Universiteit Utrecht

Kempen

Master Thesis

"Un-shelfing shelved assets to boost deal activity"

MSc Science and Business Management
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I. Management summary

The first quarter of 2022 has shown an unfavorable stock market environment for companies active in the life science and health sector. The Kempen Life Science & Health (LS&H) sector team of the investment banking department saw this reflected in a decreased deal activity. This, consequently, meant that the sector team was not measuring up the amount of deals they partook in the first quarter of the year prior. The stock market and all activities surrounding it are known for its endless opportunities and entrepreneurial environment. This means there is always room for business development and ways to be creative and work around external factors. The problem at hand was decreased deal activity and the goal was to increase deal activity. LS&H sector team is active in different types of deals, one of them being the sale and acquisition of assets. For life science companies these assets often come in the form of drugs. Many companies have drugs that they are no longer developing/ testing, otherwise known as shelved assets. If a company has shelved assets which it no longer plans to develop further, then they might be interested in selling said asset. This is where the LS&H team can step in and facilitate the process by reaching out to companies and inquire whether they are interested in selling or acquiring shelved assets from/ to another company.

This thesis explores the idea of facilitating deals as a possible form of business development. This was done by creating a theoretical framework of background information such as information on the life science stock market, the 'normal' drug developing process, the drug repurposing/ reviving process, and approaches for drug repurposing. This is followed by a quantitative and qualitative research where both the current and historic shelved asset landscape is represented. The quantitative research is in the form of a database that was created, where all currently shelved assets of life science companies were logged and analyzed. Shelved assets were admitted to the list based on a set of criteria and analyzed to gain insight in current trends and patterns. The qualitative research was a search into previous cases where a shelved asset played a central role. Examples of deals where the sale of a shelved asset led to a successful drug are described in this thesis to give some context to the possibilities and potential they hold.

The key take aways from the theoretical background were that the life science stock market and thus deal activity were down in the first quarter of 2022, as is mentioned at the beginning of this text as well. Furthermore, 'normal' drug development and clinical testing is extremely expensive and time consuming. For this reason, it might be interesting for companies to look into shelved asset drugs that has already been developed and been through some clinical trials. This shelved asset can be used for the intended disease it was developed for, in this case it will be referred to as reviving a shelved asset, or it can be tested in another disease, this will be referred to as repurposing a shelved asset. There are a few different approaches that can be taken to figure out which disease the repurposed drug might be effective in. The approaches can be divided into two types: computational approaches (data driven) and experimental approaches (research driven).

The theoretical background was followed a quantitative and qualitative research. The quantitative research was a database of current shelved assets from a number of drug developing companies. Several search methods were deployed to create a database that was as complete as possible in the given time and resources. The database consists of 73 shelved assets from 19 companies. Shelved assets

were only added to the list if they fit a predefined set of requirements. After analyzing the shelved assets, it became clear that most shelved assets were developed for oncology indications (diseases) followed by infectious diseases, neurology, and respiratory/ dermatology. This pattern mostly corresponded with the patterns seen in general drug development. Furthermore, it was shown that most of the shelved assets were in/ completed Phase I clinical testing. This was in line with what can be found in other studies and literature. Finally, the rationale given by companies for why they shelved their assets was analyzed. Shelved assets were shelved for one of four reasons: i) efficacy, ii) strategic, iii) change in risk-benefit profile, and iv) not disclosed (n.d.). For 73% of the shelved assets a rationale/ reason was provided. Most of the shelved assets (42%) were shelved for efficacy reasons, in other words the efficacy of the drug in the indication it was tested in was not high enough. However, such shelved assets do carry potential and can be repurposed in another indication. After efficacy, strategic reasons (22%) were the most prevalent reason for why an asset was shelved. If a company indicates that the shelving was based on a strategic reason, then that asset holds a lot of potential to be sold to and revived by another company. Furthermore, qualitative research was performed where summarized examples of deals revolving shelved assets were presented. The five examples display relatively unusual routes where the drug was shelved somewhere in development/ testing but turned out to be very successful upon completion. These examples show the power of shelved assets and the potential that can lead to great successes.

In conclusion, the combination of current and historical data shows that shelved assets are very prevalent and deals concerning shelved assets can be very successful. The main point of interest is however whether this approach could facilitate deals. After analyzing all the data, it seems that pro-actively proposing shelved assets as deal opportunities could benefit deal activity. The LS&H sector team is ideally positioned for this role as it is in contact with various drug developing companies and deployed for its knowledge and expertise on the market. If Kempen proposes and facilitates those deals, it is more likely that that company then also deploys Kempen for its financial advisory services. Recommendations for the execution would be to keep building the database and request more information on specific assets. Furthermore, educate the companies on the potential of shelved assets and drug repurposing, this can be done by presenting case studies of success stories. Additionally, highlight the benefits such as decreased costs, development time, and risk. However, mainly focus on non-Big Pharma companies as Big Pharma companies likely have their own instances or sales forces in place to take care of their shelved assets.

II. Introduction

II.I Context

Science and Business Management master students must follow a business internship as part of their master program. A business internship consisting of practical work within the field of business, which is completed by writing a report and giving a final oral presentation. The students are free to choose an internship of their interest. I realized during my bachelor's Biomedical Sciences that I found the materials and the subjects I was thought very interesting, however, the lab and the practical work was not very dynamic or exciting to me. Therefore, I decided to do the master science and business management at the UU. This steered me more towards business and a more corporate world. To find out where my true interest and passion was, I challenged myself to choose an internship that was very different from what I have done before. I quickly came across Kempen & Co and was drawn in by the level of professionalism and knowledge that this company had. I applied for an internship, and after a three-part interview process, I was accepted for an internship position. During this internship I was part of the Life Science and Healthcare (LS&H) sector team of the corporate finance division of Van Lanschot Kempen. The activities performed during this internship had to be translated into a research project which is what is presented in front of you right now.

II.II Problem definition

During my internship I was introduced to all the practices that surround investment banking. I noticed that investment bankers are, as one would expect, very dependent of the market and the deal activity. If the deal activity is low (deals can be defined as acquisitions, IPO's, and equity raises) then there are no deals for Kempen to collaborate on. During my internship in Q1 of 2022 the Life Science & Healthcare market was very quiet, which meant there were also less deals for the LS&H team of Kempen compared to for instance Q1 2021. Consequently, the LS&H team had to look at other ways to generate business. One way to generate business is by facilitating deals. This can be done by bringing companies that are willing to sell assets and companies that are willing to buy assets in contact with each other. This in itself is already one of activities that the LS&H team offers. However, instead of waiting for companies to come to Kempen, deals can also be facilitated by actively proposing shelved assets to companies to instigate deals. The problem at hand is decreased deal activity and the need for a type of business development that can generate business.

II.III Research questions

Creating deals can be done by instigating the sale of "shelved assets". In the Life Science field shelved assets defined as drugs that are in/ have fulfilled clinical testing phases but are dropped from further testing. This can be for several reasons which will be described later in this thesis. This thesis was written to further explore the idea of instigating the sale of shelved assets as a possible form of business development. In other words: "Is generating the sale of shelved assets a viable form of business development?". To give an answer to this question several sub questions were formulated: "**What companies have shelved assets?**", **"Why do companies shelve their assets?"**, **"Which clinical Phase are these shelved assets in?"**, and **"What is historical data for the sale of shelved assets?"**

II.IV Research methods

For this thesis two types of research were performed, quantitative research and qualitative research. These types of research generated insights into the potential of shelved assets and its prevalence, trends, and patterns.

Quantitative research

To gain insights into the shelved assets landscape a database was created where shelved assets were logged with its corresponding information. The shelved assets were selected based on a number of criteria. Furthermore, this data was analysed to increase the knowledge about the current status and trends of shelved assets.

Qualitative research

To answer the more qualitative questions, research into historical shelved assets was performed. In these examples previously shelved assets were sold and further developed/ repurposed. These examples give context to the process of un-shelfing drugs serve as inspiration for future deals.

II.V Thesis outline

This thesis aims to give a complete picture of shelved assets and its potential for business development and a reflection of my time at Van Lanschot Kempen. The thesis will start with some background on Van Lanschot Kempen, and in particular into the investment banking department. This is followed by a theoretical section to give some background on the stock market and shelved assets. Subsequently, the methods used for the research are explained followed by the results and analysis. Discussion points and limitations of the study are discussed and subsequently the conclusion and recommendations are given. This thesis ends with a self-reflection of the business internship.

III. Van Lanschot Kempen

III.I Introduction

Van Lanschot Kempen is the oldest independent financial institution in the Netherlands. It is a union of two specialist financial boutiques, who together have four centuries of experience in helping clients achieve their goals. Van Lanschot Kempen is an independent wealth manger with a strong position in the market. It provides private banking, investment management, and investment banking services to wealthy individuals and institutions. The company is currently headquartered in 's-Hertogenbosch, the Netherlands, but has offices in other major cities in Europe and the Unites States. The company is listed on the Amsterdam Stock Exchange (AMS: VLK) and as of 14/07/2022 its share price is €23,10 and its market capitalization is €934m[1].

III.II History[2,3]

In 1737 the foundations for what was to become today's listed wealth manager were laid by Cornelis van Lanschot. On 22 July 1737, Cornelis van Lanschot recorded in his *Ontfangboek* (order book) his first colonial trade purchases. He became a specialist wholesaler and retailer in colonial goods, which he bought from the Dutch East India Company. He was succeeded by his son, Godefridus van Lanschot, in 1767 who further strengthened and expanded the business. In the years that came after the company always stayed within the family and grew to what it is known as today. On 11 June 1999, Van Lanschot announced the intend to list on the Amsterdam Stock Exchange in order to improve access to the capital markets and boost brand awareness as well as emphasizing its independence. Later in 2004, Van Lanschot purchased CenE Bankier to help strengthen its position as the prime Dutch bank for individuals with a high net worth and their businesses.

In parallel with the establishment and growth of Van Lanschot, there was another organization that came into the world that would later join forces with Van Lanschot. In 1903, when the Amsterdam Stock Exchange at the Beurs van Berlage opened its doors and Arines Kempen and his younger partner Martinus de Lange (& Co) founded Kempen & Co as an independent stockbroker. The company started specializing in the trade of listed companies that operated in the Dutch East Indies. In 2007 Van Lanschot acquired Kempen & Co to bolster its position amid target clients: high net worth individuals, institutional investors, businesses, and entrepreneurs.

Near the end of 2013 Van Lanschot launched Evi van Lanschot, its online savings and investment solution. Evi van Lanschot was launched to create wealth not only for high net-worth individuals but for those who just started out on the wealth management market. In 2016 Van Lanschot acquired Staalbankiers' private banking activities to expand its assets under management and serve even more clients. A year later in 2017, shareholders approved of the name change of Van Lanschot NV in Van Lanschot Kempen NV. This was not only the introduction of a new name, but also a new brand and a new ticker symbol VLK (previously LANS). In that same year, 2017, Van Lanschot Kempen acquired UBS's Dutch wealth management activities to create a solid and differentiated offering for family offices, foundations and charities and ultra-high net worth private individuals. In 2021 Van Lanschot Kempen acquired Hof Hoorneman Bankiers as part of its growth strategy. Hof Hoorneman Bankiers is a Dutch

wealth manager with over €2bn in client assets. Later in 2021, Van Lanschot Kempen and Mercier Vanderlinden formed a partnership for its activities on the Belgian wealth management market. The partners complement each other with regards to client portfolios, networks, product offering, and geographical distribution. In 2022 Van Lanschot Kempen is focusing on forming a one brand strategy under al its branches and acquired companies.

III.III Organization structure

Van Lanschot Kempen is a large organization with 1,654 employees worldwide. It can be divided in different segments, activities, and brands. In figure 1 an organization chart is shown with on the top row the management board and beneath it their assigned responsibilities and the people in charge of those topics. As can be seen the member of the management board each have their speciality ranging from corporate to client management, investment strategies, digital, and operations. As can be seen the organization is organised in a centralized fashion, with very clear roles for each member and with subordinate roles defaulting to the guidance of their superiors.

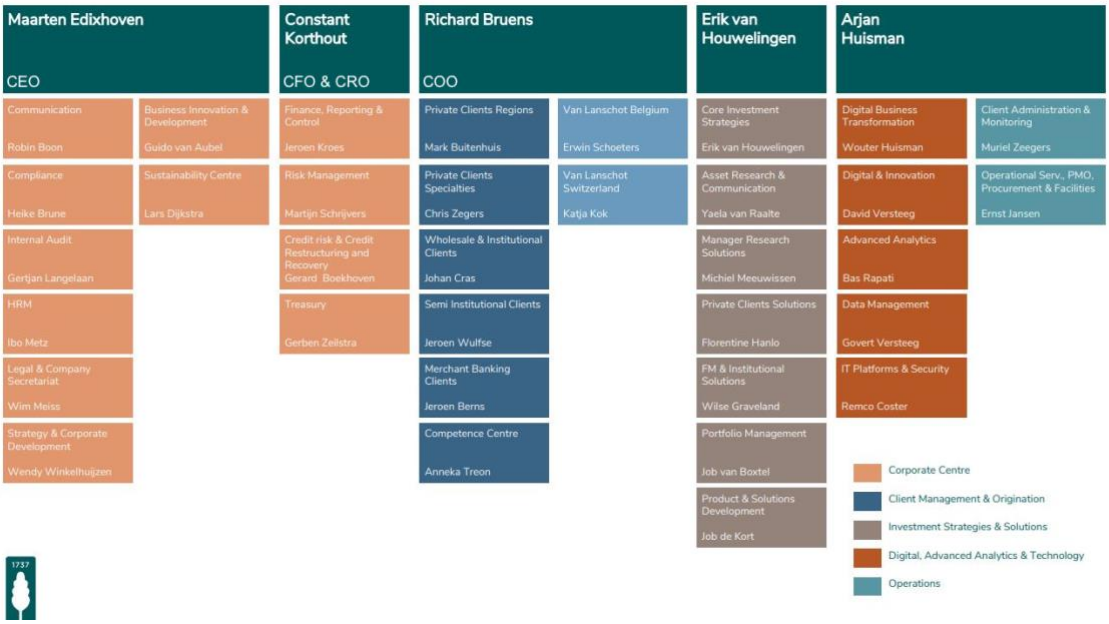

Figure 1: Organization chart of the management board and its assigned subdepartments[4]

III.IV Products & Services

As mentioned before, Van Lanschot Kempen can also be subcategorised based on its assortment of products and services. These products are housed in three different brands: Van Lanschot, Evi, and Kempen who carry out four core activities. Van Lanschot is a private bank that helps clients preserve and create wealth. Evi is an online savings and investment coach that guides new and experiences investors with their investments. Kempen can be further divided into two division: Kempen Asset Management and Kempen Merchant Banking. Kempen Asset Management is focused on long term investment strategies

Figure 2: Kempen Merchant Bank focus sectors and activities[21]

for institutional investors such as pension funds, insurance companies, banks and wealth managers, foundations and family offices as well as Van Lanschot private banking clients. Kempen merchant bank arm comprises of corporate finance and securities. Kempen corporate finance has a leading position in its sector niches, which can be seen in Figure 2, and offers specialist services in areas such as securities, mergers and acquisitions, capital market transactions and debt advisory services. Kempen Securities provides analyst research for listed companies and provides liquidity to international institutional investors for the same sectors as corporate finance is active in. Corporate finance employees have access to information about companies that is considered 'inside information', in order to keep this information away from employees working in securities there are both physical and non-physical boundaries. This is to protect the stock market and prevent insider trading. Insider trading is illegal and can lead to substantial penalties. However, by combining corporate finance, research, trading, and capital management Van Lanschot Kempen is an on-stop-shop for its clients. An overview of all the brands and services offered by Van Lanschot Kempen can be seen in Figure 3.

