

# VALUATION OF NOVO NORDISK A/S



## **Master's thesis**

Hand-in date: 15-05-2017

Supervisor: Michael Hedeman Clemens

Number of standard pages: 108

Number of characters: 245,231

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May 2017

## Abstract

This thesis aims to assess the fair value of a Novo Nordisk A/S (NOVO-B) share on April 24, 2017 and finds it to be 318.0 DKK.

The primary competitive driver in the pharmaceutical industry is having the most well-developed product. Novo Nordisk is the global market leader in diabetes care and has leading positions in multiple biopharmaceutical markets.

Novo is well positioned to maintain or further its leading position, supported by a strong portfolio of products, effective commercial operations and a strong R&D pipeline. The introduction of lower-priced biosimilar insulins, increased bargaining power of buyers and technological advances from competitors represent major threats to Novo's future profitability.

Therefore, Novo Nordisk's future revenue growth will be driven mainly by increases in volume, so Novo's historically high profitability is expected to gradually decrease but remain at a level significantly above the industry average.

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## Introduction

Today, it is easier than ever to quickly check the current share price of a company trading in a public market, but it is not easy to immediately determine whether a specific stock is under- or overvalued at its current price. If the current share price is over or below the fair share price, an investor can make a profit by either buying or selling short the share at the current traded price.

Conducting an in-depth valuation of a company can not only help the investor establish an estimate of the fair price of a company. It can also help illuminate the important assumptions and drivers underlying the future profit and cash flow potential of the company, which can help external investors or potential investor make better decisions based on their own expectations.

From a theoretical standpoint, the present fair value of an enterprise is the present value of all future cash flows. Determining estimates for the future cash flows requires forecasting based on extensive strategic and financial analysis of the underlying business. This task provides an excellent opportunity to apply the knowledge and learnings from the authors' respective M.Sc. studies.

Furthermore, Novo Nordisk A/S is an interesting company with a remarkable history of significant revenue growth. The excellent historical financial performance of both remarkable revenue growth and large margins beg the question of whether these results are sustainable in the long-run. The share price of Novo peaked at 401.3 DKK in late 2015, and subsequently declined to 225.5 by late 2016 constituting a drop of about 44%. This has investors wondering whether Novo is now undervalued, or whether the market overreacted to news regarding Novo's future growth prospects. An unbiased estimation of Novo's future potential can help shed light on this question.

Finally, valuing a pharmaceutical firm that is heavily reliant on R&D and operates all over the world provides an interesting opportunity to apply strategic and financial frameworks and analyze the influence of developments within politics, the economy, technology and new pharmaceutical innovations.

Through conducting a full-fledged valuation and subsequent sensitivity analysis, this thesis aims to illuminate the underlying value drivers of Novo's business, estimate the fair share price as of April 24, 2017 and demonstrate how key assumptions impact the future prospects of Novo Nordisk A/S.

## Problem statement

The main research question of the thesis is the following:

- What is the fair market value of one Novo Nordisk A/S (NOVO-B) share as of April 24, 2017?

To answer the primary question, multiple supplementary questions will be answered:

Industry & company overview:

- What are the main competitive drivers in the general pharmaceutical industry and within the fields that Novo Nordisk engages in?
- What business model does Novo Nordisk follow?

Strategic analysis:

- What external factors influence the cash-flow potential and risk of Novo Nordisk?
- What is the overall level of attractiveness of the industry and how does it affect Novo Nordisk?
- What are Novo Nordisk's key internal resources and capabilities?
- What are the sources and effect of Novo Nordisk's sustainable competitive advantages?
- To what extent do all these factors affect Novo Nordisk's expected future performance?

Financial analysis:

- How have Novo Nordisk's financial value drivers performed compared to the firm's peers?
- What is the historical and expected profitability of Novo Nordisk?

Forecast:

- What is the outlook for each market that Novo Nordisk operates in and how will it affect the firm's value drivers?
- How is Novo Nordisk's market share expected to develop, and how will this affect revenue growth?
- How is Novo Nordisk's financial value drivers and profitability expected to develop in the future?

Valuation:

- Based on the strategic and financial analysis, what is the fair market value of one NOVO-B share?

- What multiples are Novo Nordisk trading at and what are the fair multiples implied from the valuation?
- To what extent will the valuation change, based on minor adjustments to the underlying value drivers?
- Within what range should we expect the value of Novo Nordisk to lie within?

The main goal of the thesis is to establish an accurate estimate of Novo Nordisk's fair share price. The supplementary questions will help structure the overall analysis and provide the reader with a relevant context in which to interpret the analysis.

The thesis is based upon publicly available information from secondary sources, which can be considered equivalent to what is known as "desk research". The thesis draws upon information that can be obtained by any external investor or equity analyst, as well as private investors. Thus, the framework laid out in this thesis could also serve as a good starting ground for a private investor wishing to perform their own valuation of Novo Nordisk.

As circumstances and financial markets change, the valuation is conducted as of market closing April 24, 2017. Thus, all information used in the thesis is up-to-date until April 24, unless otherwise stated. Any information released after this date will therefore not be considered in the thesis. This also implies that an equivalent analysis with the same approach could yield different results if conducted after the cut-off date of April 24, 2017.

## Structure of thesis

This section provides an overview of the methodologies used in the paper. Also, this section will elaborate on the reasons for the choice of models and justify their selection in favor of alternatives.

We will then provide an in-depth description of the pharmaceutical industry with a specific emphasis on the fields in which Novo Nordisk operates. Following the industry description, we will provide a detailed description of Novo Nordisk, its current capital and share structure, its markets and its product portfolio. This is done to develop an understanding of the value drivers in the industry and provide a foundational understanding of Novo Nordisk as a company.

We will then focus on an analysis of the Novo Nordisk's strategic situation. The section will be devoted to understanding Novo Nordisk's sustainable competitive advantages, based on an analysis of the

characteristics of the firm's external and internal environment. The analysis will follow a top-down approach in which we start by viewing Novo's macro environment and gradually move closer to the firm. This section aims to develop an understanding of the strategic value drivers that are expected to influence the future financial performance of Novo Nordisk.

Following the strategic analysis of Novo Nordisk, the paper moves on to provide a forecast of future revenues and costs. We follow the approach recommended by Petersen and Plenborg (2012), where all line items are forecasted as a function of the forecasted revenues.

After the revenue forecast, we will present pro forma statements that will form the basis for the subsequent valuation based on discounted cash flows (DCF).

Finally, to assess the quality and sensitivity of the valuation, we will conduct a Monte Carlo simulation that will help shed light on possible outcomes if the value drivers develop differently than expected. This final section will conclude with an analysis and discussion of the valuation and the current share price. This final section will also discuss reasons for the discrepancy between the actual traded price and the estimated fair price.



## Delimitations

- For simplicity, the day of valuation is set to be April 24, 2017. We do not consider information and data that has not been made available by this day.
- We use the DCF valuation approaches as the primary tool of valuation. Multiples will be used to provide a point of comparison.
- Real options have been argued to be a valuable tool of valuation of biotechnology firms. However, based on the information available, applying the real options approach is unlikely to contribute to a more accurate valuation. Instead, we have attempted to capture some of the inherent uncertainty in forecasting by applying a Monte Carlo simulation.
- We expect that readers have knowledge of financial statement analysis, valuation and strategic analysis on the level of a student in M.Sc.AEF or M.Sc.FIN or above. As such, we assume that the readers will have an understanding of all the theories and concepts used in the thesis, and we therefore do not provide any introduction to the concepts beyond a short description. The aim of this thesis is to apply the concepts in a practical setting. If any theories are included that an AEF or FIN graduate cannot be expected to know, a further description will be provided.
- If necessary, a justification for choice of models will be provided. A brief discussion on the theoretical merits of the concepts utilized in this thesis will be provided in the methodology section.
- We assume that none of the underlying conditions that Novo Nordisk treats will be cured in neither the forecast or terminal period.
- We will only consider the business segments that Novo Nordisk currently operates in, but we will discuss how a potential shift in M&A strategy could impact Novo Nordisk.
- We will only consider financial statements dating back five years (2012-2016).
- As North America has been the most tumultuous yet important market for Novo Nordisk, we perform an individual forecast of the region for diabetes. The rest of the world (denoted "ROW") will be forecast as one market.

## Methodology

This section will provide the reader with an understanding of the methodologies used to answer the research questions. Also, this section will consider any alternative models and provide a justification for the choice of models.

### Strategic analysis

A company's strategy and environment plays a significant role in its cash-flow potential and evaluating Novo Nordisk's strategy and strategic environment is thus a key step in assessing the value of the firm.

For the strategic analysis, we will follow the framework in Petersen & Plenborg (2012) and perform a strategic analysis with the aim of identifying the key value drivers - both internal and external - that play a role in Novo Nordisk's ability to generate long-term economic profit.

The following section contains an overview of the factors that we intend to analyze along with a detailed description of how the analysis will be conducted.

### External factors

#### *Macro factors – SLEPT analysis*

The external macro environment surrounding the firm is a necessary step to analyze due to its impact on a firm's strategic decisions on how and where to compete. The most commonly used analytical tool for analyzing a company's macro environment is the PEST model (Political, Economic, Sociocultural and Technological) which we consider to be the optimal framework for this paper. The PEST analysis is very flexible and comes in a myriad of variations<sup>1</sup> including a wide range of factors (Jurevicius, 2013).

The optimal choice of model for analyzing macro factors is one that includes the factors that are relevant for the target company, and no more. The analysis should only contain elements that are expected to have a real impact on Novo Nordisk.

For the analysis of Novo Nordisk's macro environment, we have chosen to apply the SLEPT variation of the PEST. The SLEPT model is similar to the PEST in most ways, but it adds a legal dimension. One could argue that the traditional PEST covers the legal area in the P (Political), but we feel that

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<sup>1</sup> Variations include, but are not limited to: PEST, PESTLE, LONGPESTLE, PESTELI, STEEP, SLEPT, STEEPLE, STEEPLED, PESTLIED

separating the political and legal analyses is beneficial as both areas require extended explanation and analysis and are highly relevant to the specific nature of the business that Novo Nordisk operates.

In this case with Novo Nordisk, we believe that an exhaustive model such as LONGPESTLE would lead to too much redundant information and provide little analytical benefit compared to a simpler model. We have chosen the SLEPT as we consider it to provide a sufficiently expansive analysis while not contributing to information redundancy.

### *Industry factors*

Moving closer to the firm, this section will explain the framework used in analyzing factors that affect the attractiveness and development of Novo Nordisk's industry. According to Petersen & Plenborg (2012), the attractiveness of an industry is dependent on the possibilities of earning acceptable returns, defined as returns equal to or above the cost of capital.

