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EQUITY RESEARCH: NOVO NORDISK

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A Project carried out on the Master's in Finance Program, under the supervision of:

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Abstract
The aim of the thesis is that to assess how the future will unfold for the pharma company Novo Nordisk taking into account the entry of a disruptive and innovative competitor: Virta Health. As we will later further develop, Novo Nordisk has a strong pipeline of products, with its main focus on Diabetes. As we will later further develop, Novo Nordisk has a strong pipeline of products, with its main focus on Diabetes. Market potential for diabetes lies mainly in diabetes Type 2 which accounts for 90% to 95% of diabetes cases. Virta strictly targets Type 2 diabetes, setting itself apart by reversing the disease or preventing it on a whole, without the use of medicines but through a dietary solution.

Let me take you on this journey: together we will discover the secrets of diabetes and the pharma industry. Thanks to scientific innovation and research, new solutions and cures are being discovered as you read.

Keywords: NN, Valuation, Pharmaceuticals, Virta Health

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This report is part of the … report (annexed) and should be read has an integral part of it.

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Industry Overview

Types of Pharmaceutical Firms

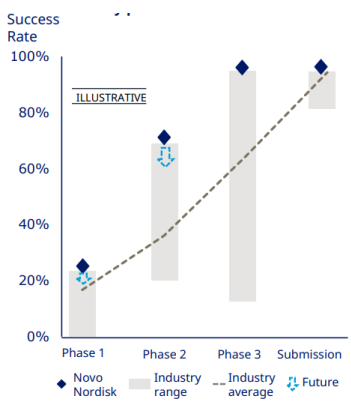
According to the US Bureau of Labor Statistics, there are three main types of pharmaceutical companies: Mainline – usually large pharmaceutical companies with a large portfolio of drugs and high-caliber R&D laboratories working to produce ground-breaking drugs (or, at least, improvements on existing drugs) and increase its portfolio of drugs and patents; Generics – companies that sell drugs whose license has expired and thus the company that has created the given drug no longer has the sole right to commercialize it; R&D companies – usually smaller companies specialized only in a very restricted set of conditions, that are focused on conducting research on potentially groundbreaking drugs (these often proceed to sell the patent or be acquired by larger pharmaceutical companies, sometimes still during the research process. Novo Nordisk is clearly a mainline pharmaceutical company and we will be focusing on the industry specifics that such companies face.

Consistent value generation for a mainline pharmaceutical company is highly dependent on its ability to manage its portfolio of drugs, patents, and its pipeline of drugs in the regulatory process of approval.

Product Lifecycle

According to Bogdan and Villiger (2008), the drug discovery and approval process can be summarized in the following way:

- The company sets out a disease as its target and begins searching for compounds that could become a treatment to the disease. A certain number of compounds is selected and further improved to enhance its ability to target the given disease.
- Then, the compound is taken to Pre-Clinical Trials, in which the compound is tested on non-human subjects (animals), in order to assess its safety for testing on human subjects; in case there is no toxicity, poor absorption and the drug treats the target disease, the regulator provides a document allowing for testing in humans (Investigational New Drug application in the U.S.);
- Phase 1 Clinical Trial: the compound is tested on a small group (20 to 80 people) of healthy human volunteers in order to test the safety on the compound, dosage, and potential side effects.
- Phase 2 Clinical Trial: Volunteers also include people affected by the disease and the group is now larger (100 to 300 people). This phase is usually divided into two sub-phases – Phase 2a: Where the effectiveness of the drug is studied; Phase 2b: Serves to show the proof-of-concept of the drug, that is, the drug's ability to tackle the target-disease in a relatively safe manner. If at this point, there is no clear advantage over other existing medications, often pharmaceutical companies will opt to stop developing the drug, given the high amounts of R&D and regulatory-related investment still to be made, and an unsatisfactory probability of success.



- Phase 3 Clinical Trial: A larger-scall clinical trial (500 to 20,000 people), where the effectiveness of the drug is verified, side-effects are registered, and the right dosage is established. An important question at this stage is also how much better is drug when compared to existing treatments.
- Approval phase: The company files the new drug application, and the relevant authorities review the results of the clinical trials. The process usually takes between 1 to 2 years unless the drug has been given “breakthrough therapy” (when clinical trial results are far superior to other existing treatments) status in previous phases. The regulator may ask for further clinical trials or even reject the application.
- Phase 4 Trials: Conducted after the launch. Are made to establish long-term safety and efficacy. New dosages, formulations and populations are tested.