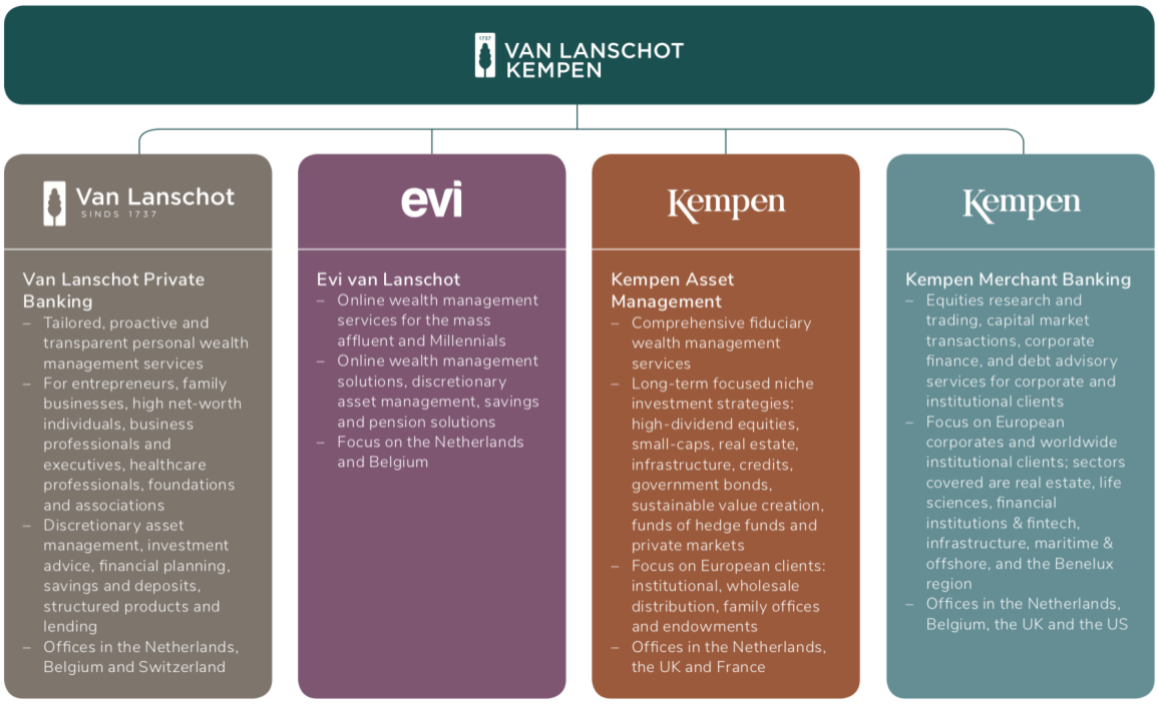

Figure 3: Van Lanschot Kempen sub-brands[5]

III.V Customers

The customers that Van Lanschot Kempen tailors to range from individuals to companies and institutions. Each department and brand have their own group of customers that they serve. Van Lanschot Kempen is a private bank that works with entrepreneurs, family businesses, high net-worth individuals, business professionals and executives, healthcare professionals, foundations, and associations. Van Lanschot the bank for wealthy clients who want to make long term investments and grow their wealth. Van Lanschot Kempen's other brand Evi is for individuals with smaller assets who are new or experienced investors in the Netherlands or Belgium who want online guidance with their investments. Between Kempen Asset Management and Van Lanschot Private Banking clients there is some overlap as clients from the Van Lanschot Private Bank are also important clients for Kempen Asset Management. However, Kempen Asset Management also services institutional investors such as

pension funds, insurance companies, banks and wealth managers, and family offices. And lastly, Kempen Merchant Banking, who's clients depend on which subdivision you look at. The clients from that the corporate finance department work with are European corporates and worldwide institutional clients who are active in the sectors real estate, life sciences, (fin)tech, infrastructure, and maritime & offshore. The Kempen Merchant Bank research (securities) department write detailed reports on a select number of public companies active in the same sectors as corporate finance specializes in. These reports can be accessed via a login portal and is behind a paywall. These reports are read by either individuals or institutions investing in those companies or companies active in those sectors themselves. And finally, there is the sales and trading (securities) department who work with public companies and investors active in the sectors mentioned earlier for both corporate finance and research. Figure 4 gives another overview on the types of clients that Van Lanschot Kempen works with, as well as which portion of the company works with that type of clients.

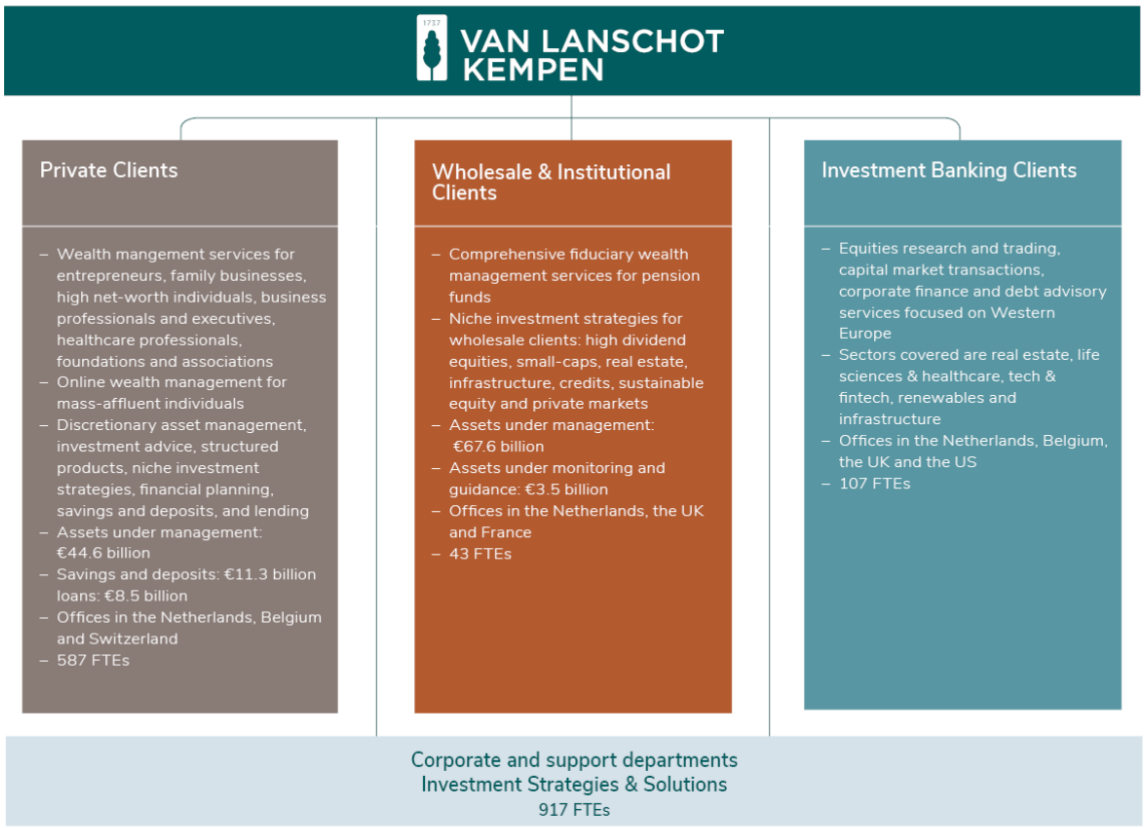

Figure 4: Van Lanschot Kempen client profiles[5]

III.VI Market analysis

The team (and corresponding market) that will be most relevant throughout this thesis is the Life Science and Healthcare sector team from the Kempen Merchant Bank Corporate Finance department. This team works with private and public companies active in the Life Science and Healthcare market. This market behaves different from other markets and that is mainly due to the way these companies become profitable. Companies in the LS&H market can be cash flow negative for a long period of time, even long after they are public. LS&H companies are (often) very innovative, which means that their product is new and needs excessive testing. Later in this thesis the road to commercialization for drugs and medical devices will be explained in more detail. For now it is important to realize that developing

drugs and medical devices is exceptionally expensive and can be anywhere between $314m up to $2.8bn[6]. This means that companies who want to develop such products need to raise a substantial amount of capital before they can bring their product to the market. The market that the LS&H corporate finance team operates in is a very specific market and is closely related to the market that the companies they work with are operating in.

To prevent confusion, current market analysis is based on the investment bank market and not on the LS&H companies' market. To analyse this market a PESTLE framework has been used, which stands for Political, Economic, Social, Technological, Legal, and Environmental. This PESTLE analysis can be seen in Figure 5. The PESTLE analysis is widely used as a tool to map out the environment that a company is in. Political situations that affect the LS&H investment bank industry are changes in taxes, the war between Russia and Ukraine, healthcare systems in different countries, and trade regulations. The economic influences are inflation, exchange rates, interest rates, and efficiency of financial markets. The social factors that influence the LS&H investment bank market are local culture, class cultures/ hierarchy and power structure, and the local willingness/ popularity to invest. Furthermore, the technological developments affecting the sector are the increased offering of online services, online meetings, and tools for data analysis. As for the legal influences there are increased capital requirements for European banks that they have to obey to by 2025 as well as sustainability regulations as per the Paris agreement 2050. And finally, environmental which consists of the COVID-19 virus outbreak (could also be placed under political with regards to the regulations), pollution and the climate crisis (which lead to the Paris Agreement), and shortages in commodities. All these aspects make up the macro environment that LS&H investment banks are in.

Figure 5: PESTLE analysis of the LS&H investment bank market

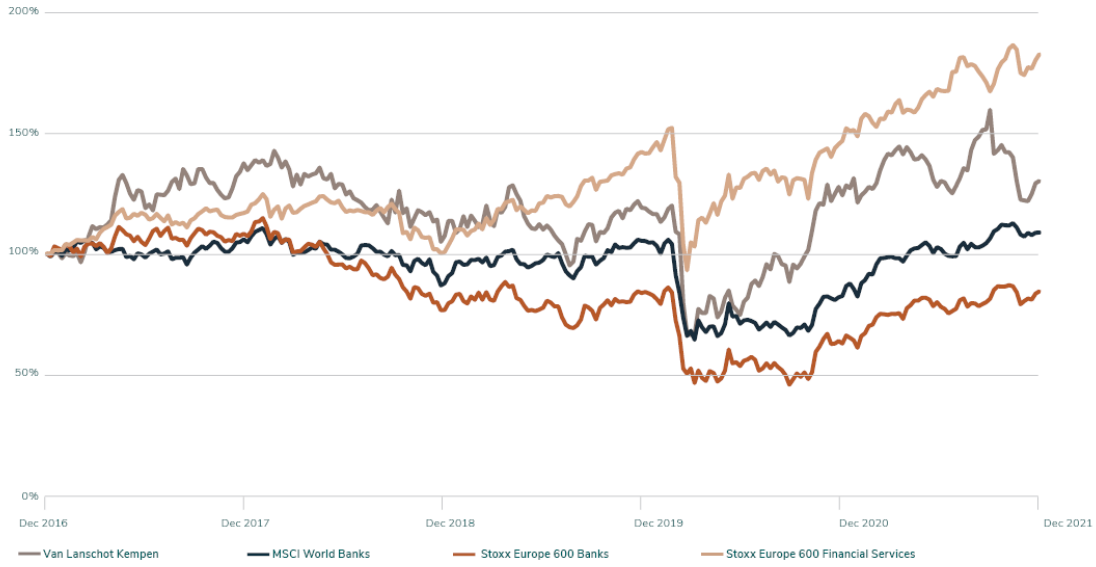

Figure 6: Movements in Van Lanschot Kempen's share price compared with industry indices[5]

III.VII Market development

The investment banking market, and especially the Life Science & Healthcare market is continuously developing. It is also greatly affected by external factors which became undeniably clear when COVID-19 hit as share prices plunged in the beginning of 2020. Figure 6 shows how COVID-19 greatly affected Van Lanschot Kempen and other banks in the market. Moreover, the market is greatly defined by its clients. Van Lanschot Kempen offers services and is therefore client orientated. Van Lanschot Kempen's clients, or the clients they wish to attract, are broad-ranging and their wishes are continuously evolving. In the beginning 2021 many clients were faced with vast amounts of liquidity from either the sale of their companies or increase in their share price. Clients in the Life Science market in particular experienced tremendous surges in their share price as this market became very hot with new gained attraction due to the COVID-19 vaccines and medicines. However, later in 2021 and beginning of 2022 business has slowed down due to inflation, rising gas prices and the war in Ukraine. However, investors, funds, and SPACs hold have a lot of fire power ready to invest any moment now. It will therefore only be a matter of time before business picks up again.