Several drivers in the industry can affect returns, but it is generally accepted that increased competition reduces the possibilities of generating returns above the cost of capital. One of the most commonly used frameworks for analyzing the attractiveness of an industry is the Five Forces analysis by Porter (Porter, 1979).

While the Five Forces model is likely the most ubiquitous model on industry environments, other theories have emerged in recent decades that some argue explains the nature of an industry in a more accurate way. One theory concerns the formation of business ecosystems (Moore, 1996).

Moore defined a business ecosystem as "An economic community supported by a foundation of interacting organizations and individuals—the organisms of the business world. The economic community produces goods and services of value to customers, who are themselves members of the ecosystem." (Moore, 1996, p. 26). The idea is that a firm exists as part of a system of interdependent actors and thus needs to develop mutually beneficial relationships with stakeholders such as customers, suppliers or competitors.

Moore's theory on ecosystems is highly applicable to technology-heavy companies, particularly within IT. For example, social networks need a user-base to become attractive to other users, and video game consoles need third-party game developers to produce games before becoming attractive products.

We do not consider the products developed and sold by Novo Nordisk to have the same degree of interdependency as for example social networks or video game consoles.

Thus, we see no added value of using an ecosystem-based analysis compared to the traditional framework established by Porter (1979), and hence the industry analysis will be conducted based on the Porter's Five Forces framework. We use Porter's Five Forces to assess the state of the industries in which Novo operates, and the firm's position within them.

### Internal factors

#### *Internal resources*

The frameworks have so far been focused on developing an understanding of the opportunities and threats Novo Nordisk faces in its external environment. Following these analyses, we will have a sense of the market size, market growth and the opportunities to earn excess returns in the industry. The next step is to assess the internal capabilities of Novo Nordisk.

A common method, and the one we choose to apply here, is to view the firm as a bundle of resources (Barney, 1991). This approach is also known as the Resource Based View (denoted "RBV"). These resources are evaluated based on several characteristics to assess their value in building a sustainable competitive advantage, which should allow the firm to produce consistent excess returns.

As is the case with most prolific theories, the resource-based view (RBV) has been subject to considerable critique from researchers in the past two decades. A key point of critique is mentioned in (Dushek, 2004) and is based on the "relational view" that firms gain competitive advantages through its inter-firm cooperation and network resources. The resource-based view sees firms as individual entities and fail to consider sustainable competitive advantages that may arise from a firm's dealings with other firms in its environment.

In this case, we do not find the criticism applicable to an analysis of Novo Nordisk. In contrast to competitors, Novo has mainly developed their internal capabilities organically (Torsoli & Kitamura, 2015) and thus we do not consider Novo Nordisk strategically reliant on inter-firm relations such as strategic alliances or joint ventures. Although Novo does engage in minor collaborative projects with other organizations (Svansø, 2017), the firm is not strategically reliant on these projects. Considering the way that Novo Nordisk approaches its products and other firms in the industry, we view the firm

sufficiently independent for the resource-based view to be the most applicable framework for analysis.

### *SWOT analysis*

Identifying the key internal and external strategic drivers is the final aspect of our strategic analysis. Since we at this point will have already performed an extensive review of Novo Nordisk's external and internal value drivers, the SWOT model will serve more as a summary of all the previous issues in a way that allows us to apply them in the upcoming financial analysis.

### *Forecasting*

The first step in forecasting line items is to determine the length of the explicit forecast. When valuing large, established firms it is often common to explicitly forecast the next five years (Petersen & Plenborg, 2012), but due to the potential impact of expected product launches and patent expiry for Novo and competitors, we believe that a longer forecast period is required to ensure that the company has achieved a steady state by the end of the forecast period. We have decided to forecast Novo's cash flows explicitly until 2030. The forecast length has been chosen based on Novo's current product pipeline, from which we predict product launches as late as 2025, hence we cannot consider a steady state until 2030 where we expect all products to have reached their long-run market shares. A forecast period further than 2030 would not contribute positively, as we believe all products currently in development will have been either launched or terminated at this time.

There are several ways to approach the forecasting of line items in the income statement and the balance sheet, but following the framework in Petersen & Plenborg (2012), we have chosen to apply a sales-driven forecast in which the different value drivers are forecast as a function of the expected level of activity (sales growth). This method is assumed to have a better link between the activity levels of a company and the related expenses and investments than i.e. a line-item approach in which each line-item is forecast without reference to the revenue. As such, revenue becomes by far the most important element of our forecast, as most line items will depend directly on it. To forecast the revenue, we have chosen a top-down approach, where we start out by forecasting the total value size of the markets in which Novo Nordisk operates. Then, we forecast the expected market share of the Novo products, which is translated into an overall figure for expected revenue growth, which will drive the forecast for line items and free cash flows to the firm (FCFF). This forecast of size, market share and revenue growth will be based upon the strategic analyses provided in accordance with the guidelines in Petersen & Plenborg (2012).

## Financial analysis and valuation model

The first step to our valuation is to choose the valuation model best suited to our task. As was the case with the strategic analysis, we aim to apply a model that fits the particular case company, while minimizing guesswork and unnecessary extra material.

There are many options when it comes to the choice of primary valuation model: Relative Multiples, Discounted Cash Flow (DCF), Liquidation and Real Options. The theoretically correct value of a company is the present value of all future cash flows meaning that a DCF analysis provides the most accurate result if used with the correct inputs. It is considered the most flexible and accurate model and it is a favorite both in the industry and among academics (Koller, et al., 2010). Thus, for this paper, the primary tool will be the Discounted Cash Flow model.

Relative Multiples is another commonly used model. The primary benefit of relative valuation models is the ease of execution. Thus, even though they may not provide as accurate a picture as the DCF-based valuation, we choose to include a relative valuation to compare Novo Nordisk with similar firms and the pharmaceutical industry in general. Relative multiples will not constitute the foundation of our valuation, but instead form a point of comparison between Novo Nordisk and its peers.

The liquidation approach is mainly used to understand the minimum value of a company, and is primarily used in the valuation of distressed firms (Petersen & Plenborg, 2012). On both a cursory glance and following an extensive analysis, we have found little evidence to suggest that Novo Nordisk could be considered distressed. Thus, a liquidation valuation will likely significantly undervalue Novo Nordisk, for which reason it will be omitted.

Another approach to consider is the Real Options approach as developed by Fischer Black and Myron Scholes (Black & Scholes, 1973). The Real Options approach has received significant attention in the valuation of biotechnology firms as it can be used to value each individual drug as an independent NPV project, with the firm's value being the combined value of all the projects (Kellogg & Charnes, 2000). Given the nature of Novo Nordisk's business, it would be possible to value the firm as a portfolio of projects. We do, however, believe that the information available to us as external analysts is insufficient to perform an accurate valuation of the firm's individual projects. Estimating the success chances and adjusted profitability ratios of each drug would rely too heavily on arbitrary judgement, and we are thus not confident in the reliability of a Real Options based approach.

Novo Nordisk stated in their 2016 annual report that they found their capital structure to “serve the interests of the shareholders and the company well, providing strategic flexibility to pursue Novo Nordisk’s vision” (Novo Nordisk Annual Report, 2016, p. 44). Thus, we expect no significant changes in the capital structure. We therefore do not consider the advantages provided by the Adjusted Present Value (APV) model to be necessary for this paper.

The Discounted Cash Flow model comes in different variations<sup>2</sup> (Petersen & Plenborg, 2012). We choose not to apply the Free Cash Flow to Equity model as that is more relevant to financial institutions (Damodaran, 2009). Due to potential challenges of accurately assessing the cash flow to equity, we also choose not to apply the Residual Income nor the Dividend Discount models.

Thus, for the valuation, we will apply the traditional Free Cash Flow to Enterprise model (Petersen & Plenborg, 2012, p. 216) exclusively. The model provides an estimate of the total enterprise value by discounting future Free Cash Flows to the firm (FCFF) with the Weighted Average Cost of Capital (WACC):

$$\text{Discounted Cash Flow to Enterprise} = \sum_{t=1}^n \frac{FCFF_t}{(1 + WACC)^t} + \frac{FCFF_{n+1}}{(WACC - g)} * \frac{1}{(1 + WACC)^n}$$

We will also provide a detailed analysis of Novo Nordisk’s expected WACC including an analysis of the appropriate beta value for the equity of Novo Nordisk.

To solidify the valuation and stress-test different scenarios, we will perform a Monte Carlo simulation of outcomes of the valuation. The MC simulation will allow us to establish confidence intervals for the current value of Novo Nordisk and illustrate the sensitivity of the valuation to changes in the value drivers.

## Data collection and source criticism

The annual reports of Novo Nordisk, Eli Lilly, Sanofi and investor presentations from Novo Nordisk and competitors will serve as the primary source of data for this thesis. We recognize that the firms might have an incentive to provide positively inflated views of the firms, and that this should be taken into

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<sup>2</sup> Including, but not limited to: Enterprise-DCF, FCFE, EVA, Dividend Discount, Residual Income, APV

consideration when collecting data from these sources. While we acknowledge this circumstance, we consider that both Novo Nordisk and its closest competitors are publicly listed companies and are subject to rule and regulations about openness, transparency and requirements about external auditing. Because of these factors, we believe that the annual reports and investor presentations from Novo Nordisk are as unbiased as they can be and of sufficiently high quality to serve as basis for the valuation. For Novo Nordisk's competitors, the same applies and we will therefore also use their annual reports without adjusting for potential bias.

The investor presentations on Novo and its competitors are similarly believed to be free of bias, as they use information from external firms reporting on the aggregated market. Any news articles and analyst reports used in this thesis will be individually assessed and are therefore also expected to be unbiased. Apart from annual reports and investor presentations, Bloomberg, FactSet, Thomson ONE Banker and Reuters will be used as data sources. These sources are used by most reputable financial institutions and are thus considered to be of high quality. Any theories and literature used in this thesis is peer reviewed and thus also considered credible.



## Industry overview

This section provides the reader with an overview of the most important characteristics of the pharmaceutical industry and serves to develop an understanding of the life cycle of a pharmaceutical product. This will let us gain a cursory understanding of the key drivers of competition in the industry.

### A pharmaceutical firm's value chain

Several types of pharmaceutical firms exist (Aitken, et al., 2014). The first two categories are API (active pharmaceutical ingredients) manufacturers which produce the raw compounds used in pharmaceutical manufacturing, and finished-form manufacturers which produce the final product that is consumed by patients. Furthermore, finished form manufacturers exist in two forms. The first is a generic company that manufactures drugs that are no longer protected by patent. The second is an innovator that invests heavily in R&D to develop and market new medicines. Novo Nordisk is a full-fledged innovator firm.

