has proved to be sustainable enough for this company to remain a significant part of the industry. Another reason for choosing this company is the fact that the quality of available data is more than sufficient to conduct an analysis in relation to the research questions. While it may be impossible to unambiguously state what the actual reasons were for smaller R&D spending and higher number of M&A transactions, it is possible to list and analyze factors that likely contributed to it.

2.2.2 Bausch Health (formerly Valeant Pharmaceuticals)

The second case studied, Bausch Health (formerly Valeant Pharmaceuticals), which, in contrast to the previous case, is a quite controversial company. It is one of the largest pharmaceutical companies in the world with an annual revenue not dipping under \$8 billion dollars in the past five years. In a similar manner to aforementioned Mylan and Turing Pharmaceuticals, based its strategy on acquiring companies and subsequently rising prices of drugs by enormous amounts. Bausch Health may prove to be an important part of the analysis as it presents a reality where pharmaceutical companies are driven purely by profits and act as if their industry was not essential to the society. Furthermore, it is an example of a company that almost completely shut down its R&D divisions and focused its efforts on M&A transactions. While the case is at the extreme end of scale in comparison to Pfizer, it is still a surprisingly similar company in many aspects. In terms of the available data, an extensive media coverage over the years increased the number of available sources needed to conduct the analysis.

2.3 Data collection and selection

According to Easterby-Smith et al., (2015), primary research (in terms of internal data) is not always the preferred method of conducting research as data on large corporations is already publicly available and may be sufficient to conduct a meaningful analysis. Furthermore, the thesis analyses a trend among some of the largest pharmaceutical corporations in the United States, and therefore potential access to internal data simply would not be achievable. For that reason, archival research is the method of collecting data utilized in this thesis which can be described as a collection and analysis of publicly available documents such as annual reports of large companies and financial databases (Easterby-Smith et al., 2015).

The thesis is based on an extensive review of 1) academic and business literature obtained through the use of search engines such as Google and Google Scholars, 2) academic journals and articles accessed through the Aalborg University digital library and 3) annual reports of the case companies. The guiding principle of the data selection in this thesis was to avoid non-credible sources that could lower the overall value of the research. Consequently, the articles utilized in this the thesis are sourced primarily from academic journals, reputable business magazines such as Forbes and Harvard Business Review, and think-tank organizations such as Roosevelt Institute. In terms of the case companies, the publicly available information is limited to company websites and annual reports (including audited financial statements) issued yearly to company shareholders and other stakeholders. The reports are highly detailed documents that can provide significant insight into a company's operations. Of course, the company data will also be collected from other publicly available sources.

2.4 Validity and reliability

Validity and reliability are essential elements of a research paper as they are an indicator of its overall quality (Easterby-Smith et al., 2015). The concept of validity concerns the number of different perspectives included in the work rather than one-sided opinions not showing the bigger picture, while reliability relates to replicability of findings by other researchers (Easterby-Smith et al., 2015).

One of efficient solutions for researchers striving to present a more complete picture of a researched phenomenon is the triangulation concept (Cohen, Manion and Morrison, 2013), which is also used in the thesis. The concept can be described as utilizing more than one method to explain a phenomenon and ensuring that the concepts of reliability and validity are adequately addressed (Cohen et al., 2013). Denzin (2009) introduced four main types of triangulation which are:

I) Data triangulation, which refers to obtaining data from as many different sources as possible (Denzin, 2009).

II) Investigator triangulation, which refers to participation of multiple people in a research (Denzin, 2009).

III) Methodological triangulation, which refers to using different qualitative and quantitative approaches (Denzin, 2009).

IV) Theory triangulation, which refers to using more than one theory and perspective to interpret a phenomenon (Denzin, 2009).

Given the aforementioned triangulation types, the thesis utilizes data, theory and methodological triangulations to address the issue of validity and reliability.

In terms of data triangulation, the trend in the pharmaceutical industry is described through the use of multiple sources presenting many different perspectives. For instance, individual case studies are not only analyzed with the use of respectable secondary sources (Forbes, NYT, Bloomberg, HBR and Fortune as well as other sources) but also through an extensive investigation of primary sources such as each company's annual reports, websites and audited financial statements. Such an approach ensures that the analysis provides an undistorted view of each company as it considers independent external opinions and information prepared by each company itself.

In relation to theory triangulation, the sections included in the literature review chapter served as a reference point to potential findings discovered during the investigation of the case companies. For instance, Chapter 3 presents the theoretical side of M&A by describing what the concept represents, analyzes the rationale behind it, and explores the main perspectives regarding the impact of such transactions on the pharmaceutical R&D. The literature review chapter also investigates how corporations are affected by shareholder

wealth maximization, stakeholder theory and agency theory. It is important to mention, however, that Chapter 3 does not comprise primarily of theories as it also includes findings (such as the analysis of the U.S. drug approval process) required to proceed with the case studies and address the research questions. In fact, the summary at the end of Chapter 3 attempts to provide an initial answer to the research questions and indicates areas of interest in relation to the case companies.

The last essential element is methodological triangulation as the case studies included in the thesis involve both qualitative (meaning-making through an analysis of non-numerical data) and quantitative research methods (meaning-making through an analysis of numerical data). In other words, the qualitative research provides a general overview of the phenomenon and the strategies utilized by each case company, while the primary motive for quantitative research is to investigate whether the trends are reflected in audited financial statements.

To conclude, validity will be addressed through the above-mentioned theories and perspectives included in the literature review as well as a multiple-case design, while reliability is ensured through data obtained from the aforementioned sources as well as the raw data from case companies. It is also noteworthy that the research is primarily exploratory and open-ended in nature, and it does not strive to create a final product in a form of a generalizable theory or test correlations between variables.

2.5 Research limitations

While the thesis may provide valuable insight into what drives pharmaceutical companies in the United States, it is crucial to describe the research limitations. Firstly, the research is based purely on publicly available information and does not include any internal data. For that reason, it is possible that certain topics may not be fully addressed without access to employees associated with the case companies. Internal primary data such as interviews would be needed to describe the R&D and M&A processes in the pharmaceutical

industry in detail. Secondly, the research was conducted in the English language exclusively which to a certain degree limited the number of available academic articles on M&A and pharmaceutical R&D.

Although the research strives to explain a phenomenon among large pharmaceutical corporations, the findings cannot be generalized to the entire industry. This is due to the fact that the pharmaceutical industry is one of the most complex sectors and of inestimable value for our society. While certain companies may not have a portfolio of drugs that is essential to human life, others may produce life-saving drugs forcing them to limit their profit-maximization strategies as they would lead to a large public outcry. There is also the matter of the company mission as some organizations may be more willing to forgo a larger share of their profits to create an image of a socially responsible corporation. In other words, the decision to substitute M&A for R&D is highly dependent on what direction executives decide to choose. For that reason, the thesis does not attempt to simply generalize that all pharmaceutical corporation utilize this strategy but rather provide information regarding the topic and explore the rationale behind it. A large number of companies (of different sizes and types) would have to be analyzed in order to make more general assumptions. Furthermore, an analysis of the sell-side position would have to be conducted to fully understand the nature of M&A transactions in the pharmaceutical industry.

Lastly, it is crucial to mention that utilizing this thesis as source of insight regarding countries outside of the United States should be done with caution. The drug approval process as well as the total market capitalization of all publicly traded companies in the United States are unique factors simply unseen elsewhere in the world. While other pharmaceutical industries outside of the United States are likely to be driven by similar factors, they were not the focal point of the thesis

Part II

3. Rationale for M&A activity within the pharmaceutical industry: Literature review

The literature review chapter begins with a general description of the M&A concept and primary motives behind M&A activity. The goal is to understand why companies may find it beneficial to acquire other firms (3.1). The section is followed by an exploration of how acquisitions influence R&D activity of companies involved in a particular transaction which provides insight into prevailing M&A trends and patterns in the pharmaceutical industry (3.2). Subsequently, the U.S. drug approval process is described in order to explore why it has been labelled as one of the most difficult in the world (3.3). Lastly, the importance of the Shareholder Wealth Maximization vs. Stakeholder Theory debate and Agency Theory are explored in terms of large corporations (3.3 and 3.4)

3.1 Motives behind M&A

While it might not be such an obvious factor at first sight, the M&A has become an incredibly important driver of the modern economy. Furthermore, many people do not realize that a mid-size company in their home country might belong to gigantic corporations such as Disney or Microsoft. It is simply because M&A is a certain kind of shortcut for executives allowing their firms to grow and acquire previously not available resources (Malik et al., 2011). In order to illustrate it, Fortune magazine analyzed the U.S media industry and concluded that six media conglomerates control the overwhelming majority of the market (Rapp and Jenkins, 2018). Lutz (2012) stated that as much as 90% of the media industry belongs to these six companies which is a shocking number if one considers that these institutions address more than 300 million people currently living in the US. While this example concerns the U.S media companies, there are other well-known cases such as the mobile phone and computer software industries. Of course, these corporations have not

achieved that level of dominance through spin-offs, but rather by successively acting on available opportunities to expand their portfolio of companies.

3.1.1 Overview

As is commonly known, M&A has become a trending concept and often appears in the popular media in terms of business or politics. According to Coates (2014), the term M&A can be described as “deliberate transfer of control and ownership of a business organized in one or more corporations” (p. 2). However, as the term consists of two words which possess a slightly different meaning, it may be quite difficult for the readers to understand what it actually represents. According to Mastracchio and Zunitch (2002), M&A can be broken into mergers, stock acquisition, and asset acquisition:

I) Mergers are characterized by the fact that the transaction can be financed through common stock and cash is not a requirement (Mastracchio and Zunitch, 2002). In other words, the process may be completed by offering acquirer’s stock to the selling shareholders (Mastracchio and Zunitch, 2002). While mergers may prove to be a significantly more expensive option than acquisitions in terms of legal costs, companies may avoid tedious financial formalities associated with the selling process and potential transactions can be finalized tax-free (Mastracchio and Zunitch, 2002). In simple terms, mergers are based on the fact that the companies become one, without issues such as negotiating the final price through various valuation techniques, and both parties are expected to benefit from the transaction.

II) Stock acquisitions are conducted through purchase of all or majority of the selling company’s stock by the acquirer which results in full ownership (Mastracchio and Zunitch, 2002). The process is characterized by time-consuming negotiations and the risk associated with inheriting potential liabilities of the purchased company (Mastracchio and Zunitch, 2002). For that reason, the acquirer has to consider various due diligence processes to mitigate the risk of potential transactions (Mastracchio and Zunitch, 2002). The most significant

difference between mergers and acquisitions is the fact that the acquiring company is not obliged to offer its stock in return which could potentially lead to dilution in ownership (Mastracchio and Zunitch, 2002).

III) Asset purchases, as the name suggests, is associated with buying carefully selected assets of the selling company (Mastracchio and Zunitch, 2002). This approach is suitable for companies that could not agree on the final form of transaction, the total worth of liabilities or assets could not be established or if it is simply more profitable for the acquirer to purchase a specific asset (Mastracchio and Zunitch, 2002).

As can be inferred from the descriptions, grouping these terms as one is a surprisingly well thought decision. In fact, mergers and acquisitions are often used interchangeably as they are all based on the same concept – the acquirer obtains assets from another company (Duksaite and Tamosiuniene, 2009; Malik et al., 2011). For the purpose of this thesis, it may be easier to conceptualize the aforementioned types of transaction as different routes leading to the same goal. While choosing one particular strategy over another may prove to have different financial or legal implications, it does not necessarily matter as the acquiring company will be in sole ownership of a vital resource. Each company simply chooses the most efficient approach that enables them to successfully conclude their own M&A transaction.

3.1.2 Rationale for M&A

According to Duksaite and Tamosiuniene (2009), the management line constantly searches for opportunities to grow and satisfy the needs of shareholders. While companies can of course utilize the opportunity to base their growth on internal development, this approach often does not offer the same pace of progress and scale M&A can bring (Duksaite and Tamosiuniene, 2009). Some of the identified major factors incentivizing M&A activity are

1) synergy, 2) agency motive, 3) managerial overconfidence, 4) efficiency gains (Malik et al., 2011) and 5) killer acquisitions (Cuningham et al., 2018):

I) Synergy, which Megginson et al., (2008) explains with a simple quote from the former CEO of Disney, Michael Eisner, being ‘ $1 + 1 = 4$ ’ (p. 578). Surprisingly, this short equation provides substantial insight into the motives of companies engaging in M&A. The meaning behind the quote is simple – executives of large corporations believe that a potential transaction will significantly enhance the processes and overall performance of their organization.

Megginson et al. (2008) focuses on three specific types of complements which are financial, operational and managerial synergies. Potential post-merger financial synergies pertain to less expensive capital, through reduced cost of equity, tax advantages, lower default risk or more stable cash flows (Megginson et al., 2008). As can be inferred from the description, this kind of synergy is not necessarily based on complementing the primary business line, but rather pertains to the overall financial condition of the companies involved in the transaction. The operational synergy concerns areas such as economies of scope, economies of scale and resource complementariness (Megginson et al., 2008). In this case, the company’s processes are directly affected by the potential transaction which may result in reduced production costs or complement their current portfolio (Megginson et al., 2008). Lastly, managerial synergies pertain to value added from merging two management teams specialized in different areas (Megginson et al., 2008). ‘

To expand on the synergies, it is important to mention that international M&A transactions have become an essential part of corporate strategy. According to Awate et al. (2014), subsidiaries in foreign locations allow companies to take advantage from national innovation system, region-specific alliance or more advanced technologies. In fact, it is quite possible that at a certain point foreign subsidiary becomes more proficient at R&D than the

headquarters (Awate et al., 2014). Vestas, a Danish wind turbine manufacturer, is definitely a great example of this approach as the company utilizes a borderless R&D strategy and benefits from region-specific competencies (Awate et al., 2014). Another example is an Indian wind turbine manufacturer, Suzlon, which acquired all its patents through M&A transaction in Europe and the United States (Awate et al., 2014). In terms of financial synergies from cross-border M&A transaction, merging companies often have the opportunity to change their residency through so called corporate inversion (Marples and Gravelle, 2014). By doing so, a company may benefit, for example, from lower tax rates or region-specific subsidies (Marples and Gravelle, 2014).

II) Agency motive, which Malik et al. (2011) depicts as a constant struggle between the shareholders and executives. This factor is characterized by the fact that the actual owners of a company and the directors may have divergent objectives and visions (Malik et al., 2011). In terms of M&A, executives may potentially utilize acquisition to further strengthen their personal position which is not necessarily in line with the overall direction of the organization (Malik et al., 2011). In fact, it is quite reasonable to assume that executives prioritize their own well-being over the needs of shareholders. Agency motive will be described in detail later in the chapter as it provides invaluable insight on why certain companies may choose to participate in M&A activity that does not necessarily benefit their organization.

III) Managerial overconfidence which Malik et al. (2011) describes as managers being too confident in their ability to recognize the factual value of potential M&A activity. It is often characterized by overvaluation of targets which leads to perceived underperformance of acquired companies in the long-term (Malik et al., 2011). According to Malmendier and Tate (2008), executives uncritical towards their own ability to successfully manage an organization are more likely to engage in less profitable M&A transactions. In contrast to the

agency motive, overconfident managers may truly believe they add value to the shareholders; however, their organization is indirectly damaged through a series of mediocre M&A decisions (Malmendier and Tate, 2008).

IV) Efficiency gains corresponds to the redistribution of resources among merging companies (Malik et al., 2011). In other words, companies can potentially increase efficiency by moving capital between companies in such a way that maximizes the overall productivity. This factor incentivizing M&A transactions likely comes from the belief that each company is in possession of resources that would significantly benefit the other.

V) Killer acquisitions originate from an extensive research conducted by Cunningham et al. (2018) which analyzed more than 4000 pharmaceutical companies in the past 25 years in relation to purely strategic acquisitions aimed at eliminating potential competition. The article estimates that each year as many as 6% of all acquisitions in this sector are conducted for purely strategic reasons involving immediate termination of the acquired company (Cunningham et al., 2018). Furthermore, the actual number is likely to be significantly higher as the carried-out calculations included solely cases where the buyer did not take advantage of the competitor drug (Cunningham et al., 2018). The actual significance of the findings becomes apparent when one realizes the overall effect on both the acquirer and the industry as a whole. Companies unwilling to innovate may conclude that utilizing killer acquisitions as a tool to retain their market position is a more feasible solution than traditional R&D. Consequently, the pharmaceutical industry is potentially in danger of being in innovation impasse.

3.1.3 Summary

While M&A can potentially be broken into three different concepts, in terms of the research question the most appropriate approach is to think of it as one strategy – obtaining crucial assets from other companies. It is more important, however, to understand the rationale behind engaging in M&A transactions as they. *Table 3.1.3* below summarizes the aforementioned factors and assigns them to either “Takeover driven by financial motives” or “Takeover driven by operational motives”. The differentiation serves the purpose of being a certain kind of guideline allowing more efficient interpretation of the motives behind M&A. As can be inferred from the described factors, the management clearly engages in M&A to either strengthen their core business operations or to improve their market position and profitability. A greater understanding of these two categories may prove to be crucial in understanding why an executive may find it more beneficial to acquire a company than to engage in R&D.

Table 3.1.3
The main reasons to engage in M&A transactions

Takeover driven by financial motives	Takeover driven by operational motives
Agency motives Managerial overconfidence Killer acquisitions Financial synergies	Efficiency gains Managerial synergies Operational synergies

Note. The main reasons to engage in M&A transactions based on Cunningham, Ederer and Ma (2018), Malik, Anuar, Khan and Khan (2011), Malmendier and Tate (2008) and Megginson, Smart and Lucey (2008)

3.2 The impact of M&A on pharmaceutical R&D

While the previous section describes potential factors incentivizing M&A transactions, the purpose of this section is to explore why M&A may be a legitimate substitute for R&D among pharmaceutical firms. R&D can be described as a mean to assume the lead in a competitive business environment through innovation and launch of new products and services (Kenton, 2020). As a result, lack of internal R&D departments may force companies to rely on external partners or M&A transactions (Kenton, 2020). In terms of the pharmaceutical industry, it is presumably more practical to describe the efficiency of R&D as a “launch of new medicines (output) in the rate of the monetary investments required for R&D (input)” (Schuhmacher et al., 2016, p. 1).

3.2.1 Overview of R&D trends in the pharmaceutical industry

R&D is undeniably a crucial element of the pharmaceutical industry with companies spending on average 17% of their revenues ("Average Research & Development Costs", 2020). To put it in perspective, only the semiconductor industry is known to put a higher priority on R&D assigning around 25-28% of their revenues ("Average Research & Development Costs", 2020). While the industry-wide R&D spending in 2020 is predicted to reach as much as 160 billion dollars, the potential return on investment is not satisfactory from an investor's point of view (Schuhmacher et al., 2016). This is simply because pharmaceutical companies do not put on the market the required number of new drugs that would allow them to experience the expected year-to-year growth and profitability (Schuhmacher et al. 2016). Given that the R&D process of a new drug is characterized by substantial investments amounting to more than 3 billion dollars (Schuhmacher and Kuss, 2018) and average commercialization time of 17 years (Kruse et al., 2014), it is reasonable to assume that firms move beyond internal development to counterbalance the low efficiency.