Company Overview

Novo Nordisk, based in Bagsværd (Copenhagen, Denmark), was founded in 1989 as a result of the merger of two small Danish companies Nordisk Insulinlaboratorium and Novo Terapeutisk Laboratorium, both focused on the production of insulin for the treatment of diabetes 1 and 2. The company is listed on both the Danish and NYSE markets, operates in 80 countries and has approximately 45 000 employees (Nvo Nordisk Report, 2020).

Share Structure

Novo Nordisk has a total share capital of DKK 470,000,000 (Novo Nordisk report) which is divided into A share capital with a value of DKK 107,487,200 and B share capital of DKK 362,512.80. The A shares, unlike the B shares, are not listed and held by Novo Holding A/S, a danish liability company wholly owned by the Novo Nordisk foundation. Each A share carries 200 votes against 20 carried by the B shares, this vote division allows the holders of the A shares to have 76.5% of the votes even though the capital held is only 28.1%.

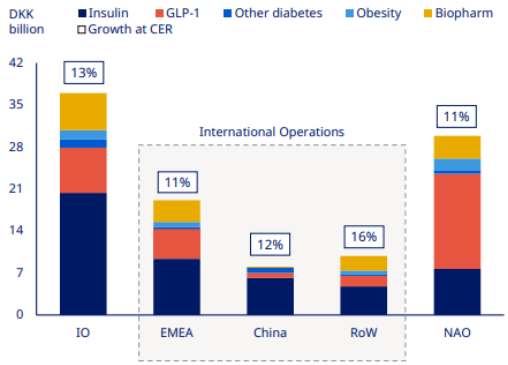
Through its in the assemblies through its voting rights, the foundation can pursue two main objectives: to ensure stability in research and commercial activities and to support scientific and humanitarian purposes. The corporate structure and commitment of the parent company also protect Novo Nordisk from hostile takeovers, and for this reason it is possible to consider the risk of acquisition by third parties as not relevant for the analysis.

Dividend Policy

Novo Nordisk's dividend policy is in line with that of other companies in the sector. In March 2020, the company paid a final dividend of DKK 5.35 per share regardless of whether it was of type A or B (Novo Nordisk Report). This amount is equivalent to a payout ratio of 50.5%, which is in line with the 53.5% payout ratio in the pharmaceutical sector. In March 2021, on the other hand, the board of directors decided to issue a final dividend of DKK 5.85 and thus pay a total of DKK 9.81, including the first tranche, achieving a payout similar to the previous year of 50% (Novo Nordisk does not pay dividends on the treasury shared held by the company itself).

Profit reserves not issued in the form of dividends have been used to carry out a share repurchase transaction in 2020 with a value of approximately DKK 17 billion. Subject to significant investment

opportunities, the company expects to carry out a further repurchase transaction in 2021 to cut tradable B-shares by 1.7% (Novo Nordisk Report).



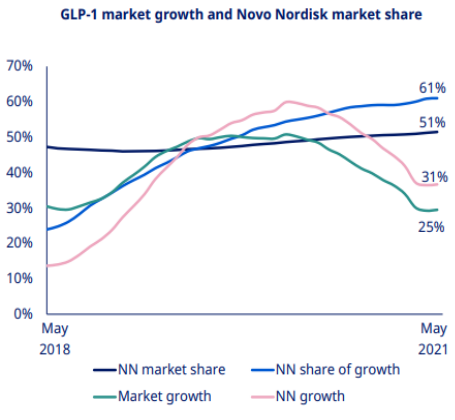
Sales Regions

Novo Nordisk operates in approximately 170 different countries worldwide (Novo Nordisk Report). The company divides its business into International Operations which includes EMEA (Europe, Middle East and Africa), Region China and the rest of the world and North America Operation which in turn includes US and Canada. The latter division highlights how dominant the US market is in NN's sales.