An innovator's core business primarily relies on its research and development (R&D). A new drug goes through rigorous testing and multiple trial phases (illustrated in Figure 2 in the next section) to reach the market. Trials involve tests on both animals and humans in multiple settings to determine its efficacy and safety of use (US Food and Drug Administration, 2017a). The process of developing and approving a new drug can take more than a decade, and costs can reach more than a billion US dollars (ITA, 2016). Roughly half of new medicines fail in the later stages of testing, and even the ones that succeed often fail to make a profit for the firm. Only 20% of new drugs generate returns above the average cost of development, and according to the US Census Bureau (and cited in ITA, 2016, p. 3), less than 10% of all biopharmaceutical firms are profitable.

Pharmaceutical firms usually conduct research on multiple promising compounds at any given time. This is due to both the long development process from initial discovery to marketable product, as well as the high failure rate of new drugs. These compounds will enter new development phases at different times and thereby create a continuous pipeline for the pharmaceutical firm. Novo Nordisk is no different in this regard, as we will demonstrate later.

According to Campbell (2008)<sup>3</sup>, key competitive advantages within R&D comes from being the first on the market with a new drug (which lets the firm operate without competition from substituting

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<sup>3</sup> The remainder of this section is derived from Campbell, 2008

products) and having the most efficient treatment for the target condition (which makes patients favor that treatment). By using the aforementioned continuous development of new compounds, a firm can regularly release new drugs or improved versions of existing ones, thus ensuring competitiveness.

As the final product gets ready for launch, manufacturing is prepared for global distribution. In manufacturing, the main sources of competitiveness originate from the development of reliable and cost effective production. Manufacturing of drugs is a highly regulated and complex field, and a drug that has previously been approved can find its approval revoked if the regulatory demands in manufacturing are not met. Due to these high quality concerns, most pharmaceutical firms rely on just a few, key manufacturing plants to make overseeing them easier.

Commercial operations serve as the front office of pharma, and creates demand via promotional programs. In most industries, demand comes from the consumer wanting to use a specific product, and the consumer has full discretion over which product to invest their money in. The pharmaceutical industry differs from this by having doctors prescribe medication and, depending on country, having the state, employer or insurance pay the majority of the costs associated with the drug. Thus, the “consumer” has less choice on which product to use but is typically less affected by differences in price. All three groups, doctors, patients and payers, have different preferences when it comes to drug prescription.

A doctor’s primary function is the effective treatment of harmful conditions, and as such, they are incentivized to prescribe the most effective drug available. Patients may have personal preferences from previous usage or from advertising or other promotional activities. Depending on the level of reimbursement, they may also be affected by the price. The payers’ primary incentive is to minimize costs by choosing the least expensive treatment. The choice of which drug is prescribed thus heavily depends on the balance between all three actors and may vary heavily depending on the level of reimbursement a patient has available.

This unique balance means that when a pharmaceutical company wants to create demand, they have to influence all three groups in order for doctors to prescribe their product. This is done through specialized sales efforts that are tailored to specific products, regions and consumer groups, making each area important areas of competition for a pharmaceutical firm.

Balancing the needs of several distinct group for each product in the promotional efforts requires substantial resources. In the United States, pharmaceutical companies engage directly with physicians through a large salesforce (Fugh-Bergman, et al., 2007) with the aim of driving demand through personal relations with doctors. As doctors engage with both patients and insurance firms in the US, building a relationship with physicians is key to sales in the country. As a result, pharmaceutical firms spent an estimated \$5 billion in 2000 on one-on-one contact with doctors, about a third of total advertising expenses (Fugh-Bergman, et al., 2007).

Apart from engaging in development and manufacturing of new drugs, many innovators seek to expand their operations outside their own capabilities. This is done by engaging in mergers & acquisitions or by developing strategic alliances to improve the firm's portfolio. This is often done by acquiring firms that own patents or compounds that can be directly added to the product portfolio or to speed up development (ITA, 2016). The business development units of pharmaceutical firms thus play a key role in supporting the firm's R&D department by filling up holes in the product pipeline.

To maintain public safety standards, the pharmaceutical industry is highly regulated, and getting a new drug approved requires a heavy commitment from both researchers and regulatory staff. Pharmaceutical companies therefore tend to invest heavily in regulatory functions in order to meet the demands of regulatory agencies whose standards and approval processes often differ by country.

Lastly, as with most other industries, pharmaceutical companies rely on a number of general support functions such as legal, HR, finance and IT. Generally speaking, these functions exist to maintain the overall integrity of the firm and is rarely a source of competitive advantage (Aitken, et al., 2014). The aim of these functions is therefore primarily to maintain the firm in the most cost-efficient manner possible.

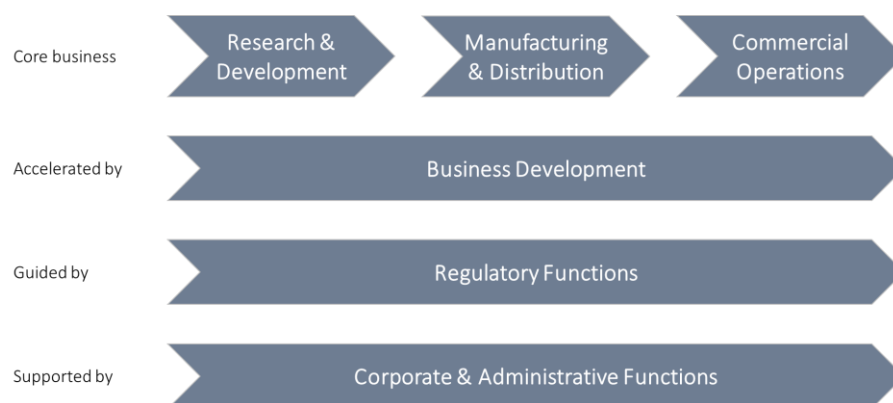


Figure 1: Overview of the value chain of a pharmaceutical firm. Compiled by authors. Source: Campbell (2008), pg. 10

## Pharmaceutical product life cycle

### The drug development process

The first step of drug development<sup>4</sup> is the Discovery phase, in which the primary goal is the discovery of new compounds that can be beneficial. New compounds can be discovered in a multitude of ways, from the result of targeted tests on specific diseases to large-scale test of molecular compounds to find all possible beneficial effects against a large number of conditions (US Food and Drug Administration, 2017a). Potentially, thousands of compounds can be candidates at this early stage, and once researchers find a promising compound they move to the Development phase in which they perform experiments on the potential benefit, optimal dosages, potential side effects, interaction with other drugs and a range of other key characteristics. These experiments are performed in labs or through computer simulations.

The most promising of these compounds enter pre-clinical trials where tests are performed using the compound on animals. The primary goal of the pre-clinical tests is to examine the drug's level of toxicity, or the potential of the drug to cause serious harm.

If the compound is deemed safe for human use, it proceeds to the third stage and enters clinical trials on humans. Pre-market clinical trials consist of three phases: 1) Tests on 20-100 healthy volunteers or people with the target condition with the primary aim being to test safety and dosage levels. 2) Several hundred individuals with the target condition with the purpose of determining efficacy and side effects. 3) 300-3,000 volunteers with the target condition to determine efficacy and monitoring of adverse reactions.

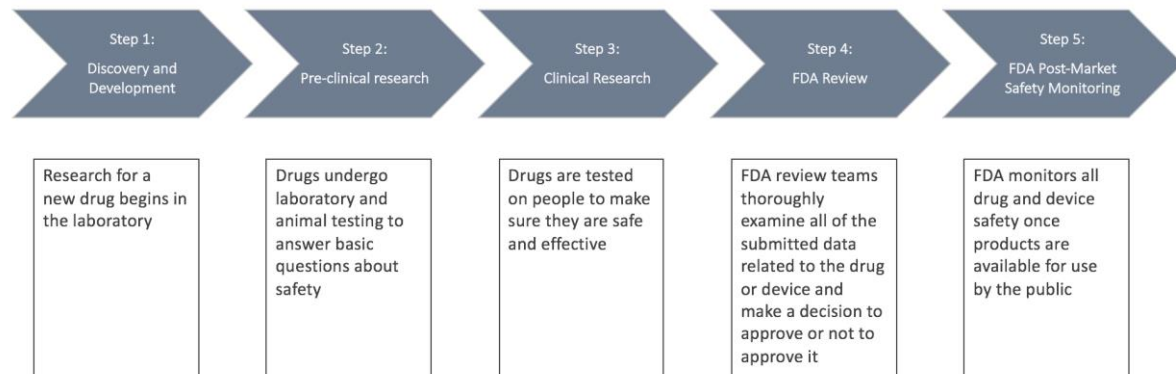
If all three trials are successful, the drug is submitted to the FDA for approval. Most drugs follow the standard review system (US Food and Drug Administration, 2017b) in which the target time for approval is 10 months. Some drugs, which represent major advances in treatment or provide treatment to previously untreatable conditions can be subject to a Priority Review which takes approximately 6 months.

If the drug is approved by the FDA and reaches the market, it will be subject to Phase 4 trials or Post Market Safety Monitoring to ensure the validity of the results of the previous trials. Phase 4 can be either mandated by the FDA or voluntarily undertaken by the firm to test potential new markets, or

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<sup>4</sup> The following contains a description of the process of getting a drug approved by the US Food and Drug Administration (FDA). Other countries and markets have local agencies serving a similar function.

for other reasons (such as testing on pregnant women who may not be willing to submit themselves for the previous trials). The safety surveillance exists to detect any rare or long-term side effects on a large population and over a longer period.



*Figure 2: The drug development process. Compiled by authors. Source: US FDA. Other countries have agencies serving similar functions*

Getting a compound through all the stages of development and successfully market it is a long and resource-consuming process. Out of every 10,000 new compounds discovered, only 250 make it to pre-clinical trials. Out of those 250, 5 make it to clinical trials on humans, and only 1 in five succeed in all pre-market trial phases (Stevens, 2016). The entire process usually takes between 12 and 18 years and the cost to develop a single drug in the US is approximately \$1.2 billion (Holland, 2013). Due to the time, costs and high failure-rate of new medicines, the long and continuous product pipeline plays a key role in ensuring a constant revenue stream.

### The importance of patents

The patenting of compounds plays an important role in the pharmaceutical industry, especially in the case of research-based innovators like Novo Nordisk. Due to the high costs associated with developing new drugs, the years in which the inventing firm has the exclusive right to market the product are extremely important. When a promising compound is discovered, the firm typically moves to patent it in order to protect their rights to the drug. The patent typically lasts for 20 years (TRIPS, Article 33) from the moment they are filed.

A patent is usually filed when the promising compound is discovered, and not when it is brought to the market, which means that the effective period of commercial exclusivity is much less than the 20 years, with studies showing an average commercial protection period of 11-12 years with not all of those being peak sales years (Campbell, 2008, p. 34). This incentivizes pharmaceutical firms to be as

efficient as possible to minimize pre-market phases and thereby maximize the effective commercial protection period.