III.VIII Main competitors

Van Lanschot Kempen is active in a number of fields and has therefore, as a whole, many competitors. When we zoom in on the Kempen Corporate Finance Life Science & Healthcare division we can identify the following competitors: Jeffries, Carnegie, HC Wainwright, SVB Leerink, JP Morgan, Morgan Stanley, BofA Securities, Bryan Garnier, and DNB. These are all investment banks who are active in Europe and work with Life Science and Healthcare companies. Figure 7 shows the deal activity of Kempen & Co. Based on its equity capital markets activities in Europe in 2019-2021 Kempen & Co can be identified as the investment bank who participated in the most deals.

	Kempen & Co	Jefferies	Carnegie	HC Wainwright	SVB Leerink	JPMorgan	Morgan Stanley	BofA Securities	Bryan Garnier	DNB
# of Deals	47	42	35	27	26	25	24	23	23	23
# of IPOs	12	10	3	5	11	6	9	12	3	3
# of Follow-ons	35	32	32	22	25	19	13	11	20	20
Total value (€bn)	6.1	5.9	1.8	2.3	3.7	7.2	8.4	8.4	1.8	1.0

Figure 7: League table of banks in ECM transactions by European Life Sciences corporates 2019-2021

III.IX Financials & Shareholders

2021 was a strong financial year for Van Lanschot Kempen, which resulted in a profit of €143.8m which allowed them to propose a dividend of €2.00 per share for 2021. Figure 8 shows the key financial figures of 2021, full financial results can be found in Appendix A. The increase in net result compared with 2020 is due to several factors: (i) growth in assets under management, (ii) book

Key figures	2021	2020
Net result (€ million)	143.8	49.8
Dividend per share (€)	2.00	0.70
Efficiency ratio, excluding special items (%)	68.9	85.7
CET 1 ratio (%)	23.7	24.3
Return on average CET 1 based on underlying net result (%)[1]	15.7	4.4
Balance sheet total (€ billion)	16.3	15.1
Loan portfolio (€ billion)	8.9	8.4
Client assets (€ billion)	131.1	115.0
Assets under management (€ billion)	112.1	99.0
Employees (FTEs at year-end)	1,654	1,564

Figure 8: Key financial figures Van Lanschot Kempen

profits and valuation gains led to a substantially higher income, and (iii) slight negative performance structured product activities.

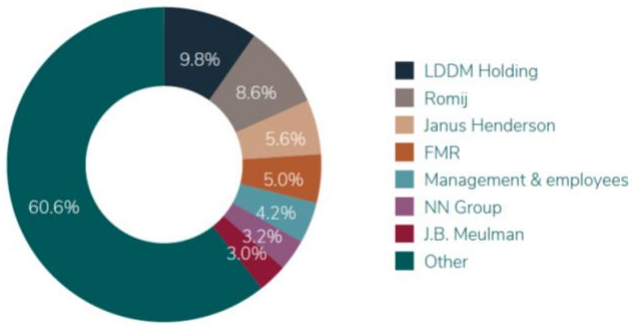

Figure 9: Van Lanschot Kempen depositary receipt holders

In 2021 there were some changes in the shareholder base of Van Lanschot Kempen. APG Asset Management, Reggeborgh and B.H.F. ten Doeschot sold (part of) their take and Romij and J.B. Meulman became new shareholders. Shareholder structure as of end of 2021 is shown in Figure 9.

III.X Strategy

Van Lanschot Kempen strategy is based on 5 pillars. The pillars can be seen in Figure 10 and have been created to be a leading player in their relevant markets and geographies. The first one is to accelerate growth organically and inorganically, by acquiring companies for synergies and increase scale. Since 2015 Van Lanschot Kempen grew through 6 acquisitions/ partnerships. Their second strategy pilar is to advance through digitalisation and advanced analytics, to improve service and productivity. However, digital is never at the expense of the personal as they let the client chose whether they want to communicate face-to-face, online or by phone. The next pillar is to achieve their sustainability ambitions. Since 2021 they have introduced three themes through which they want to make an impact: climate and biodiversity, smart and circular economy, and living better for longer. The following strategic pillar is to act as one, to leverage their full potential. And finally, to attract, develop and retain the workforce. By investing in their people so that they can fully embrace both sustainability and technology.

Figure 10: Van Lanschot Kempen strategic pillars

IV. Theoretical section

IV.I Life science stock market

This thesis is based upon the Life Science & Healthcare sector team at Kempen. This chapter gives a theoretical background into the life science stock market and its development over the years. The life science stock market behaves rather different than other stock markets. This is because the life science companies behave different than other types of companies. Life science companies usually take a long time to become profitable and often go public even before they turn a profit. This is because their product (a drug or medical device) needs to go through several, costly, and extensive rounds of testing before it can reach the market. This process will be explained in more detail later. Life science companies need substantial funding to finance the development and testing of their assets. Due to strict safety and efficiency regulations a lot of drugs do not reach the market, which further piles on the expenses for one successful drug. However, if they do reach the market, they are often very profitable and will generate high revenues. This makes investing in life sciences companies a very high-risk practice, however there is also the possibility of a high pay off. Life science investors, more than other investors, look at how much a company can be worth in the future as opposed to what it is worth today. The expected future value of a company is greatly influenced by many external factors. As can be seen in Figure 11, the Nasdaq Biotechnology Index (life science stock market) experienced high growths but also steep declines in the past 12 years compared to the general markets. These fluctuations can be attributed to internal and external events. An example of an external event is the recent COVID-19 outbreak. This first caused a great decline during its onset March 2020, as it did in many other markets. However, this quickly turned around when (Big) Pharma companies developed much needed vaccines, which resulted in a substantial upsurge of their share price. This increased the popularity of investing in life science companies, which is represented by the peaks seen in the graph after Q2 2020. However, in the last few months (Q1 2022) the life science market is not seeing a lot of action and share prices are dropping. This has great implications for both life science companies and for the companies whose

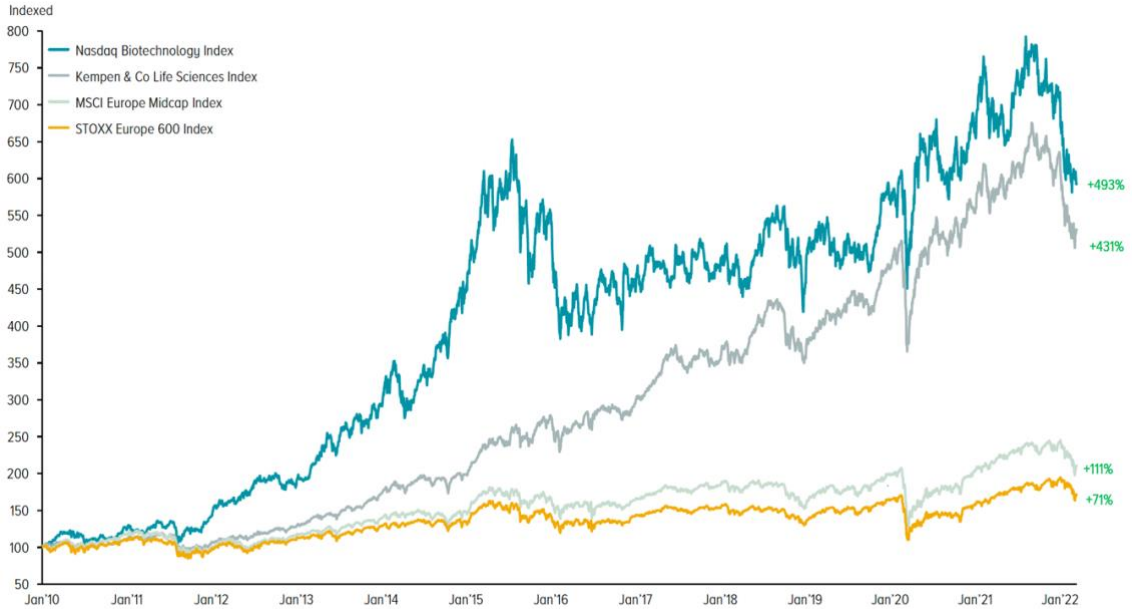

Figure 11: Indexed performance of life science stock and general markets over 12 years (Source: Kempen Analysis - Bloomberg)

business is built around life science company deals, such as the Life Science & Healthcare sector team at Van Lanschot Kempen.

IV.II Life Science & Healthcare sector team

The Kempen corporate finance department has several sector teams, among which the Life Science & Healthcare (LS&H) sector team. This team was briefly discussed in the Van Lanschot Kempen chapter, but in this chapter, we will dive more into the responsibilities and services offered by this sector team. The LS&H team offers financial and advisory services. They are in contact with LS&H companies and investors and offer (financial) advice on deals. These deals include capital raises, initial public offerings, mergers & acquisitions, and debt advisory. When a LS&H company is planning to instigate a deal in any of those domains, they often enlist the help of an investment bank to guide this process. But it also works the other way around, investors can also come to Kempen if they for instance are looking for investment opportunities that fit their investment portfolio. This means that Kempen has a unique position and complete overview of the market and its players. They are often in contact with both investors and companies to discuss their current status and future plans. However, Kempen's revenue mainly comes from deals or if they are working on a deal where they can install a retainer. The number of deals is greatly depended on state of the market. The LS&H team does a lot of preparatory work that is not for a direct profit but works towards creating credibility for the team's knowledgeability and to facilitate deals. If deal activity is low, the LS&H team must look even more at opportunities to generate or facilitate deals.

IV.III Drug development and clinical testing

Life science companies that develop drugs go through several drug development stages and clinical testing Phases. The 'standard' road from idea to market is to start with the development of a drug. This is done by the research and development (R&D) department of a company. Developing a drug is very expensive and companies often dedicate a large portion of their capital to R&D. Once a promising compound (drug) has been identified, it is tested and optimized *in vitro* (pre-human testing). If all tests show good results and the FDA (US) or EMA (Europe) give their approval, then the drug can be tested in humans. The FDA and EMA are regulatory bodies that assure the quality of newly developed drugs and extensively test new drugs that wish to enter clinical testing and eventually the market. Once they give their permission a drug can enter the so-called clinical testing phase that is subdivided into three Phases. Phase I often consists of 20 to 100 healthy volunteers or people with the disease/condition and is focussed on assessing the safety and dosage of the drug. Phase II can consist of up to several hundred people with the disease/ condition with the purpose of assessing efficacy and side effects. If the drugs

Phase	Participants	Length	Purpose	% Drugs that move to next phase	Cost
I	20 – 100 healthy volunteers or people with the disease/ condition	Several months	Safety and dosage	70%	USD 1.4 – 6.6 million
II	Up to several hundred people with the disease/ condition	Several months – 2 years	Efficacy and side effects	33%	USD 7.0 - 19.6 million
III	300 - 3,000 people with the disease/ condition	1 – 4 years	Efficacy and monitoring adverse reactions	25% - 30%	USD 11.5-52.9 million
IV	Several thousands people with the disease/ condition	-	Safety and efficacy	-	-

Figure 12: Overview clinical phases and corresponding costs[22,23]

are successful in Phase I and II and meet their primary endpoints, then a drug continues to Phase III. Primary endpoints are specific predefined values and outcomes that the drugs must induce in the patients in order for the trial to be successful. Phase III consist of 300 to 3,000 participants with the disease/ condition and is focussed on the efficacy and monitoring adverse reactions. If Phase III trials are also found to be successful, then a drug can be filed for registration and approval for the market. This has to be done by the local regulatory body (FDA or EMA). When a drug is approved and released on the market, a Phase IV study can be conducted to further test the safety and efficacy of the drug. In Figure 12 you can see an overview of all the Phases and the percentage of drugs that go from one phase to the next. The U.S. National Institutes of Health (NIH) estimates that 80% of all drugs that enter clinical testing never reach the market[7]. As can be seen in Figure 12 there are many drugs that do not continue from one Phase to the next, which is not always due to safety issues. An article published in Nature stated that, between 2013 and 2015, only 24% of drugs in clinical trials were stopped due to safety issues[8]. More recently Yale published an article where they mentioned that "a lack of efficacy" and "strategic business decisions" were the top two reasons given for abandoning drug developed[9]. If a drug is removed from clinical testing it becomes a shelved asset. Shelved assets that are shelved due to strategic or efficacy reasons might be interesting for other companies to pick up and further develop.

IV.IV Repurposing/ reviving shelved assets

Shelved assets are, as mentioned above, drugs that are for some reason no longer in development/ clinical trials. If the drug shows a good safety profile but lacks efficacy in the primary indication, a new use for the drug can be found in another indication. This is also referred to as redirecting, repurposing, repositioning, and reprofiling of a drug. A company can choose to repurpose a drug themselves or they can sell the drug to another company who can then further develop and test the drug. Often times when a company shelves their asset (drug) they do so because of a strategic business decision. In this case there are often no efficacy problems, however, the company has decided that it will no longer develop and test the drug. This could for instance be because the company is prioritizing other drugs or if the company ran out of funds and can no longer afford the development and clinical trials. Either way, a strategically shelved asset can be sold to a company that wants to further develop and test the drug and has sufficient funds to do so. The sale of shelved asset can benefit multiple parties, it benefits the seller who has a financial gain, the buyer who has potential financial gains in the future if the drug is successful, and financial advisors (like Kempen) and other collaborators working on the deal. Marketed drugs can also be repurposed; however, this thesis focuses only on the repurposing of drugs that are not yet marketed.