Products & Market Analysis

Long-acting: In the long-acting category, NN maintains a very strong presence worldwide with three currently marketed drugs: Tresiba, Levemir and Xultophy. Levemir, the once dominant insulin in the mid-2010s, is now slowly decreasing its market share while Tresiba holds approximately 20% of the market in both US and RoW, being currently near its peak sales value. Xultophy enjoyed a successful launch in both US and abroad, but is not generally believed to eventually reach the same success as Levemir, due to the strong competition from Sanofi's also recent Toujeo and Eli Lilly's Basaglar. The current leading drug in the market is Sanofi's Lantus, which is nonetheless decreasing its market share; **Pipeline**: Although the market size of branded (as opposed to generic) long-acting insulin is falling in the U.S., and RoW is expected to eventually follow the same trend, NN has in its late stage pipeline a product that a company argues will "change the insulin market" – **Insulin Icodec –** the first-ever once-a-week insulin in the market (insulins are usually taken daily). The drug has shown outstanding results in clinical trials, namely against Lantus, the current leader. It is widely expected to, upon regulatory approval, to take large chunks of Lantus' market share and be preferred to Sanofi's Soliqua and Eli Lilly's Basaglar.

Fast-acting: The fast-acting insulin market is mostly split between NN's NovoRapid and Eli Lilly's Humalog, the latter having the lead in the US while NN has in RoW. NN has recently (2018) launched Fiasp, largely to replace NovoRapid, while Sanofi recently issued Admelog, a biosimilar to Humalog (and a cheaper alternative to the latter). Eli Lilly holds a promising drug in its late stage pipeline – Lyumjev, which may prove to be a serious contender against NN's Fiasp for market leadership in fast-acting. **Pipeline**: NN currently has no major product in its fast-acting pipeline, which may be justified as Fiasp has been launched relatively recently and also since neither does Eli Lilly have other products in late pipeline (other than Lyumjev).



GLP-1: The GLP-1 market is currently the most exciting in the diabetes field, as GLP-1 products show significant improvements over insulin and also give the companies more optionality, since GLP-1 products have also shown potential in a wide range of issues associated with metabolic disorders. NN is currently very dominant in this market and the contenders are Eli Lilly and Astra Zeneca. For most of the last decade the market has been dominated by NN's Victoza, both in the US and abroad, only recently reducing its market share as patent expiry dates neared. Now, the US market is led by Eli Lilly's Trulicity, whose leadership is expected to be short-lived as NN has

recently launched Ozempic – a much awaited replacement to Victoza, which has demonstrated better performance and does not come (as of current data) with the potential pancreatitis risks of Victoza. Having only reached the market in 2019, Ozempic has been experiencing incredible growth, already having more than 30% market share in both the US and abroad and is also one of the main drivers of NN's expected performance in the near terms. **Pipeline:** Rybelsus is an NN product that has just left the pipeline and is expected to eventually replace Ozempic as the market leader. However, Eli Lilly has Tirzepatide in its late-stage pipeline, a drug that has showed markedly better results than Ozempic in clinical trials and is projected by some to have a peak sales potential worldwide of 10 Billion USD, more than any GLP-1 drug to date. Tirzepatide thus poses as a serious threat to NN's GLP-1 segment.

Obesity: NN is the absolute leader in the Obesity market. It enjoyed market dominance with its first obesity product (semaglutide marketed as Saxenda), whose growth projections have nonetheless been disrupted by the Covid-19 crisis, being considered not as essential as Diabetes drugs. In 2021, NN has launched yet a new diabetes drug (Wegovy) which has been showing astonishing growth rates and is often identified, along with Ozempic, as the main near-term growth driver for for NNs revenues. NN has virtually no contenders in this industry. **Pipeline:** Currently NN has no obesity drugs in its late-stage pipeline, which is justified given Wegovy's recent launch and lack of contenders. It is nonetheless testing (Ph1 and Ph2) a new class of products (cagrilintide, an amylin analogue, i.e. non-GLP-1) which when combined with Wegovy, yields even better results.

Biopharm: NN has been facing increasing competitive pressures in its biopharma segment, as drugs that long held its dominance in their respective therapeutic areas. In Haemophilia, NovoSeven still holds a market-leading position, but faces the threat of Roche's Hemlibra, while NovoThirteen faces increasing pressure froma series of drugs from Takeda. In growth disorders, Norditropin has been holding its market share, mostly due to supply chain issues in competitor companies, but also NN's recent approval of Sogroya may increase the company's lead in this market.

Others (Pipeline): As mentioned, NN is venturing into other areas, and currently has in Ph 2 trials an GLP-1 product (semglutide) for Non-Alcoholic Steatohepatitis (NASH), where NN aims to reproduce the Obesity market's situation (being first entrant, as currently there are no pharmacological treatments for NASH) – it is estimated that about 60% of diabetics suffer from Non-Alcoholic Fatty Liver Disease (precursor to NASH). It also has, from its acquisition of Corvidia in 2018, an ongoing Phase 2 trial for a product (Ziltivekimab) for Cardiovascular Disease.