When a drug loses its patent protection, its sales are quickly eroded by generic substitutes. These generics are bio-equivalent to the original drug and must have the same attributes as the original (US Food and Drug Administration, 2017c) in dosage form, strength, safety and other general characteristics<sup>5</sup>. These generics do not have to conduct clinical trials as they are comparable to the original drug, but instead conduct brief bioequivalence tests. This process is much shorter and means that generics typically reach the market shortly after the original patent expires.

The generics are typically priced at a fraction of the original drug price, which usually leads to erosion of the original drug's profitability (van de Vooren, et al., 2015). This further necessitates the constant flow of new compounds for research-based pharmaceutical companies to remain profitable. As we will demonstrate later, a noteworthy aspect of patents is that they are not always filed at the same time in all countries, nor do all countries provide the same allowance for duration of the patent, leading patents to expire at different times in different countries meaning that the product life cycle for pharmaceuticals is not uniform across countries.

There are ways that a pharmaceutical company can extend its patent of a drug. If the approval of a new compound takes longer than expected to complete, it is possible for the patent holder to apply for extension of the patent through the Patent Term Restoration Program (US Food and Drug Administration, 2017d). This is only possible if the marketable time of the product is less than 14 years, and up to a maximum of 5 years can be restored to the patent. Another way to keep an off-patent drug relevant is through the use of special delivery systems, support programs or other initiatives not directly related to the compound. An example is Novo's Norditropin<sup>6</sup>, a treatment for growth hormone deficiency. Competitiveness in the market for growth hormone therapy is largely determined by convenience and patient-care programs and not the drugs themselves, so even though the drug's patent expires in 2017 (Novo Nordisk Annual Report, 2016, p. 101), no biosimilars are expected to enter the market.

Despite the importance of patents in ensuring that a newly developed drug generates adequate returns, having a patented drug does not guarantee monopoly. Other innovators are free to pursue

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<sup>5</sup> Despite the similarity of the terms, there is a difference between drugs that are biosimilar and bioequivalent.

<sup>6</sup> See the segment on Growth Hormones in Porter's Five Forces for more

development of their own compound with similar properties, providing competition through substituting products.

Typically, when a new type of treatment is discovered, the innovator enjoys a period of monopoly by being first mover, but it does not take long for the competition to catch up. In the 1970's, the average time from first market entry to entry of a follow-up drug was 10.2 years (DiMasi & Paquette, 2004), but by the late 90's this period of exclusivity has shrunk to just 1.2 years.

#### Summary of competitive factors in the pharmaceutical industry

As is the case in most industries, pharmaceuticals compete heavily on the characteristics of their products. The extremely R&D-heavy nature of pharmaceuticals, as well as the high regulatory standards mean that developing a new drug and entering the market may take many years and often costs hundreds of millions of dollars. The high failure rate and costs of R&D, combined with the demand for high-quality treatment means that pharmaceutical firms tend to work on multiple new drugs in their pipeline at any given time.

There is a constant high pressure on developing and receiving approval of new drugs as efficiently as possible. This is a result of the temporary nature of patents which are important in order to gain a satisfactory return on the significant investment of developing a new drug. Although the effect has lessened recently, being first-to-market with a new treatment means that a firm can enjoy a period of monopoly until competing firms develop drugs with similar functions. Lastly, the high demands of regulatory agencies need to be met despite the pressure for efficient research and development.

Within manufacturing and distribution, demand forecasting is important in order to minimize costs. The complex nature of drug manufacturing causes most pharmaceutical companies to rely on one or very few major production centers, making potential breakdowns a liability. Similar to R&D, manufacturing and distribution is also subject to high regulatory demands. Striking the right balance between the two forces of efficiency and regulatory demands is key in ensuring competitiveness in the industry.

Driving sales are three primary consumer groups: patients, doctors and payers, and to successfully launch and market a drug, it is necessary to influence all three groups. The demands and bargaining power of the different groups differ between markets, making it necessary to tailor sales efforts to each market.

Overall, competition happens on multiple levels and excellence in all fields is necessary to succeed in the competitive pharmaceutical industry.

### Biosimilars versus generics

Whether a drug will be subject to generic or biosimilar competition after patent-expiry is a matter of its molecular characteristics. Two overarching classes of drugs exist that differ in size, manufacturing methods, action in the body and suitability for certain drug forms (Bayer Pharmaceuticals, 2017). Small-molecule drugs are chemically manufactured that make up roughly 90% of the drug market. In contrast, large-molecule drugs, or biologics, are protein-based medications<sup>7</sup>.

The definition of a small- vs. large-molecule drug is not clearly defined, and the FDA has no clear description on how they define it. Generally speaking, a small-molecule drug has a molecular weight of no more than 900 daltons<sup>8</sup>, although most are significantly smaller than that (The Motley Fool, 2017). Humans cannot absorb drugs with sizes larger than 900 daltons by ingestion, so biological drugs such as insulin will typically need to be injected. For an investor, the distinction between small- and large-molecule drugs is very important, as small-molecule drugs can be copied by generics, while large-molecule drugs can only be copied by development of a biosimilar drug.

A generic drug is characterized by “a chemically derived drug developed to be equivalent to an originator that has already been authorized. Only the inactive ingredients (or ‘excipients’) may differ in the generic and its originator. The concept of bioequivalence is fundamental for generics. These small and not very complicated chemical entities are relatively easy to synthesize and have predictable performance in humans, since they are exact copies of the originators.” (van de Vooren, et al., 2015).

A generic is approved when it can prove bioequivalence – that it has the same biological effect as the original drug. In drugs with smaller molecules, producing a generic is a matter of mixing together the same ingredients. However, with biological medicine, simply mixing together the same ingredients cannot be relied on to produce the same result. As biological products are significantly more complex and are manufactured using living organisms, production method has a significant impact on their

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<sup>7</sup> The terms large-molecule, biological and protein-based drugs are synonyms and will be used interchangeably throughout this paper

<sup>8</sup> A standard unit of mass used in chemistry and pharmaceuticals. Is equal to 1 g/mol. Otherwise known as a Unified Atomic Mass Unit



effect. Since patent holders are not required to inform of their production methods, using specific techniques and materials can be a way to “protect” off-patented products from generic competition.

Instead, a biological drug that goes off-patent can be targeted by a biosimilar. A biosimilar is designed to be the equivalent of a biological drug whose patent has expired (van de Vooren, et al., 2015). The active ingredients in the two drugs are generally the same, although there may be slight differences due to the complex nature of a biological drug. A biosimilar should aim to have the same effect as the original, and should thus be neither superior nor inferior to the original product. The FDA will approve a biosimilar if it has “the same mechanism of action, route of administration, dosage form, and strength as the reference product” (US Food and Drug Administration, 2015). In addition, a biosimilar can only be approved to treat the same conditions as the original.

Thus, creating a biosimilar requires significantly larger investment, as competitors need to develop a product with largely the same characteristics as another advanced molecule, but without having access to all the necessary information to do so. The effect on prices, and therefore competition, also differs between the two types of off-patent drugs. Biosimilars tend to be discounted at 10-30% compared to the originals (van de Vooren, et al., 2015), which is much less than regular generics which are often priced at a discount of 80-90% compared to the original. This is assumed to be due to the increased efforts required to receive approval and market a biosimilar. The diabetes care industry has historically seen little competition from generics or biosimilars, as most modern insulins are still under patent protection. However, Eli Lilly released the first biosimilar insulin in 2016, a copy of Sanofi’s Lantus priced at a 15% discount, and multiple biosimilars are in development (see Threat of substitution in Porter’s Five Forces for more).

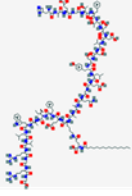
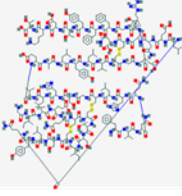
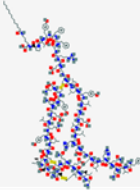

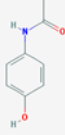
Product	Victoza	NovoRapid	Levemir	Tresiba	Panodil
Product type	GLP-1	Rapid-acting insulin	Long-acting insulin	Ultra-long-acting insulin	Pain and fever medication
Molecular weight (daltons)	3751.3	5825.6	5916.9	6104.0	151.2
Molecular structure					

Figure 3: Overview over the molecular structure and weight of some of Novo's key products. Panodil has been included to illustrate a typical small-molecule drug. Compiled by authors. Source: (U.S. National Library of Medicine - National Center for Biotechnology Information, 2017)

Novo's products are all large-molecule biological products (see Figure 3), so the main threat to Novo's products are the biosimilar products, where the price discount is expected to be less than that of generic products. This is a very important distinction as the introduction of generics generally is associated with a heavy decrease in profitability, whereas we have yet to see the full consequences on the profitability of "original products" due to the introduction of biosimilars. The analysis of biosimilar competition and its potential impact on Novo's sales will follow in the Porter's Five Forces analysis.

## Company description

In this section, we will provide a detailed overview of Novo Nordisk as a company, providing a solid foundation for the upcoming strategic analysis.

Novo Nordisk can trace its roots back to the founding of two small Danish companies, Nordisk Insulinlaboratorium and Novo Terapeutisk Laboratorium founded in 1923 and 1925 respectively. Since the beginning, they were both focused on manufacturing insulin to treat type 1 and 2 diabetes, and after merging in 1989, they created Novo Nordisk (Novo Nordisk, 2017a). The company became listed on the Danish stock exchange in 1974 and on the New York Stock Exchange in 1981. Novo has offices

or affiliates in 77 countries and approximately 42,500 employees worldwide (Novo Nordisk Annual Report, 2016).

## Share structure

Novo Nordisk has a total share capital of DKK 510,000,000 which is split into an A share capital of nominally DKK 107,487,200 and a B share capital of 402,512,800. The A shares are not listed, but instead held by Novo A/S, a limited liability firm fully owned by the Novo Nordisk Foundation. The B shares are publicly traded. Each A share carries 200 votes, and each B share carries 20.