The repurposing of drugs is based upon the scientific principle that drugs often have more than one target and can interact with multiple pathways and can therefore be effective in more than one indication[10]. Drug repurposing is not a new concept, some very well-known drugs are repurposed drugs. For instance, Aspirin which was created for the treatment of Analgesia revealed to be very potent for the treatment of colorectal cancer. This was also the case for Rituximab that was originally developed to treat several types of cancer but is now widely used rheumatoid arthritis. And maybe one of the most well-known and older examples is Sildenafil (Viagra) that was originally developed to treat Angina but is now used to treat erectile dysfunction[11]. In other words, drug repurposing is not new, but it has been gaining popularity in recent years when the world was struck by the COVID-19 virus. People were in urgent need of a cure, and drugs had to be developed fast. To combat this time limit scientist turned to drugs that had already been developed for other indications and looked if they were effective in patients

suffering from COVID-19. This did not only safe them time, but also money as these drugs had already been developed and tested for safety, both very costly processes. Drug repurposing can not only be useful in a time of crisis where there is an urgent need for a drug, but it can also be used to combat rare diseases. The expected profits for a drug developing company are dependent of the patient population of the drug they are developing. In other words: "How many people will need their drug?". Understandably, companies will go for diseases that have large patient populations and consequently there are less drugs for rare diseases. However, this is where drug repurposing/ reviving can help by decreasing the costs as the drug is already developed (and tested) and only needs to be tested for efficacy in the rare disease. This makes it more attractive for a company to bring a rare disease drug to the market.

IV.V Approaches for drug repurposing

It might sound simple to 'just repurpose' a drug to be used in another indication, however, there is quite some work that goes into drug repurposing. As mentioned above, a drug often has more than one target. However, the challenge is to find what these targets are. This can be done by two types of approaches: computational approaches and experimental approaches (see Figure 13). These drug repurposing approaches are explained in a review written by Pushpakom *et. al.* and will be described shortly in this thesis[11].

Computational approaches, shown in blue, analyse data such as gene expression, molecular/ chemical structure, or electronic health records. Together with all the data that is known about diseases and previously tested aspects of drugs the computer can analyse and compare all the data. However, this approach relies heavily on the data available about a drug, disease, and gene expression. Nevertheless, computational approaches, as described in the review by Pushpakom *et. al.,* have brought forward a number of successfully repurposed drugs.

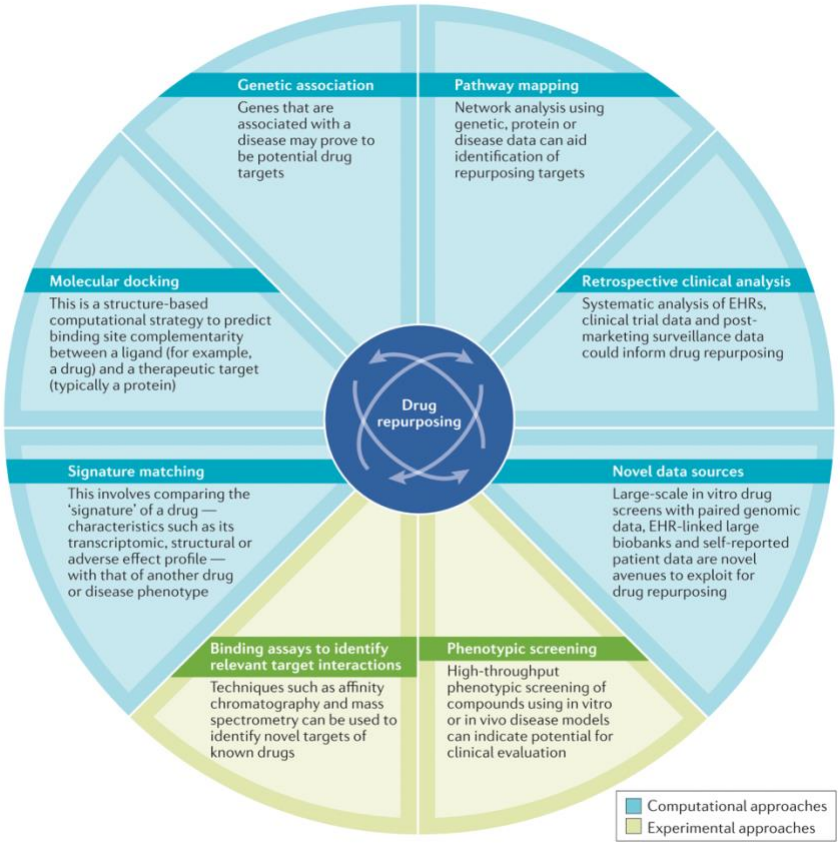

Figure 13: Approaches used for drug repurposing [11]

Experimental approaches, shown in green, refer to approaches that gather information by performing tests and experiments. Which is different from computational approaches where no new data is

gathered. Experimental approaches shine light on the drug and through different experiments increase the understanding of a drug and the possible fit for another indication.

Drug repurposing is however never without risk, even after repurposing and testing a drug can still fail. Furthermore, there are some patent and intellectual property issues that might present itself when dealing with drugs that are already marketed. Therefore, this thesis only focuses on drugs that are not yet marketed and no longer in development/ testing for other indications.

V. Method

To get a clear image of the shelved asset landscape different types of data collection were performed. Both quantitative and qualitative data were gathered to most accurately answer the question whether facilitating the sale of shelved assets is a viable form of business development. To analyse the current landscape a quantitative method was used where data was logged in a database and subsequently analysed. And to get insight into previous deals qualitative data was gathered about those deals.

V.I. Data collection shelved assets database (quantitative)

In order to gain insight and knowledge about the shelved company landscape quantitative research was performed where several approaches/ sources were used to gather data on companies and shelved assets. The drug developing company landscape knows a few large players who are referred to as Big Pharma. Big Pharma companies are companies that are on a list of the biggest and most influential pharma companies. Companies that are not on that list will be referred to as non-Big Pharma. There are a few different variations of this list, however the companies that are Big Pharma according to Kempen are: AbbVie, Amgen, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Glaxosmithkline, Johnson & Johnson, Merck, Novartis, Pfizer, Roche, Sanofi, and Takeda. Collecting data on the shelved assets of Big Pharma companies was done by analysing their annual and quarterly reports. Often, but not always, companies announce which drugs are still in development and which drugs are no longer in development and are thus shelved assets. Another source of data was controlled vocabulary and free text terms related to discontinuing, terminating, shelving assets which were used to search Google, Pubmed, FierceBiotech, and other biotech blogs/ analyst websites. Data collection for non-Big Pharma companies was done in a similar way, however, this was more focussed on biotech blogs and free text searches as reading all the reports of all the non-Big Pharma companies would have been impossible. Additionally, companies that indicated they were shelving an asset in meetings with the LS&H team were also added to the database. This information came from a list supplied by the LS&H team which also included other shelved assets from their searches. This list was filtered based on the hereafter mentioned predefined criteria. Study inclusion was limited by a number of criteria: i) the drug had to be shelved in 2020 or later, ii) the drug could not already be marketed for another indication, iii) the drug was not in development/ clinical trials for another indication, iv) the rationale for shelving the asset was not related to toxicity issues, and v) the drug had completed at least a Phase I clinical trial. The data that was extracted included the company name, drug/asset name, mechanism of action/ target, technology, therapeutic area, indication, development stage, NCT number, company rationale, and the source. The company rationale was condensed to one of four options: i) efficacy, ii) strategic, iii) change in risk-benefit profile, and iv) not disclosed (n.d.).

V.II Analysis

Data was analysed using Microsoft Excel, no statistical tests were performed as this was not the purpose of this research. The figures and analyses mainly served to visualize and explain the data gathered.

V.III Data collection previous deals (qualitative)

In addition to the quantitative research this thesis also contains qualitative research. This qualitative research is in the form of stories that summarize the events and profits of previously performed deals with shelved assets. The deals were searched based on controlled vocabulary and free text terms related to shelved assets, deals, repurposing, and reprioritising on Google, Pubmed, FierceBiotech, and other biotech blogs/ analyst websites. The main outcomes of interest were the profits and successes of the deals. Inclusion was limited based on the following criteria: i) the deal involved a shelved asset and ii) the deal did not include a drug that was already marketed/ used in another indication

Company	Asset	Therapeutic area	Indication	Development stage	Company rationale
AbbVie	Rova-T	Oncology	Lung cancer (SCLC)	Phase III	Efficacy
AbbVie	ABBV-8E12	Neurology	Progressive Supranuclear Palsy	Phase II	Efficacy
AbbVie	ABBV-119	Respiratory / dermatology	Cystic fibrosis	Phase II	Efficacy
Amgen	AMG 171	Endocrine / Metabolic	Obesity	Phase I	Efficacy
Amgen	AMG 596	Oncology	EGFRvIII	Phase I	Strategic
Amgen	AMG 673	Oncology	AML	Phase I	Strategic
Amgen	AMG 212	Oncology	Prostate cancer	Phase I	N.d.
Amgen	AMG 211	Oncology	Colorectal cancer	Phase I	N.d.
Amgen	AMG 330	Oncology	AML	Phase I	Efficacy
Amgen	AMG 427	Oncology	AML	Phase I	N.d.
AstraZeneca	AZD0284	Respiratory / dermatology	Psoriaris	Phase I	N.d.
AstraZeneca	AZD0449	Respiratory	Asthma	Phase I	N.d.
AstraZeneca	AZD4635 (imaradenant)	Oncology	Prostate cancer	Phase II	Efficacy
AstraZeneca	AZD9496	Oncology	Oestrogen receptor positive breast cancer	Phase II	Efficacy
AstraZeneca	MEDI5083	Oncology	Solid tumours	Phase I	Efficacy
AstraZeneca	AZD7594 (Velsecorat)	Respiratory / dermatology	Asthma / COPD	Phase I	Strategic
AstraZeneca	AZD0548 (Abediterol)	Respiratory / dermatology	Asthma / COPD	Phase I	Strategic
AstraZeneca	AZD5634	Respiratory / dermatology	Cystic fibrosis	Phase I	Efficacy
AstraZeneca	MEDI3902	Respiratory / dermatology	Pneumonia	Phase I	Efficacy
AstraZeneca	MEDI7219	Endocrine / Metabolic	Type-2 diabetes	Phase I	Strategic
AstraZeneca	AZD6615	Cardiovascular	dyslipidaemias	Phase I	Strategic
AstraZeneca	MEDI2228	Oncology	Multiple myeloma	Phase I	Efficacy
AstraZeneca	MEDI5395	Oncology	Solid tumours	Phase I	Efficacy
AstraZeneca	AZD9567	Inflammatory	Chronic inflammatory diseases	Phase II	N.a.
AstraZeneca	MEDI0457	Oncology	HPV types 16 and 18	Phase II	N.a.
AstraZeneca	AZD2811	Oncology	Solid tumours	Phase II	Efficacy
AstraZeneca	ALXN1830 (orilanolimab)	Autoimmune	Warm autoimmune hemolytic anaemia	Phase I	Strategic
AstraZeneca	AZD2816	Infectious	COVID-19	Phase III	Strategic
AstraZeneca	MEDI6012	Cardiovascular	Several	Phase II	Efficacy
Bayer	BAY 1817080 (eliapixant)	Respiratory / dermatology	Refractory chronic cough	Phase II	Change in risk-benefit profile
Bayer	Rogaratinib	Oncology	Carcinoma, Transitional Cell	Phase II/III	N.a.
Bayer	Combi IUS LNG/IND	Women's health		Phase II	N.a.
Bristol Myers Squibb	BMS-986036 (pegbelfermin)	Endocrine / Metabolic	NASH	Phase II	Change in risk-benefit profile
Bristol Myers Squibb	Avadomide (CC-122)	Oncology	Lymphoma	Phase I	Efficacy
GlaxoSmithKline	GSK3389245A	Infectious	RSV	Phase II	Efficacy
Johnson & Johnson	JNJ-64140284			Phase I	Strategic
Johnson & Johnson	JNJ-73763989	Infectious	Hepatitis B	Phase II	Strategic
Johnson & Johnson	JNJ-53718678 (Rilematovir)	Infectious	RSV	Phase II	Strategic
Johnson & Johnson	HVTN 705/HPX2008	Infectious	HIV	Phase II	Efficacy
Johnson & Johnson	JNJ-66525433	Autoimmune	Ulcerative colitis	Phase I	N.d.
Merck KGaA	M7824 (bintrafusp alpha)	Oncology	Biliary tract cancer	Phase II	Efficacy
Novartis	CAD-1883	Neurology	Spinocerebellar ataxia	Phase I	Strategic
Roche	RG6296 / AFM26	Oncology	B cell maturation	Phase I	N.d.
Roche	RG6247 / 4D-110	Ophthalmology	Choroideremia	Phase I	Change in risk-benefit profile
Roche	4D-125	Ophthalmology	X-linked retinitis pigmentosa	Phase I	Change in risk-benefit profile
Roche	RG6232	Oncology	Metastatic melanoma	Phase I	N.d.
Roche	RG7992 (BFKB8488A)	Endocrine / Metabolic	NASH	Phase I	Change in risk-benefit profile
Roche	RG6367	Ophthalmology	Choroideremia	Phase II	Change in risk-benefit profile
Roche	RG6422	Infectious	COVID-19	Phase III	Efficacy
Roche	PCO371	Endocrine / Metabolic	Hypoparathyroidism	Phase I	Change in risk-benefit profile
Roche	RG7440	Oncology	Breast cancer	Phase III	Efficacy
Roche	RG6151	Respiratory / dermatology	Asthma	Phase I	N.d.
Roche	RG6149 (astegolimab)	Infectious	COVID-19	Phase II	N.d.
Roche	RG7880	Infectious	COVID-19	Phase II	N.d.
Roche	RG6000	Neurology	Amyotrophic lateral sclerosis (ALS)	Phase I	N.d.
Roche	RG7861	Infectious	*Staphylococcus aureus* infections	Phase I	N.d.
Roche	RG6217	Infectious	Hepatitis B	Phase I	N.d.
Roche	RG7388 (idasanutlin)	Oncology	AML	Phase II	Efficacy
Roche	RG1662	Neurology	Down syndrome	Phase II	N.d.
Takeda	TAK-609	Neurology	Hunter syndrome	Phase II/III	Efficacy
Takeda	TAK-906	Gastrointestinal	Gastroparesis	Phase IIb	Efficacy
Takeda	TAK-935 (soticlestat)		15q duplication syndrome, CDKL5 deficiency disorder	Phase II	Efficacy
Takeda	TAK-924 (pevonedistat)	Oncology	High-risk Myelodysplastic Syndrome, Unfit Acute Myelogenous Leukemia	Phase III	Efficacy

Figure 14: Big Pharma company shelved assets

VI.I Shelved assets database

After analysing numerous webpages, news articles, and comparing pipelines, 73 shelved assets fit the criteria and were added to the databased. The drug producing companies are divided into Big Pharma and non-Big Pharma. The shelved assets were from 19 companies of which 11 were Big Pharma companies and 8 were non-Big Pharma companies. In figure 14 and 15 the shelved assets for Big Pharma and non-Big Pharma are shown, the extended versions of these tables can be found in Appendix B. As can be seen in the figures, the number of shelved assets that could be found for Big Pharma companies was much higher than the number of shelved assets that could be found for non-Big Pharma companies.