Biopharm

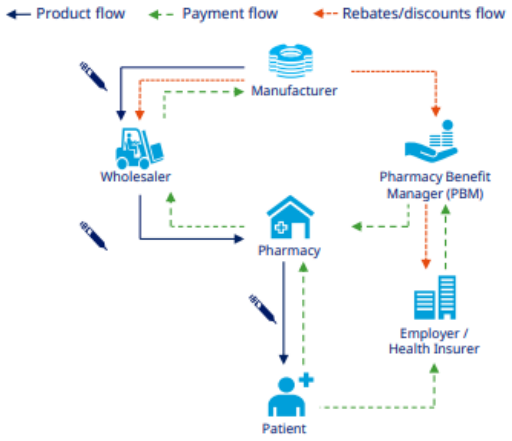
Biopharm Segment

The second main segment into which NN splits its operations is Biopharm. In this segment, Novo Nordisk mainly targets Haemophilia, Growth Disorders and Hormone Replacement Therapy, with the first two representing the larger part of revenues from this segment. Although NN only derives 15% of its revenue from this segment, it is the second largest competitor in the haemophilia market and is arguably its most robust segment (in terms of being less exposed to significant shocks from demand). It is also arguably the sector that may provide most future growth opportunities for NN.

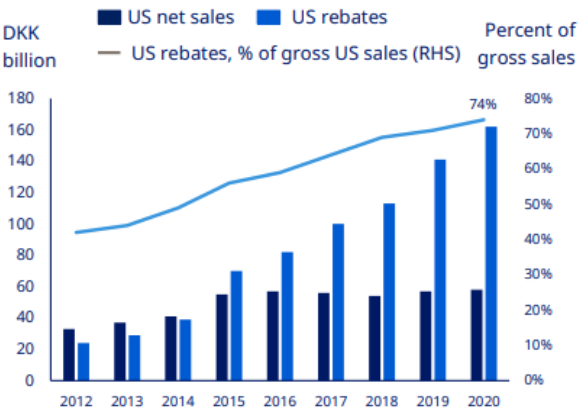
Haemophilia

Haemophilia is a disease that in most occurrences is inherited (genetic), however, it may also occur spontaneously (that is, without family precedence, through a sudden gene alteration) which are, as of today, unexplained. The estimates of the number of hemophilia patients worldwide ranges between 500 thousands to 1.1 million as of 2019. The main symptom of hemophilia is excessive bleeding, which can happen both internally as externally. Additionally, hemophilia patients are at higher risk of a series of complications, namely joint issues, cardiovascular disease, and kidney disease. Until the 1960s, life expectancy of hemophilia patients was only about eleven years, this has since increased significantly as new treatments have bene developed – currently, life expectancy is only about 10 years lower than the overall average. There are three types of Haemophilia, which happen due to malfunctions in different blood clotting agents – Haemophilia A (80% of all cases), B (16% of all cases) and the milder and rarer C (4% of all cases). NN's products treat types A and B.

Commonly Identified Risks



Three main risks are commonly identified for Novo Nordisk: **1) Price pressures**, especially in the insulin market in the U.S. There have been campaigns worldwide to lower insulin prices, and the problem is even more underlined in the United States where a highly complex health insurance system is in place, which further increases the distance between manufacturer and patient and has includes additional entities which wield significant bargaining power – so much so that even though NN's drug prices have been increasing, on average 14% a year between 2015 and 2019, its net revenues from the U.S. continued to be mostly flat, mainly because the 74% of NN's gross revenue value is lost to sales rebates and other deductions from the list price that result from the American Healthcare-Pharmaceutical ecosystem. Thus, NN may become subject to a situation where there are increasing demands for price decreases, while not being in a position to bargain with other stakeholders such as Wholesalers and Pharmacy Benefit Managers Given, thus taking on the bulk of the price reductions.



2) Biosimilars: are, as the name indicates, non-synthetic drugs (i.e., drugs that include living organisms as an important component, as opposed to generics), that are very similar to the original product. These are allowed to be manufactured after a patent has expired. NN's products have thus far not been a major target of biosimilars, mainly because producing a biosimilar insulin is in itself quite expensive (hence the modest discounts when compared to the original, only about 15% for insulins). Thus far only Sanofi's Lantus has been aggressively targeted by biosimilars, having bitten off a large chunk of its revenues post-patent expiry. Although NN is vulnerable to this risk as any other company is, it is well protected by its bespoke pipeline management – as soon as a patent expires, NN tends to have another strong contender to take its place.