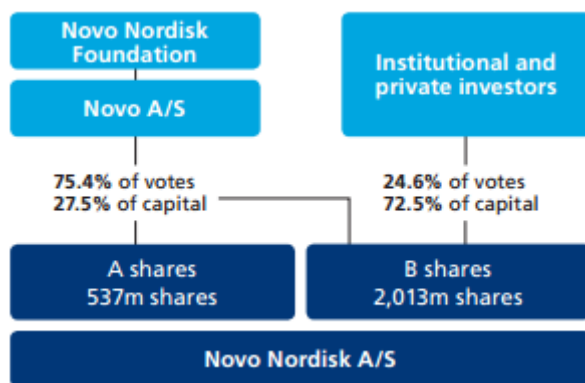


Figure 4: Novo Nordisk share structure ultimo 2016. Source: Annual Report 2016, p. 45

As can be seen in the figure, the Novo Nordisk Foundation thus owns the majority of the votes. The goal of the Foundation is twofold: “To provide a stable basis for the commercial and research activities conducted by the companies within the Novo Group, and to support scientific and humanitarian purposes (Novo Nordisk Annual Report, 2016, p. 44)

Two individuals serve both on the board of Novo A/S as well as Novo Nordisk A/S, ensuring that the interests of the company and its controlling shareholders are aligned. Furthermore, the Articles of Association of Novo A/S state that the A shares cannot be divested, ensuring that Novo A/S maintains the majority of the votes in Novo Nordisk A/S (Novo Nordisk Annual Report, 2016, p. 93).

The ownership structure and commitment from its parent company protects Novo Nordisk from hostile takeovers, ensuring that the company can maintain its R&D-activities and follow the vision and mission of the Foundation and its subsidiary. We therefore consider the risk of a hostile takeover of Novo Nordisk to be non-existent. As such, hostile takeovers will not be commented on further in this thesis.

## Sales regions

The conditions that Novo Nordisk aims to treat affect people worldwide, and the firm extends its sales efforts globally with activities in around 170 countries (Novo Nordisk Annual Report, 2016, p. 4). Novo divides its operations into five geographic regions: Pacific, Region China, Europe, USA and International Operations (Rest of the world). Until 2016, Canada was included as part of a North

American region, but in order to align with management structure and strategy, USA was made a separate market and Canada joined the Pacific region.

Figure 5 shows the geographic distribution of sales in Novo Nordisk in the last 5 years. The figure shows that USA is by far the most important market, accounting for 37% of the sales growth, as well as 51% of overall revenue in 2016.

Because of the dynamics of the American health sector, as well as the overall importance of the market, the US will be the primary focus of the thesis and analyzed separately from the rest of the world.

### Products and R&D pipeline

This section will contain a description and brief analysis of Novo's current R&D pipeline. All models showing the products currently in development can be seen in the 2016 annual report on pages 20-21 as well as Novo's 2016 Full Year Investor Presentation on pages 68 & 99. For a more in-depth analysis of Novo's products and its competitors, see the section on competition in Porter's Five Forces.

Since its inception, Novo Nordisk has been focused on the treatment of diabetes, primarily via the production of insulin. They have since branched out into 3 other areas: Haemophilia, growth disorders and obesity. Novo is in a position of market leadership within diabetes and growth disorders and are pursuing leadership in the treatment of Haemophilia and obesity (Novo Nordisk Annual Report, 2016, p. 4).

Compared to most other large pharmaceutical firms, Novo Nordisk has a relatively narrow focus, choosing to only target these four segments. Novo's drugs are also solely protein-based (Novo Nordisk Annual Report, 2016, p. 16) and they only market prescription

### SALES BY GEOGRAPHIC REGION

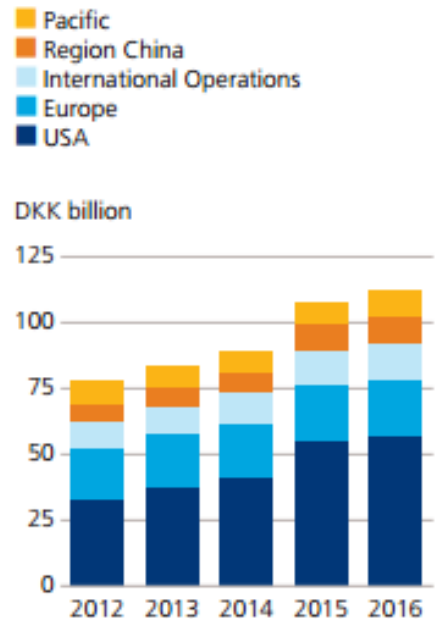


Figure 5: Novo Nordisk Sales by Geographic Region. Source: Annual Report 2016, p. 14

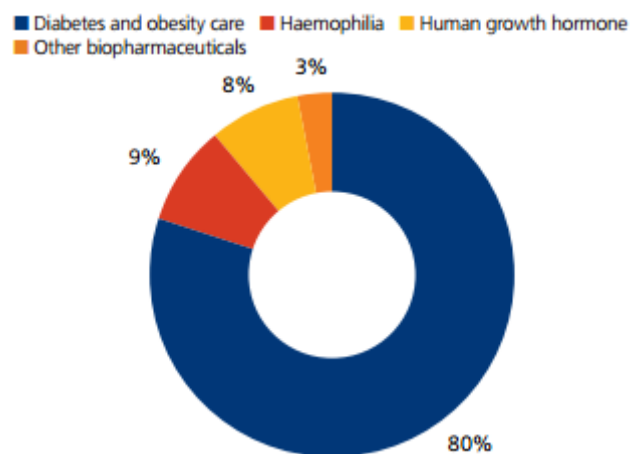


Figure 6: Sales by business segment. Source: Novo Nordisk Annual Report 2016, p. 68

medicine, with no over-the-counter (OTC) products.

Diabetes is by far Novo Nordisk's biggest segment, being responsible for approximately 80% of the firm's total revenue as well as 87% of the sales growth (Novo Nordisk Annual Report, 2016, p. 68).

### Diabetes

Novo Nordisk's primary focus since its inception has been the effective treatment of type 1 and type 2 diabetes. Diabetes is a group of diseases that manifests as a prolonged period of elevated blood sugar levels (WHO, 2017). There are two primary types of diabetes. Type 1 diabetes is an autoimmune condition causing the body's immune system to attack the insulin-producing cells, resulting in a failure of the pancreas to produce insulin and a life-long dependency on daily insulin injections. Type 2 diabetes arises from the failure of body cells to respond adequately to the insulin produced. With roughly 90% of diabetics suffering from type 2 (International Diabetes Federation, 2015), it is by far the most common type of diabetes and Novo Nordisk's primary source of revenue.

As opposed to many other conditions, treating diabetes cannot be done through a one-size-fits-all solution, as doses vary depending on the patient's gender, age, body size, activity levels, diet and other factors. Because of this, modern insulin is divided into three overall categories: long-acting, fast-acting and premix. The difference between them is the longevity of their effect as well as the speed in which the body reacts to them, otherwise known as action profiles.

Long-acting insulin lasts 12-36 hours depending on the compound and aims to maintain a constant insulin coverage in order to counteract the liver's natural production of glucose (UCSF, 2017). Fast-acting insulin is quickly absorbed and lasts a maximum of a few hours. It is intended to be taken together with meals, mimicking the body's natural production of insulin. The premix is a blend of the two types.

Diabetes treatment is Novo's largest segment as well as the fastest growing with an average annual growth rate of 17.7% in the past 5 years (Novo Nordisk Investor Presentation: Full Year, 2016, p. 28). Novo has been market leader within diabetes for more than 10 years, and currently holds an approx. 27% market

Product	Segment	% of sales	Patent expiration
Victoza	GLP-1	18%	USA: 2023 EU: 2023
NovoRapid	Fast-acting	18%	USA: 2017 EU: 2017
Levemir	Long-acting	15%	USA: 2019 EU: 2018
NovoMix	Premix	9%	USA: 2017 EU: 2015
Tresiba	Fast-acting	4%	USA: 2029 EU: 2028

Figure 7: Major Novo Nordisk products in diabetes treatment. Compiled by authors. Source: Investor Presentation Full Year 2016, p. 33 & 107

share globally (Novo Nordisk Investor Presentation: Full Year, 2016, p. 30). The fast-acting segment has been stable at 34% of the market, while long-lasting has grown from 37-40% and premix decreased from 29-26% in the past five years (Novo Nordisk Investor Presentation: Full Year, 2016, p. 40).

Currently, the five most important products in the diabetes care segment are Levemir, NovoRapid, NovoMix, Tresiba and Victoza, shown in the figure. Several of these products are approaching patent expiration, and Novo's ability to find replacements for them will be an important indicator of future sales. We will therefore describe Novo's R&D pipeline to better understand the firm's ability to maintain or improve sales by providing replacements.

#### GLP-1

Product	Type	Status (phase)				
		1	2	3	Filed	Appr.
Semaglutide (NN9535)	Once-weekly GLP-1 analogue					
OG217SC (NN9924)	Long-acting once-daily oral GLP-1 analogue					
Semaglutide QD (NN9535)	Once-daily GLP-1 analogue					

Victoza is one of Novo's most important products, so finding an effective replacement is key. Looking at Novo's pipeline, they are working on multiple replacements. The results for the once-weekly Semaglutide have been promising, showing a significant reduction in the risk of major cardiovascular events (Novo Nordisk Investor Presentation: Full Year, 2016, p. 71). Novo filed the product for approval in the US and EU in December 2016 (Novo Nordisk Annual Report, 2016, p. 10). Given the time until the Victoza patent expires, there is little risk that Novo will not have a replacement ready by 2023.

#### Fast-acting

Product	Type	Status (phase)				
		1	2	3	Filed	Appr.
Fast-acting insulin aspart (N1218)	New formulation of insulin aspart					
Mealtime insulin (NN1406)	Liver-preferential mealtime insulin					

Along with Victoza, NovoRapid is Novo's most sold product. The patent expires in 2017, but Novo has managed to gain approval of its replacement. In March 2017, Novo announced that Canada would be the first country to market the new product which has been given the name Fiasp (Novo Nordisk Pressemeddelelse, 2017). The new product has shown several significant improvements over NovoRapid, most importantly a much faster absorption which allows the patient to inject it either before or after a meal (NovoRapid can take up to 30 minutes to work and therefore needs to be taken

before the meal). In long-term studies, it has shown to be able to significantly reduce blood sugar. These results are promising, but Novo has released no information on its market performance so far. It is expected to reach the EU markets in the first half of 2017.

Fiasp was submitted to the FDA in the end of March 2017 (Medwatch, 2017) and it is certain that the patent will not expire within the forecast period of this thesis. Since the replacement is in the earliest stages of clinical trials, we will not speculate in its efficacy or its market potential.

#### *Long-acting*

Product	Type	Status (phase)				
		1	2	3	Filed	Appr.
LAI287 (NN1436)	Long-acting once-weekly basal insulin analogue					

Levemir is Novo's primary long-acting insulin and has a global market share of approx. 20% (Novo Nordisk Investor Presentation: Full Year, 2016, p. 46). Levemir's patent will expire in 2018 and 2019 in the EU and US, respectively, necessitating a replacement. In 2015, Novo released Tresiba which is a once-daily long-acting insulin that has shown positive results in trials, significantly reducing the frequency of severe hypoglycemia<sup>9</sup>. Tresiba has now launched in 52 countries, including the primary markets of the EU, USA and Japan and it has been well received.