Figure 14 shows a list of shelved assets from Big Pharma companies. Big Pharma companies, like any other public company, publish annual and quarterly reports. Most of the data from Figure 14 originates from those reports. In these reports they often update their stakeholders on their pipeline and changes in their pipeline. Most companies give a reason/ rationale if they shelf an asset, however, there are instances where an asset is shelved without reason or announcement.

In Figure 15 shows a list of shelved assets from companies that can be considered Non-Big Pharma companies. As can be seen in this figure this list is much shorter. The source for most of these assets are news articles and company press releases found after pre-defined specific searches.

Company	Asset	Therapeutic area	Indication	Development stage	Company rationale
Arrowhead	ARO-ENaC	Respiratory	Cystic Fibrosis	Phase I/II	Efficacy
Biogen	BIIB078	Neurology	Amyotrophic lateral sclesrosis	Phase I	Efficacy
Orion Corporation	ODM-104	Neurology	Parkinson's disease	Phase IIb/III	Strategic
Silverback Therapeutics	SBT6050	Oncology	HER2 positive solid tumours	Phase I/Ib	Efficacy
Silverback Therapeutics	SBT6290	Oncology	Advanced solid tumours	Phase I/II	Efficacy
Genocea	GEN-009	Oncology	Solid tumours	Phase I/IIa	Strategic
Genocea	GEN-011	Oncology	Several tumours	Phase I	Strategic
Black Diamond Therapeutics	BDTX-189	Oncology	EGFR and HER2 driven cancers	Phase I/II	Strategic
Imara (tovinontrine)	IMR-687	Haematology	Sickle cell, beta thalassemia and heart failure	Phase IIa/IIb	Efficacy
Lisata Therapeutics	Xowna	Cardiovascular	Coronary microvascular dysfunction	Phase IIb	Efficacy

Figure 15: Non-Big Pharma company shelved assets

VI.II Analysis shelved assets database

To create an insight and better understanding of the prevalence and trends of shelved assets several analyses were performed on the data. The first aspect of shelved assets that can be noted is the therapeutic area in which the drug is being developed in. In Figure 16 shows the distribution of shelved assets across different therapeutic areas. This figure shows that the largest number of shelved assets were being developed for oncology indications followed by infectious diseases, neurology, and respiratory/ dermatology. Oncology shelved assets have the highest share in both Big Pharma and non-Big Pharma.

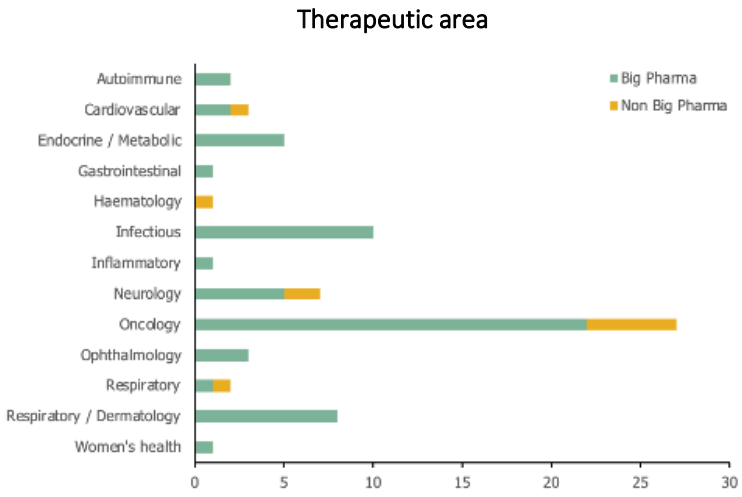

Figure 16: The distribution of therapeutic areas in which the shelved assets were developed for

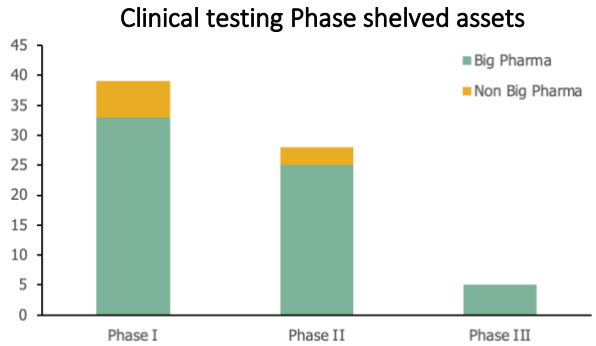

Figure 17: Highest clinical testing Phase of the shelved assets at the moment of shelving

The second aspect that was analysed was the clinical Phase an asset is in when it gets shelved. As can be seen in Figure 17 most of the shelved assets have reached/ completed phase I of clinical testing. This is closely followed by the number of shelved assets in Phase II. However, only a small number of shelved assets have reached Phase III of clinical testing. If an asset had was described to be in two Phases (e.g., Phase II/ III) then that asset was assigned to the lowest Phase mentioned.

The third and last aspect of the shelved assets that was analysed was the rationale given by the companies for shelving their asset. Figure 18 shows the distribution of reasons for why an asset was shelved. Assets that were shelved due to toxicity reasons were not included in the database and

therefore not included as a rationale for shelving. For most shelved assets a reason/ rationale was provided for why it was shelved (74%, 53/72). The most prevalent rationale for shelving was an "efficacy" based rationale (42%, 30/72), which means that the drug either showed to little efficacy in the intended indication or it did not outperform the current standard of care for that indication. Followed by efficacy reasons were strategic reasons for shelving (22%, 16/72). A strategic reason for shelving is when a company is (re)focussing its efforts into other drugs than the shelved asset which could be for a number of reasons. For instance, the company does not have sufficient funds to put all their drugs through clinical testing and therefore has to shelve an asset. Another reason could be that the company is active in several therapeutic areas and want to focus on only one or two therapeutic areas and therefore shelves the asset(s) that it developed in other areas. And lastly, the change in risk-benefit profile (10%, 7/72). Drugs always carry a risk profile that must be outweighed by the benefits a drug offers, otherwise admission of the drug would not be sensible. If during clinical testing (or because of external events) it becomes apparent that the current risks are no longer justifiable for the perceived benefit in a specific indication then that could be a reason for a company to shelf that asset.

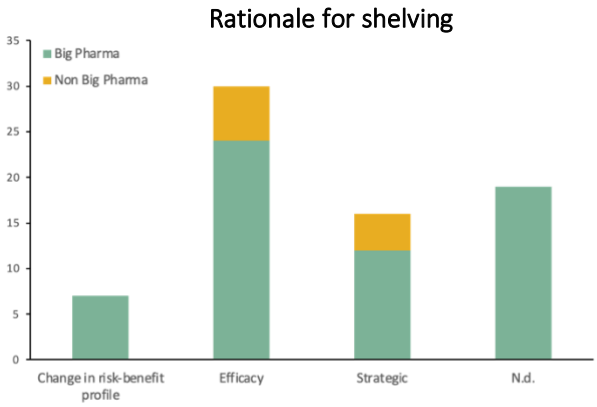

Figure 18: The type of rationale given by the company for shelving its asset(s)

VI.III Previous shelved asset deals

Bringing new life into shelved assets is not a new concept, and data and information about previous deals with shelved assets were analyzed to give context to process and idea. The following examples have been selected based on predefined criteria and the key take aways have been summarized to give an insight into the potential of shelved assets.

I. Daptomycin

Daptomycin was developed by Eli Lilly to treat infectious diseases but when it ran into some efficacy issues it shelved the asset for four years before out licensing it to Cubist. Cubist further developed Daptomycin to be used as an antibiotic for the treatment of complicated SSSI and *S. aureusbacteremia* and successfully brought the drug to the market in 2003. It became the most financially successful IV antibiotic in US history and has earned Eli Lilly over $333m in royalties on the product sale[12].

II. Momelotinib

Momelotinib was originally developed by Cytopia Ltd. which was acquired for $14m and merged with YM BioSciences. Momelotinib was led through Phase I/II studies that identified its unique anemia benefit. YM BioSciences was then acquired by Gilead for $465m in 2013 with intentions of performing a Phase III clinical trial in the second half of 2013. However, this Phase III trial does not happen, and the asset is shelved until 2018 when Sierra Oncology acquires Momelotinib for $3m upfront and further develops it. Recently, GSK has announced the acquisition of Sierra Oncology for $1.9bn for its near-approval cancer drug which will file for U.S. approval in the second quarter and European approval in the third quarter of 2022[13,14].

III. Lartruvo

Lartruvo was developed as a combination therapy and marketed by Eli Lilly to treat advanced and metastatic soft tissue carcinoma, however, two years later additional studies showed no added effect compared to chemotherapy alone. The drug was taken took it off the market and was shelved. Recently it was licensed to Telix for $5m who sees its potential as a targeting agent for radiopharmaceutical imaging and treatment. Lilly could receive up to $225m in regulatory and commercial milestones[15]l.

IV. Plerixafor (Mozobil®)

Plerixafor was initially developed for the treatment of HIV, based on its role in blocking $CXCR_4$, by AnorMED. However, development was terminated due to poor oral bioavailability, cardiac disturbances, and its teratogenic potential. Plerixafor was then repurposed as an immunostimulant used to multiply hematopoietic stem cells in cancer patients. Subsequently, AnorMED was bought by Genzyme for $580m for is leading late-stage product candidate Plerixafor (Mozobil®)[16].

V. Sapanisertib and Mivavotinib

Last year (2021) Calithera Biosciences bought two shelved assets from Takeda for $10m upfront. The two shelved assets were sapanisertib for squamous non-small cell lung cancer (NSCLC) and mivavotinib targeting non- Hodgkin's lymphoma as well as diffuse large B-cell lymphoma. There is some overlap for Calithera as their other drug, telaglenastat, was also targeted at NSCLC but failed to pass a midstage kidney cancer test. Calithera bought Takeda's shelved drugs to strengthen its pipeline and because they matched their experience[17].

VII. Discussion

The goal of this thesis was to explore the possible business development in the form of instigating deals with shelved assets. This thesis analyses shelved assets, its prevalence, and its potential. The research looked at the current status of shelved assets and previous deals surrounding shelved assets that enhance the understanding of its potential use. However, as any research, this research has some discussion points that should be taken into account. The results, the implications of these results, and the corresponding discussion points will be discussed in this chapter. According to Biotechgate's database there are 19,698 drug developing companies worldwide[18]. Additionally, ClinicalTrials.gov currently lists 417,550 clinical trials (as of 08/06/2022). Understandably, it is nearly impossible to create a hundred percent accurate reflection of the shelved assets all these companies have. However, by taking a sample from this group and analysing the data collected we can still say something about the group as a whole and see trends and patterns.

In the first sub chapter "VI.I Shelved assets database" a database of shelved assets was created. As mentioned above this is not a reflection of all the shelved assets from all the drug developing companies. The drug producing companies are divided into Big Pharma and non-Big Pharma as can be seen in Figure 14 and 15, respectively. As Big Pharma usually has many assets in development they were also expected to have more shelved assets as they constantly have to respond to clinical outcomes and have to (re)strategies their next steps. As can be seen in the figures there were much more shelved assets found for Big Pharma then for non-Big Pharma companies. This was for two reasons: i) as mentioned they simply have more drugs in development and therefor logically generate more shelved assets and ii) since they are much bigger there is much more attention for those companies, in other words more analyst coverage and more information that can be found on the internet. Another aspect that should be taken into account when looking at Big Pharma companies is that they are very large and mature. Most, if not all, Big Pharma companies recognise the potential of shelved assets and have their own sales forces as well as other initiatives who are responsible for the shelved assets[19].

The fact that the non-Big Pharma shelved asset list was much shorter does not mean that those type of companies do not have shelved assets. The length of the list is most likely due to the fact that their shelved assets were harder to track down. The shelved assets of those companies are much more spread out between the companies and due to the limited time this research was done in, it was impossible to analyse them all.

Shelved assets were only added to the list if they matched a predefined list of requirements. One of those requirements was that the rationale for shelving could not be related to toxicity findings. However, in hindsight it might still be useful to add those shelved assets to the database as changes in dosage or admission routes can influence toxicity. Therefore, a drug that is toxic in one study based on a specific dosage/ formulation could be found to be not toxic and effective in study.

The second sub chapter "VI.II Analysis shelved assets database" goes into the patterns that can be identified in the data.

The first aspect that was analysed were the therapeutic areas in which the shelved assets were being developed for, which can be seen in Figure 15. The pattern seen in this figure largely corresponds to the patterns that can be seen in general drug developed[20]. However, in the general drug development trends respiratory/ dermatology does not have a share as high as it has for the shelved assets. This could

be explained by the recent COVID-19 outbreak that caused some people to have respiratory complications. This had many drug developers over the world working on a COVID-19 drug, of which now many are being shelved as more effective drugs are reaching the market and COVID-19 is getting less prevalent.

The second aspect that was analysed was the clinical phase the shelved assets were in when they were shelved. As can be seen in Figure 16 the largest share of assets was shelved after Phase I. As mentioned earlier, and shown in Figure 12, putting drugs through clinical trials is very expensive. Therefore, it is strategically wiser for a company to 'fail' early and cheap rather than late and expensive. It is important to realize that once a drug is shelved after Phase I it has not actually been cheap as millions have likely been invested in the R&D and clinical trial phase. However, it is cheaper when compared to a drug that has gone to Phase II or even Phase III trials. Therefore, more attractive for another company to buy and further developed than drugs that have already been further tested and that are likely more expensive to buy.