3) Foreign currency risk: NN is based in Denmark yet operates worldwide, namely in many currencies that do not have a direct pairing with DKK. NN nonetheless resorts to diligent management of its FX risks, and we will not be giving them much attention in this report, given

the much larger scale of other risks we have identified.

Valuation

Valuation in the pharmaceutical industry involves higher degrees of complexity than in most other industries. Future revenues are highly uncertain, and companies are in a constant state of contingency due to the inherent unpredictability of clinical trial outcomes, different and changing regulatory frameworks in different countries, risks associated with longer-term outcomes of products, moves by competitors, and changing demographic dynamics, to name a few. In theory, such a description calls for assessing a pharmaceutical company as a set of options, where each project (drug) is essentially a set of potential future outcomes, the likelihood of which is derived from a mix of historical outcomes and understanding of the specific case at hand. This approach is mostly used to value smaller pharma and biotech firms, or separate projects within larger pharmaceutical firms – where real-options analysis, weighted net present value and monte-carlo simulations are often used. However, such approaches become less adequate to value large pharmaceutical firms, which have significant pipelines and a wide variety of different commercialized products. Besides being highly impractical, the value of such firms is arguably not “just” the sum of the value of each project, as their scope generates various synergies as well as inefficiencies which are hardly attributable to one single project. Large pharmaceutical companies are very diligent at managing risks associated to its pipeline, so much so that a phase III clinical trial failure of a highly promising drug or recall of a blockbuster drug would pose a challenge but would generally not be fatal. A phase I clinical trial failure often barely reflects in the company’s share price, while some biotech firms derive their entire valuation from products that are in pre-clinical trials. There is still, of course, a probabilistic dimension in the forecasts made for large pharma, but much broader generalizations are made, given that often market dynamics are highly dependent on the moves of only a few (large) competitors, and products for many conditions are already offered by such firms for many decades and thus there is a reasonable basis for assuming some predictability for certain markets.

Thus, we will follow the practice of most large pharma industry analysts and propose a share price based on a discounted cash flow valuation. We will not do this necessarily from a belief of being closer to an “intrinsic” valuation, but because we are bringing forth a factor that is not being considered by the analyst community and want to the demonstrate its impact on the value that is generally attributed to Novo Nordisk. By doing so we also assume a soft version of the perfect market hypothesis, that is, that the approximate market price is generally a reasonable reflection of all the information available to the public (for a commonly accepted valuation framework), but can of course be subject to inefficiencies. We consider that we will be adding value with our report by identifying one such inefficiency, most likely generated by “theory-induced-blindness”, as many years of adherence to a certain paradigm in diabetes treatment has been beneficial to investors, to NN, to medical practitioners, and also to many patients, ranging from those to whom NNs products are life-saving, to those who can live relatively normal lives thanks to NNs products (in the absence of a better understanding of type 2 diabetes) – that is, we consider that there is no need for any extraordinary insight to start to consider the potential impact that companies like Virta or low-carb/ketogenic diets in general may have on the prospects of drugs targeting diabetes and obesity, and that this should be reflected in the share price of NN.

Forecasts

Revenues

Being the products of greatest relevance for Novo Nordisk's top and bottom line, we projected NN's diabetes products in greater detail. We applied the consensus CAGRs for the industries of the different types of products, and then made an estimate of what would be each products' market share in a given year. Given its advantages/disadvantages vs competitors, and also patent expiry date. We forecasted the products' performance separately for North America and the Rest of the World (i.e. all countries outside of North America), given slightly different dynamics and patent expiry dates in both areas. One more reason for such split, is our intent to assess the impact of Virta Health, which we believe should only be applied to North America, given the ambiguities and sweeping assumptions that would need to be done for the startup to swiftly spread its client base abroad.

Long-acting: In the long-acting category, we expect Tresiba to be NN's major contestant as it takes away Lantus' slowly declining market share while also competing against other similar products to Lantus such as Toujeo and Soliqua. Eventually we expect that by 2024 Insulin Icodec should be approved and start to firmly take away market share from the remaining contestants, which by the end of the d ecade should still not have an appropriate competitor.