After an extended approval process, Tresiba launched in the US in January 2016 and has reached a 15% share among new-to-brand prescriptions, and a 5.5% overall market share. Both Tresiba and Levemir has been helped by a formulary change for CVS. The drug accounted for 47% of Novo's overall sales growth in 2016, and sales of Tresiba surpassed DKK 4 billion in 2016, up from just 1.3 billion in 2015. Feedback from patients and physicians in all markets has been positive. In the US, the compound has achieved wide commercial and Medicare Part D formulary coverage. Overall, Tresiba has performed satisfactorily since its launch and Novo Nordisk expects the compound to be a major value driver in the coming years (Novo Nordisk Annual Report, 2016, p. 2).

A major factor for Tresiba's continued success will be Novo's ability to achieve the same reimbursement rate as other long-acting insulins. So far, penetration has been high in all markets where Tresiba is reimbursed at a similar rate to competitors, but relatively modest in markets with less or no reimbursement (Novo Nordisk Annual Report, 2016, pp. 6, 7).

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<sup>9</sup> Low blood-sugar

Tresiba's patent will expire in 2028 and 2029 in the EU and US, respectively. Since Tresiba has just recently launched and there is more than 10 years to expiration, Novo has not made significant progress on its replacement yet. LAI287 is the project name for a once-weekly basal insulin that could potentially replace become Novo's new long-acting product, but with little information released so far, its impact will not be further analyzed in this thesis.

### Premix

Product	Type	Status (phase)				
		1	2	3	Filed	Appr.
Xultophy (IDegLira)	Once-daily mix of Tresiba and Victoza					
Ryzodeg	Once-daily mix of Tresiba and NovoRapid					

NovoMix's patent expired in 2015 and 2017 in the EU and US, respectively, but Novo has two new mixed solutions that have already been approved.

Xultophy is a mix between Tresiba and Victoza aimed at type 2 diabetics. The product received approval from the FDA in the end of 2016 and Novo expects its commercial launch in the US in the first half of 2017. It has already been launched in 9 European countries and has shown significant reduction in hypoglycemic events and weight loss. The results so far have been positive, and launch operations are proceeding as planned.

Ryzodeg is a mix of Tresiba and NovoRapid and was first launched in Mexico in 2014 and is now on the market in 10 countries. Feedback from users and the market has been encouraging, and Novo is expecting to launch the product in more markets in 2017.

Xultophy and Ryzodeg will both expire in 2028 and 2029 in the EU and US, respectively. As no information on new development has been released, speculation on their replacements will not take place in this thesis. The most likely scenario is that their eventual replacements will consist of mixtures of Novo's next generation of long-acting and fast-acting compounds, which are both in the earliest stage of trials.

### New treatment forms

Product	Type	Status (phase)				
		1	2	3	Filed	Appr.
Anti-IL-21 T1D (NN9828)	Beta-cell preservation treatment for people newly diagnosed with type 1 diabetes					



Since insulin was first developed in 1921, type 1 diabetics have solely received monotherapy with insulin (American Diabetes Association, 2012). While insulin allows type 1 diabetics to live healthy and long lives if they are adequately treated, the drug has reached such a level of sophistication that newly developed compounds are but marginal improvements on their predecessors, and multiple researchers are looking into other ways to treat insulin-dependent diabetics (Gruber, 2016). For Novo to continue servicing the type 1 diabetes market with patented products, the firm is considering other treatment options.

The only compound that has reached trial phases yet is Anti-IL-21, a mixture of an Interleukin-21 compound<sup>10</sup> and liraglutide (the same biological compound as used in Victoza and Saxenda). The goal is to preserve the beta-cells of newly diagnosed type-1 diabetics by halting their immune response to their own insulin-producing cells, as well as using the GLP-1 agonist to stimulate the body to produce new insulin. While this would not be a definitive cure for type 1 diabetes, it would potentially allow type 1 diabetics to produce their own insulin instead of relying on injections. This would vastly improve the life of the large share of diabetics that cannot adequately control their diabetes.

The product is currently in phase 2 of clinical trials, meaning that it still has many years before it potentially reaches the market. Even then, the compound would mainly be useful for newly diagnosed type 1 diabetics, as they still produce some levels of insulin themselves. As such, this product is unlikely to benefit the majority of type 1 diabetics, but would help those newly diagnosed. In the US alone, the number of type 1 diabetics is expected to rise from 1.25 million today to 5 million by 2050 (JDRE, 2017), so the future market potential is significant.

#### *Conclusion on diabetes pipeline*

Novo Nordisk has launched several new compounds in the last year, with updates to both its long-lasting, fast-acting and mixed products. Their current R&D pipeline in these segments therefore primarily consists of compounds in the earliest stage of development, and we cannot predict when these will launch. At the current time, it is also very difficult to predict their impact on the market with any degree of certainty. Feedback on all their new products has been positive however. The only segment that has shown a significant update within the forecast period is the GLP-1 agonists, where Victoza is set to expire in 2023. Novo's pipeline do contain several new replacements, however, and results so far have been positive. Thus, it is unlikely that Novo will be caught with a non-patented

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<sup>10</sup> Interleukin are proteins that regulate the immune system and have previously been indicated to be associated with the development of both types of diabetes

segment within our forecast period. Rather, the discussion will center around the ability of new products to maintain profitability.

#### *“The Rule of Halves” in the diabetes care market*

When predicting the potential market size for diabetes in the future, a useful concept, and one that Novo Nordisk uses, is the “Rule of Halves”. The Rule of Halves states that out of all diabetics, only about 50% of them are currently diagnosed. Out of this half, only half of these receive treatment, and only half of those achieve treatment targets, and yet again half of these achieve the desired outcomes.

Thus, out of approx. 415 million diabetics globally, only a quarter of them have been reached by the industry and less than 26 million are treated optimally and live a life free of complications from diabetes.

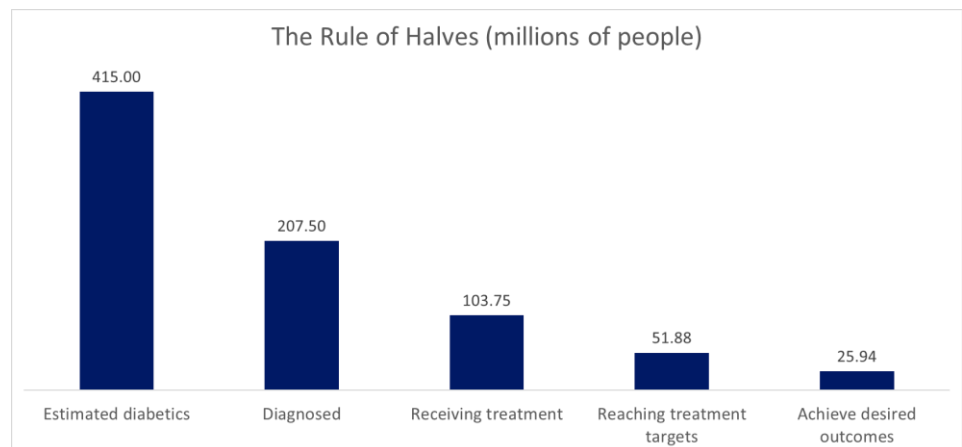


Figure 8: Overview of the treatment status of diabetics using the Rule of Halves. Compiled by authors. Source: Annual Report 2016, p. 23

While a rough approximation, The Rule of Halves can be used as an approach for measuring the potential market size for diabetes treatment. It also indicates that there are opportunities for diabetes firms to seek ways to improve the diagnosis rates of the condition, as well as seek ways to serve the majority of diabetics that are as-of-yet untreated.

## Obesity and others

Product	Type	Status (phase)				
		1	2	3	Filed	Appr.
Semaglutide (NN9536)	Long-acting once-daily GLP-1 analogue to treat obesity					
AM833 (NN9838)	Once-weekly amylin analogue to treat obesity					
G530S (NN9039)	Glocagon analogue intended to be used with semaglutide to treat obesity					
PYY 1562 (NN9747)	An appetite-regulating hormone, to be used alone of in combination with semaglutide to treat obesity					
GG-co-agonist 1177 (NN9277)	Glucagon and GLP-1 co-agonist intended for the treatment of obesity					
Semaglutide NASH (NN9931)	Long-acting once-daily GLP-1 analogue intended as treatment for non-alcoholic steatohepatitis (NASH)					

Obesity (as defined by a BMI in excess of 30) affects more than 600 million adults worldwide, and is a major health concern. However, only 10 million people are currently receiving pharmacological treatment as few options exist, and even fewer with adequate reimbursement.

For Novo Nordisk, obesity is a relatively new field, having entered the market in 2015 with their new drug Saxenda (Novo Nordisk Annual Report, 2016, p. 17). Saxenda consists of the same compound as Victoza, but is given in a larger dose (3 mg as opposed to 1.8 mg). The product was developed “by accident” as patients would report weight loss as a side effect of using Victoza in the trials. Since launching in the US in 2015, Saxenda has gained market leadership with an overall market share of 35% and is now marketed in 15 countries worldwide. Sales of Saxenda in 2016 amounted to DKK 1,577 million, up from DKK 460 million in 2015.

Since it is based on the same compound as Victoza, the patent for Saxenda will expire in 2023. Novo has great ambitions for its Obesity segment, and are currently pursuing 5 different treatments, all of which are in relatively early stages. Furthermore, Novo is trying to improve the understanding of obesity and obesity-related comorbidities. Novo already has a leadership position within obesity treatment with Saxenda, but due to the small size of the current market, their main goal in the near future is to expand the market size. The aim is for obesity to reach the same status as type 2 diabetes in terms of awareness, and thereby develop an acceptance of medical treatment of obesity (Novo Nordisk Annual Report, 2016). Whether Novo can succeed in this ambitious goal is yet to be seen, but obesity represents a major opportunity for growth in the future. The extensive R&D pipeline for obesity treatments underline the value potential that Novo Nordisk sees in this segment.

## Haemophilia

Product	Type	Status (phase)				
		1	2	3	Filed	Appr.
N9-GP (nn7999)	A glycopegylated long-acting recombinant coagulation factor IX intended to offer prophylaxis and treatment of bleeds aimed at Haemophilia type B					
N8-GP	A glycopegylated long-acting recombinant coagulation factor VIII intended to offer prophylaxis and treatment of bleeds aimed at Haemophilia type A					
Concizumab (NN7415)	An antibody against Tissue Factor Pathway Inhibitor (TFPI) intended for bleeding prevention					

Haemophilia is a hereditary condition which prevents the blood from clotting. It exists in two types: A, which prevents the body from producing the blood clotting factor VIII, and type B, which leads to a deficiency of blood clotting factor IX. Type A has an estimated global population of 350,000 and type B has an estimated population of 70,000 (Novo Nordisk Annual Report, 2016, p. 31). If untreated, haemophilia causes internal bleedings leading to stiffness, pain, severe joint damage and even death.