Internal R&D has become a secondary source of drug innovation among pharmaceutical companies as the negative correlation between R&D cost and productivity is simply unbearable for many firms (Shepherd, 2018). While in-house drug development was the preferred option in the previous century, it is no longer profitable nor efficient to continue this strategy (Shepherd, 2018). According to Schuhmacher et al. (2016), the unsatisfactory efficiency of R&D forces pharmaceutical companies to remodel their current internal processes and shift their focus towards external opportunities such as M&A, strategic collaborations and partnerships, virtual R&D or venture capital investment. In fact, an extensive research of trends in the pharmaceutical industry productivity shows that as many as 73% of established pharmaceutical companies were in the process of restructuring their drug development processes (Kruse et al., 2014), and almost 50% their product portfolio was obtained externally (Schuhmacher et al., 2013). Having established that large pharmaceutical companies are on the lookout for opportunities that would allow them to remain the key players on the market, the question is how it can be achieved and at what cost. While large pharmaceutical corporations possess the resources required to further develop externally obtained drugs, they do not necessarily have to develop new medicines at all as they can simply acquire well-known products that would enhance their portfolio.

3.2.2 The effect of M&A on R&D

M&A has become a tangible concern for the antitrust authorities as the pharmaceutical companies may engage in this type of transaction for purely profit-driven motives (Shepherd, 2018). In fact, researchers and antitrust authorities struggle to agree on the actual effect of M&A on R&D (Richman et al., 2017; Shepherd, 2018). While certain studies point at possible negative correlation between M&A and R&D productivity (Haucap and Stiebale, 2016; Ornaghi, 2009; Comanor and Scherer, 2013), some researchers uphold a quite different view and believe that lack of internal R&D not only does not hamper the overall innovation,

but also becomes the industry standard for drug development (Richman et al., 2017; Shepherd, 2018). For that reason, the two, to a certain degree different perspectives, will be described. To begin with, studies stressing the potential negative correlation between M&A and R&D will be explored, followed by studies pointing at drug development revolving around external sources being a new reality in the pharmaceutical industry.

Perspective I. The difficulty of exploring the actual effect of M&A on innovation and R&D is that many other factors exist that can influence corporations to change their focus towards acquisitions or in-house drug development (Ornaghi, 2009). The study conducted by Ornaghi (2009) strived to address this issue by a careful selection of “a control group whose pre-existing observable characteristics are similar to the merging companies” and “control for the effects of exogenous technological shocks” (p.78). Therefore, the research provides valuable insight as the author understands the many factors that may potentially incentivize companies to choose this particular direction for their organization and constructed the econometric model accordingly. While the study could not unambiguously conclude that M&A has a negative effect on R&D, it does suggest that large pharmaceutical corporations do in fact experience an overall decrease in innovation as compared to the control group (Ornaghi, 2009). Furthermore, the study found that companies with low-performing stock, expiring patents and lack of market-ready drugs are more likely to utilize M&A as a tool to fill out R&D gaps (Ornaghi, 2009). It is also in line with the research conducted by Danzon et al. (2007) as it found that vast majority of pharmaceutical companies engage in M&A to address their relatively bad performance also reflected in its stock price.

Another research, conducted by Harvard Business Review, explored this topic and found that M&A does in fact significantly reduce patenting and R&D spending during the post-transaction period (Haucap and Stiebale, 2016). The most surprising finding, however, is that competitors of the merging firm also reduced their R&D spending by 20% on average

within four years (Haucap and Stiebale, 2016), which suggests that largest pharmaceutical companies benefit from decreased competition and find it more efficient to abandon their drug development efforts to a certain degree. Furthermore, the research found that pharmaceutical corporations tend to target firms with a closely related portfolio of drugs in-development that may prove to be fierce competitors in the future (Haucap and Stiebale, 2016). In other words, the goal of transactions is not necessarily to acquire new innovative drugs in-development, but rather to increase the efficiency of their current portfolio and reduce competition in some of their projects. It is in line with the case of killer acquisitions in the pharmaceutical industry introduced by Cunningham et al. (2018) which was mentioned in the previous section. This type of acquisition decreases the chance of drugs being developed and acts as a disincentive to innovate (Cunningham et al., 2018). The authors also pointed out that the regulatory bodies become increasingly aware of the new tactics being based on acquiring innovative competitors (Haucap and Stiebale, 2016). An example here is a merger between Pfizer and Hospira which was approved only after Pfizer agreed to sell the European rights to a drug in-development that was likely to be discontinued after the transaction (Haucap and Stiebale, 2016). Had the antitrust authorities not reacted, the overall innovation in this area of research would have been worse off.

Comanor and Scherer (2013) also suggests a negative correlation between these two variables and presents another interesting reason why M&A may potentially decrease R&D productivity. Namely, the fact that too many R&D projects in the pipeline may lead to an overall decrease in productivity (Comanor and Scherer, 2013). It is a quite interesting explanation of the phenomenon as it suggests that pharmaceutical corporations are not necessarily capable of further developing all of the drugs acquired through M&A. The possibility that many projects are cancelled due to M&A is quite reasonable as the acquirer cannot give the same priority to all drugs in the pipeline. Another interesting finding

discussed by Comanor and Scherer (2013) is the fact that out of five largest pharmaceutical firms analyzed, only Lilly, a company that was not involved in large mergers between 1989 and 2011, had a relatively high degree of parallelism. In other words, the company utilized a strategy of developing several versions of the same drug concurrently to increase the success rate of its drugs in-development (Comanor and Scherer, 2013). The authors suggest that M&A may result in cost-cutting activities and while parallelism can significantly increase the success rate, some pharmaceutical companies believe it is nothing more than a wasteful activity (Comanor and Scherer, 2013). It is especially visible in the case of Pfizer as it closed several research centers after its merger with Wyeth (Comanor and Scherer, 2013). In fact, LaMattina (2011) explains that mergers acted as an incentive for Pfizer to close several research centers in order to satisfy the expectations of shareholders. Furthermore, according to LaMattina (2011), pharmaceuticals firms used to be proud of their substantial R&D spending; however, the trend has changed, and further cuts are to be expected.

To conclude, the aforementioned findings provide one significant hint – certain pharmaceutical companies may utilize strategies driven purely by profit maximization. While large corporations such as Lilly believe that in-house drug development should be the backbone of their strong market position, other firms, such as Pfizer, find it easier to simply acquire a company with market-ready medicines. As previously described, it is not uncommon for companies to neglect R&D, and consequently patch up the holes through M&A transactions. Given the previously described findings, it is interesting to see how this strategy performs over a longer period of time. As the study conducted by Danzon et al. (2007) showed, it is going to be difficult for companies utilizing M&A to address R&D gaps to achieve long-term success.

Perspective II. While the focal point of the previous studies was to analyze the negative effect of M&A on R&D, there are certain researchers that believe it is in fact the new

reality that does not necessarily have a negative effect on the overall innovation. To begin with, Richman et al. (2017) conducted a longitudinal study of 17 firms in the pharmaceutical industry to explore the effect of M&A transactions on their performance. The results were actually in line with the aforementioned studies as the R&D and general and administrative expenses in relation to their sales fell following the transactions (Richman et al., 2017). It, of course, does not necessarily imply lower overall quantity of successfully developed drugs since M&A can bring products in stages not requiring further significant investments. In fact, it is exactly what the authors found as M&A contributed, at least to a certain extent, to a larger quantity of drugs achieving the human trials stage (Richman et al., 2017).

Furthermore, the study suggested that larger acquisitions may be more focused on drugs in the later stage of development (Richman et al., 2017). In other words, when large pharmaceutical companies engage in costly transactions, they primarily expect to obtain drugs that could be put on the market relatively quickly. In contrast, the purpose of smaller acquisition is to acquire both, drugs in early and late development phases (Richman et al., 2017). The study goes as far as to suggest that large pharmaceutical companies are simply better at navigating through the regulatory processes and marketing associated with an introduction of a new drug (Richman et al., 2017). It, of course, means that small and medium-sized enterprises are more R&D focused and are later acquired by capital-heavy entities (Richman et al., 2017). The authors believe that it is caused by a significant structural change in the pharmaceutical industry as the large corporation increasingly rely on licensing and acquiring of innovative projects whereas start-up and small companies drive the overall innovation (Richman et al., 2017). The study presents an interesting perspective on how the industry functions as it appears that it simply changed how it operates. Interestingly, lower R&D among large corporations engaging in M&A transactions does not necessarily mean that

the society would be worse off; however, the fact that companies choose potential new drugs based on how quickly they can be successfully commercialized may prove to be an issue.

Shepherd (2018) introduces another interesting perspective on how internal R&D is not necessarily the point of interest for large pharmaceutical corporations. The author argues that researchers misjudge how the modern innovation ecosystem functions (Shepherd, 2018). According to Shepherd (2018), M&A transactions allow companies to specialize in what they do best, which in this case can be described as acquiring external R&D and putting new medicines on the market. Furthermore, the concerns about lower innovation among large pharmaceutical companies caused by M&A would have only been relevant had they been the primary source of new drugs (Shepherd, 2018). However, according to Shepherd (2018), biotech companies and small and medium-sized enterprises are responsible for breakthrough innovation in the modern drug development ecosystem. To expand on the topic, Shepherd (2018) argues that a higher demand for external R&D actually benefits the overall innovation as small and medium-sized enterprises are driven by potential monetary reward once their drugs become promising enough to be acquired by a large corporation.

To conclude, the above-mentioned studies suggest that sourcing external R&D is the new reality in the pharmaceutical industry. Furthermore, it appears that this approach may increase the overall innovation rate as each company simply specializes in its specific core capabilities. It is important to remember, however, that companies tend to make less-than-optimal decisions and it should be expected, for example, that a company falls into a “slippery slope trap”. A company may continuously increase its reliance on externally acquired assets to such a degree that its core capabilities slowly disappear. As is commonly known, the business world is neither black nor white and even the most optimistic studies tend to have certain drawbacks.

3.2.3 Summary

To summarize, the largest difference between these two perspectives is that a certain share of researchers sees M&A transactions in the pharmaceutical industry as a purely profit maximization tool, while the other part believes that obtaining R&D through M&A is the new industry standard. Likely the most appropriate approach is to connect these two perspectives as the truth lies somewhere in between. The aforementioned studies are clear about signs of negative correlation between M&A and R&D; however, companies can be motivated to engage in this kind of transactions for very different reasons. As previously described, companies may be driven by purely financial incentives as well as factual desire to introduce new drugs to the market. While there definitely are signs that external R&D is becoming the new industry standard, it is crucial to analyze the factors that contribute to this decision as it determines the overall strategy of a company. Furthermore, even pharmaceutical companies driven primarily by operational synergies may become too dependent on M&A transactions which is likely not sustainable in the long term.

3.3 Drug approval process in the United States

Academic researchers are quite clear about the importance of drug approval process in the U.S pharmaceutical ecosystem (Richman et al., 2017; Shepherd, 2018; Comanor and Scherer, 2013; Ornaghi, 2009). As previously mentioned, drug development involves substantial investments and it might take many years to introduce a new drug to the market. In fact, the drug approval process might be responsible for this situation to a certain degree as companies are required to successfully navigate through strict approval phases. For that reason, it is obvious that the U.S. pharmaceutical companies put the Food and Drugs Administration (FDA), a regulatory agency in the United States, at the center of their business activity. It is also important to mention that the FDA is quite unique as it is the only agency responsible for the drug approval process while, for example, the EU utilizes three agencies

(Kasyhap et al., 2013). The drug approval process in the United States is also one of the most difficult in the world (Kasyhap et al., 2013), which only strengthens its influence on a company's development strategy.

3.3.1 Overview

While it might hard to believe, even defining what constitutes a “drug” may prove to be a challenge. According to Van Norman (2016), FDA utilizes specific guidelines allowing it to asses if a particular substance can be used for medical purposes. As is commonly known, certain products (such as vitamins) cannot be marketed as substances meant to cure any diseases as they have not gone through rigorous test. It may be a strategic move for many companies since the potential product is not required to be thoroughly tested, and therefore the road to reach the market is significantly shorter.

It is noteworthy that drug development process does not necessarily start with FDA as potential substances are thoroughly researched by scientists before they are deemed likely to successfully complete clinical trials in humans (Van Norman, 2016). Once a company becomes confident enough that their drug may prove to be a valuable asset, a company faces a number of options allowing it to submit an application called investigational new drug (IND) required to conduct human trial (Van Norman, 2016). If FDA grants a permission to begin human trials, a company is allowed to go through three rigorous phases with a success rate of about 10% (Van Norman, 2016). Lastly, assuming that a drug successfully passed all phases, a company is required to submit a New Drug Application (NDA) to FDA (Van Norman, 2016). There is also, of course, the exclusivity period granted to a company that first markets a drug which significantly influences the strategy of the largest pharmaceutical corporations in the United States. For that reason, the drug approval process can be broken into three stages which are 1) pre-clinical trials, 2) clinical trials in humans and New Drug Application (NDA) and 3) exclusivity period and generics which will be discussed in the following sections.

3.3.2 *Pre-clinical trials*

To start with, it is important to mention that the approval process with the FDA and human trials associated with it are in fact a rather late stage. This is because identifying a new potential drug requires a significant amount of time. The first step of drug development requires scientists to thoroughly understand the process of a disease and identify potential areas where their drug would positively affect the treatment (Van Norman, 2016). Once a company identifies the potential direction for its new drug, pre-clinical trials are conducted in animals to test the safety and effectiveness of the substance (Van Norman, 2016). Given that the pre-clinical trials were successful, a company can begin to formulate clinical trials in humans that could be later proposed to FDA and start designing a manufacturing plan (Van Norman, 2016). The last step involves designing and testing the stability and purity of a drug throughout the manufacturing process (Van Norman, 2016). Granted that a company is satisfied with the results, an application to FDA regarding clinical trials in humans can be submitted (Van Norman, 2016).

The application to FDA, IND, can be submitted either for commercial or research purposes (“Investigational New Drug”), which of course can potentially result in a different treatment by the regulatory agency. There are three types of the IND applications which are as follows (Van Norman, 2016):

I) Investigator IND is submitted by a doctor and often involves a sponsor which may be a pharmaceutical company (“Investigational New Drug”). This doctor (investigator) is required to supervise the administration of the drug (“Investigational New Drug”). In order to successfully proceed with an IND application, it is recommended to enter a Pre-IND Consultation Program offered by FDA to ensure that the process is smooth (“Investigational New Drug”). If FDA does not respond within 30 days of the application, the doctor has the right to proceed with the clinical trials (Van Norman, 2016). However, there is a possibility of

so called “clinical hold” introduced by FDA, which may potentially delay the trials, in case there are issues that must be addressed (Van Norman, 2016).

II) Emergency use investigational new drug (EIND) as the name suggests can be used in cases requiring quick acceptance. The application can also be used in a situation when patients are not eligible to participate in clinical trials; however, they would like to participate regardless of the situation (“Investigational New Drug”). This approach is not, of course, popular among pharmaceutical companies oriented towards commercial activities. The most recent example may be COVID-19 as sick patients are in need of instant solutions that could potentially save their lives.

III) Treatment IND is a certain kind of a shortcut for promising drugs that can be used in diseases without any other alternative drugs (“Investigational New Drug”). The application provides permission to use the drugs prior to completion of clinical trials in humans (“Investigational New Drug”). The requirements, however, are quite strict as it can be used only in case of the most malignant diseases (Van Norman, 2016). This application is also not necessarily suitable for pharmaceutical companies striving to increase their revenues.

As described in this section, having a promising drug is only the first step. Not only does a company have to correctly submit an application, but also needs to convince the FDA of its usefulness. There is also the case of potential delays as FDA may be concerned about certain aspects of a drug. Once an application is successfully processed, a company can proceed to clinical trials in humans.

3.3.3 Clinical trials in humans and New Drug Application (NDA)

According to Van Norman (2016), there are three main reasons for conducting clinical trials. The first one concerns safety which can be described as exploring potential adverse effects and establishing the most efficient dose (Van Norman, 2016). The second one relates

to efficacy which explores whether the drugs in fact offer more positive benefits to health than placebo (Van Norman, 2016). Lastly, effectiveness, to test the drug in real life conditions such as interactions with other drugs (Van Norman, 2016). The clinical trials in humans consist of four stages which are Phase 0 and Phase I lasting approximately two and a half years, Phase II lasting three years and Phase III lasting three and a half years (Van Norman, 2016).

Phase 0, as the name suggests, is not the actual part of the clinical trials and is more of a ‘warm-up’ before the actual trials (Van Norman, 2016). It is characterized by a smaller number of participants and low dose of a drug (Van Norman, 2016). This phase can be utilized to assess early on whether a drug will be effective, and to prepare for potential further clinical trials (Van Norman, 2016). A company has the right to conduct Phase 0 while waiting for acceptance of IND application (Dimasi et al., 2016).

Phase I is the first set of trials in the process and is primarily focused on identifying safe dosages and side effects (Van Norman, 2016). The number of participants is still low as compared to the next phases (“FDA Drug Approval”); however, it allows a company to see if their drug meets the minimum safety standards. According to a study conducted by Dimasi et al. (2016), 59.5% entering Phase I reach the next phase and the mean cost for this stage of clinical trials amounted to \$25.3 million in 2013 dollars.

Phase II is the second set of trials with the purpose of establishing the aforementioned efficacy while at the same time continuously paying attention to the safety of the drug (“FDA Drug Approval”). In this case, the number of participants significantly increases, and placebo may be incorporated what enables companies to thoroughly understand their drug (“FDA Drug Approval”). Before a company can proceed to the next phase, results of the clinical trials have to be submitted and discussed with FDA (“FDA Drug Approval”). According to a study conducted by Dimasi et al. (2016), the mean cost of this phase amounted to \$58.6 in 2013 dollars, and only 21.2% of drugs entering Phase 1 completed this stage.

Phase III is the last stage and basically a large-scale confirmation of all previous findings (“FDA Drug Approval”). The best representation of this is the number of participants as these clinical trials require approximately 10 times more people than Phase II (“FDA Drug Approval”). Since Phase III is a significantly larger undertaking than all previous stages, these clinical trials can take as long as three and a half years with the mean cost of \$255.4 million in 2013 dollars (Dimasi et al., 2016). What is important, however, is the fact that only 13% of drugs entering Phase I successfully complete Phase III (Dimasi et al., 2016).

Successful completion of all three phases is not the end of the road as a company still has to submit an NDA application which needs to thoroughly describe the results of the clinical trials in humans. The company is obliged to wait for FDA’s final decision and prepare itself for potential requirements to conduct additional Phase 4 clinical trials or implement corrections to the NDA application (Van Norman, 2016). Once an NDA is accepted, a company is allowed to manufacture and put a drug on the market.