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Long-Acting North Am.	$ 44,300	$ 44,685	$ 38,944	$ 31,434	$ 28,326	$ 23,004	$ 24,385	$ 24,872	$ 25,370	$ 25,877	$ 26,395	$ 27,187	$ 28,002	$ 28,842	$ 29,707	$ 30,599
Growth Rate		1%	-13%	-19%	-10%	-19%	6%	2%	2%	2%	2%	3%	3%	3%	3%	3%
Tresiba®	0%	5%	13%	17%	20%	20%	20%	21%	21%	21%	22%	23%	24%	23%	21%	21%
Xultophy®	0%	0%	0%	2%	3%	3%	4%	4%	5%	12%	10%	9%	8%	9%	10%	11%
Levemir®	30%	28%	25%	23%	19%	14%	11%	7%	4%	2%	1%	1%	4%	2%	1%	1%
Icodec										1%	3%	6%	8%	13%	16%	20%
Lantus	68%	59%	49%	38%	30%	30%	25%	23%	21%	18%	17%	15%	12%	10%	10%	8%
Toujeo	2%	8%	9%	8%	8%	9%	11%	11%	12%	12%	12%	11%	11%	11%	11%	10%
Soliqua	0%	0%	0%	0%	0%	0%	3%	4%	6%	6%	6%	7%	8%	9%	10%	11%
Basaglar & Biosimilars	0%	0%	5%	13%	21%	24%	27%	29%	29%	29%	28%	26%	25%	23%	21%	18%

Fast-acting: As mentioned earlier, with companies' greater focus on GLP-1 and other potential once-weekly options, this category is possibly going to see less activity. A transfer in dominance is expected between NovoRapid and Fiasp, yet the latter will have to fend off against products similar to Eli Lilly's former Blockbuster Humalog, such as Lyumjev and Admelog. Nonetheless, Clinical Trials have shown Fiasp to outperform these new drugs, hence we are confident that it will retain the lead, but will not hold much more than third of the market, as it is significantly superior to competitors.

GLP-1: Currently the most exciting sector. With the retreat of AstraZeneca whose Bydureon and Byetta held significant presences in the market, and with a projected slow decline of Eli Lilly's Trulicity, NN was set to dominate the GLP-1 market for the following decade, with its products and pipeline covering short term (Victoza), medium term (Ozempic) and long term (Rybelsus) revenues. However, Eli Lilly's late-stage pipeline drug Tirzepatide showed unmatched results and the drug is now frequently projected to be a future blockbuster, with some analysts speculating its market share to be at 80% by 2030. We however opt for a more conservative forecasted, also taking into account any potential delays with the approval or other related issues and keep Tirzepatide's share at just above 50% by 2030, being followed by Rybelsus and Ozempic by the end of the decade.

Premix: This category features insulins that are a mix of two different types of insulin. A "premix

market" is not often defined, occasionally with some premix products being included in another market and often considered separately. We have forecasted NNs NovoMix, its product with the biggest number of users in the US (being also the cheapest after Human Insulin), to continue its slow decline. Although its patent has long expired, it is still popular due to its reliability and affordability. In the absence of any other benchmarking information, we have estimated Ryzodeg's growth rate as the average growth of its two constituents (insulin degludec, such as Tresiba, and insulin aspart, such as Fiasp).

Obesity: Expectations regarding obesity products have been among the main protagonists in NNs recent rise in share price. After Saxenda's lackluster performance in the last few years, the astonishing launch of Wegovy has reignited excitement regarding a potential branded obesiy market (created and led by NN). After being approved in the US in late 2020, Wegovy seems to be on track to surpass Saxenda's revenue in its first year of commercialization, without apparently taking away market share from Saxenda (50% of new prescriptions are entirely new to Obesity medications, while most of the other half eats into revenues of "smaller" Obesity drugs). We do acknowledge that it is an impressive drug, that allows for up to 20% weight loss, yet we only adhere to more conservative consensus estimates (which are still very generous, with around 50% CAGR until 2030), while Saxenda will slowly decline.

Biopharm: The entire segment is set to experience a decline in importance in NN's overall revenue numbers, yet in both haemophilia and growth disorders it will not experience declines in absolute terms, as products are either very well protected by patent expiry deadlines even beyond the forecast horizon, or can maintain solid market positioning even after patent expiry, such as NovoSeven.

Final Valuation

By using this model, and taking the WACC from Bloomberg (and forecast that in future years it returns to usual values closer to 6%, rather than current 8%). We arrive at a share price of around 530 DKK, which is also within reasonable bounds of the comparables analysis with industry peers. We thus believe that it is overvalued vs current price (around 635 DKK), and we recommend to sell.

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