Novo Nordisk has been serving people with haemophilia for more than two decades with NovoSeven (Novo Nordisk Annual Report, 2016, p. 31). The patent for this drug has expired, but Novo has developed an improved isomer version which is stable at room temperature (as opposed to needing refrigeration) and which expires in 2024. NovoSeven can serve both type A and B patients, but it is limited to a relatively small segment of patients – between 3,500-4,000 people in total (Novo Nordisk Investor Presentation: Full Year, 2016, p. 94).

The market for haemophilia exhibits similar traits as the diabetes market in that only a minority is adequately treated: 45% is diagnosed, 15% receive treatment, 6% are prophylactic<sup>11</sup> and 3% have pristine joints. Thus, the market still has significant room to grow.

NovoSeven has been a major contributor to Novo's sales with a stable annual revenue of approx. DKK 10 billion. In the past year however, US sales of NovoSeven has decreased significantly, falling by DKK 593 million (Novo Nordisk Investor Presentation: Full Year, 2016, p. 7). The reason for this decline is a new product called ACE 910, developed by the Swiss firm Roche. ACE 910 has not yet passed the clinical trials, but due to the relatively small number of patients, the trial has caused NovoSeven's sales to decline significantly. ACE 910 is seen as significantly more sophisticated than NovoSeven, being a prophylactic product as opposed to reactionary. It is not yet certain if ACE 910 will pass the clinical trials, but in the likely scenario, that it does it is expected to capture significant market shares.

Apart from NovoSeven, Novo entered the wider haemophilia market in 2014 with NovoEight, a treatment for people with Haemophilia type A (Novo Nordisk Annual Report, 2016, p. 17). It is not an

<sup>11</sup> Meaning no need for reactive treatment when bleeding occurs

inhibitor like NovoSeven but instead targets the entire type A segment of 350,000 patients. It has gained regulatory approval in 43 countries and is currently marketed in 26 countries.

Lastly, Novo markets NovoThirteen, a prophylactic treatment aimed at a small subset of type A patients. The global number of patients for this treatment is 900 (Loiborg, 2012), and its effect on Novo Nordisk's sales is therefore limited.

The patent for NovoEight is due to expire in 2028/2030 in the EU/USA. Novo has filed for approval of N9-GP, a long-acting treatment for Type B haemophilia. When N9-GP is approved, Novo will be able to service the entire haemophilia market, valued at DKK 64 billion and growing (Novo Nordisk Annual Report, 2016, p. 17). Additionally, N8-GP, a long-term compound offering treatment and prophylaxis is in phase 3 of clinical trials and is expected to be filed for approval in 2018. The performance of N8-GP will be key in building Novo's market share among Type A patients.

In May 2015, Novo Nordisk announced the construction of a new facility in Kalundborg, aimed at producing ingredients for NovoSeven and future haemophilia-related products. The facility is expected to be operational by 2020. This investment in both research and facilities underlines Novo's high ambitions for their Haemophilia division, and its performance is likely to be a big factor in Novo's continued success.

#### Growth disorders

Product	Type	Status (phase)				
		1	2	3	Filed	Appr.
Somapacitan (NN8640)	A long-acting human growth hormone intended for once-weekly injections					

Growth hormone deficiency impairs a child's growth, and can negatively affect the heart, lungs, bones, brain and overall body composition of both children and adults (Novo Nordisk, 2017b). The condition is currently treated with a daily injection, and can be administered both to children and adults. Novo Nordisk has serviced patients with growth disorders for four decades (Novo Nordisk Annual Report, 2016, p. 17) and is currently marketing the product Norditropin. An estimated 2 million people suffer from the condition and the global market for growth disorder treatments is approx. DKK 18 billion. Novo Nordisk is the market leader, with a global value-based market share of 37%.

The patent for Norditropin is set to expire in 2017. The replacement, Somapacitan is in phase 3 of clinical trials. Somapacitan is intended for once-weekly injections, and is therefore a more convenient option than the once-daily Norditropin.

Even though Norditropin's patent will expire in the current year, Novo is unlikely to see competition from generics due to the proprietary multi-use delivery system (Sagonowsky, 2017) which is still under patent protection. As such, the patent's expiration is unlikely to have a significant impact on Novo Nordisk's sale of Norditropin.

#### Conclusion on products and R&D

Novo Nordisk has introduced several new major products to their respective markets recently, including the long-acting insulin Tresiba, the fast-acting Fiasp, two new premixes and a new Victoza-based compound to fight obesity. The impact of these new drugs on Novo Nordisk's sales is not entirely clear yet, but judging from Novo's own statements, the reception from the market has been positive. Seen in isolation, Novo Nordisk should be well equipped to serve their four segment for the foreseeable future, but we will need a better understanding of Novo's competitors in each field to understand whether there are others that may have an impact on Novo's sales. The primary concern for Novo thus seems not whether they have products ready to replace the ones that go off-patent, but whether their new products are sufficiently attractive compared to competing offers, and whether Novo can succeed in commanding top prices for its products in the future as well.

## Strategic analysis

The strategic analysis of both external and internal factors will serve as the basis for the revenue forecast. The analysis is split into an analysis of external factors through a SLEPT analysis, a Porter's Five Forces analysis and analysis of Novo Nordisk's internal resources and capabilities under the RBV framework.

### SLEPT analysis

As discussed in the initial introduction, we will utilize a SLEPT analysis to illuminate Political, Social-Demographic, Economic and Legal aspects that could impact Novo Nordisk.

#### Social and demographic

Main takeaways:

- Expected growth in total population
- Increases in global prevalence rates of diabetes and obesity
- Expected increase in global diagnosis rates
- Continued growth in obesity and diabetes prevalence in the US

Novo Nordisk markets products that deal with both inherited and lifestyle diseases. As for the inherited diseases (diabetes type 1, haemophilia and growth disorders), the total market size grows proportionally to the population growth rate as prevalence rates for inherited diseases are expected to remain the same leaning towards a slight increase (You & Henneberg, 2016). You & Henneberg (2016) notes an increasing trend in type 1 diabetes prevalence, citing natural selection as a possible cause, but generally the scientific community is puzzled as to what is driving the increase (McKenna, 2016) (International Diabetes Federation, 2015).

However, as the growth in prevalence rate has been immaterial, we assume that the market size of inherited diseases will follow the world population growth. World population is expected to increase to between 9.6 to 12.3 billion in 2100 (Gerland, et al., 2014). Figure 9 summarizes population projections and expected annual growth rates based on data from the United Nations (United Nations, 2015).

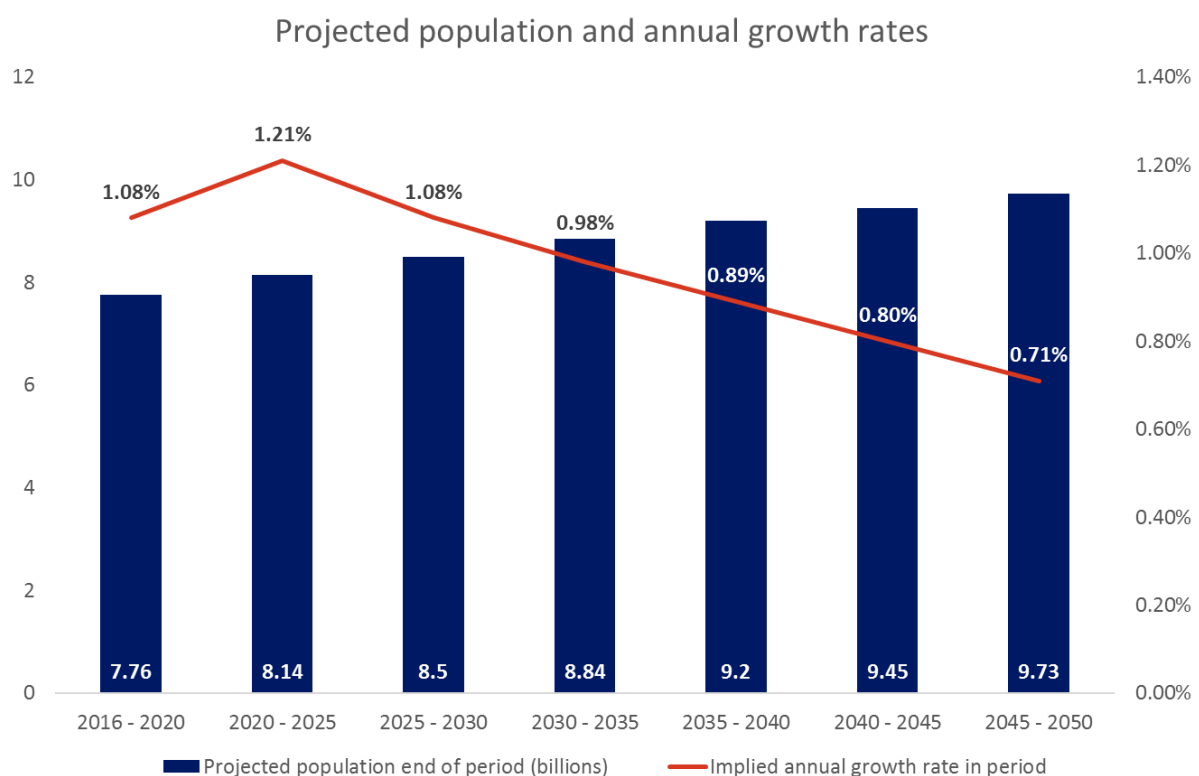


Figure 9: Projected population figures and annual growth rates. Compiled by authors. Source: United Nations, 2015

As Figure 9 shows, the annual growth rate in global populations is expected to reach a maximum around 2025, and after that a gradual decline is expected.

To determine the market for drugs for the treatment of lifestyle diseases (type 2 diabetes and obesity), it is necessary to consider lifestyle and obesity trends globally as a sedentary lifestyle and especially obesity are primary causes of type 2 diabetes.

According to both the World Health Organization (WHO, 2016), Novo Nordisk (Novo Nordisk Annual Report, 2016, p. 22) and external researchers (International Diabetes Federation, 2015), the prevalence rates of both obesity and type 2 diabetes are expected to increase in the future. By 2040 the expected global prevalence rate of diabetes is expected to reach 10.4% compared to 8.8% in 2015 (International Diabetes Federation, 2015).

Some recent figures have suggested that the obesity rates will continue to increase, albeit at a slower pace because of government programs and heightened awareness about the health risks associated to severe obesity (OECD, 2014). Other projections suggest that the global obese population will increase from 392 million individuals in 2005 to 1.2 billion individuals by 2030 (Kelly, 2008) implying a global prevalence rate of 14.1%.