3.3.4 Exclusivity period and generics

It is important to note that successful completion of the drug approval process does not equal unlimited monopoly period. In fact, Harvard Medical School conducted a research to explore the exclusivity period granted to pharmaceutical drug manufactures by the U.S. regulatory bodies. According to the study, once pharmaceutical companies discover a new drug, the most common patent protection period amounts to 20 years (Kesselheim et al., 2017). Since the application is done prior to clinical trials, the period is reduced by the amount of years needed to complete the drug approval process. Still, a company has the right to apply for certain extensions such as additional five years of patent-term restoration during clinical trials or by obtaining new patents involved in the manufacturing process of the drug (Kesselheim et al., 2017). Additionally, once the drug approval process is completed, manufacturing companies enjoy a guaranteed period granted by the FDA which ensures that a

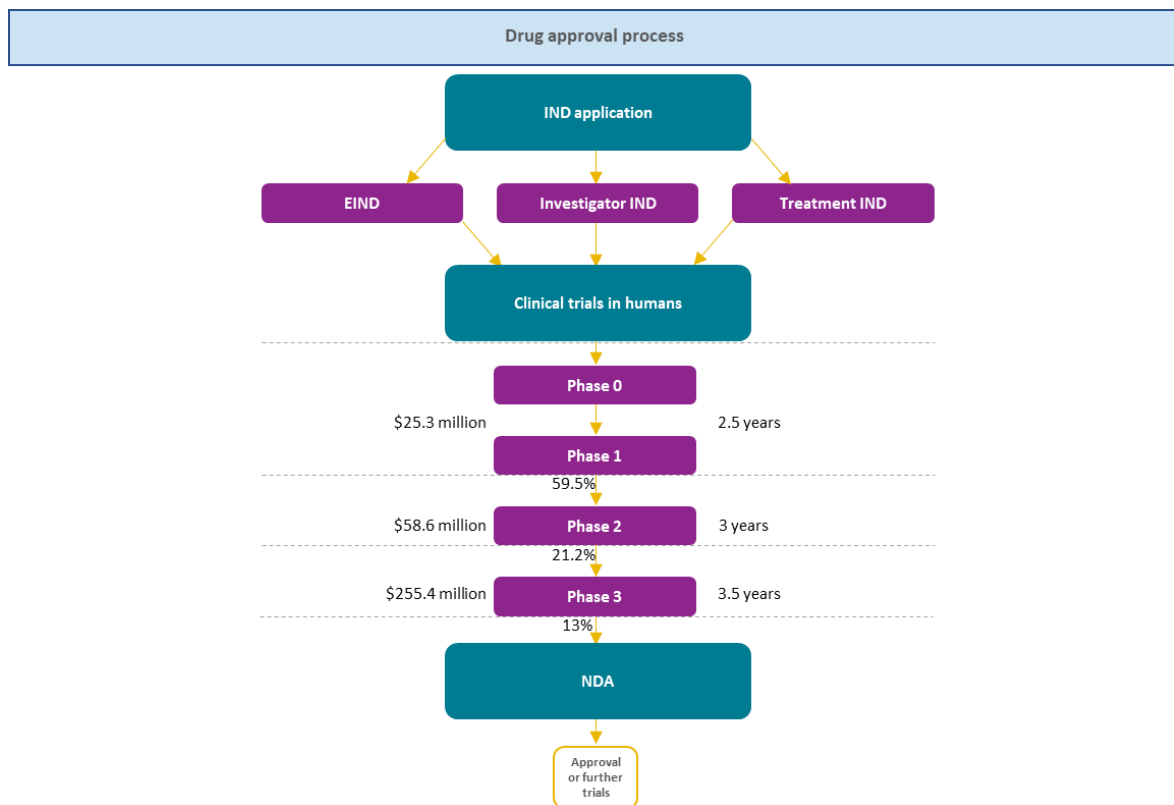
generic version (a substitute with the same active ingredient) of the drug cannot be approved (Kesselheim et al., 2017). The most common period amounts to 6 years; however, treatments for certain diseases, such as cancer, may benefit from 10 to 12 years of exclusivity (Kesselheim et al., 2017).

3.3.5 Summary

The drug approval process introduced in the previous sections perfectly explains why the pharmaceutical industry is consolidated to such an extent. While the aforementioned costs seem substantial, it is only a small share of the total investments drug development requires. According to study a conducted by Dimasi et al., (2016), the out-of-pocket and capitalized R&D expenses amounted to as much as \$1.4 billion and \$2.5 billion in 2013 dollars, respectively. Smaller companies simply do not possess enough capital, and therefore liquidity, to conduct extensive trials and accurately navigate the FDA process. The description of the approval process also provides rationale for large corporations in the United States engaging in M&A transactions. The risk associated with the process and the amount of time needed to successfully develop a drug are factors that the management line and shareholders are likely to avoid. In fact, it is completely understandable that a CEO finds it easier to acquire drugs in later stages than to develop a drug from scratch and hope it becomes profitable after 10 years. The whole process is summarized in *Figure 3.3.5* below.

It is also important to consider the exclusivity period granted by the regulatory bodies and its significant influence on the pharmaceutical industry. The fact that companies are required to commit to such a substantial investment and take advantage of only a limited period of monopoly suggest that drug pipelines must be constantly replenished to ensure stable revenue levels. Consequently, large pharmaceutical companies are required to constantly look for new opportunities, which, of course, include acquisitions that provide relatively risk-free drug portfolios.

Figure 3.3.5
Drug approval process in the United States



Note. Steps of the drug approval and data regarding the steps process from “FDA Drug Approval”, “Investigational New Drug” and Dimasi et al. (2016)

3.4 Shareholder Wealth Maximization vs. Stakeholder Theory

In order to thoroughly understand a company, an analysis of the factors that incentivize it to commit to a specific path of development may prove to be crucial. Of course, the most obvious culprit for many would be profit maximization; however, it does not fully reflect the situation large corporations face. It is common knowledge that the overwhelming majority of corporations are traded on the stock exchange which results in investors putting pressure on the management line. According to Smith (2003), the debate regarding shareholder wealth maximization versus stakeholder value maximization is in fact a large dilemma among companies. The pharmaceutical industry, however, faces a completely different situation as the global health system depends on its performance. For that reason, the actual drivers behind their strategy are of utmost importance in this case. The two perspectives will be describing in the following sections.

3.4.1 Shareholder wealth maximization

While shareholder (stockholder) and stakeholder theories appear to be quite different perspectives, they are, in fact, a part of corporate social responsibility as they both suggest what the ultimate goal of a corporation should be (Smith, 2003). In terms of the shareholder theory, it is based on an assumption that the management line should focus purely on satisfying the shareholders of their company (Smith, 2003). Furthermore, managers are not only expected to govern their organization in a way that is in line with shareholders' expectations, but also to prioritize stockholders over all other entities (Smith, 2003). Therefore, companies utilizing the shareholder theory should not be over-involved in any activities such as charitable work. Shareholder theory is, of course, also associated with an increased focus on short-term gains which puts the long-term gains of a company at risk (Smith, 2003). As history has shown, shareholder wealth maximization may lead to large-scale scandals such as the well-known fall of Enron, one of the largest electricity corporation in the world, which falsified its financial reports to look better on paper.

The pharmaceutical industry is an excellent example of how increasing the value of a company is prioritized over the well-being of patients. To put it in perspective, only one organization out of the 10 largest pharmaceutical corporation spent more on R&D than sales and marketing in 2013 (Milani and Duffy, 2019). Of course, as previously mentioned, pharmaceutical companies still spend a significant share of their revenues on R&D, but it is important to see both sides of the story. Large spending on sales and marketing suggests that companies are incredibly selective about their drugs and prioritize their development. Milani and Duffy (2019) goes as far as to say that the investments in R&D made by pharmaceutical giants do not meet the needs of the society as they are targeted towards the wealthy segment.

Milani and Duffy (2019) has an explanation for the above-mentioned business reality which is the fact that a phenomenon called corporate financialization has become an

important factor. Corporate financialization is based on an assumption that the profit of a corporation no longer comes exclusively from their core business activity, but rather from financial activities (Milani and Duffy, 2019). Moreover, the concept points out that companies increasingly prioritize paying dividends over reinvesting their earnings as a mean to support long-term wellbeing of their organization (Milani and Duffy, 2019). An example of this situation is how the spending of the U.S pharmaceutical industry was structured between 2006 and 2015. According to Milani and Duffy (2019), during that period of time the 18 largest American pharmaceutical corporations spent \$516 billion and \$465 billion on buybacks and dividends and R&D, respectively. There is also the case of raising drug prices by unethical amounts which was described in the introduction. When seeing such prioritization of financial activities over core drug development activities an interesting question appears. Why is it so prevalent among large corporations? The answer is quite simple – because the management is allowed to do it. In fact, Perkins (2001) is convinced that pharmaceutical companies are nothing more than typical profit-driven organizations and it should be expected that they will prioritize their own wellbeing. While it is not necessarily ethical, corporations are not obliged to serve the society and managers understand that. If they do not exhibit the profit-maximization mindset, shareholders do not hesitate to replace them with individuals that will play the game exactly as they are told (Milani and Duffy, 2019; Smith, 2003).

3.4.2 Stakeholder theory

While the previous sub-section describes the management line as driven primarily by profit and the wellbeing of shareholders, stakeholder theory takes more of a holistic approach. According to Smith (2003), stakeholder theory states that managers should represent all stakeholders and ensure their interests are protected. The main stakeholders of a company described in a research conducted by Min and Desmoulins-Lebeault (2018) are management, communities, customers, employees, suppliers and shareholders. It is important, however, to

mention that all stakeholders cannot not be treated as equal and the current business situation should determine the priority (Min and Desmoulins-Lebeault, 2018). Another characteristic of the theory is that the wellbeing of all stakeholders should be pursued over potential profits (Min and Desmoulins-Lebeault, 2018). With that knowledge, it becomes clear that stakeholder theory suggests that corporations are not only responsible for a sustainable growth of their organization, but also of the society as a whole.

In a similar manner to shareholder wealth maximization, the stakeholder theory plays a significant role in the pharmaceutical industry. This is because pharmaceutical corporations are responsible for wellbeing of millions of people. In fact, certain companies exist that take advantage of their status as the essential element of the world economy. A study conducted by Min and Desmoulins-Lebeault (2018), which surveyed the top 50 pharmaceutical corporations, aimed to explore their attitude towards corporate sustainability activities. The authors considered four hypotheses stating that protecting interests of internal and external stakeholders increases corporate profitability, stakeholder management improves long-term profitability and triple bottom line approach is a part of stakeholder management (Min and Desmoulins-Lebeault, 2018). Interestingly, the responses of the surveyed companies were overwhelmingly positive to all of the questions (Min and Desmoulins-Lebeault, 2018) which suggests that managers see the value of including the wellbeing of the society as a whole in their development strategy. Of course, the study only analyzed the attitude of managers towards corporate sustainability; however, it still shows that the stakeholder theory may prove to be a profitable long-term option. It is important to remember that even though managers see value in the stakeholder theory, shareholders are an entity with the power to significantly limit their actual options.

In order to illustrate the stakeholder theory, it may be useful to analyze the case of Novo Nordisk, one of the largest producers of diabetes medications in the world. In fact, their

effort has been noticed as they have been voted the most sustainable company in the world in 2012 (Smith, 2012). Novo Nordisk believes it is responsible for the wellbeing of people with diabetes, and therefore introduces new initiatives such the DAWN programme with the goal of improving their quality of life or National Diabetes Programmes (NDPs) which strives to improve state-wide understanding and treatment of diabetes among many countries (Tidd et al., 2005). Through the use of the stakeholder approach, Novo Nordisk does not pursue an image of a soulless corporation, but rather a business partner that actually cares about the society as a whole (Tidd et al., 2005). While it is important to remember that Novo Nordisk is a Danish company and cultural differences likely play significant role, this example shows that pharmaceutical companies not only are able to play a role of a caring corporation, but also are able to do so profitably.

3.4.3 Summary

The above-mentioned perspectives suggest that while managers may see value in satisfying the needs of the society as a whole, they are very limited by the owners of their company. Furthermore, the tendency to prioritize short-term gains over long-term wellbeing of their organization is also clearly visible. In terms of pharmaceutical corporations, the two perspectives provide valuable insight on why managers may be pressured into M&A transactions that would shorten the time required to put new drugs on the market. As the case of Novo Nordisk shows, smart corporate sustainability may prove to be a very viable development option for pharmaceutical corporations; however, shareholders do not necessarily believe that long-term gains are better than safe bets in a form of yearly dividends.

3.5 Agency theory

This section is more of an extension of the previous section as it expands on the question relating to the factors that incentivize managers to act in a specific pattern.

According to Kaplan Financial, largest training providers in accountancy and financial

services, agency theory is a unique concept as it suggests that executives not necessarily act purely on behalf of the owners of their company ("Agency theory"). An agent is an entity employed by a principal to perform certain tasks; however, their ultimate goals may differ. Despite the fact that managers have the fiduciary responsibility to not act against a principal, they may do so unintentionally ("Agency theory"). For instance, executives are driven by factors such as their reputation and potential remuneration and the primary concern of the owners is to keep the value of their share at the highest possible level ("Agency theory"). Therefore, company owners incur substantial costs related to this issue as they have to implement attractive compensation packages or monitoring programs that would allow them to control executives ("Agency theory").

In terms of M&A transactions, it is an interesting case as executives do not necessarily benefit from this activity. In fact, Gay and Denning (2014) suggest that executives do not find value in this type of transactions as it dilutes their actual power through an increased number of management board members. Furthermore, they are not afraid to protect their personal position even it may potentially lead to a decreased value of their company (Gay and Denning, 2014). That is, of course, when incentives come in as the owners would like their company to go in a direction that would benefit them. According to Bebchuk and Fried (2003), the perfect incentive program would involve a plan capable of convincing executives to engage in relatively risky situations that could maximize the shareholder value but would not put them in danger. One of incentive plans strongly suggested by regulators and shareholders was to link executives' pay to their performance through equity-based compensation (Bebchuk and Fried, 2003). By doing so, managers are forced to care more about the stock value of their company as their own wellbeing depends on it. In fact, this option allowed many managers in the U.S. to significantly increase their remuneration in 1990s (Bebchuk, and Fried. 2003).

The problem is, however, that company owners are put in an unfavorable situation which leads to less than optimal decisions. Firstly, Bebchuk and Fried (2003) discusses a very interesting topic regarding the overestimated compensation of executives due to their substantial power over the shareholders' payouts. In other words, company owners may be willing to pay more than needed just to ensure that the value of their company is protected. The second problem described by Bebchuk and Fried (2003) concerns the fact that equity-based compensation encourages managers to engage only in M&A transactions that would not lower the current value of their company, and therefore ignore opportunities related to long-term wellbeing of their organization.

The last section in the literature review chapter related to the relationship between owners of a company and managers as this kind of relationship is often characterized by a higher degree of information asymmetry. Executives possess a tremendous power over an organization and there is a possibility that their goals are not aligned with the ones of the shareholders. For that reason, the owners may be forced to implement specific incentive plans ensuring that the value of their company is kept on a satisfying level. These incentives may be one of the reasons why managers tend to engage in M&A transactions that provide immediate boost to their organization instead of utilizing more of a holistic approach. It appears that the modern structure of corporations may encourage less-than-ideal decisions to a certain degree as both executives and shareholders seem to prioritize short-term gains.

3.6 Summary

In terms of the research questions, the literature review provides a valuable insight into what drives pharmaceutical corporations in the United States. Surprisingly, it appears that in terms of acquisitions, the pharmaceutical industry does not differ significantly from other industries which are not necessarily crucial drivers of public health. M&A transactions are utilized not only as a tool to enhance current operations but also to gain financial synergies

and limit potential competition. Furthermore, factors such as shareholder pressures and managerial overconfidence play a role in virtually all acquisitions resulting in compromises that may lead to less than optimal decisions. It is also important to consider the uniqueness of the U.S. drug approval process as well as the exclusivity period associated with it which significantly affect the overall strategy of pharmaceutical companies. These characteristics are simply unseen in non-pharmaceutical sectors which should be remembered when analyzing performance of such companies.

While the research questions cannot be fully addressed prior to the case studies in the following chapters, the primary drivers behind the decision to engage in M&A transactions instead of conducting internal R&D are clearly visible. Based on the literature review, it is possible to infer that the main factors incentivizing pharmaceutical companies to substitute M&A for R&D are:

I) Maneuvering the regulatory requirements. Pharmaceutical companies are forced to constantly fill R&D gaps due to loss of exclusivity of their blockbuster drugs. Since the drug approval process is not only incredibly risky and expensive but also time consuming, pharmaceutical corporations may need to acquire companies with the most promising drug portfolios to ensure that their revenues are protected for years to come.

II) Shareholder pressures on management. Shareholders (as the owners of a company) expect executives to implement profit-driven strategies that are not necessarily in line with the specificity of the pharmaceutical industry. In fact, it may also apply to managers with experience gathered in more commercial sectors. As a result, acquisitions may be conducted for purely financial reasons and unprofitable R&D operations are subject to continuous cuts in funding.

III) Financial motives. The pharmaceutical industry has become commercialized to such a degree that only new innovative treatments with the highest potential rate of return are worth pursuing. For that reason, M&A becomes a viable strategy as it allows executives to cherry-pick the most promising drugs. Based on the literature review, it is also possible that pharmaceutical industries utilize acquisitions to limit competition (killer acquisitions) or gain financial synergies (lower tax rates).

The aforementioned findings will be tested in a real-life setting by conducting case studies of Pfizer and Bausch Health in the following chapters.

Part III

4. The relationship between practice and theory: Analytical framework

The literature review was a crucial chapter as it established the foundation for the case studies. Furthermore, it provided guidance on how to approach the research and what to look for in the analyzed companies. Pfizer and Bausch Health's annual reports are mines of information and only a targeted approach allows a researcher to extract the right data. Based on the research conducted in the literature review chapter, the case studies will be organized in the following manner:

I) The first part of each case study, a company overview and history, will be analyzed in terms of the findings presented in the literature review chapter. The primary goal is to understand what drove the companies throughout the years and how they became reliant on externally acquired R&D. For that reason, the largest acquisitions will be analyzed in order to explore the primary M&A motives behind them as well as investigate how R&D operations were affected by such transactions. Another point of interest will be the CEOs and their relationship with shareholders. As can be inferred from the literature review chapter, the relationship between executives and owners of a company has an immense impact on a company's direction. The overview will serve as a starting point for the second part of the case studies by identifying the key events in their history that are likely reflected in the numbers provided in annual reports (primarily audited financial statements)

II) The second part of each case study will focus on the analysis of annual reports and proxy statements. It expands on the previous section by analyzing correlations between the events described in the overview and actual numbers included in financial statements (such as revenues). As previously mentioned, a targeted approach will be utilized in order to efficiently extract data. Based on the literature review chapter, the key areas identified are 1) key

business segments, 2) R&D spending, 3) management and 4) shareholders. Data for each of these sections will be extracted to investigate how they either contributed to or were affected by acquiring other companies to fill R&D gaps. For instance, the findings described in the literature review chapter suggest that pharmaceutical companies are driven by the desire to smooth out their future revenues due to loss of exclusivity for certain drugs. The analysis conducted in this part will explore whether the data included in annual reports (such as R&D spending, dividends or drugs portfolios) is a reflection of such theory.

The primary purpose of the above-mentioned parts as well as the literature review chapter is to harmonically complement each other and provide strong foundations for conclusion in relation to the research questions. While the qualitative research is utilized to provide insight into how the companies operated through the years, the quantitative research seeks to present how acquisitions are clearly reflected in a company's financial condition.