The third and final aspect that was analysed were the rationales/ reasons given by the companies for why they shelved their asset. There has been some research done on this in the past by other researchers who based their findings on scientific papers. Current findings were done based on data available on the company website, reports, and/or new articles. Interestingly, there was much overlap between the findings done by other researchers and current study[9].

The final sub chapter "VI.III Previous shelved asset deals" goes into the qualitative research and displays examples from previous shelved asset deals.

The first example of Daptomycin displays the potential an efficacy based shelved asset has for repurposing and for further development which can lead to success and high profits.

The second example of Momelotinib displays the potential a strategically shelved asset has when it is further developed and can becomes very successful and profitable.

The third example of Lartruvo displays a failed drug that is sold to be repurposed for another indication.

The fourth example of Plerixafor displays how a 'failed' drug can still become successful in another indication and consequently very profitable.

The fifth example Sapanisertib and Mivavotinib display how the acquisition of shelved assets can be a strategic move for a company to strengthen its pipeline.

VIII. Conclusion & Recommendations

In conclusion, shelved assets are very prevalent, and the rationales companies give for shelfing their assets imply promising opportunities for other companies to further develop those assets. The number of shelved assets, and thus opportunities for possible deals, is likely much larger than displayed in current research. Furthermore, previous deals involving shelved assets show that there is a potential of such a deal being very profitable and successful. Based on the data displayed and analysed in this thesis actively instigating deals with shelved seems to be a viable form of business development. It will take quite some effort to make the database complete and up to date. However, such a database can be very useful to match assets with potential buyers and will increase deal activity, which is favourable for the LS&H team who can profit by collaborating on these deals.

Some recommendations for Kempen would be to expand current database and reach out to the corresponding companies to request more information on the shelved assets and whether they are still shelved and whether they would be willing to sell. Kempen has a unique position in the market where they are in contact with a lot of players in the field. This will be very advantageous for the execution of this type of business development. Furthermore, another recommendation would be to have examples, such as described in this thesis, that show the potential of shelved assets and how assets can overcome efficacy/ safety issues when administered in different formulations, through different administration routes, or in different indications. It is essential that potential buyers understand the potential of shelved assets in order to instigate deals. Another recommendation would be to highlight the benefit of shelved assets: i) decreased risk of failure as the drugs have already been found to be safe in pre-clinical and early stage clinical testing, ii) decreased costs as the drug had already gone through several expensive steps in the drugs development and testing phase, iii) accelerated time frame of drug development as several steps in the process are already completed, and iv) its potential to also treat rare diseases. Additionally, a recommendation would be for Kempen to focus on both Big Pharma and non-Big Pharma companies. As mentioned previously, Big Pharma companies likely have their own sales force/ instances. However, logging and presenting their shelved assets to potential buyers can still generate deals on the buy side and is therefore an important aspect to include.

IX. Self-reflection

When I started this internship on Monday the 7th of February, I was blissfully unaware of what was laying ahead of me. Of course, I had expectations of how things were going be and what my days would be like, but those expectations have been significantly excided. On the basis of the following questions, I would like to summarise my experience:

What did you expect/want to learn from the internship?

I expected to learn a lot during this internship, my background is of course in the life sciences with a dash of business skills gathered over the first few months of this academic year. However, my financial knowledge was minimal. I therefor expected to learn a lot about finance, about how the (life science) stock markets work, how companies get funding etc. Which is also what I wanted to learn. Additional to the content and substance of this internship there was something else that I wanted to learn, or better said experience, which was the corporate culture. The internships I did before this internship were both in the laboratory, which is, as I can say now, a very different environment then I experienced at Kempen. However, this kind of slow, not very dynamic environment that I experienced in the lab was actually one of the main reasons why I wanted to steer my future into another direction. I was therefore very much looking forward to this energetic and high-pace environment I was expecting at Kempen.

What did you learn?

I learned a lot, which is kind of cliché to say but it is honestly true. I learned things that I did not even expect to learn. I learned how financing of companies is organized, how companies can raise money when they are private and how companies raise money when they go/are public. I also learned how trends about the market are formed, and how to gather data and interpret it. Furthermore, I learned how the financing for drug development and clinical testing is organized, and what strategic steps to take to have the highest chance to get a drug (successfully) through clinical testing. On a personal/ soft skills level I also learned a lot, for instance how to communicate with colleagues on expectations and planning. As well as how to manage my time and spent is in the most efficient manner. Both this know-how knowledge and social knowledge are very valuable to me, and I am happy to bring this with me in my future career.

What was your biggest challenge?

I think for me in this internship there were two challenges. The first one was that I had very minimal financial knowledge, which meant that to understand some cases or events I had to do a few google searches. At the end of the internship, I also had to perform a valuation of a company where this lack of financial knowledge was very challenging. However, I (somewhat) figured and was able to present a valuation which I was very proud of, not necessarily because I thought it was the best valuation they had ever seen, but because I managed to produce something that I did not think I could in the beginning of my internship. The other challenge I faced during this internship were the long working hours. My day started around 9:00 and I usually did not leave the office before 21:00, often leaving at 22:00 or 23:00. I noticed that by the time it was 21:00 I was in my head already working towards finishing my

work and going home. This was a challenge I eventually did not really overcome, but one that actually made me realize that long working hours were not for me.

Which knowledge and skills did you lack at the start of your internship assignment, and which study components were the most useful?

The skill that I (to my opinion) lacked very much was of course, as also mentioned above, the financial skills. However, during writing my thesis and presentation I did not need these skills as I tailored the project to my abilities.

How did the internship contribute to your professional development?

This internship contributed to my professional development in a number of ways. The most important one for me is that it gave me confidence. I now know that I can go into a position and find my way. I also learned and experienced soft skills needed for a smooth co-existence with my colleagues. I now also know what I bring to the table and how I can be an asset to a team.

A strength/weakness analysis of your performance. (What did you do well; what would you do differently if you had to do the project again)

If I had to analyse my performance I would say that strengths of mine are that I pick up information fast, I am committed to understanding dynamics and processes and quickly give things a place in my head. I have a good work ethic and can manage my time and priorities. I am also social and can connect with a variety of people which helps me collaborate with my colleagues.

My weaknesses would be that I sometimes find it hard to say no, if somebody needs help with something and asks me for help I find it hard to say no. Furthermore, my work ethic drops when it gets later, and I do not always triple check my work. That last aspect is something that I would do differently if I would start a project again. However, my work ethic dropping as it gets later is not something I think I will face again as I am not planning on working those hours again.

How did the internship relate to the courses in the FBE programme? And was there a link with the internship done in the first year of the SBM master?

This internship related the most to the finance course taught in the FBE programme. Other courses that were somewhat useful were international businesses and operations management. However, the difference between theory and practice is of course always very big. As for the link with the internship done in my first year there was pretty much none. The only maybe small link I can think of is that the first internship was a drug development internship and at Kempen we worked with companies that developed and marketed drugs. So that did give me somewhat of an insight into how such companies work and operate.

What are the implications for a first job? What would you do differently in your first job?

For my first job I will send invites to have coffees with all my colleagues right away. Making a connection and an effort to get to know everyone is really important and something that I did not do enough during this internship. I will also give myself time to honestly assess what I do and do not like in a job and clearly vocalize this.

X. Acknowledgements

I would like to take a moment to thank my supervisors Maria Popova and Tim Louwman for their supervision, support and reviewing this thesis. I would also like to thank the Life Science & Healthcare team for trusting me with the work they gave me and answering all questions I had. And finally, I would like to thank my UU supervisor Klaas Springer for the guidance and for reviewing this thesis.

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Appendices

Appendix A: Financials

€ million	2021	2020		H2 2021	H1 2021
Statement of income					
Net result	143.8	49.8		85.5	58.3
Underlying net result	159.9	51.0		100.7	59.2
Efficiency ratio (%)	68.9	85.7		65.5	73.1

€ billion	31/12/2021	31/12/2020		30/06/2021	
Client assets	131.1	115.0	14%	121.0	8%
– Assets under management	112.1	99.0	13%	104.2	8%
– Assets under monitoring and guidance	3.5	3.2	10%	3.2	10%
– Assets under administration	3.8	2.7	40%	3.4	12%
– Savings and deposits	11.7	10.1	16%	10.2	15%

€ million	31/12/2021	31/12/2020		30/06/2021	
Statement of financial position and capital management					
Equity attributable to shareholders	1,308	1,254	4%	1,291	1%
Equity attributable to AT1 capital securities	102	102	0%	102	0%
Equity attributable to non-controlling interests	0	0		0	
Savings and deposits	11,730	10,141	16%	10,228	15%
Loans and advances to clients	8,876	8,448	5%	8,663	2%
Total assets	16,307	15,149	8%	15,030	8%
Loan-to-deposit ratio (%)	75.7	83.3		84.7	
Total risk exposure amount	3,927	4,195	-6%	4,586	-14%
Common Equity Tier 1 ratio (%)[1]	23.7	24.3		21.9	
Tier 1 ratio (%)[1]	26.3	25.4		23.1	
Total capital ratio (%)[1]	30.1	27.4		25.2	
Liquidity coverage ratio	172.0	177.4		158.8	
Net stable funding ratio	163.0	161.8		155.6	

Key figures[2]	2021	2020		H1 2021	
Weighted average of outstanding ordinary shares (x 1,000)	40,910	40,989	0%	40,986	0%
Underlying earnings per ordinary share (€)	3.74	1.08		1.36	
Return on average Common Equity Tier 1 capital (%)[3]	15.7	4.4		11.0	
Number of staff (FTEs at period end)	1,654	1,564	6%	1,588	4%

Financial results (€ million)	2021	2020		H2 2021	H1 2021
Commission	385.5	296.4	30%	209.9	175.7
– of which securities commissions	330.1	247.4	33%	183.4	146.7
– of which other commissions	55.4	49.1	13%	26.5	28.9
Interest	153.6	152.1	1%	77.5	76.1
Income from securities and associates	65.9	17.7		43.6	22.3
Result on financial transactions	-10.3	-32.3		-5.5	-4.8
Income from operating activities	**594.7**	**434.0**	37%	**325.4**	**269.3**
Staff costs	273.0	239.3	14%	143.6	129.3
Other administrative expenses	119.7	115.3	4%	60.3	59.4
– of which regulatory levies and charges	13.9	11.1	25%	4.0	9.9
Depreciation and amortisation	17.3	17.2	0%	9.2	8.1
Operating expenses	**409.9**	**371.8**	10%	**213.1**	**196.8**
Gross result	**184.8**	**62.2**		**112.3**	**72.5**
Addition to loan loss provisions	-11.7	1.9		-8.1	-3.5
Other impairments	-6.5	—		-4.3	-2.2
Impairments	**-18.1**	**1.9**		**-12.4**	**-5.7**
Operating profit before tax of non-strategic investments	4.8	1.7		4.1	0.7
Operating profit before special items and tax	**207.7**	**62.0**		**128.8**	**78.9**
Amortisation of intangible assets arising from acquisitions	11.3	6.2	82%	7.6	3.7
Expenses related to accounting treatment of Mercier Vanderlinden	8.5	—		8.5	—
Provision for revolving consumer credit	3.3	—		3.3	—
Restructuring charges	3.9	1.6		2.6	1.2
Other one-off items	2.3	—		2.3	—
Operating profit before tax	**178.5**	**54.2**		**104.5**	**74.0**
Income tax	34.6	4.4		19.0	15.7
Net result	**143.8**	**49.8**		**85.5**	**58.3**
Underlying net result	**159.9**	**51.0**		**100.7**	**59.2**

Underlying net result (€ million)	2021	2020	H2 2021	H1 2021
Net result	**143.8**	49.8	85.5	58.3
Expenses related to accounting treatment of Mercier Vanderlinden	8.5	—	8.5	—
Provision for revolving consumer credit	3.3	—	3.3	—
Restructuring charges	3.9	1.6	2.6	1.2
Other one-off items	2.3	—	2.3	—
Tax effects	-1.8	-0.4	-1.5	-0.3
Underlying net result	**159.9**	51.0	100.7	59.2

Operating segments in 2021 (€ million)	Private Clients	Wholesale & Institutional Clients	Investment Banking Clients	Other	Total
Statement of income					
Commission	244.4	81.4	55.3	4.5	**385.5**
Interest	140.2	—	0.0	13.4	**153.6**
Other income	2.4	—	4.8	48.4	**55.6**
Total income from operating activities	**387.0**	**81.4**	**60.1**	**66.2**	**594.7**
Staff costs	89.3	10.1	24.0	149.6	**273.0**
Other administrative expenses	59.0	6.7	7.8	46.2	**119.7**
Allocated expenses	106.2	54.2	9.3	-169.7	—
Depreciation and amortisation	1.4	—	0.3	15.6	**17.3**
Total expenses	**255.9**	**71.0**	**41.4**	**41.6**	**409.9**
Operating result before tax	**131.1**	**10.4**	**18.8**	**24.6**	**184.8**
Impairments	-10.9	—	—	-7.2	**-18.1**
Operating result before tax of non-strategic investments	—	—	—	4.8	**4.8**
Operating result before one-off charges and tax	**142.1**	**10.4**	**18.8**	**36.5**	**207.7**
Amortisation of intangible assets arising from acquisitions	9.8	0.8	—	0.8	**11.3**
Expenses related to accounting treatment of Mercier Vanderlinden	8.5	—	—	—	**8.5**
Provision for revolving consumer credit	3.3	—	—	—	**3.3**
Restructuring charges	3.9	—	—	—	**3.9**
Other one-off items	2.3	—	—	—	**2.3**
Operating result before tax	**114.3**	**9.6**	**18.8**	**35.8**	**178.5**
Underlying result before tax	**132.3**	**9.6**	**18.8**	**35.8**	**196.4**

Commission

Commission (€ million)	2021	2020		H2 2021	H1 2021
Securities commissions	330.1	247.4	33%	183.4	146.7
– Management fees	305.5	225.4	36%	171.0	134.5
– Transaction fees	24.6	21.9	12%	12.4	12.2
Other commissions	55.4	49.1	13%	26.5	28.9
Commission	**385.5**	**296.4**	**30%**	**209.9**	**175.7**