5. Case study – Pfizer

In this chapter, the case of Pfizer will be thoroughly analyzed to understand the rationale behind the decision to engage in the largest acquisitions ever concluded in the pharmaceutical industry. Firstly, the story of pre-21st century Pfizer will be explored to see what drove the company throughout the years. Secondly, the key events in the 21st century will be analyzed to identify potential trends as well as to understand the company's overall business strategy in the past 20 years (5.1). Lastly, the annual reports will be reviewed in relation to the previous findings to see which factors contributed to the decision to substitute R&D for M&A (5.2). Additionally, the goal of the analysis is to assess whether the strategy utilized by Pfizer is sustainable in the long term.

5.1 General Overview

While the first part of the overview concerns a more general description of Pfizer's historical strategic decisions, the second half addresses potential implications of conducting some of the largest M&A transaction in the pharmaceutical industry (even as of today). The primary goal is to show that many factors are involved and the rationale behind each of the decisions to engage in acquisitions of this scale is not as simple as, for example, "large operational gains" described in the annual reports following the transactions.

As is commonly known, Pfizer has concluded a significant number of M&A transactions in the past 20 years; however, only three have significantly affected the company and the U.S. pharmaceutical industry as a whole. Namely, the three transactions were 1) acquisition of Warner-Lambert in 2000, 2) acquisition of Pharmacia in 2003 and 3) acquisition of Wyeth in 2009. Each of the major M&A transactions will be reviewed to understand the rationale behind such a decision as well as its potential effect on R&D.

5.1.1 *Pre-21st century*

It is important to note that the overview of the pre-21st century Pfizer is based purely on an analysis of Pfizer websites such as "Pfizer website accomplishments" and "Pfizer website history". Throughout the research the company websites proved to be not only the most detailed source of information but also one of the most reliable due to continuous public scrutiny. Each information in the section not relating to the aforementioned websites will be cited accordingly.

Pfizer has been a crucial part of the United States pharmaceutical industry for a substantial amount of time as the company was founded in 1849 in New York. The founders were Charles Pfizer and Charles Erhart, young entrepreneurs from Germany, who combined their knowledge in chemistry and confectionery. The cooperation proved to be fruitful as their first product, an antiparasitic substance Santonin blended with almond-toffee flavoring, turned

out to be a successful drug allowing them to pursue their entrepreneurial dream. Another milestone is the year 1869 and associated with it American Civil War which significantly increased the demand for products such as painkillers and disinfectants. Pfizer successfully addressed the specific market needs and efficiently grew its operations to double its revenue and reach a point of 150 new employees by 1868. The turning point in Pfizer's history, however, was the year 1880 and the decision to begin manufacturing citric acid as the company swiftly became the market leader in this area with clients such as Coca-Cola or Pepsi-Cola. The company experienced impressive growth for the next 30 years reaching a revenue exceeding \$3 million in 1906. According to the earliest available data provided by the U.S. Bureau of Labor Statistics, this amount in 1913 would equal to \$79,014,795.92 in March 2020 (U.S. Bureau of Labor Statistics, 2020).

As the above-mentioned key milestones in the history of Pfizer show, the company has been a very business-oriented entity from the very beginning, successfully acting on all available opportunities. However, the product that crowned the company as one of the pharmaceutical market leaders, was penicillin. In fact, had the company not gathered an expertise in the field of fermentation as a manufacturer of citric acid in the early years, the company would have not been able to conduct the transformation in such a swift manner. While Alexander Fleming was the microbiologist responsible for discovering the penicillin mold in 1928, Pfizer was the first company to perfect the manufacturing process which enabled mass production and turned the organization into the largest supplier of the drug to the allied forces during the World War Two ("Pfizer: The making of a global drugs giant", 2014). The success was not a coincidence as the management board of Pfizer put down a significant bet on penicillin in 1941 not only by reconfiguring its current infrastructure, but also heavily investing in new facilities. It is noteworthy that the company was privately held at the time, and the executives put their own wealth at risk. Interestingly, the great success

likely acted as a catalyst to monetize the company as the owners offered 240,000 new common stock to the public in 1942.

The next 50 years were characterized by continuous development of the following areas:

I) Increased international presence was an essential part of Pfizer's strategy. In years 1950-1951, the company established an international division known for its extensive autonomy and lack of continuous approval-process from the U.S. headquarters regarding not only everyday regular decisions but also the ones of high importance. A great example is a partnership with a Japanese firm, Taito, created in 1955 to manufacture and distribute antibiotics in that region. The company was later acquired by Pfizer in 1983 in an apparent strategic move to increase its profits by removing an intermediary. Another strategy Pfizer utilized to increase its international presence was to set up R&D on three continents to boost the drug discovery process.

II) Further development of the antibiotic segment was another area Pfizer focused on. As previously mentioned, penicillin was a drug that turned the company into a pharmaceutical powerhouse and influenced the future direction of the firm. Another antibiotic, Terramycin, was added to the portfolio in 1950 as a result of the first drug development program implemented by Pfizer. Subsequently, the company introduced Vibramycin in 1967, an antibiotic with a wide range of applications. These were followed by Unasyn in 1986, an injectable antibiotic, and Zithromax in 1992 comprising azithromycin, a widely used substance to this very day.

III) Development of marketing and sales capabilities in which Pfizer saw an opportunity to strengthen its organization. An example here would be an establishment of Pfizer Pharmaceutical Sales Force in 1950 comprising of eight sales representatives with the

sole purpose of educating doctors about the available drug portfolio and selling the company's inventory to wholesalers. Three years later the Company acquired J.B. Roerig & Company specializing in nutritional supplements with a strong marketing department which to this day is an integral element of Pfizer. Pfizer also got involved in certain initiatives such as Sharing the Care providing medications to one million low-income patients and International Trachoma Initiative striving to eliminate the disease. While the mentioned initiatives are praiseworthy, they are also fantastic marketing opportunities that are capable of reaching many previously not available markets.

The pre-21st century Pfizer is characterized by an ability to sense new opportunities and successfully act on them. The company was able to immediately adjust their organization to new markets trends which proved to be a significant edge over its main competitors. The main example here, of course, is how Pfizer efficiently addressed the needs of the American Civil War and the World War Two by providing products of the utmost importance to the wellbeing of soldiers. There is also the case of successfully identifying citric acid and cooperation with brands such as Coca Cola, Pepsi-Cola and Dr. Pepper as a potentially profitable business area. This strategic choice is also a proof of Pfizer's ability to efficiently reconfigure its assets to swiftly transition from a clearly commercial business area to mass-production of penicillin. Furthermore, the aforementioned examples showed that the company stayed on top of industry trends by engaging in M&A transactions, international expansion and seeing value in marketing of their products.

The link between the "modern" and "old" Pfizer was definitely William Campbell Steere Jr, a Stanford graduate and a longtime employee (Elkind and Reingold, 2014). Steere joined the company as a drug salesman in 1959; however, throughout the years turned into an essential element of the company and became the CEO in 1991 (Elkind and Reingold, 2014). In fact, Steere was the reason behind Pfizer's decision to focus primarily on the

pharmaceutical area and higher R&D spending associated with it (Elkind and Reingold, 2014). Interestingly, one of the CEO's dream was to transform Pfizer into the market leader (Elkind and Reingold, 2014) and the Warner-Lambert acquisition was an opportunity which simply could not be ignored.

5.1.2 Warner-Lambert: 2001

In 2000, Pfizer acquired Warner-Lambert which contributed to its position as the largest pharmaceutical corporation in the world at the time ("Pfizer annual report 2000"). The transaction cost the company 2.75 of a share per one share belonging to Warner-Lambert which translated to approximately \$90.27 billion (Petersen, 2000). Interestingly, Pfizer acquired Warner-Lambert through a hostile takeover (Petersen, 2000). Lipitor, a drug licensed from Warner-Lambert at the time, was an important revenue source, and therefore Pfizer was afraid the license agreement would have been terminated had Warner-Lambert concluded an acquisition of a company allowing it to market the drug itself (Petersen, 2000). Since the drug had the potential to be the most profitable pharmaceutical product in the world (which proved to be true in the following years), the company could not lose such a valuable source of revenue (Elkind and Reingold, 2014). As a result, Pfizer not only blocked Warner-Lambert's potential transaction (which was associated with contractual penalties) but also actively tried to acquire the company until the deal was completed (Petersen, 2000).

In terms of the drugs obtained, company benefited from the transaction primarily through drugs such as Lipitor as well patents that contributed to the creation of Ibrance and Lyrica. There were also synergies in the sales department as the company added 2500 sales representatives as well as an increase in the number of employees in the R&D area making it the largest in the world in 2000 (Petersen, 2000). Lastly, the shareholders benefited from an immediate increase in the value of their shares ("Pfizer annual report 2000"). Nevertheless,

the company was quite clear about potential cost cutting activities involving layoffs and cuts in funding in the years following the transaction (“Pfizer annual report 2000”).

When it comes to the actual R&D spending, Pfizer and Warner-Lambert’s spending amounted to \$2,776 and \$1,259 billion in 1999, respectively (Warner-Lambert annual report 1999; “Pfizer annual report 1999”). Since the R&D spending in the years 2001 and 2002 equaled to \$4,776 and \$5,176, respectively, it appears that the company kept the R&D level of the two companies for two years. It is not possible, however, to see the long-term consequences of the merger as the company conducted another large acquisition in 2003. Prior to the transaction, Warner-Lambert was the 7th largest pharmaceutical company in the U.S. (Slud, 2000) which shows the scale of potential R&D activities lost in the industry. The company likely “cherry-picked” the most promising assets and discontinued operations that were not necessarily in line with Pfizer’s strategy.

It appears that this acquisition was driven primarily by the Pfizer’s executives being afraid that a potential termination of Lipitor licensing agreement could lead to substantial future revenue losses. It is quite understandable as Lipitor achieved sales over \$10 billion in 2005-2010 making it by far the most profitable drug in the world (“Pfizer annual reports”). In terms of the main reasons to engage in M&A transaction described in the literature review, it is quite difficult to unambiguously choose the right category in this case. Firstly, it is a certain kind of a killer acquisition as Pfizer was set to remove the potential competition, Warner-Lambert. Secondly, the transaction can be described as driven by operational synergies and gains in efficiency. Despite the fact the company wanted to become the sole owner of Lipitor, it also significantly benefited from other drugs in the portfolio, R&D know-how as well as strong sales department. Lastly, managerial overconfidence seems to be a factor as the decision to spend \$90 billion dollars was to a large degree driven by one drug. To put it in perspective, Pfizer spent approximately a 20-year R&D budget (at the time of the acquisition)

on a single M&A transaction. Even though Warner-Lambert was acquired through stock, Pfizer denied itself the opportunity to improve its core R&D capabilities. While such a strategic decision regarding Lipitor is to be expected from companies in purely commercial industries, the pharmaceutical companies (as a sector responsible for wellbeing of millions) utilizing this business approach may be quite a surprise.

5.1.3 Pharmacia: 2003

Soon after the Warner-Lambert acquisition, Henry “Hank” McKinnell Jr. took the helm of the company (Elkind and Reingold, 2014). McKinnell joined the company in 1971 and was known to be of high intelligence but often too unrealistic regarding the goals set for the company (Elkind and Reingold, 2014). At that time, Pfizer was at the top of the pharmaceutical industry, and therefore expectations towards the company were incredibly high. While the Warner-Lambert acquisition contributed to the portfolio significantly, the shareholders were keen to build the momentum (Elkind and Reingold, 2014). However, the company’s pipeline simply could not support the ambitious goals.

In 2003, Pfizer acquired Pharmacia in a stock-for-stock transaction involving 1.4 Pfizer’s shares for each Pharmacia’s share with an approximate value of \$60 billion (Sorkin, 2002), which allowed the company to retain its position as one of the largest pharmaceutical companies in the world. The most significant drugs acquired through the merger were Celebrex, Detrol, Xalatan, Genotropin, Zyvox, Camptosar and Bextra billion (“Pfizer annual report 2003”). In a similar manner to the case of Warner-Lamber and Lipitor, Pfizer already marketed Celebrex and the acquisition gave the company full rights to the drug (“Pfizer annual report 2003”). Celebrex was not only a well-selling drug but also a product that could potentially become a great addition to Lipitor which already gained the blockbuster status. The aforementioned drugs were not, however, the only significant assets obtained from Pharmacia. According to Sorkin (2002), Pfizer also got in possession of promising drugs that

were already in the final stages of development. Furthermore, the company added a significant number of promising chemical entities to its portfolio as well as received access to new markets (through Pharmacia's assets) such as cancer treatment and ophthalmology (Sorkin, 2002). Through this merge, Pfizer's R&D spending in 2004 amounted to \$7,684 billion which was actually relatively close to what the spending of the two companies was prior to the transaction as Pfizer and Pharmacia's R&D amounted to \$5,176 billion ("Pfizer annual reports") and \$2,359 billion ("Pharmacia annual report 2002") in 2002, respectively.

There were, however, certain R&D cuts associated with the transaction. To begin with, Pfizer closed a biotech unit in San Francisco, four Chicago-based laboratories and a research center in France and laid off a share of its research employees involved in Michigan operations (Brickley, 2003). According to Brickley (2003), 12% of Pfizer's major research centers were significantly affected by the merger. An example here is Sugan, a research center that was bought by Pharmacia only four years prior to the transaction (Brickley, 2003). Overall, the company expected to reduce costs by \$1.4 billion, \$2.2 billion and \$2.5 billion in 2003, 2004 and 2005, respectively, primarily driven by cuts in R&D, administration, manufacturing, purchasing and distribution (Sorkin, 2002). Despite the cuts, it appears that the company achieved significant operational synergies as the R&D spending was on a comparable level. It has to be remembered, however, that even if the R&D spending remains on a comparable level, the company may simply allocate funds differently from current drugs-in-development to the ones acquired from the company. Such a merger is characterized by a complete reorganization of assets and discontinuation of certain programs is to be expected.

To conclude, the merger with Pharmacia appears to be an actual attempt at achieving large operational synergies following the transaction and incentivizing the sales growth required by the shareholders. While quite significant layoffs were present, the merged R&D spending was on a comparable level to the spending of individual companies. It is in line with

the case of Warner-Lambert. Still, it should be noted that one of the factors that likely contributed to this transaction is the fact that Pharmacia had full rights to Celebrex, one of the most important drugs in Pfizer's portfolio. In a similar manner to Lipitor, the company did not want to risk losing such an important source of revenue. Regarding the main reasons to engage in M&A transactions described in the literature review chapter, they are likely similar to the ones described in the case of Warner-Lambert. The only exception is that the transaction likely was not a killer acquisition as it was more of a friendly merger and the company simply wanted to reap the full benefits of Celebrex. In terms of operational synergies, Pfizer clearly benefited from Pharmacia's R&D, drug portfolio as well as other intellectual property in possession. It also appears that the company gained on efficiency in certain areas. However, it is possible that managerial overconfidence played a significant role in this transaction as the company spent \$60 billion three years after the largest acquisition in the pharmaceutical industry in history.

5.1.4 Wyeth: 2009

The acquisition of Wyeth is a fascinating case as it is a result of previous mergers as well as an effect of questionable leadership presented by the executives at the time. In order to understand this particular transaction (as well the consequences of two large mergers), it is crucial to analyze the years leading up to the acquisition of Wyeth.

Interestingly, Pfizer's problems began as soon as McKinnell (handpicked by William Campbell Steere) became the CEO of the company (Elkind and Reingold, 2014). The previous CEO, however, did not leave the company as he received a "consulting contract", an office and remained on the Pfizer's management board (Elkind and Reingold, 2014). Of course, the fact that such a personality still possessed significant influence over the company was destined to lead to potential conflicts among the top executives. In fact, this is exactly what happened as McKinnell and Steere became antagonistic towards each other to such a

degree that McKinell made an unsuccessful attempt to terminate the contract of the other (Elkind and Reingold, 2014). As a consequence, McKinell's tenure was characterized by weak and divided leadership (Elkind and Reingold, 2014). It proved to be an issue as in the years following the large two mergers shareholders expected a substantial year-to-year growth that Pfizer simply could not provide (Elkind and Reingold, 2014).

By the time Jeff Kindler, former executive at McDonald's, was appointed the CEO of Pizer in 2006, the value of the company's stock decreased significantly under McKinell's tenure (Elkind and Reingold, 2014). As Kindler was not experienced in managing a pharmaceutical company, he was characterized by a more commercial approach towards the company's operations (Elkind and Reingold, 2014). The newly appointed CEO needed to quickly address the current issues as market analysts were quite outspoken about the unavoidable revenue losses resulting from the upcoming loss of exclusivity for its blockbuster drug Lipitor (Elkind and Reingold, 2014). Most likely the largest issue was Kindler's overconfidence in his own strategic decisions in many aspects of everyday business activities which in connection with lack of expertise on the pharmaceutical industry proved to be disastrous (Elkind and Reingold, 2014). For instance, Kindler strived to develop new blockbuster drugs and his strategy was based on investing heavily in two promising substance which were supposed to drive Pfizer's revenues for many years (Elkind and Reingold, 2014). The projects turned out to be highly unsuccessful and devoured billions of dollars forcing the company to take drastic measures including job cuts amounting to 10% of the worldwide workforce and closure of R&D centers as well as manufacturing plants (Smith, 2007). Given the critical situation of Pfizer, the acquisition of Wyeth seemed to be a necessity rather than an opportunity to grow. While the acquisitions of Warner-Lambert and Pharmacia provided an opportunity to experience an immense growth, integrating such sizeable organization into the structures of Pfizer likely proved to be too difficult in the long term.

The Wyeth acquisition cost Pfizer \$68 billion dollars (primarily cash obtained from five banks) and resulted in significant operational overlaps which led to a notable decrease in costs (Hall, 2009). The crucial drugs obtained through this transaction were Prevnar and Enbrel, as well popular consumer health business brands (Hall, 2009). As can be inferred from *Table 5.2.1 B*, the drugs are continuously an essential element of Pfizer's product portfolio which suggests that the company benefited from the purchase in the long term. The transaction was also associated with large R&D cuts as the company laid off 11,900 employees, primarily in the R&D and manufacturing departments, and closed eight factories in the eight months following the transaction (Smith, 2010). However, a simple look at the annual reports for Pfizer and Wyeth prior to the transaction present the extent of the R&D loss. The joint R&D spending would have amounted to \$11,318 ("Wyeth annual report 2008"; Pfizer annual report 2008") in 2009, which is \$2 billion more than the actual 2010 R&D expenses. Furthermore, the R&D spending in 2012 fell to the lowest level since 2006 suggesting that Pfizer continued substantial R&D cuts and Wyeth's \$3 billion spent yearly on R&D was erased.

The acquisition of Wyeth can be defined as a "gasp for air" since years of internal conflicts and questionable decisions proved to be disastrous for the company's operations. This M&A transaction was clearly an extreme type of operational synergy and efficiency gain as the company not necessarily planned to grow, but rather strived to survive and retain its current position. In fact, it appears that Pfizer used Wyeth to simply patch up all areas that were lacking depth. While it may be tempting to conclude that the transaction was another example of managerial overconfidence, it is not necessarily the case this time. The company was in actual danger of losing its position as one of the top companies in the world pharmaceutical industry and was forced to act. In fact, it appears that the acquisition allowed Pfizer to rebuild itself to a certain degree as the company is in quite a good shape as of today.

5.1.5 The most recent acquisitions: 2010-2019

According to Mikael Dolsten, Pfizer's chief scientific officer, in the past 10 years the company strived to reorganize its R&D operations to decrease the overall reliance on large M&A transactions (Wright, 2019). Given that the largest M&A transactions included Hospira in 2015 (\$16.1 billion), Medivation in 2016 (\$14.3 billion) and Array in 2019 (\$11.2 billion), it can be concluded that the company achieved that goal to a certain degree as one of the acquisitions analyzed above cost more than all acquisitions in the past ten years ("Pfizer annual reports 2015"; "Pfizer annual reports 2016"; "Pfizer annual reports 2019"). Furthermore, as can be seen in *Table 5.2.1 B*, the most recent Pfizer's drug portfolio is also much more diversified compared to 2006. At that time, Lipitor corresponded to around 25% of the total revenues ("Pfizer annual reports 2005"). Nonetheless, it must be mentioned that the company attempted to merge with Allergan in 2015 in a transaction worth \$160 billion ("Pfizer annual reports 2015"). It is, of course, in opposition to what Mikael Dolsten described. Had the regulatory bodies not intervened, the transaction would have been concluded ("Pfizer annual reports 2015").

5.2 Analysis: Pfizer's Annual Reports

5.2.1 Key business segments

As at 31 December 2019, the company divided its business operations into three key segments which can be seen in the *Table 5.2.1 A* ("Pfizer annual report 2019").

Table 5.2.1 A
Pfizer's key business segments

Key business segments in 2017-2019			
USD'millions	FY17	FY18	FY19
Biopharma	35,530	37,558	39,419
Upjohn	13,447	12,484	10,233
Consumer Healthcare	3,472	3,605	2,098
Other	97	-	-
Total	52,546	53,647	51,750
Biopharma's share	67.6%	70.0%	76.2%
Upjohn	25.6%	23.3%	19.8%
Consumer Healthcare	6.6%	6.7%	4.1%

Note: The table was prepared based on information provided by Pfizer in Annual Report 2019

I) The first segment, Biopharma, concerns discovery and development of new drugs for sectors such as hospital, inflammation and immunology, internal medicine, oncology and vaccines ("Pfizer business units"). The main purpose of this business group is to find new innovative therapies that would address diseases without a definitive cure ("Pfizer business units"). As can be seen in *Table 5.2.1 A*, it is by far the largest segment with the revenue corresponding to 76.2% of the total sales. The composition of Pfizer's sales is crucial as it gives insight into its complex operations. The fact that Pfizer primarily focuses on the Biopharma segment suggests that the company relies heavily on the drug pipeline to stabilize its yearly revenues. In other words, the company is required to continuously put new drugs on the market as their leading products are bound to lose their exclusivity. The only possible solutions are to maintain relatively high R&D spending and/or acquire external pharmaceutical drugs through licensing or acquisitions.

II) The second segment, Upjohn, relates to sales of pharmaceutical drugs that are either generic or off-patent ("Pfizer annual reports"). The key areas are cardiovascular, ophthalmology, neurology and pain, psychiatry and urology ("Pfizer business units"). As described in the literature review chapter, once a pharmaceutical drug loses its exclusivity, its price drops significantly, and other companies are permitted to manufacture products with identical pharmaceutical ingredients. In the case of generic drugs, R&D may be substituted by

skilled marketing and sales departments as the products are no longer characterized by any unique features. In fact, a company involved in generics business is a subject to one of basic economic theories – elasticity. For that reason, Pfizer is required to compete with its competitors by either adjusting the price of its products or reducing the cost base. While Upjohn is substantially smaller compared to Biopharma, the revenue suggests that it is still a significant enough segment to potentially invest in it.

III) Lastly, Consumer Healthcare, is a segment based on a similar concept to Upjohn and does not require substantial investment in R&D. The segment relates to over-the-counter drugs as well as dietary supplements for everyday use (“Pfizer business units”). Since the products in this segment do not require any intellectual property, the competitive landscape is likely characterized by fierce competition.

As can be inferred from the description of the key business segments, Pfizer balances between low and high margin products posing substantially different risk. Once a new drug in the Biopharma segment is put on the market, a company takes advantage of a “monopoly period” which can prove to be an excellent source of revenue; however, the costs associated with this path may prove to be unbearable for many companies. In contrast, the other two segments are nothing more than a never-ending mission to reduce costs and attract customers. Of course, the low margins are likely not sufficient to ensure constant progress which is likely the reason why Pfizer primarily focuses on the high-margin Biopharma segment.

It is important to mention that the business segments have not changed significantly since 1999 (the year prior to the first large acquisition). According to “Pfizer Annual Report 1999”, the two segments were pharmaceuticals and animal health, with pharmaceutical drugs primarily driving the revenue. Interestingly, the numerous M&A transactions have not affected its core capabilities as compared to Bausch Health (described in the next chapter) which completely remodeled its business core.

To expand on the key business segments, as at 31 December 2019 the company listed 48 pharmaceutical drugs marked as key products, out of which 38 and 10 belonged to Biopharma segment and Upjohn segment, respectively. As can be inferred from *Table 5.2.1 B* below, Pfizer primarily addresses the markets of the utmost importance to the society as the drugs likely contribute to a lower mortality rates among patients. It creates, of course, a certain sense of socially responsibility and the company is expected to potentially decrease their profits (however, is not obliged to) for the greater good.

Table 5.2.1 B
Pfizer's drug portfolio

Pfizer's drug portfolio				
USD*millions	FY17	FY18	FY19	Origin
Biopharma - Internal medicine:				
Eliquis	2,523	3,434	4,220	Jointly-developed with Bristol Myers Squibb (Thomas, 2012)
Chantix/Champix	997	1,085	1,107	In-house (Jordan and Xi, 2018)
Premarin family	977	832	734	Acquisition of Wyeth in 2009 ("Wyeth Acts to Protect", 1995)
BMP2	261	279	287	Acquisition of Wyeth in 2009 (Obyme, 2002)
Toviaz	257	271	250	Licensed from Schwarz Pharma ("Toviaz approval", 2019)
Other	3,213	2,969	2,521	Not applicable
	8,229	8,869	9,119	
Biopharma - Inflammation & Immunology:				
Xeljanz	1,345	1,774	2,242	In-house (LaMattina, 2012)
Enbrel	2,452	2,112	1,699	Acquisition of Wyeth in 2009 ("Immunex/Wyeth Enbrel Launch", 1998)
Inflectra/Remsima	419	642	625	In-house (Biologic of J&J's drug) (Biegi, 2017)
Eucrisa	67	147	138	Acquisition of Anacor in 2016 (Palmer, 2016)
Other	103	45	29	Not applicable
	4,386	4,720	4,733	
Biopharma - Oncology:				
Ibrance	3,126	4,118	4,961	Acquisition of Warner-Lambert in 2000 (Jarvis, 2014)
Sutent	1,081	1,049	936	Acquisition of Pharmacia in 2003 ("Sutent - Max Planck Innovation")
Xtandi alliance revenues	590	699	838	Acquisition of Medivation in 2016 (Puzzanghera, 2016)
Xalkori	594	524	530	Acquisition of Pharmacia in 2003 (Sagonowsky, 2017)
Inlyta	339	298	477	In-house ("Axitinib")
Bosulif	233	296	365	Acquisition of Wyeth in 2009 (Richards, 2012)
Retacrit	67	82	225	Acquisition of Hospira in 2015 ("Product Profile of Pfizer's Epoetin")
Mektovi	-	-	49	Acquisition of Array BioPharma in 2019 (Hargreaves, 2019)
Braftovi	-	-	48	Acquisition of Array BioPharma in 2019 (Hargreaves, 2019)
Other	274	406	585	Not applicable
	6,304	7,471	9,014	
Biopharma - Hospital:				
Sulperazon	471	613	684	In-house (Allen, 1987)
Medrol	540	493	469	Acquisition of Pharmacia in 2003 ("REGULATION (EEC)", 2003)
Vfend	421	392	346	In-house ("Pfizer website history")
Zithromax	299	326	336	Licensed from Pliva ("Azithromycin: A world best-selling Antibiotic, 2009)
EpiPen	290	303	303	Acquisition of King in 2010 (Edwards, 2010)
Fragmin	306	293	253	Acquisition of Pharmacia in 2003 (Pineo and Hull, 2017)
Zyvox	281	236	251	Acquisition of Pharmacia in 2003 (Lueck, 2000)
Zosyn/Tazocin	195	230	200	Acquisition of Wyeth in 2009 ("CHMP assessment report", 2011)
Tygacil	260	249	197	Acquisition of Wyeth in 2009 ("Wyeth's antibiotic Tygacil")
Diffucan	180	189	190	In-house (Richardson, 1996)
Panzyga	-	39	183	Licensed from Octapharma ("Pfizer Notice")
Other	5,125	4,593	4,360	Not applicable
	8,369	7,955	7,772	
Biopharma - Vaccines:				
Prevnar 13	5,601	5,802	5,847	Acquisition of Wyeth in 2009 (Bernstein, 2003)
Nimenrix	86	140	230	Purchased from GlaxoSmithKline (Campion, 2015)
FSME/IMMUN-TicoVac	134	184	220	Acquisition of Baxter's portfolio of vaccines in 2014 (Campion, 2014)
Trumenba	88	116	135	Acquisition of Wyeth in 2009 ("Trumenba", 2019)
Other	91	90	73	Not applicable
	6,001	6,332	6,504	
Biopharma - Rare Disease:				
Genotropin	532	558	498	Acquisition of Pharmacia in 2003 ("Pharmacia Genotropin")
BeneFIX	604	554	488	Acquisition of Wyeth in 2009 ("Dr. Earl W. Davie")
Vyndaqel/Vyndamax	123	148	473	Acquisition of FoldRx Pharmaceutical in 2010 ("Vyndaqel")
Refacto AF/Xyntha	551	514	426	Acquisition of Wyeth in 2009 (Long, 2008)
Somavert	254	267	264	Acquisition of Pharmacia in 2003 (Letter, 2001)
Other	176	170	129	Not applicable
	2,240	2,211	2,278	
Total Biopharma segment	35,529	37,558	39,420	
Upjohn segment:				
Lyrice	5,065	4,970	3,321	Acquisition of Warner-Lambert in 2000 (Silverman, 2008)
Lipitor	1,915	2,062	1,973	Acquisition of Warner-Lambert in 2000 (Petersen, 2000)
Norvasc	932	1,029	950	In-house (Godfraind, 2017)
Celebrex	775	686	719	Acquisition of Pharmacia in 2003 (Kolata, Pollack and Meier, 2004)
Viagra	1,204	636	497	In-house (Anderson, 2020)
Effexor	297	311	336	Acquisition of Wyeth in 2009 (Saul, 2009)
Zoloft	291	298	294	In-house (Fox, 2015)
Xalatan/Xalacom	335	318	281	Acquisition of Pharmacia in 2003 (Zerhouni, 2004)
Xanax	225	223	198	Acquisition of Pharmacia in 2003 (Rogers, 2019)
Revatio	252	227	144	See Viagra (Anderson, 2020)
Other	2,158	1,725	1,519	Not applicable
Total Upjohn segment	13,447	12,484	10,233	Obtained through acquisition: 32
Total Consumer Healthcare segment	3,472	3,605	2,098	In-house: 12
Total Other	97	-	-	Other: 4
Total revenue	52,546	53,647	51,750	Total: 48

Note: The table was prepared based on information provided by Pfizer in Annual Reports 2017-2019

As at 31 December 2019, the revenue was driven primarily by Eliquis, Enbrel, Ibrance, Enbrel, Prevnar-13 and Xeljanz in Biopharma segment while Upjohn segment was mainly supported by Lyrica, Lipitor, Norvasc and Celebrex. It is important to note that the each year a pharmaceutical company's revenue is dictated by loss of exclusivity which allows competitors to put on the market their own version of the drug. This case is no different as Pfizer is also subject to potential losses in sales. An example here are Viagra, Lipitor and Lyrica which experienced loss of exclusivity in December 2017, November 2011 and June 2019, respectively ("Pfizer annual report 2019"). A great representation of the trend is Viagra with a 59% decrease in revenue in 2019 as compared to 2017 and Lyrica noting a 33% decline in revenue in 2019 as compared to 2018. In terms of the upcoming years, the exclusivity of Eliquis, Chantix, Ibrance, Xeljanz and Prevnar-13 are bound to expire in 2026 (Liu, 2019), 2020 ("Pfizer annual reports"), 2023 (Dabney, 2016), 2025 (Genco, 2019) and 2026 (Dabney, 2016), respectively. As a result, the company is required to constantly update their portfolio to ensure that their revenue remains on a comparable level. Given the previously described drug approval process in the U.S. (as well as in other countries), it is understandable that Pfizer utilizes M&A transactions as a relatively safe solution for pipeline gaps. By acquiring external R&D, the company is able to "cherry-pick" the most profitable combinations of products and avoid risk associated with drug development. It is important to remember that Pfizer is a large pharmaceutical corporation with obligations to shareholders. For that reason, it is completely logical to expect the company to "smooth out" their future revenues through acquisitions as traditional R&D does not provide them with the same level of certainty.

The most important finding, however, is the origin of Pfizer's drug portfolio as it confirms that the company relies heavily on M&A transactions to support their drug pipeline. *Table 5.2.1 B* presents the origin of each key drug as at 31 December 2019. Based on the research, 32 products, or 67%, originated from companies acquired by Pfizer while 12 drugs,

or 25%, were developed in-house. Of course, it does not necessarily mean that the company sourced ready-to-market drugs and simply reaps the benefits of newly obtained assets. As described in the literature review chapter, there is a tendency for pharmaceutical companies to acquire drugs in the late stage of clinical trials which is likely the Pfizer's strategy. For that reason, externally sourced drugs still incur costs associated with the final phases of drug approval process as well as expenses related to market introduction of a product. Nevertheless, it can be said with certainty that M&A transactions serve as a substitute for R&D (at least in the early stages) and are the primary driver of the company's drug pipeline. Furthermore, Chantix and Xeljanz are the only in-house products with revenue over \$1 billion which suggests that the company does not rely on its internal R&D to ensure smooth future but rather utilizes it as a supplement to externally sourced drugs. In terms of Pfizer, pipeline gaps seem to contribute significantly to higher frequency and value of M&A transactions.

Lastly, licensing seems to be the least preferred method of obtaining drugs among the key products listed in the Pfizer annual reports. While one cannot simply conclude that the company does not license its drugs as the "Other" revenue positions and drugs-in-development are quite significant as well, the potential preference for purchasing over licensing may be quite logical. Potential licensing agreements are likely to be associated with certain restrictions and large costs if a drug becomes successful. For that reason, it is expected that a company would prefer to own its assets (if a previous owner is open to a transaction) and remove all intermediaries. To a large extent, licensing may be similar to the previously mentioned acquisition of a Japanese partner. Why should a company share profits with other institutions if there is an opportunity to reap the full benefits of a product?

5.2.2 R&D

In each of its annual reports, Pfizer stresses out the importance of R&D in the overall success of this organization; however, one can also find a note stating the process is expensive

and unpredictable (“Pfizer annual reports 2019”). Furthermore, the company informs the readers in each of its reports that the specificity of the industry requires them to constantly update their drug portfolio (“Pfizer annual reports 2019”). Since annual reports are usually addressed towards shareholders and potential investors, the company is obliged to ensure that each stakeholder is aware of how the pharmaceutical industry operates. As described in the literature review chapter, there is no guarantee that a drug-in-development will ever reach the market and become profitable.

Currently, Pfizer is in control of nine R&D centers out of which seven are in the United States and two in the United Kingdom (“Pfizer R&D Locations”). In terms of R&D drug pipeline for each of the segments, as at 31 December 2019 Upjohn and Consumer Healthcare were in charge of their own R&D units, while Biopharma was supported by two internal organizations being Global Product Development and Worldwide Research, Development and Medical (“Pfizer annual reports 2019”). It is noteworthy that the current structure is a result of Pfizer’s decision to reorganize its R&D model to address each of the key segments in a more efficient manner (“Pfizer annual reports 2019”).

Table 5.2.2 shows that the R&D as a share of revenue has been rather stable in the 21st century amounting to approximately 12%-17%; however, there are certain factors that might not be visible at first glance. In the past 20 years company underwent three major acquisitions of its rivals, Warner-Lambert in 2000, Pharmacia in 2002 and Wyeth in 2009. In light of that information, why did the R&D spending remain on a comparable level to the one in 2003 if acquired companies also possessed substantial R&D resources? Of course, potential synergies could lead to a decrease in costs, but one could assume that post-acquisition R&D spending of two merged companies would have been significantly higher than the one of an individual organization. The R&D spending has not changed significantly since 2003 and it is

likely that the acquisitions were purely an attempt to address the imperfections of Pfizer's R&D model.

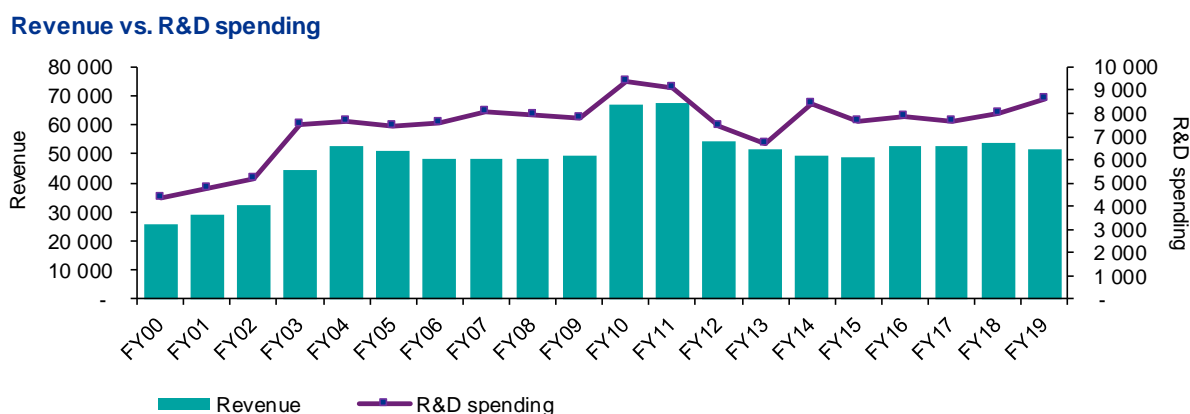
Table 5.2.2
Pfizer's revenue and R&D spending

Revenue and R&D spending										
USD'millions	FY00	FY01	FY02	FY03	FY04	FY05	FY06	FY07	FY08	FY09
Revenue	26 045	29 024	32 373	44 736	52 516	51 298	48 371	48 418	48 296	49 269
R&D spending	4 374	4 776	5 176	7 487	7 684	7 442	7 559	8 089	7 945	7 824
R&D as % of revenue	16,8%	16,5%	16,0%	16,7%	14,6%	14,5%	15,6%	16,7%	16,5%	15,9%
Revenue and R&D spending										
USD'millions	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19
Revenue	67 057	67 425	54 657	51 584	49 605	48 851	52 824	52 546	53 647	51 750
R&D spending	9 392	9 112	7 482	6 678	8 393	7 690	7 872	7 657	8 006	8 650
R&D as % of revenue	14,0%	13,5%	13,7%	12,9%	16,9%	15,7%	14,9%	14,6%	14,9%	16,7%

Note: The table was prepared based on information provided by Pfizer in Annual Reports 2000-2019

An increase in both sales and R&D spending visible in *Figure 5.2.2* appeared shortly after an acquisition of Warner-Lambert in 2000, Pharmacia in 2003 and Wyeth in 2009; however, the numbers either dropped or stayed on a comparable level within 3 years. The culprit may be the fact that each of the transactions concerned large organizations and stagnation likely resulted from inefficient integration of newly acquired companies. It is also important to mention that R&D accounted for 13%-17% of the revenue in the analyzed periods which is likely Pfizer's spending target. While setting such spending goals is quite rational, it should be considered that during the period following a transaction certain R&D operations might be a subject to cuts in funding in order to remain in the spending range.