Interest

Interest (€ million)	2021	2020		H2 2021	H1 2021
Gross interest margin	172.7	169.9	2%	89.7	83.0
Interest income and charges on hedge derivatives	-15.1	-5.4		-9.5	-5.6
Interest equalisation	-16.2	-19.7		-7.9	-8.4
Clean interest margin	**141.3**	**144.8**	**-2%**	**72.3**	**69.0**
Miscellaneous interest income and charges	9.4	4.0		4.0	5.4
Loan commission	2.9	3.3	-11%	1.3	1.6
Interest	**153.6**	**152.1**	**1%**	**77.6**	**76.1**

Income from securities and associates

Income from securities and associates (€ million)	2021	2020		H2 2021	H1 2021
Dividend	10.9	8.3	31%	6.8	4.0
Realised capital gains	19.0	0.6		18.8	0.2
Valuation gains and losses	36.1	8.8		18.0	18.1
Income from securities and associates	**65.9**	**17.7**		**43.6**	**22.3**

Income from, and book value of, securities and associates (€ million)	Income 2021	Income 2020		Book value year-end 2021	Book value year-end 2020
Van Lanschot Participaties (minority interests)	36.5	14.2		52.2	47.4
Bolster Investment Coöperatief UA	3.9	4.1		51.3	37.0
Co-investments in own products	23.0	-0.9		202.3	146.3
Other equity investments	2.6	0.3		1.7	1.7
Total from securities and associates	**65.9**	**17.7**		**307.5**	**232.4**

Result on financial transactions

Result on financial transactions (€ million)	2021	2020		H2 2021	H1 2021
Result on securities trading	1.7	2.1	-21%	0.5	1.2
Result on currency trading	8.7	8.2	6%	4.3	4.4
Result on investment portfolio	3.0	0.4		2.7	0.3
Result on hedges	-20.7	-38.7		-9.2	-11.4
Other income	-3.0	-4.3		-3.8	0.8
Result on financial transactions	**-10.3**	**-32.3**		**-5.5**	**-4.8**

Operating expenses

Operating expenses (€ million)	2021	2020		H2 2021	H1 2021
Staff costs	273.0	239.3	14%	143.6	129.3
Other administrative expenses	119.7	115.3	4%	60.3	59.4
– of which regulatory levies and charges	13.9	11.1	25%	4.0	9.9
Depreciation and amortisation	17.3	17.2	0%	9.2	8.1
Operating expenses	**409.9**	**371.8**	**10%**	**213.1**	**196.8**

Impairments

Impairments (€ million)	2021	2020		H2 2021	H1 2021
Addition to loan loss provisions	-11.7	1.9		-8.1	-3.5
Other impairments	-6.5	—		-4.3	-2.2
Impairments	**-18.1**	**1.9**		**-12.4**	**-5.7**

Special items

Special items (€ million)	2021	2020		H2 2021	H1 2021
Amortisation of intangible assets arising from acquisitions	11.3	6.2	82%	7.6	3.7
Expenses related to accounting treatment of Mercier Vanderlinden	8.5	—		8.5	—
Provision for revolving consumer credit	3.3	—		3.3	—
Restructuring charges	3.9	1.6		2.6	1.2
Other one-off items	2.3	—		2.3	—
Special items	**29.3**	**7.8**		**24.3**	**5.0**

Earnings per share

Earnings per share (€ million)[4]	2021	2020		H2 2021	H1 2021
Net result	**143.8**	49.8		85.5	58.3
Share of non-controlling interests	-0.1	-0.1	-13%	0.0	-0.1
Share of holders of AT1 capital securities	-6.8	-6.8		-3.4	-3.4
Net result for calculation of earnings per ordinary share	**137.0**	43.0		82.1	54.9
Earnings per ordinary share (€)	**3.35**	1.05		2.01	1.34
Underlying net result for calculation of earnings per ordinary share	**153.1**	44.2		97.3	55.8
Underlying earnings per ordinary share (€)	**3.74**	1.08		2.38	1.36
Weighted number of outstanding ordinary shares (x 1,000)	40,910	40,989			

Client assets

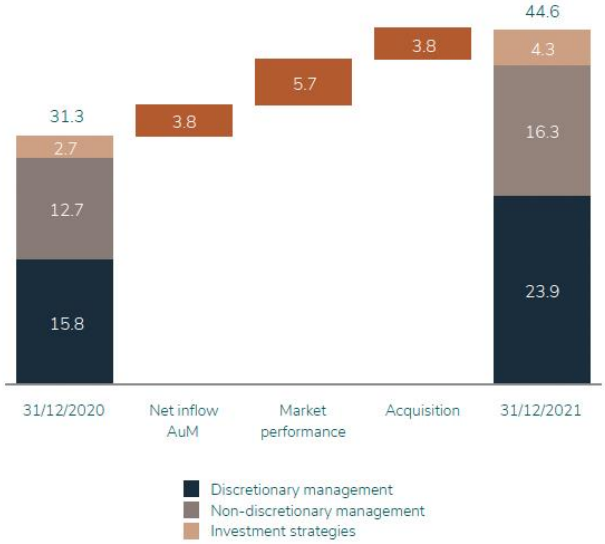
Client assets (€ billion)	31/12/2021	31/12/2020		30/6/2021	
Client assets	**131.1**	115.0	14%	121.0	8%
Assets under management	112.1	99.0	13%	104.2	8%
Savings and deposits	11.7	10.1	16%	10.2	15%
Assets under monitoring and guidance	3.5	3.2	10%	3.2	10%
Assets under administration	3.8	2.7	40%	3.4	12%
Client assets	**131.1**	115.0	14%	121.0	8%
Private Clients	58.6	42.8	37%	48.7	20%
Wholesale & Institutional Clients	71.1	70.9	0%	70.6	1%
Other	1.5	1.3	18%	1.7	-10%

Client assets (€ billion)	Private Clients	Wholesale & Institutional Clients	Other	Total
Client assets at 31/12/2020	**42.8**	**70.9**	**1.3**	115.0
Assets under management in/outflow	3.8	-4.0	0.0	-0.2
Savings and deposits in/outflow	1.6	—	-0.1	1.6
Market performance of assets under management	5.7	3.8	0.0	9.5
Change in assets under monitoring and guidance	—	0.3	—	0.3
Change in assets under administration	0.8	—	0.3	1.1
Client assets acquisition	3.8	—	—	3.8
Client assets at 31/12/2021	**58.6**	**71.1**	**1.5**	**131.1**

Loan portfolio

Loan portfolio (€ million)	31/12/2021	31/12/2020		30/6/2021	
Mortgages	6,337	6,039	5%	6,154	3%
Other loans	2,199	1,997	10%	2,137	3%
Loan portfolio	**8,536**	**8,036**	6%	**8,291**	3%
Mortgages distributed by third parties	389	476	-18%	432	-10%
Total	**8,925**	**8,512**	5%	**8,723**	2%
Impairments	-49	-64	-23%	-61	-20%
Total loan portfolio	**8,876**	**8,448**	5%	**8,663**	2%

AuM Private Clients
(€ billion)



AuM Wholesale & Institutional Clients
(€ billion)

Appendix B: Tables shelved assets

Table shelved assets Non-Big Pharma companies

Company	Asset	Mechanism of action/Target	Technology	Therapeutic area	Indication	Development stage	NCT number	Company rationale/ comment	Source
Arrowhead	ARO-ENaC			Respiratory	Cystic Fibrosis	Phase I/II	NCT04375514	Safety/ efficacy	https://www.fiercebiotech.com/biotech/arrowhead-changing-horses-for-enac-pulmonary-program-as-phase-1-2-asset-shelved
Biogen	BIIB078			Neurology	Amyotrophic lateral sclesrosis	Phase I	NCT03626012	Safety/ efficacy	https://www.fiercebiotech.com/biotech/ionis-biogen-call-it-quits-als-med-after-it-flunks-phase-1-trial
Orion Corporation	ODM-104	COMT inhibitor	Small molecule	Neurology	Parkinson's disease	Phase IIb/III		Strategic	Received through reach out by Kempen
Silverback Therapeutics	SBT6050	HER2-TLR8	ImmunoTAC conjugates	Oncology	HER2 positive solid tumours	Phase I/Ib	NCT05091528	Safety/ efficacy	https://ir.silverbacktx.com/news-releases/news-release-details/silverback-therapeutics-updates-strategic-priorities-and-reports
Silverback Therapeutics	SBT6290	Nectin4-TLR8	ImmunoTAC conjugates	Oncology	Advanced solid tumours	Phase I/II	NCT05234606	Safety/ efficacy	https://ir.silverbacktx.com/news-releases/news-release-details/silverback-therapeutics-updates-strategic-priorities-and-reports
Genocea	GEN-009	Neoantigen vaccine	Vaccine	Oncology	Solid tumours	Phase I/IIa	NCT03633110	Strategic	https://www.fiercebiotech.com/biotech/fierce-biotech-layoff-tracker-2022
Genocea	GEN-011	Neoantigen specific peripheral T cell therapy	T cell therapy	Oncology	Several tumours	Phase I	NCT04596033	Strategic	https://www.fiercebiotech.com/biotech/fierce-biotech-layoff-tracker-2022
Black Diamond Therapeutics	BDTX-189		Small molecule	Oncology	EGFR and HER2 driven cancers	Phase I/II	NCT04209465	Strategic	https://www.fiercebiotech.com/biotech/black-diamond-runs-rocky-terrain-trims-30-workforce-and-cuts-precision-oncology-program
Imara (tovinontrine)	IMR-687	PDE9 inhibitor		Haematology	Sickle cell, beta thalassemia and heart failure	Phase IIa/IIb	NCT04411082	Safety/ efficacy	https://www.fiercebiotech.com/biotech/imara-flunks-phase-2b-trials-sickle-cell-and-thalassemia-wiping-out-clinical-pipeline
Lisata Therapeutics	Xowna		Cell therapy	Cardiovascular	Coronary microvascular dysfunction	Phase IIb		Safety/ efficacy	https://www.fiercebiotech.com/biotech/supply-chain-challenges-upend-caldrius-coronary-artery-disease-trial

Table shelved assets Big Pharma companies (1/3)

Company	Asset	Mechanism of action/Target	Technology	Therapeutic area	Indication	Development stage	NCT number	Company rationale	Source
AbbVie	Rova-T	Antibody-drug conjugate targeting DLL3	Antibody	Oncology	Lung cancer (SCLC)	Phase III	NCT02674568	Safety/ efficacy	https://news.abbvie.com/news/press-releases/abbvie-discontinues-rovalpituzumab-tesirine-rova-t-research-and-development-program.htm
AbbVie	ABBV-8E12	Humanized IgG4 antibody	Antibody	Neurology	Progressive Supranuclear Palsy	Phase II	NCT02880956	Safety/ efficacy	https://www.alzforum.org/therapeutics/tilavonemab
AbbVie	ABBV-119	C2 corrector		Respiratory / dermatology	Cystic fibrosis	Phase II	NCT04853368	Safety/ efficacy	https://www.fiercebiotech.com/biotech/abbvies-cystic-fibrosis-long-game-doesnt-pay-galapagos-med-fails-triple-combo
Amgen	AMG 171	CD3		Endocrine / Metabolic	Obesity	Phase I	NCT04199351	Safety/ efficacy	https://www.hotstock-insights.com/amgen-quietly-kills-an-obesity-program-casting-bleak-future-for-once-promising-target/
Amgen	AMG 596	EGFRvIII / CD3 on T cells	Monoclonal antibody / Bispecific T-cell engager (BiTE)	Oncology	EGFRvIII	Phase I	NCT03296696	Strategic	https://www.evaluate.com/vantage/articles/news/snippets/reality-bites-amgens-bispecifics
Amgen	AMG 673	Anti-CD33 BiTE	Monoclonal antibody / Bispecific T-cell engager (BiTE)	Oncology	AML	Phase I	NCT03224819	Strategic	https://www.evaluate.com/vantage/articles/news/snippets/reality-bites-amgens-bispecifics
Amgen	AMG 212	PSMA x CD3 BiTE	Monoclonal antibody / Bispecific T-cell engager (BiTE)	Oncology	Prostate cancer	Phase I	NCT01723475	N.d.	https://www.evaluate.com/vantage/articles/news/snippets/reality-bites-amgens-bispecifics
Amgen	AMG 211	Bi-specific CEA-directed CD3 BiTE	Monoclonal antibody / Bispecific T-cell engager (BiTE)	Oncology	Colorectal cancer	Phase I	NCT02291614	N.d.	https://www.evaluate.com/vantage/articles/news/snippets/reality-bites-amgens-bispecifics
Amgen	AMG 330	Anti-CD33 BiTE	Monoclonal antibody / Bispecific T-cell engager (BiTE)	Oncology	AML	Phase I	NCT04478695	Safety/ efficacy	https://investors.amgen.com/static-files/990dbe48-aa5d-4d12-8c6b-aec454eea7e4
Amgen	AMG 427	FLT3 BiTE	Monoclonal antibody / Bispecific T-cell engager (BiTE)	Oncology	AML	Phase I	NCT03541369	N.d.	https://www.fiercebiotech.com/biotech/amgen-pauses-flt3-bispecific-trial-resumes-dosing-bcma-study
AstraZeneca	AZD0284	Inverse retinoic acid-related orphan receptor gamma agonist	Small molecule	Respiratory / dermatology	Psoriaris	Phase I	NCT03310320	N.d.	https://www.astrazeneca.com/our-therapy-areas/pipeline.html#
AstraZeneca	AZD0449	Inhaled JAK-1 inhibitor	Small molecule	Respiratory	Asthma	Phase I	NCT03766399	N.d.	https://www.astrazeneca.com/content/dam/az/PDF/2021/full-year/Full-year-2021-results-clinical-trials-appendix.pdf
AstraZeneca	AZD4635 (imaradenant)	Adenosine A2A receptor antagonist	Small molecule	Oncology	Prostate cancer	Phase II	NCT04089553	Safety/ efficacy	https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2020/pdf/AstraZeneca_AR_2020.pdf
AstraZeneca	AZD9496	Estrogen receptor inhibitor blocking growth of ER-positive and ESR1 mutant breast tumours	Small molecule	Oncology	Oestrogen receptor positive breast cancer	Phase II	NCT02780713	Safety/ efficacy	https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2020/pdf/AstraZeneca_AR_2020.pdf
AstraZeneca	MEDI5083	CD40 agonist	Fusion protein	Oncology	Solid tumours	Phase I	NCT03089645	Safety/ efficacy	https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2020/pdf/AstraZeneca_AR_2020.pdf
AstraZeneca	AZD7594 (Velsecorat)	Glucocorticoid receptor modulator	Small molecule	Respiratory / dermatology	Asthma / COPD	Phase I	NCT02645253	Strategic	https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2020/pdf/AstraZeneca_AR_2020.pdf
AstraZeneca	AZD0548 (Abediterol)	Beta-2 agonist	Small molecule	Respiratory / dermatology	Asthma / COPD	Phase I	NCT02777827	Strategic	https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2020/pdf/AstraZeneca_AR_2020.pdf
AstraZeneca	AZD5634	Epithelial sodium channel inhibitor	Small molecule	Respiratory / dermatology	Cystic fibrosis	Phase I	NCT02679729	Safety/ efficacy	https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2020/pdf/AstraZeneca_AR_2020.pdf
AstraZeneca	MEDI3902	Type-3-sectreion protein PcrV and Psl exopolysaccharide	Monoclonal antibody	Respiratory / dermatology	Pneumonia	Phase I	NCT02255760	Safety/ efficacy	https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2020/pdf/AstraZeneca_AR_2020.pdf
AstraZeneca	MEDI7219	GLP-1 receptor agonist	Peptide	Endocrine / Metabolic	Type-2 diabetes	Phase I	NCT03362593	Strategic	https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2020/pdf/AstraZeneca_AR_2020.pdf
AstraZeneca	AZD6615	PD-L1 mAb + PARP inhibitor	Monoclonal antibody	Cardiovascular	dyslipidaemias	Phase I	NCT04055168	Strategic	https://www.astrazeneca.com/content/dam/az/Investor_Relations/annual-report-2020/pdf/AstraZeneca_AR_2020.pdf