Figure 5.2.2
Pfizer's revenue vs. R&D spending



Note: The figure was prepared based on information provided by Pfizer in Annual Reports 2000-2019

5.2.3 Management

For the purpose of this thesis, only the CEO will be described as it is the person responsible for the overall success or failure of an organization. CEOs have the final say in all major decisions and are the bridge between the owners and the company. In the case of Pfizer, the Company had four CEOs in the past 20 years which can be seen in *Table 5.2.3 A*.

Table 5.2.3 A
Pfizer's CEOs in 2001-2020

Chief executive officers in 2001-2020	
CEO	Tenure
Henry McKinnell	2001-2006
Jeff Kindler	2006-2010
Ian Read	2010-2019
Albert Bourla	2019-present

Note: The table was prepared based on information provided by Pfizer in Annual Reports 2000-2019

Interestingly, large M&A transactions seemed to shorten the tenure of CEOs to a certain degree as a new CEO was appointed soon after the acquisition of Warner-Lambert in 2000, and Wyeth in 2009. It is possible that a transaction of this type simply required new management to handle the post-acquisition integration of a new organization. In fact, it is a quite logical possibility as whenever two companies of that size merge, a complete reorganization of internal processes is needed to such an extent that a fresh perspective might be required. Another interesting trend concerns the remuneration the year after an acquisition. As can be seen in *Table 5.2.3 B*, the remuneration of CEOs experienced an increase in the years following each acquisition in 2000, 2003 and 2009.

Table 5.2.3 B
Pfizer's CEO compensation

CEO compensation										
USD*thousands	FY00	FY01	FY02	FY03	FY04	FY05	FY06	FY07	FY08	FY09
CEO total compensation	9 203	13 163	11 436	10 706	17 184	12 767	9 799	13 075	15 548	14 898
CEO compensation										
USD*thousands	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19
CEO total compensation	17 396	25 013	25 634	18 948	23 283	17 988	17 321	27 914	19 549	16 286

Note: The table was prepared based on information provided by Pfizer in Proxy Statements 2000-2019

Of course, the numbers should be analyzed with caution as there are many factors in play that may affect the total compensation but are either not available to the public or difficult to fully understand to individuals not associated with Pfizer. Nevertheless, the above remuneration serves as a good reminder of how vulnerable the remuneration of executives is to the performance of their organization. It is also important to remember that it is quite popular for large public companies in the United States to reward executives with equity, which distorts the real value of compensation. In fact, *Table 5.2.3 C* presents the composition of Pfizer's remuneration in 2019 with equity awards representing 66.3% of the total compensation. It appears that the shareholders of the company prefer to act preventively towards potential principal-agent problems and ensure that the compensation structure is tied to the well-being of company owners.

Table 5.2.3 C
Composition of Pfizer's CEO compensation in 2019

CEO's compensation in FY19	
USD'thousands	FY18
Base salary	1,200
Stock awards	6,744
Option awards	4,050
Non-equity incentive plans	2,520
Deferred income	984
Other compensation	788
Total	16,286
Equity as % of compensation	66.3%

Note: The table was prepared based on information provided by Pfizer in Proxy Statement 2019

As previously mentioned, the equity awards should be viewed with caution as the compensation is not an actual cash flow but rather the present value of company shares offered. Nevertheless, the numbers confirm that the remuneration is tied to the performance of the company to a certain degree.

Lastly, it appears that Ian Read's tenure was significantly longer as compared to his predecessors. According to Mikael Dolsten, the chief scientific officer, Pfizer strives to decrease its reliance on M&A transactions by launching a company-wide transformation of its

R&D core capabilities and Ian Read has been a significant piece of the jigsaw (Wright, 2019). Of course, it is difficult for an external observer to find the actual reason behind his long tenure; however, it is a factor worth keeping in mind. As previously described, there were no comparable acquisitions in the past ten years which should also be kept in mind. The case of Kindler and McKinnell, however, is significantly more complicated as their less-than-optimal decisions led to large operational inefficiencies. Their tenures were shortly described in the previous section.

5.2.4 Shareholders

As is commonly known, large international corporations rely heavily on its shareholders to finance their organization. For that reason, the owners are the most influential stakeholders and are capable of dictating the future direction of their organization. It is important to remember, however, that publicly traded companies are usually owned by profit-driven entities that are primarily focused on large return on their investment. In fact, it is a completely natural behavior as perhaps all investors wish to receive the largest possible payouts in the minimum amount of time. As *Table 5.2.4 A* presents, the top 10 largest shareholders comprise primarily asset management institutions which represent 31% of the total shareholders. Pfizer's ownership structure suggests that the executives are likely to be pressured to ensure satisfactory dividends and show stable revenue with long-term growth prospects. While it may seem as a simplistic approach on the investor side, shareholders would like to see either growing or stable revenues throughout the years (even if it is not exactly the true representation of a company) and that is what may drive executives to make less-than-optimal decisions. In its annual reports, Pfizer is quite clear about its commitment to increasing the shareholder value

Table 5.2.4 A
Pfizer's top 10 shareholders

Pfizer's top 10 shareholders as at 13.04.2020	
% of total shares	
The Vanguard Group, Inc.	7,9%
SSgA Funds Management, Inc.	5,3%
BlackRock Fund Advisors	4,9%
Wellington Management Co. LLP	3,5%
Capital Research and Management Co	3,4%
Geode Capital Management LLC	1,6%
Northern Trust Investments, Inc	1,3%
Norges Bank Investment Management	1,1%
T. Rowe Price Associates, Inc	1,1%
State Farm Investment Management	1,0%
Total	31,0%

Note: The table was prepared based on information provided by "CNN Money: PFE – shareholders"

As can be inferred from *Table 5.2.4 B* the company strived to keep dividend payouts at around 10% of revenue. Even though the acquisitions significantly influenced the company's cash flow, shareholders could still expect regular payments on a relatively comparable level. It suggests that shareholders are clearly one of the most important stakeholders for Pfizer and their well-being affects the overall strategy. As is commonly known, dividend payouts are a sign of good financial health which suggests that Pfizer promoted an image of a company pursuing sustainable growth.

Table 5.2.4 B
Pfizer's revenue and dividends

Revenue and dividends										
USD'millions	FY00	FY01	FY02	FY03	FY04	FY05	FY06	FY07	FY08	FY09
Revenue	26 045	29 024	32 373	44 736	52 516	51 298	48 371	48 418	48 296	49 269
Dividends	2 197	2 715	3 168	4 346	5 200	6 000	7 300	8 200	8 600	5 500
Dividend as % of revenue	8,4%	9,4%	9,8%	9,7%	9,9%	11,7%	15,1%	16,9%	17,8%	11,2%
Revenue and dividends										
USD'millions	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19
Revenue	67 057	67 425	54 657	51 584	49 605	48 851	52 824	52 546	53 647	51 750
Dividends	6 100	6 200	6 500	6 600	6 600	6 900	7 300	7 700	8 000	8 000
Dividend as % of revenue	9,1%	9,2%	11,9%	12,8%	13,3%	14,1%	13,8%	14,7%	14,9%	15,5%

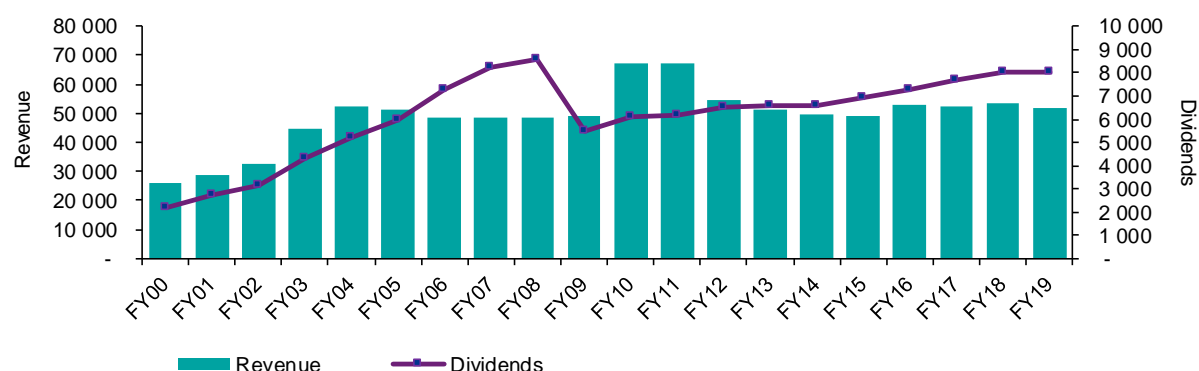
Note: The table was prepared based on information provided by Pfizer in Proxy Statements 2000-2019

In order to better illustrate the trends, *Figure 5.2.4* presents how dividends fluctuated in the periods under consideration. Interestingly, Pfizer paid out higher dividends following the merger with Pharmacia but lower dividends after the acquisition of Wyeth. It is likely that the significant difference is associated with the type of M&A transaction utilized. Mergers, as

the name suggests, concerns combining two entities into one, while acquisition is a more one-sided transaction. For that reason, it is quite possible that the mergers between Pfizer, Warner-Lambert and Pharmacia could result in higher dividends to partially offset the stock dilution. In contrast, it appears that the acquisition of Wyeth was not a beneficial transaction for shareholders in terms of dividends as the payouts were significantly lower despite larger sales. The explanation is in fact quite simple, since the transaction was primarily financed with cash, the cash outflow forced the company to significantly reduce the payouts. Given Pfizer's commitment to shareholders, it is possible that the Wyeth transaction was motivated by operational requirements and it was looked upon in terms of an investment for the future, rather than as a burden.

Figure 5.2.4
Pfizer's revenue vs. dividends

Revenue vs. Dividends



Note: The figure was prepared based on information provided by Pfizer in Annual Reports 2000-2019

Still, a simple analysis of revenue and dividends to conclude on the effect of M&A transactions on shareholders. The basic finance concept suggests that prior to an acquisition the share price of an acquiring company is bound to drop as it often pays premium for the target and is required to externally finance its operations. However, it should be expected that the company's value will significantly increase in the future. For that reason, shareholders are likely to benefit from such a transaction as the shares in their possession will be of higher value. In terms of actual dividends, it is important to remember that stock dilution following

mergers, mentioned in the literature review chapter, may significantly lower individual payouts.

5.3 Conclusion

In terms of the overall conclusion, it appears that the company strived to inorganically grow through large M&A acquisitions and failed doing so. While obtaining external R&D may be an efficient strategy, the post-merger integration of enormous corporations may prove to be a challenge and likely for that reason Pfizer noted the long-term joint R&D lower than the one of individual companies. Since the strategy of pharmaceutical companies is heavily based on replenishing drugs with upcoming loss of exclusivity, inorganic growth may put companies such as Pfizer in an unfavorable situation. As in the previously described findings, in-house drug development has not necessarily been Pfizer's specialization and overwhelming majority of products originated at external companies. For that reason, Pfizer is under a constant threat of losing significant sources of revenue which is addressed by engaging in M&A transactions. It is important, however, to notice the difference between purely synergy-based acquisitions regarding certain promising assets, and acquisitions driven primarily by financial goals such as protection of the rights to Lipitor. As described in the literature review chapter, sourcing R&D externally may prove to be a new reality for large corporations; however, a company still needs to possess the right R&D core allowing it to develop promising substances. It is possible that Pfizer lacked the right balance between external and internal R&D sources in 2000-2009 and Ian Read attempted to address it.

Based on the analysis, it appears that the decisions made in relation to the acquisitions were, to a certain degree, driven by managerial overconfidence and the belief that Pfizer is capable of being the world pharmaceutical leader. For instance, the acquisition of Warner-Lambert driven primarily by one drug was a bold strategy and not necessarily the right one. It is simply uncommon to see two large acquisitions of direct rivals within three years in one of

the largest industries in the world and even the greatest of minds may find it difficult to efficiently integrate these two organizations in such a short amount of time. Furthermore, since the management of companies acquired through mergers expect to receive comparable rank and status in the newly formed organization, potential dilution in ownership could be an issue. There is also the problem of shareholders that expect a healthy return on their investment, and since each acquisition requires their support, the expectations are bound to raise. As can be inferred from the analysis, the revenue has not change significantly since 2004 and that is likely not what the shareholders expected after expensive acquisitions of that scale. It does not necessarily mean that the management was the only factor. Shareholders played a significant role as well as they surely were tempted by the image of Pfizer becoming the largest player in the world pharmaceutical industry.

As previously described mentioned, Pfizer's CSO and CEO noticed the need to stop relying on large M&A transactions to such an extent. In fact, the company has been quite successful as Pfizer is still one of the largest pharmaceutical corporations in the world. They have utilized a more sustainable strategy and the M&A spending in the past 10 years, combined, amounted to less than one of the three key transactions described above. In addition, the drug portfolio is much more diversified which may reduce the number of strategic killer acquisitions such as the one of Warne-Lambert. It does not change the fact, however, that large M&A transactions are simply too tempting to not include it in the corporate strategy. As described throughout the chapter, it allows a company to address operational gaps and increase the overall value. It has to be remembered that in the past ten years the company strived to acquire Allergan, which would have been the largest transaction in the pharmaceutical industry ever concluded. The real question is, however, what would have happened had the regulatory body not stopped the enormous merger with Allergan? It

appears that such a shortcut is simply too hard to ignore whenever an opportunity arises, and Pfizer is likely to once more stray from the organic growth path in the future.

6. Case study - Bausch Health

As is commonly known, Bausch Health has been a quite controversial company in the past 10 years and the factors which contributed to their corporate strategy may not be as obvious as it may seem. In a similar manner to the previous case, the chapter begins with an overall description of the company's history which provides information regarding their development path throughout the years (6.1). The section is followed by a thorough analysis of Bausch Health's annual reports in relation to its M&A and R&D activity (6.2). The primary goal of these two sections is to understand the rationale behind such a unique strategy and the factors that contributed to its eventual failure.

6.1 Overview

It is important to note that Bausch Health's overview section is structured in a quite different manner. Since the company's history was not necessarily driven by any specific large transaction, a more general approach is utilized to understand the M&A strategy. For that reason, the section is broken into specific periods of time which provide insight into what factors drove the company throughout the years. Bausch Health has conducted a significant number of acquisitions in the past 20 years and an analysis of its history may prove to be an invaluable source of information regarding factors incentivizing M&A activity in the pharmaceutical industry.

6.1.1 Milan Panic's era: 1960-2002

Bausch Health was established in 1960 by a Yugoslavian refugee specialized in chemistry, Milan Panic (Arnold, et al., 2011). Initially the company operated under the name of International Chemical & Nuclear Corporation (ICN) and was primarily involved in sales

of chemicals and drugs (Arnold, et al., 2011). The company was known for its growth strategy based on small acquisitions of promising substances; however, the product which allowed the company to experience substantial growth was Ribarivin¹, an antiviral drug (Arnold, et al., 2011). The drug was later approved as a hepatitis-C therapy (Arnold, et al., 2011). Since the market for antiviral drugs was not in abundance at the time, ICN's drug proved to be a significant source of revenue until generics appeared (Arnold, et al., 2011). Nonetheless, the large growth did not come until the strategic decision to explore international markets ("ICN Pharmaceuticals, Inc."). Panic returned to his home country to acquire Galenika Pharmaceutical in 1991, a manufacturer and distributor, making ICN one of the first Western pharmaceutical companies to make an investment in the post-communist Eastern Europe ("ICN Pharmaceuticals, Inc."). Other substantial acquisitions in the 1990s involved a Russian pharmaceutical company, Oktyabar (which later became the largest pharmaceutical concern in Russia) as well numerous facilities in other post-soviet states and Western Europe, Africa, Asia and Australia ("ICN Pharmaceuticals, Inc."). Another large strategic move concerns a merger between ICN Pharmaceuticals, ICN Biomedicals, SPI Pharmaceuticals, and Viratek which created ICN Pharmaceuticals, Inc in 1994 (Hamashige, 1994). In 1996, the company's sales exceeded \$500 million ("ICN Pharmaceuticals, Inc.").

Still, the company was characterized by a poor leadership and Panic's decisions were not necessarily beneficial to the company. For instance, Panic bet on Ribavirin to such an extent that the company was involved in false advertisement claiming that his product is an efficient treatment for AIDS (which triggered intervention of Securities and Exchange Commission) ("ICN Pharmaceuticals, Inc."). There were also cases of misstatements in the financial statements ("ICN Pharmaceuticals, Inc."). Another controversy was associated with Panic's return to his home country to take the role of the Yugoslavian Prime Minister in 1992 (Cole, 2001). Interestingly, the CEO rewarded himself with a significant bonus despite the

Note¹: Interestingly, Bausch Health has recently initiated Virazole (Ribavirin) clinical studies in patients with COVID-19.

fact that the company's financial performance was unsatisfactory, and Panic acted as a public officer in Yugoslavia at the time ("ICN Pharmaceuticals, Inc."). However, his political career lasted only a year and resulted in a conflict with the Yugoslavian government leading to a significant loss in revenues for INC ("ICN Pharmaceuticals, Inc."). Despite all these controversies, INC was a relatively respected mid-size company in the 1990s with the revenues driven primarily by ribavirin and antibacterial drugs ("ICN Pharmaceuticals, Inc.).

Given the above-mentioned controversies, Milan Panic's era began to crumble at the end of 1990. Not only were the controversies associated with Milan's conduct damaging the company, but also shareholders showed signs of impatience related to unsatisfactory stock performance despite rapidly rising sales (Cole, 2001). Furthermore, Panic's misconduct was serious to such a degree that SEC sought to forbid him from running a publicly traded company ever again ("ICN Pharmaceuticals, Inc."). However, the factor that was simply too much to digest for shareholders was Panic's decision in April 2002 to create a spinoff out of INC's R&D department, traded on the New York Stock Exchange, which contributed to a \$33 million bonus (Reed, 2002, May 6). In June 2002, the shareholders won the battle with the founder of the company as he officially resigned from his position (Lubove, 2002). The company's problems, however, were not over as the organization was in a critical condition and all personal connections in Eastern Europe belonging to the former CEO were lost (Reed, 2002, July 29)

6.1.2 Transformation into Valeant Pharmaceuticals: 2002-2010

In 2003, soon after Robert W. O'Leary took over the CEO position, the company changed its name to Valeant Pharmaceuticals as a sign for potential investors that the company is committed to setting a new beginning (Arnold, et al., 2011). The transformation involved heavy restructuring efforts such as reorganization of its manufacturing and supplier networks as well as improvement of its financial condition through restructuring of debt

(Arnold, et al., 2011). These activities allowed the company to engage in the acquisitions of Amarin Pharmaceuticals, Xcel Pharmaceuticals and the drug Tamarin in the years 2004-2005 (Arnold, et al., 2011). Still, the restructuring activities proved to be insufficient as the blockbuster drug ribavirin (representing as much as 25% of the revenue) was about to face fierce competition from a newly approved generic version (Arnold, et al., 2011).

However, the event that could be defined as the catalyst for the controversial events 10 year later was likely the death of Robert W. O'Leary in 2006, the CEO (Arnold, et al., 2011). Since O'Leary was not only the face of transformation, but also a very experienced and respected personality in the industry, it can be said with certainty that his strategic approach must have been difficult to imitate (Arnold, et al., 2011). His successor, Timothy C. Tyson, was known to have a quite different strategy. In the years 2006-2007, the company decided to focus primarily on drugs that were in the late development stages as a cost-cutting strategy involving a significant decrease in the R&D spending, layoffs and closure of manufacturing and development facilities (Arnold, et al., 2011). Two years after the appointment, Tyson resigned from this position and was succeeded by J. Michael Pearson, a former head of McKinsey's global pharmaceutical practice (Arnold, et al., 2011).

Pearson's tenure was a very interesting one from the very beginning as his compensation was a unique combination of equity-based packages (Lublin, 2009). The remuneration was linked to the performance of the company to an extent unseen in public companies (Lublin, 2009). For instance, Pearson was required to buy at least \$3 million in stock, was not allowed to sell his shares for a specific period of time and could keep some of his restricted shares only if the year-to-year growth amounted to 15% through 2011 (Lublin, 2009). Consequently, the CEO's compensation structure likely contributed to an aggressive profit-driven business strategy. The first element of Pearson's plan was to decrease the R&D budget at the time by half (Rockoff, 2009), which is of course a practice not recommended in

the pharmaceutical industry. In fact, Valeant was convinced that R&D spending should be left for small biotech companies and the funds obtained through reductions in research are better spent on acquisitions (Rockoff, 2009). It appears that Wall Street was satisfied with the approach as Valeant's shares increased by 60% in 2008 alone (Rockoff, 2009). The second element of Pearson's plan was to limit the focus of the company to two pharmaceutical areas, dermatology (primarily because it is known to be a low-risk business) and neurology (Arnold, et al., 2011). For the next two years, the company utilized a relatively aggressive M&A strategy acquiring numerous companies to increase its offerings (Arnold, et al., 2011).

6.1.3 Merger with Biovail: 2010

Another key milestone in Pearson's strategy to aggressively grow through acquisitions was the reverse merger with Biovail which cost approximately \$3.2 billion, and was financed primarily by stock (Merced, 2010). As the name suggests, it was a reverse transaction which is characterized by the fact that the acquiring company is not the majority owner of the newly formed entity (at least on paper). As a consequence, Valeant was acquired by Biovail despite being a significantly larger entity. As is commonly known, the U.S. taxation system is one of the strictest in the world and the regulatory authorities heavily limit the potential growth. For that reason, the primary drivers behind the decision to pursue the merger were in fact the favorable tax conditions in Canada as well as Biovail's unique structure (involving intellectual property assets in Barbados) allowing Valeant to significantly reduce its cost base (Praet, 2014). Interestingly, the favorable tax treatment significantly contributed to its aggressive acquisition strategy as they simply had more capital than their competition based in the United States (Praet, 2014). The acquisition was also characterized by significant reductions in employment following the merger as the joint employment fell by around 25% (Arnold, et al., 2011). Furthermore, the company decided to close nine R&D sites as Valeant's goal was no longer to produce new products, but rather obtain promising revenue

sources through acquisitions (Arnold, et al., 2011). The shareholders were the biggest winners of this transaction, as Valeant and Biovail's stock value increased immediately after the announcement (Merced, 2010).

6.1.4 The fall of Valeant Pharmaceuticals: 2010-2016

The merger with Biovail was an impressive example of Pearson's financial-engineering skills; however, it was only the first step in Valeant's strategy to hack the standard approach of conducting business in the pharmaceutical industry. The company continued aggressive acquisition conducting over 100 transactions and companies in the years 2008-2015 (Surowiecki, 2019). The company's R&D at that time was as low as 3% ("Bausch Health annual reports") which is in fact in line with Pearson's negative approach towards in-house development. The cost cutting activities associated with newly acquired companies were also unseen in the industry as Valeant usually reduced the employment by half (Surowiecki, 2019).

Still, the strategic move that caused public outrage related to the so called "price skimming" which may be defined as setting artificially inflated prices until the point when other market players propose a suitable substitute. According to a study conducted by Deutsche Bank, as many as 54 drugs sold by Valeant experienced on average a 66% increase in price (Gandel and Reuters, 2016). Furthermore, an analysis of all U.S. drugs which experienced an increase corresponding to 300%-1200% in the years 2013-2015 found that half of the drugs originated from Valeant (Surowiecki, 2019). In fact, Valeant's strategy was quite simple as it was a variation of the well-known economic law – price elasticity of demand. The company would acquire seemingly undervalued drugs with a relatively weak competitive landscape and then increase prices by substantial amounts. A great example of this strategy was the acquisition of Nitropress and Isuprel of which Valeant immediately increased the price by 212% and 525%, respectively (Lorenzetti, 2015). Another great

example are the rights to Glumetza, Syprine and Cuprimine acquired in 2010 which saw an increase of approximately \$9 thousand, \$20 thousand, and \$25 thousand in the following years, respectively (Pollack and Tavernise, 2015). The problem was, however, that the inelastic demand resulted from life-saving characteristics of the drugs and patients simply could not stop their therapies. The strategy was incredibly beneficial to the shareholders (as well Pearson and his equity-based compensation) as the company's share price rose from \$50 in 2012 to as much as \$350 in 2015 (Williams, 2017). The growth of that scale is simply unseen among large corporation in the U.S. pharmaceutical industry.

Major issues associated with this strategy arose when generic drugs appeared on the market and Valeant no longer could justify the high prices. In order to protect its revenue sources, the company engaged in a scheme that allowed Valeant to work around competition (Williams, 2017). In 2013, the company contributed to creation of Phillidor, a specialty online pharmacy which concerned primarily distribution of Valeant's drugs and processed all insurance claims relating to prescriptions (Williams, 2017). Following the price increases, customers could simply contact Phillidor which would enroll them in a subsidy program that would cover the copayment (the amount that the insurer would not cover) (Williams, 2017). In other words, if the value of the prescription was \$10 thousand out of which 80% was covered by the insurer and 20% by the patient, Valeant would reimburse the patient's share which still left the company with a profit amounting to \$8 thousand. For that reason, it should not be a surprise that the substantial price hikes as well as the fact that the cooperation of Phillidor and Valeant showed signs of monopolistic practices, forced the regulatory bodies in the United States to intervene. In 2015-2016 the company was investigated by Securities and Exchange Commission, the U.S. congressional committee as well as influential politicians such as Hillary Clinton and Bernie Sanders (Gandel and Reuters, 2016). Valeant's stock

decreased by 90% (Gandel and Reuters, 2016), and the fall of the company became one of the most controversial cases in the history of the U.S. pharmaceutical industry.

6.1.5 Transformation into Bausch Health: 2016-present

In May 2016, Joseph Papa succeeded Pearson as the CEO of Valeant. As compared to Pearson, Papa was significantly more experienced in running a pharmaceutical company with 35 years of experience in this area (Thomas, 2016). The new CEO was welcomed by likely the biggest crisis in Valeant's history as the company's debt amounted to as much as \$30 billion dollars (Erman, 2018), the public image was completely devastated, and the years of inorganic growth significantly limited potential routes of development. For that reason, the management decided to change its name to Bausch Health, taken from Bausch and Lomb, the primary line of business at the time (accounting for 50% of the revenue) (Erman, 2018). In fact, the company's focus changed from being a purely pharmaceutical company to a more diverse organization manufacturing other medical devices and products as well (Gurdus, 2018).

6.2 Analysis: Bausch Health's Annual Reports

6.2.1 Key business segments

As can be seen in *Table 6.2.1 A*, the key segments in 2017-2019 were:

I) Bausch and Lomb, accounting for approximately 55% of the total sales in the last three years. The business line originates from a company of the same name acquired in 2013, which cost approximately \$8.7 billion (Grossberg, 2013). Based on "Bausch Health Annual Report 2019", the segment primary concerns ophthalmology branch with the main focus being eye lenses, vitamins and minerals, eye medications and other medical devices.

II) Salix, accounting for 18%-23% of the total sales in the periods under consideration. The segment originates from Salix Pharmaceuticals, a company acquired in

2015 which cost approximately \$14.5 billion (Soto et al., 2015). The sales in this line of business are primarily driven by gastrointestinal drugs accounting for \$979 million, \$1.2 billion and \$1.4 billion in 2017, 2018 and 2019, respectively, with the key drugs being Xifaxan, Glumeteza, Relistor, Trulance and Plenvu (“Bausch Health Annual Report 2019”).

III) Ortho Dermatologics, which has been one the key segments for more than 10 years. The segment concerns primarily dermatological products (such as gels) and devices (“Bausch Health Annual Report 2019”).

IV) Other Diversified Products, which to a large degree concern neurological drugs (one of the key segments historically) such as Syprine, Cuprimine (“Bausch Health Annual Report 2019”), known for significant price hikes in the past.

Table 6.2.1 A
Bausch Health’s key business segments in 2017-2019

Key business segments in 2017-2019			
USD'millions	FY17	FY18	FY19
Bausch and Lomb	4,795	4,664	4,739
Salix	1,566	1,749	2,022
Ortho Dermatologics	721	617	565
Other Diversified Products	1,642	1,350	1,275
Total	8,724	8,380	8,601
Salix	18.0%	20.9%	23.5%
Bausch and Lomb's share	55.0%	55.7%	55.1%

Note: The table was prepared based on information provided by Bausch Health in Annual Report 2019

Table 6.2.1 B below was prepared for comparative purposes in order to present how the company evolved in the past 10 years. Not to mention the key business segments in pre-21st century comprising primarily antiviral and antibacterial drugs. For that reason, definitely the most interesting finding is that currently the two largest segments originate from companies that were acquired within this time span. Since these revenue sources account for approximately 80% of the total sales, it is almost as if Bausch Health were a completely different company. While the company’s history is quite controversial, it is still interesting to see how inorganic growth through continuous acquisitions completely remodeled its identity.

Not only did the company substitute R&D for M&A, but also changed its core to such an extent that not much is left of the organization it used to be. To put it into perspective, the company's revenue used to be supported primarily by antiviral and antibacterial drugs.

Table 6.2.1 B
Bausch Health's key business segments in 2010-2012

Key business segments in 2010-2012			
USD'millions	FY10	FY11	FY12
U.S. Dermatology	221	576	1,159
U.S. Neurology and Other	657	822	794
Canada and Australia	162	340	544
Emerging Markets	142	726	1,050
Total	1,181	2,463	3,547

Note: The table was prepared based on information provided by Bausch Health in Annual Report 2012

In terms of the drug portfolio, an analysis in the image of the table prepared in the previous chapter is not needed. Pfizer, despite certain drawbacks, still relies on drug development to a large extent. As described in the overview, Bausch Health completely abandoned R&D in favor of M&A transactions which contributed to the fact that the company's portfolio is driven exclusively by externally sourced drugs. Furthermore, as described above, a significant share of the company's business segments no longer concerns strictly pharmaceutical drugs.

6.2.2 R&D

As can be inferred from *Table 6.2.2*, simple numbers from an annual report can be a powerful source of information regarding a company's history. For the purpose of this analysis, the past 14 years were analyzed as 2005 (and the former CEO's disease) may be treated as the turning point in the company's history. As previously described, the company used to be a quite successful pharmaceutical company revolving around R&D activities. The company, however, began moving in a completely different direction with Pearson's arrival in 2008. *Table 6.2.2* illustrates the trend perfectly as the sales (and M&A) began to increase while R&D spending began to drop. For instance, Bausch Health's sales in 2012 were approximately four times higher than they were in 2007; however, the R&D spending was

even lower than it was in 2007. Still, the most unbelievable finding is that the company concluded hundreds of transactions, but R&D remained on the same level through the years. It appears that the company must have completely disregarded all acquired R&D departments and either sold them or simply closed the facilities. In fact, a research assessing the value of the overall R&D lost as a result of Bausch Health's strategy would have been an excellent idea.

Table 6.2.2
Bausch Health's revenue and R&D spending

Revenue and R&D spending								
USD'millions	FY05	FY06	FY07	FY08	FY09	FY10	FY11	FY12
Revenue	824	863	872	715	789	1 181	2 427	3 480
R&D spending	114	105	98	70	48	68	66	79
R&D as % of revenue	13,9%	12,2%	11,2%	9,8%	6,0%	5,8%	2,7%	2,3%

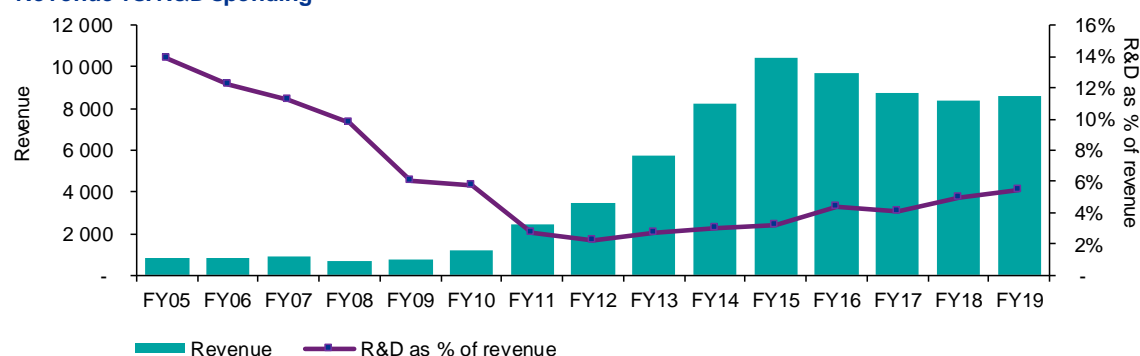
Revenue and R&D spending							
USD'millions	FY13	FY14	FY15	FY16	FY17	FY18	FY19
Revenue	5 770	8 206	10 447	9 674	8 724	8 380	8 601
R&D spending	157	246	334	421	361	413	471
R&D as % of revenue	2,7%	3,0%	3,2%	4,4%	4,1%	4,9%	5,5%

Note: The table was prepared based on information provided by Bausch Health in Annual Reports 2005-2019

In order to better illustrate the trends, *Figure 6.2.2* presents how much the company spent on R&D in relation to its revenue. It is a great confirmation of the events provided in the overview as a significant drop could be noticed in 2008 and then in 2011 after the Biovail merger followed by a steady 2%-3% range for the next 5 years. It appears that the company reached the limit of how little it could spend on the R&D to still operate in the pharmaceutical industry.

Figure 6.2.2
Bausch Health's revenue vs. R&D spending

Revenue vs. R&D spending



Note: The figure was prepared based on information provided by Bausch Health in Annual Reports 2005-2019

As mentioned before, pharmaceutical drugs were no longer the company's focus in 2019 which is likely the explanation why the company did not increase its R&D spending after Papa took the helm of Bausch Health. Still, it is worth mentioning that as at 31 December 2019 the company was in possession of 23 R&D facilities with 1,400 employees ("Bausch Health Annual Report 2019"). It does not change the fact, however, that the budget of this size is simply too slim to successfully navigate numerous clinical trials phases (as in the literature review). It is possible that the inorganic growth throughout the years simply took away the ability to successfully conduct the pharmaceutical R&D and Papa did not find it profitable to rebuild the research capabilities.

6.2.3 Management

In a similar manner to Pfizer, the management played an unmeasurable role in the company's controversial strategy. *Table 6.2.3 A* present the chief executive officers that were in charge of the company in the past 15 years. As previously mentioned, it all started with the death of O'Leary which completely disrupted the company's transformation following the controversy with the company's founder, Panic.

Table 6.2.3 A
Bausch Health's CEOs in 2002-2020

Chief executive officers in 2002-2020	
CEO	Tenure
Robert W. O'Leary	2002-2006
Timothy Tyson	2006-2008
J. Michael Pearson	2008-2016
Joseph C. Papa	2016-present

Note: The table was prepared based on information provided by Bausch Health in Annual Reports 2002-2019

In fact, researchers can easily notice certain trends in the years 2008-2016 by simply analyzing the remuneration of CEOs. *Table 6.2.3 B* presents the compensation of CEOs throughout the years while *Table 6.2.3 C* presents the compensation of Tyson, Pearson, and Papa in their last year of work. The numbers from the Proxy Statements, however, are shown just for indicative purposes as they do not reflect the real value of remuneration. The main

reason is that Pearson (as described in the overview) was compensated with the company's shares in various combinations as can be seen in *Table 6.2.3 C*. According to Milstead (2015), his cumulated shares amounted to \$3 billion which is an unbelievable amount for a CEO running a company of that size. This is because his fortune moved in parallel with Bausch Health's value, which, in fact, makes the company a bookish example of the agency theory.

Table 6.2.3 B
Bausch Health's CEO compensation

CEO compensation							
USD'thousands	FY05	FY06	FY07	FY08	FY09	FY11	FY12
CEO total compensation	2 754	4 973	3 840	9 767	4 755	36 710	6 113
CEO compensation							
USD'thousands	FY13	FY14	FY15	FY16	FY17	FY18	FY19
CEO total compensation	6 998	10 376	141 577	11 974	4 895	17 142	17 142

Note: The table was prepared based on information provided by Bausch Health in Proxy Statements 2005-2019

Table 6.2.3 C
Compensation of CEOs in 2007, 2015 and 2019

Tyson's compensation in FY07		Pearson's compensation in FY15		Papa's compensation in FY19	
USD'thousands	FY07	USD'thousands	FY15	USD'thousands	FY19
Base salary	894	Base salary	-	Base salary	1,500
Stock awards	311	Stock awards	140 305	Stock awards	10,287
Option awards	2,539	Option awards	-	Option awards	2,000
Non-equity incentive plans	-	Non-equity incentive plans	2 000	Non-equity incentive plans	3,240
Other compensation	95	Other compensation	773	Other compensation	115
Total	3,840	Total	143 077	Total	17,142
Equity as % of compensation	74.2%	Deferred equity award until FY19	308 874	Equity as % of compensation	90.6%
		Equity as % of compensation	99.5%		

Note: The table was prepared based on information provided by Bausch Health in Proxy Statement 2007

Note: The table was prepared based on information provided by Bausch Health in Proxy Statement 2015

Note: The table was prepared based on information provided by Bausch Health in Proxy Statement 2019

The shareholders implemented an extreme kind of equity-based compensation with safety clauses such as deferred remuneration (based on year-to-year growth) and required investments in the company's stock with the use of Pearson's private funds. While it is an excellent strategy to ensure that the CEO will prioritize the company's value, it also endangers the CEO's financial wellbeing and incentivizes. Not only was Pearson in danger of losing millions of his own funds invested in the company, but also the deferred compensation caused him to aggressively grow the company's value. In addition, the CEO definitely knew that the shareholders would have not hesitated to replace him had his performance been unsatisfactory. What the shareholders did not anticipate, however, was that Pearson would pursue legally questionable activities. As can be seen in *Table 6.2.3 C*, \$309 million was

available to him on the condition that the company experiences a year-to-year growth which only contributed to his aggressive acquisition strategy.