Table shelved assets Big Pharma companies (2/3)

Company	Asset	Mechanism of action/Target	Technology	Therapeutic area	Indication	Development stage	NCT number	Company rationale	Source
AstraZeneca	MEDI2228	IgG1 linker	Monoclonal antibody	Oncology	Multiple myeloma	Phase I	NCT03489525	Safety/ efficacy	https://www.fiercebiotech.com/biotech/astrazeneca-drops-bcma-drug-after-seeing-early-clinical-data
AstraZeneca	MEDI5395	PD-L1 inhibitor	Attenuated Newcastle disease virus	Oncology	Solid tumours	Phase I	NCT03889275	Safety/ efficacy	https://www.astrazeneca.com/content/dam/az/PDF/2021/q3/Year-to-date_and_Q3_2021_results_clinical_trials_appendix.pdf
AstraZeneca	AZD9567	Glucocorticoid receptor modulator	Small molecule	Inflammatory	Chronic inflammatory diseases	Phase II	NCT04556760	N.a.	https://www.astrazeneca.com/content/dam/az/PDF/2021/q1-2021/Q1_2021_results_clinical_trials_appendix.pd
AstraZeneca	MEDI0457	E6 and E7 oncogenes for HPV-16/18 and IL-12 adjuvant	DNA vaccine	Oncology	HPV types 16 and 18	Phase II	NCT03439085	N.a.	https://www.sec.gov/ix?doc=/Archives/edgar/data/1055726/000119312521313502/d254133d8k.htm
AstraZeneca	AZD2811	Aurora kinase B inhibitor	Small molecule	Oncology	Solid tumours	Phase II	NCT02579226	Safety/ efficacy	https://www.astrazeneca.com/our-therapy-areas/pipeline.html
AstraZeneca	ALXN1830 (orilanolimab)	Rc receptor antagonist	Monoclonal antibody	Autoimmune	Warm autoimmune hemolytic anaemia	Phase I	NCT04956276	Strategic	https://www.astrazeneca.com/our-therapy-areas/pipeline.html
AstraZeneca	AZD2816	SARS-COV-19 (Beta variant spike protein)	Monovalent vaccine	Infectious	COVID-19	Phase III	NCT04973449	Strategic	https://www.astrazeneca.com/our-therapy-areas/pipeline.html
AstraZeneca	MEDI6012	Recombinant human lecithin cholesterol acyltransferase		Cardiovascular	Several	Phase II	NCT03578809	Safety/ efficacy	https://www.astrazeneca.com/content/dam/az/PDF/2021/q1-2021/Q1_2021_results_clinical_trials_appendix.pdf
Bayer	BAY 1817080 (eliapixant)	Purinergic P2X3 antagonist	Small molecule	Respiratory / dermatology	Refractory chronic cough	Phase II	NCT04545580	Change in risk-benefit profile	https://media.bayer.com/baynews/baynews.nsf/id/8D5D4D684755D4C5C12587DF003C4A54?open&ref=irrefndcd
Bayer	Rogaratinib	Multikinase inhibitor	Small molecule	Oncology	Carcinoma, Transitional Cell	Phase II/III	NCT03410693	N.a.	https://www.bayer.com/sites/default/files/2022-03/Bayer-Annual-Report-2021.pdf
Bayer	Combi IUS LNG/IND			Women's health		Phase II	NCT03562624	N.a.	https://www.bayer.com/sites/default/files/2022-03/Bayer-Annual-Report-2021.pdf
Bristol Myers Squibb	BMS-986036 (pegbelfermin)	FGF-21	Therapeutic protein	Endocrine / Metabolic	NASH	Phase II	NCT03486912	Change in risk-benefit profile	https://www.fiercebiotech.com/biotech/bristol-myers-becomes-latest-victim-unforgiving-nash-as-mid-stage-asset-shelved
Bristol Myers Squibb	Avadomide (CC-122)	Cereblon-modulating agent (CELMoD)	Small molecule	Oncology	Lymphoma	Phase I	NCT03283202/ NCT01421524	Safety/ efficacy	https://www.evaluate.com/vantage/articles/events/conferences/ash-2021-bristol-reveals-its-sons-revlimid
GlaxoSmithKline	GSK3389245A	Recombinant chimpanzee adenovirus vector vaccine	Adenoviral vector vaccine	Infectious	RSV	Phase II	NCT03636906	Safety/ efficacy	https://www.fiercebiotech.com/biotech/gsk-drops-phase-2-viral-vector-rsv-vaccine-pediatric-ages
Johnson & Johnson	JNJ-64140284					Phase I	NCT04033458	Strategic	https://clinicaltrials.gov/ct2/show/NCT04033458
Johnson & Johnson	JNJ-73763989	RNAi	Antiviral	Infectious	Hepatitis B	Phase II	NCT05005507	Strategic	https://clinicaltrials.gov/ct2/show/NCT05005507?term=janssen&recrs=h&strd_s=01%2F01%2F2015&strd_e=05%2F23%2F2022&draw=2&rank=9
Johnson & Johnson	JNJ-53718678 (Rilematovir)		Small molecule	Infectious	RSV	Phase II	NCT04978337	Strategic	https://clinicaltrials.gov/ct2/show/NCT04978337
Johnson & Johnson	HVTN 705/HPX2008		Antiviral	Infectious	HIV	Phase II	NCT03060629	Safety/ efficacy	https://www.jnj.com/johnson-johnson-and-global-partners-announce-results-from-phase-2b-imbokodo-hiv-vaccine-clinical-trial-in-young-women-in-sub-saharan-africa
Johnson & Johnson	JNJ-66525433			Autoimmune	Ulcerative colitis	Phase I	NCT04457960	N.d.	https://www.clinicaltrialsarena.com/analysis/pipeline-moves-jj-ends-ulcerative-colitis-trial-further-study-may-be-unlikely/
Merck KGaA	M7824 (bintrafusp alpha)	Combination of TGF-beta trap with anti-PD-L1	Bifunctional fusion protein immunotherapy	Oncology	Biliary tract cancer	Phase II	NCT03833661	Safety/ efficacy	https://www.merckgroup.com/en/annualreport/2021/_assets/downloads/entire-merck-ar21.pdf
Novartis	CAD-1883	Positive allosteric ion channel modulator	Small molecule	Neurology	Spinocerebellar ataxia	Phase I	NCT04301284	Strategic	https://www.evaluate.com/vantage/articles/events/company-events/biohavens-high-risk-bet

Table shelved assets Big Pharma companies (3/3)

Company	Asset	Mechanism of action/Target	Technology	Therapeutic area	Indication	Development stage	NCT number	Company rationale	Source
Roche	RG6296 / AFM26	BCMA x CD16A	Monoclonal antibody	Oncology	B cell maturation	Phase I		N.d.	https://www.evaluate.com/vantage/articles/news/corporate-strategy/roche-takes-tim-3-battle-novartis
Roche	RG6247 / 4D-110	Gene transference	Gene therapy	Ophthalmology	Choroideremia	Phase I	NCT04483440	Change in risk-benefit profile	https://www.evaluate.com/vantage/articles/news/corporate-strategy/roche-takes-tim-3-battle-novartis
Roche	4D-125	Gene transference	Gene therapy	Ophthalmology	X-linked retinitis pigmentosa	Phase I	NCT04517149	Change in risk-benefit profile	https://www.evaluate.com/vantage/articles/news/corporate-strategy/roche-takes-tim-3-battle-novartis
Roche	RG6232	Antineoplastics	Monoclonal antibody	Oncology	Metastatic melanoma	Phase I	NCT04551352	N.d.	https://www.evaluate.com/vantage/articles/news/corporate-strategy/year-tigit-and-alzheimers-roche
Roche	RG7992 (BFKB8488A)	FGFR1 x KLB	Monoclonal antibody	Endocrine / Metabolic	NASH	Phase I	NCT02593331	Change in risk-benefit profile	https://www.fiercebiotech.com/biotech/roche-lets-go-etro-dumping-phase-3-crohn-s-prospect-18-months-after-posting-weak-colitis
Roche	RG6367	Anti-VEGF x Ang2	Monoclonal antibody	Ophthalmology	Choroideremia	Phase II		Change in risk-benefit profile	https://www.fiercebiotech.com/biotech/roche-lets-go-etro-dumping-phase-3-crohn-s-prospect-18-months-after-posting-weak-colitis
Roche	RG6422			Infectious	COVID-19	Phase III		Safety/ efficacy	https://www.fiercebiotech.com/biotech/roche-lets-go-etro-dumping-phase-3-crohn-s-prospect-18-months-after-posting-weak-colitis
Roche	PCO371	PTH1R agonist	Small molecule	Endocrine / Metabolic	Hypoparathyroidism	Phase I	NCT04209179	Change in risk-benefit profile	https://www.evaluate.com/vantage/articles/news/corporate-strategy/year-tigit-and-alzheimers-roche
Roche	RG7440	pan-Akt inhibitor	Small molecule	Oncology	Breast cancer	Phase III		Safety/ efficacy	https://www.fiercebiotech.com/biotech/roche-chucks-out-phase-3-ipatasertib-combo-tests-midstage-il-33-asthma-btki-arthritis
Roche	RG6151	JAK inhibitor	Small molecule	Respiratory / dermatology	Asthma	Phase I		N.d.	https://assets.cwp.roche.com/f/126832/x/67e19b2e03/irp210421.pdf
Roche	RG6149 (astegolimab)	IL-33 inhibitor	Monoclonal antibody	Infectious	COVID-19	Phase II	NCT03615040	N.d.	https://assets.cwp.roche.com/f/126832/x/67e19b2e03/irp210421.pdf
Roche	RG7880	IL-22 inhibitor	Fusion protein	Infectious	COVID-19	Phase II	NCT03558152	N.d.	https://assets.cwp.roche.com/f/126832/x/67e19b2e03/irp210421.pdf
Roche	RG6000	Dual leucine zipper kinase inhibitor	Small molecule	Neurology	Amyotrophic lateral sclerosis (ALS)	Phase I		N.d.	https://assets.cwp.roche.com/f/126832/6183c11069/irp201015.pdf
Roche	RG7861	Anti-wall-teichoic acid (WTA) Thiomab	Monoclonal antibody	Infectious	*Staphylococcus aureus* infections	Phase I		N.d.	https://assets.cwp.roche.com/f/126832/6183c11069/irp201015.pdf
Roche	RG6217			Infectious	Hepatitis B	Phase I	NCT03762681	N.d.	https://www.fiercebiotech.com/biotech/roche-drops-hep-b-antiviral-as-late-stage-pipeline-tests-largely-track-despite-covid
Roche	RG7388 (idasanutlin)	MDM2	Small molecule	Oncology	AML	Phase II	NCT02545283	Safety/ efficacy	https://www.fiercebiotech.com/biotech/roche-drops-hep-b-antiviral-as-late-stage-pipeline-tests-largely-track-despite-covid
Roche	RG1662	GABAA alpha5 receptor negative allosteric modulator	Small molecule	Neurology	Down syndrome	Phase II	NCT02024789	N.d.	https://assets.cwp.roche.com/f/126832/4cace296a4/irp200422.pdf
Takeda	TAK-609	Investigational form of idursulfase	Enzyme	Neurology	Hunter syndrome	Phase II/III		Safety/ efficacy	https://www.takeda.com/investors/financial-results/
Takeda	TAK-906	Dopaming D2/D3 receptor anatagonist (oral)	Small molecule	Gastrointestinal	Gastroparesis	Phase IIb	NCT03544229	Safety/ efficacy	https://www.takeda.com/investors/financial-results/
Takeda	TAK-935 (soticlestat)	CH24H inhibitor (oral)	Small molecule		15q duplication syndrome, CDKL5 deficiency disorder	Phase II	NCT03694275	Safety/ efficacy	https://www.takeda.com/investors/financial-results/
Takeda	TAK-924 (pevonedistat)	NEDD 8 activating enzyme inhibitor (injection)	Small molecule	Oncology	High-risk Myelodysplastic Syndrome, Unfit Acute Myelogenous Leukemia	Phase III	NCT03268954	Safety/ efficacy	https://www.takeda.com/investors/financial-results/