6.2.4 Shareholders

A business textbook would likely describe the board of directors (and by association, CEOs) as the hand of shareholders; however, it is not as simple as it may seem. As can be inferred from *Table 6.2.4*, the top shareholders as at 31 December 2019 were exclusively asset management companies (just like in the Pfizer's case). It is, of course, completely, normal and only represents the current standard among publicly traded companies. Since shareholders of public companies comprise primarily asset management companies, the relationship between executives and owners is simplified – investors want to see a great return on their investment. It is likely the case of Bausch Health as Pearson received specific key performance indicators (such as the ones in his equity-based compensation) to be achieved until an indicated date and it was up to the CEO's discretion how to proceed with the strategy.

Table 6.2.4 A
Bausch Health's top shareholders as at 31.12.2019

Bausch Health's top shareholders as at 31.12.2019	
% of total shares	
FIL Ltd	7,6%
Paulson & Co., Inc.	5,9%
VA Partners I, LLC	5,1%
Total	18,6%

Note: The table was prepared based on information provided by Bausch Health in Proxy Statement 2019

An interesting finding concerns the fact that Bausch Health has not been paying regular dividends. *Table 6.2.4 B* presents the only years the dividends were paid, with the largest one relating to the merger with Biovail. It is interesting as the pharmaceutical industry is usually characterized by stable dividends (for instance, Pfizer). Dividends are known to be a sign of good financial health providing assurance for investors. It is also difficult to define the Bausch Health as an organization in the “growing phase” as its strategy was based on continuous purchases and cash would be needed on a regular basis. For that reason, it appears

that manipulating the stock price is the only possibility for the shareholders to increase the value of their investment.

Table 6.2.4 B
Bausch Health's revenue and dividends in 2005-2020

Revenue and dividends in 2005-2020						
USD'millions	FY05	FY06	FY07	FY08	FY09	FY10
Revenue	824	863	872	715	789	1 181
Dividends	28	22	-	180	147	356
Dividends as % of revenue	3,4%	2,5%	-	25,2%	18,6%	30,2%

Note: The table was prepared based on information provided by Bausch Health in Annual Reports 2005-2020

6.3 Conclusion

Ironically, Bausch Health strived to mitigate the risk associated with R&D by constant acquisitions and in return the company only increased it. The company minimized its R&D spending to an uncommon level (2%-3%) in the pharmaceutical industry which resulted in a strictly inorganic growth strategy. As a result, lack of stable revenue sources forced the company to constantly look for interesting assets to acquire which of course were not unlimited. Bausch Health simply could not grow with its own internal assets. As a result, the company engaged in legally questionable strategies to ensure year-to-year growth.

The primary parties responsible for the situation seem to be the overly profit-driven shareholders and CEO. The aforementioned structure of Pearson's compensation as well as the fact that the company did not pay dividends significantly contributed to the inorganic growth strategy. There was no other possibility to profit off the company but by increasing the share price (which could be artificially inflated). It does not necessarily mean that the business strategy utilized was wrong – perhaps it would have succeeded in a different industry. The uniqueness of the pharmaceutical industry (such as the loss of exclusivity and the scale of public interest) makes it unwise to think that a drug may be marketed in the image of a smartphone. Price hikes may be acceptable in a smartphone industry; however, they definitely will not be in relation to life-saving drugs.

Interestingly, Bausch Health practically became an asset management company through its acquisitions driven purely by financial motives. The goal of M&A transaction was not to increase the efficiency of the company's operations, but rather omit the development process completely and acquire cut-and-dried revenue sources. Bausch Health started as a quite respectable mid-size pharmaceutical company and currently there is not much left regarding its old identity. Interestingly, the company attempted to outrun its controversial past twice (or even three times if one considers the Biovail merger) as INC and Valeant turned out to be a disappointment. The real question is, will Bausch Health rebuild its core capabilities and become a reliable company?

7. Cross-case analysis

It appears that a certain misperception regarding pharmaceutical companies being dedicated to a higher cause exists. Contrary to what might be a popular belief, modern pharmaceutical companies are not obliged to save the world. In fact, they are expected to make profits for their owners in a similar manner to other profit-driven industries. The case companies are a perfect example of this view as the primary purpose of each of the M&A transactions conducted by these organizations was to benefit them financially. While choosing specific acquisition targets, Pfizer and Bausch Health were motivated purely by the profit potential of drug portfolios with an example here being Lipitor in relation to the former, and Nitropress and Isuprel in regard to the latter. Furthermore, both companies engaged in numerous M&A transactions in order to quickly achieve an upward growth trajectory required by their shareholders. Since R&D can be acquired externally, what is the rationale for internal R&D? It is safe to assume that such a question among executives likely justified cuts in R&D departments. The problem is, however, that while the acquisitions increased the short-term value of their companies, the long-term wellbeing of their organizations was clearly negatively affected.

Of course, it does not necessarily mean that acquisitions in the pharmaceutical industry are not needed. As previously described, the U.S. drug approval process is an incredibly risky undertaking and corporations with their duty to shareholder value simply cannot rely on internal R&D. Both companies clearly suffered from loss of exclusivity (Pfizer with Lipitor and Bausch Health with Ribavirin) and M&A transactions seemed like the only viable solution at the time. In fact, such a behavior is quite justified. Companies such as Pfizer clearly cannot lose 25% of its yearly revenues as they would become unable to meet their yearly obligations (which is the bankruptcy equivalent). It appears that M&A itself is not the issue – the implementation of the strategy is. Both companies could have maximized their drug development capabilities by acquiring innovative companies for a rational price: however, they were driven by financial incentives and acquired often overpriced and less-than-optimal targets. Furthermore, they did not keep the right balance between internal and external R&D and became reliant on new acquisition to a large extent. However, there is only a limited number of companies available for sale and they are required to continuously conduct new transactions.

Interestingly, the cases of Pfizer and Bausch are quite similar in many aspects. Even though the exaggerated M&A-based business model of the latter has severely backfired in the recent years, it was a quite rational strategy and likely would have worked in a different industry. In fact, both companies utilized strategies popular in more commercial sectors, and they failed doing so. The cases also provide interesting insight into the debate regarding the effect of M&A on pharmaceutical companies. Is M&A harmful to the pharmaceutical industry? The answer appears to be neither yes nor no. Acquisitions may significantly increase the efficiency of large pharmaceutical corporations; however, only if the primary purpose is to gain operational synergies. As described throughout the research, profit-driven acquisitions may lead to potential cuts in research departments and unimpeded price increases

of prescription drugs. It is important to consider, however, that the thesis assumed the buy-side position, and it is not possible to state whether the sell-side companies benefited from such transactions. While further research is required to provide actual evidence, it is quite likely that substantial payouts associated with M&A transactions may incentivize smaller organizations to continuously increase the attractiveness of their drug portfolios. Furthermore, smaller companies may potentially benefit from exponential growth as they would obtain access to substantial capital as well as advanced product development and marketing know-how. In a perfect world, corporations would utilize M&A transactions in areas where smaller companies have the competitive advantage over their larger counterparts which would increase the overall efficiency. Problems arise, however, when pharmaceutical companies (such as Pfizer and Bausch Health) are driven primarily by factors such financial incentives or company value which lead to less-than-optimal decisions.

To conclude, it appears that the case studies confirmed the findings presented in the literature review regarding the main factors incentivizing pharmaceutical companies to substitute M&A for R&D. While Pfizer and Bausch Health took advantage of operational synergies gained from such transactions as well, they were primarily driven by the regulatory requirements, shareholders pressures and financial motives. In the eyes of executives, internal R&D simply appeared to be the least profitable path characterized by substantial uncertainty as compared to acquisitions.

Part IV

8. Conclusion in relation to the research questions

The purpose of the thesis is to understand the rationale behind substituting M&A transactions for internal R&D in the pharmaceutical industry. Furthermore, the goal is to assess if the strategy is sustainable enough that other companies in the industry are likely to follow. The study addressed the research questions by analyzing the history of each of the case companies as well as reviewing certain information found in their annual reports. Since the research is exploratory in nature, the findings should be treated with caution as they are primarily an overview of trends in the United States. Nevertheless, the analysis of the case companies may serve as a potential source of insight into what drives the U.S. pharmaceutical industry (since the U.S. companies dominate the world industry, it may also be applicable to other countries).

In terms of the first research question:

Why do certain companies in the U.S. pharmaceutical industry find it more beneficial to base their strategies on increased M&A activity instead of more traditional in-house drug development?

The key factors incentivizing pharmaceutical companies to abandon R&D in favor of M&A transactions identified during the writing process can be divided into three main areas which are **1) Maneuvering the regulatory requirements, 2) Shareholder pressures on management and 3) Financial motives**. They will be described in the sections 8.1, 8.2 and 8.3.

Lastly, the section 8.4 addresses the second research question which is:

Is the strategy sustainable enough that more companies can be expected to implement it as part of their long-term business model?

8.1 Maneuvering the regulatory requirements

As described throughout the thesis, the U.S. pharmaceutical industry is surely one of the most challenging business sectors to manage. Development of new drugs is not only expensive and difficult to arrange operationally, but also exceptionally risky. Even if a drug is successfully developed, patent expirations dates force companies to constantly look for another opportunity as they are bound to lose a significant source of revenue. In fact, this is exactly what happened in the cases of Pfizer (Lipitor and Celebrex) and Bausch Health (Ribavirin). In order to understand what drives the pharmaceutical industry in the United States, it is crucial to realize that each new drug is exclusive only for a predetermined period of time which means that certain strategies have to be implemented to smooth out the revenues throughout the years. Since the drug approval process is simply too risky to base the entire strategy on the R&D process (such as Kindler's disastrous decision to focus on two blockbuster drugs), a company is forced to source pipeline drugs through M&A transactions to ensure stable revenues.

8.2 Shareholder pressures on management

Based on the analysis of the companies, it appears that shareholders put pressure on management to ensure constant growth and a healthy return on their investment. In both cases, shareholders likely played a large role in the decision to pursue M&A transactions. For instance, Pfizer engaged in the largest acquisitions in history of the pharmaceutical industry to achieve growth that would have not been available organically. In the case of Bausch Health, the composition of Pearson's compensation linked his wellbeing to the company to such an extent that the CEO was practically forced to make less-than-optimal decisions. There is also the case of company value that is likely to increase following a transaction. This indicator was of utmost important for Bausch Health investors as it was the only possibility to make a profit.

The case companies simply favor M&A transactions over internal R&D as it is a more predictable strategy allowing them to maximize shareholder value.

8.3 Financial motives

Both companies were characterized by transactions driven, to a large extent, by financial motives. While it is not necessarily a surprise as it is likely one of the primary goals for the overwhelming majority of companies, pharmaceutical companies are likely to be held to a higher standard. Pfizer motivated its decision to acquire Warner-Lambert by potential loss of Lipitor, while Bausch Health simply acquired undervalued drug portfolios to later increase prices by large amounts. It appears that the two companies prioritized profitable activities and the acquisitions appeared to be the most promising strategies at the time. In fact, both Pfizer and Bausch Health were led by CEOs with more commercial experience and it should be expected that their strategies would imitate other industries. Internal R&D is to a certain degree a lottery and M&A transaction are a tool that allows a company to acquire cut-and-dried sources of revenue.

8.4 Sustainability

Regarding the second research question, it appears that prioritizing M&A transactions over internal R&D is likely to become a distinct characteristic of the pharmaceutical industry. Based on the analysis, it appears that decreasing revenues due to loss of exclusivity are an industry-wide problem and internal R&D activities are simply not sufficient to address it. For that reason, M&A transactions are a relatively simple shortcut that allows pharmaceutical companies to address their current needs and mitigate the risk. The cases suggest, however, that large acquisitions are not necessarily efficient and internal R&D capabilities are still an essential element of each company. It seems that the most efficient solution for large corporations is to specialize in late approval phases and only acquire drugs that are expected to be put on the market relatively quick. However, the above-mentioned factors incentivizing

higher frequency of M&A transaction suggest that companies may still make less-than-optimal decisions and, theoretically, end up in a crisis such as Pfizer in 2005-2012 and Bausch Health in the past five years.

To conclude, it appears that the strategy is sustainable to a large extent given that the right balance between internal and external R&D is kept. In fact, it appears that most of the largest pharmaceutical industries in the U.S. will have to engage in M&A transactions at some point to ensure that their drug pipeline is full. The analysis of the companies showed that the U.S. pharmaceutical corporations are primarily profit-driven organizations and risky activities such R&D simply do not meet the definition of stable business in the eyes of investors. For that reason, acquisitions will likely remain a preferred method of obtaining promising drugs.

9. Discussion: Going beyond the research questions

During the writing process certain fruitful and promising areas for future research were identified which will be described briefly in the following sections.

9.1 The effect of pharmaceutical M&A on the society

As can be inferred from the conducted research, acquiring R&D through M&A can be a quite beneficial strategy if certain balance between internal and external activities is kept. Furthermore, it is important to remember that relatively low innovation among large corporations is not necessarily an issue as there still are small and medium-sized enterprises which introduce new chemical substances. In a perfect world, large corporation would utilize their large funding to develop substances acquired from entities such as universities or simply smaller pharmaceutical companies; however, the actual business environment is often driven by less-than-rational motives. The issue is not how the case companies clearly put too much emphasis on M&A transactions and reduced their own core competencies, but rather how they damaged the overall innovation level in the pharmaceutical industry by cherry-picking

profitable drugs and discarding the rest. It is important to remember that each acquired company likely possessed drugs in its portfolio with limited potential to be profitable in the future but of the utmost importance to critically ill patients around the world. Further research in this domain may reveal the actual effect of M&A on the pharmaceutical industry and show whether large corporations contribute to the society being worse off.

To expand on the issue, academic researchers and regulatory bodies should analyze the micro and macro-economic consequences of strategies based on continuous M&A transactions. It can be safely assumed that there is a limit to how many companies with promising drug portfolios will be available for sale. What will happen to companies such as Pfizer once all available opportunities will be depleted? Based on the analysis of the case companies, it is not unrealistic to expect that their revenues would fall by as much as 50%. In terms of the macro-economic consequences, it may be interesting to investigate how M&A transactions affect the total innovation level in crucial segments, such as cancer or diabetes, and if certain restrictions should be introduced to limit consolidation in the pharmaceutical industry.

9.2 The implications of consolidation on COVID-19 crisis

Interestingly, the writing process began prior to the outbreak of COVID-19 and it is unimaginable how relatable the thesis has become to the current world situation. While analyzing the governments around the world struggle with the virus one question appears – is the world pharmaceutical industry as prepared as it could have been? It is a very relatable question as COVID-19 vaccine efforts are led by small and medium-sized enterprises such as German BioNTech and CureVac. Since large amounts of available capital do not necessarily convert to more innovative drugs introduced to the market, it is interesting to hypothesize how the world pharmaceutical industry would have looked like had it not been so consolidated. Of course, in order to answer such a question an extensive research would be needed analyzing

all acquired companies that could have potentially contributed to COVID-19 vaccine efforts but lost its R&D capabilities as a result of post-transaction integration.

In terms of the U.S. pharmaceutical industry, the scale of the problem is clearly visible on the news. For instance, it has been made public that the Trump administration attempted to persuade German CureVac to relocate to the United States. By doing so, the U.S. citizens would have been the first patients to have access to the vaccine once it is developed. Why does the largest pharmaceutical industry in the world need to rely on other countries to produce innovative drugs? In fact, the answer may be found in the analysis of the case companies present in the thesis. While the U.S. companies have mastered the commercial side of the industry, they are not necessarily the most efficient innovators in the world. Further research in this aspect should analyze why the U.S. pharmaceutical industry, despite its status as the world leader and substantial funding, is not necessarily winning the COVID-19 race.

9.3 Antitrust issues in the pharmaceutical industry

Due to the high complexity of the U.S. antitrust laws, the topic was not addressed in the thesis. However, the limits associated with the regulations in the currently binding law may prove to be a significant factor in how pharmaceutical companies proceed with their M&A strategy. As described throughout the thesis, the drug approval process as well as the loss of exclusivity looming over executives incentivize monopolistic behavior. For instance, branded drug manufacturers strive to prolong the exclusivity period by actively hindering generic competition (Fox, 2017). Furthermore, as in the case of Pfizer and Lipitor, pharmaceutical companies may engage in aggressive takeovers to protect valuable sources of revenues. The problem is, however, that the pharmaceutical sector is likely one of the most difficult subjects for antitrust policy due to its technological uniqueness as well its fundamental significance for the society. While certain behavior may be purely monopolistic, it is likely the regulatory bodies are forced to turn a blind eye to highly questionably

transactions in order to allow corporations (important from society's point of view) to continuously profit from their operations and deliver crucial drugs to patients.

Interestingly, the Pfizer and Allergan merger briefly described in the previous chapters failed to materialize due to new regulations introduced by the U.S. State Treasury. According to Gomes-Casseres (2016), the primary motive behind the merger was to significantly decrease taxes by relocating headquarters to Ireland (quite similar to the previously described Valeant and Biovail merger). While the purpose of the new law was to minimize tax inversions, it is safe to assume that the timing was likely associated with the merger which was poised to be by far the largest pharmaceutical acquisition in history. It is interesting that such a widely criticized transaction was prevented due to a potential decrease in tax revenues and not its status as a substantial threat to the overall innovation in the industry. Consequently, Pfizer was obliged to pay a break-up fee of \$150 million to Allergan. Interestingly, there were other successfully prevented mergers such as Staples and Office depot or Halliburton and Baker Hughes which were not approved due to their harmful impact on competition (Gomes-Casseres, 2016). Why was Pfizer's merger not subject to similar treatment? It likely stems from the fact that it was not a domestic transaction which falls under different regulations. Had the \$160 billion transaction concluded, Pfizer would have had the upper hand against its competition and likely dictated the direction of the U.S. pharmaceutical industry.

As can be inferred from the thesis, the pharmaceutical industry is simply incomparable to other sectors requiring tailored approach in relation to both, policy making and management strategies. While further research in this aspect is needed, it appears that the authorities should consider partially restricting M&A strategies by, for example, putting a cap on the total value of transactions or basing decisions primarily on the actual motives behind transactions (see Chapter 3 section 1). It is important to mention, however, that the antitrust

authorities are aware of the issue and slowly redesign their approach. For instance, as described in the previous chapters, the EU antitrust authorities intervened when Pfizer acquired Hospira by requiring that duplicate drug portfolios are sold to external parties. As a result, patients benefited from increased competition in this area. The business landscape is continuously changing, and public policy should closely follow to ensure that patients' rights are protected. It is especially important as the world pharmaceutical industry becomes increasingly commercialized and specialized legal departments allow corporations to successfully maneuver international antitrust laws.

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