In Novo's currently most important market, the United States, obesity prevalence is expected to increase to 42% by 2030 (Finkelstein & al., 2012). The same trend is observed in Europe, where obesity rates are increasing except in Italy, where the trend apparently has been bucked (OECD, 2014). Interestingly, the same upwards trend has been recognized for China, which now has the largest number of obese individuals of any country in the world (Global Times China, 2016).

Finally, the expected increase in diagnosis rates will also help expand the market for Novo's products. Currently, there are no projections regarding futures diagnosis rates available, but as the industry has an interest in increasing diagnosis rates and thus breaking "the rule of halves" (Novo Nordisk, 2014), it is reasonable to expect that diagnosis rates will increase in the future. Currently, diagnostic rates are significantly higher in developed countries in Europe and North America than in emerging economics, which demonstrates that there is still ample room for a substantial increase in the global diagnosis rate.

Also, expecting better diagnosis rates in the future is also supported by the trend in economic development in emerging economies, such as China (refer to Figure 11 in the economic section of this analysis). As the economy expands, more people will gain access to health care and proper diagnostic capabilities.



Assessing the available literature summarized in International Diabetes Federation (2015), we find that there is widespread consensus both in the industry and from independent researchers that the total global population, prevalence rates of both diabetes and obesity, and global diagnosis rates are expected to grow. Further, it is worth noting that 80% of people living with diabetes live in low to middle-income countries, where economic growth will enable an increasing number of patients to purchase their needed medication.

Thus, in conclusion, social and demographic trends remain highly favorable for growth in the markets targeted by Novo. In particular, obesity rates are expected to grow significantly, and this segment therefore represents a considerable potential upside for Novo Nordisk.

## Legal

Main takeaways:

- Refusal of authorities to approve new drugs is the main legal threat
- Competitors challenging patent infringements and fines or reparations in case of malpractice are normal legal risks in the industry
- The total legal risk is considered low compared to industry standards

An integral part of operating a pharmaceutical company is managing legal affairs, where protection of intellectual property plays the most significant role (Novo Nordisk Annual Report, 2016, p. 41).

Novo faces continual legal risks from the patent filing and renewal processes with relevant authorities in the countries where Novo operates (Novo Nordisk Annual Report, 2016, p. 43). There have been a few cases in India (Abbott, 2013), where the local courts have refused to recognize patents, but these cases have been related to “non-active drugs” – generics - and not biosimilars. For this reason, we do not view the risk of patent non-recognition to be a relevant risk for Novo Nordisk.

Instead, the main legal risk is related to the drug approval process by the US FDA, EU EMA and similar agencies. Due to the high requirements for efficacy and safety, health authorities regularly reject the approval of new drugs (Rapaport, 2015). As we have previously mentioned, due to the limited lifetime of a patent, the period of exclusivity under patent protection represents a significant share of the products overall revenues. A delay in approval thus has the potential to cause billions in foregone revenues.

Currently, the most important legal issue for Novo is the lacking FDA approval for its fast-acting insulin “Fiasp”, which is set to replace NovoRapid that as of writing holds a 18% market share in the market for fast-acting insulin (Novo Nordisk Annual Report, 2016, p. 10). Fiasp was approved for marketing in the EU and Canada in January 2017 (Novo Nordisk Annual Report, 2016, p. 10). Novo is planning to re-submit Fiasp for FDA approval within the next three months for an expected launch in 2018 (Novo Nordisk Investor Presentation: Full Year, 2016, p. 17) and as it has already been approved in the EU and Canada, we view the risk of non-approval as low.

Furthermore, Novo is at constant risk of lawsuits filed by competitors due to patent and/or intellectual property disputes or consumers because of alleged side-effects from Novo’s products (Novo Nordisk Annual Report, 2016, p. 41). According to Novo, none of the current lawsuits related to side-effects from its products are expected to impact financial results material (Novo Nordisk Annual Report, 2016, p. 71). Regarding patent disputes, Novo has previously delayed its launch of a new product due to the risk of infringement of current patents. Despite of FDA approval in 2013, Novo delayed launching NovoEight until 2015 due to the risk of patent infringement (Staton, 2013a).

The legal risks assessed above are aligned with what can be expected for a pharmaceutical company of Novo’s size and geographical coverage. Non-approval or delays in approval of new drugs can lead to considerable foregone revenues, and we thus consider this a key risk for Novo Nordisk. Conversely, the competition faces a similar legal risk, which represents a potential upside for Novo. An example of a competitor’s legal risk potentially impacting Novo positively can be seen in the Inhibitor segment of haemophilia, where NovoSeven is currently leader. Roche’s ACE910, which is currently in phase 3 trials is seen as a significant improvement, but has experienced a few hurdles in the latest trial (Carroll, 2017). A delay in the launch of ACE910 will allow NovoSeven to retain its share of the market for a longer time than expected. Thus, drug approval is a significant risk, but carries both potential upsides and downsides for Novo Nordisk.

## Economic

Main takeaways:

- Demand for Novo Nordisk products are largely unaffected by business cycles
- An economic downturn could shift patient preferences towards cheaper alternatives
- Exchange rate fluctuations is the principal risk related to the external economy
- Financial risk is adequately managed through hedging and risk management procedures

In the context of Maslow's Hierarchy of Needs, the need for medication can be considered as being at the bottom of the hierarchy as it relates to survival and physical well-being (Maslow, 1954). Thus, the need and demand for medication should theoretically be independent of business cycles as patients will prioritize purchases of needed medicine before other less important consumption.

Given the very basic need for medication, it is likely that any adverse effects on the revenues of Novo Nordisk from the introduction of biosimilars will play out regardless of economic development. However, studies have shown that insulin-dependent diabetics are willing to consider lower-priced copy-versions options of their current insulin if approved by the FDA (Rotenstein, et al., 2012)<sup>12</sup>. An economic downturn could exacerbate this effect, as more patients could be incentivized or even forced to allocate less resources to healthcare spending. Furthermore, as many Americans are now moving to insurance plans with higher co-payments to lower their premiums (Novo Nordisk Annual Report, 2016, p. 34), the cost of drugs increasingly must be borne by patients themselves. This may serve to further exacerbate any negative impact of an economic downturn on patient-consumer preferences for Novo's products.

The question of whether total health care expenditure per capita is affected by business cycles has not been studied extensively, but (Cleeren, et al., 2016) find that health care expenditure per capita responses to business cycle fluctuations vary notably across countries and private and public health care expenditure. Both increases and decreases in spending were observed, and thus it is difficult to make a definitive conclusion based on the empirical observations.

Considering Figure 10 and Figure 11, we see that the trend in health care spending per capita has been mostly linear over the longer term, whereas real GDP per capita in the G7 countries have fluctuated substantially in the same periods. Notably, the US real GDP per capita declined from 2008 to 2009, but the US, China and Japan (US and China accounted for more than 60% of sales in 2016) increased their net spending per capita from 2008 to 2009.

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<sup>12</sup> See our analysis of substitutes in Porter's Five Forces for more details

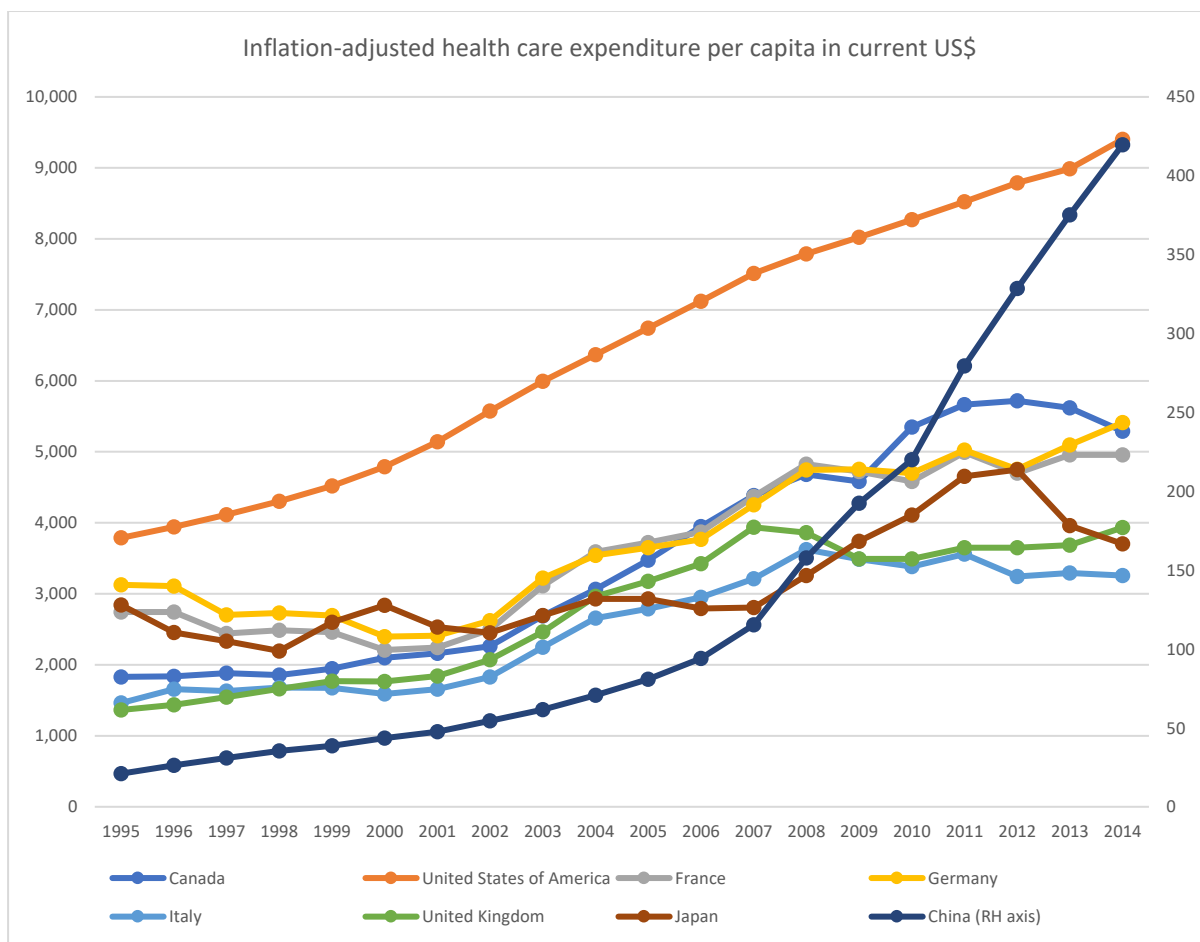


Figure 10: Inflation-adjusted expenditure on health care in current US dollars. Compiled by authors.

Source: OECD, 2016

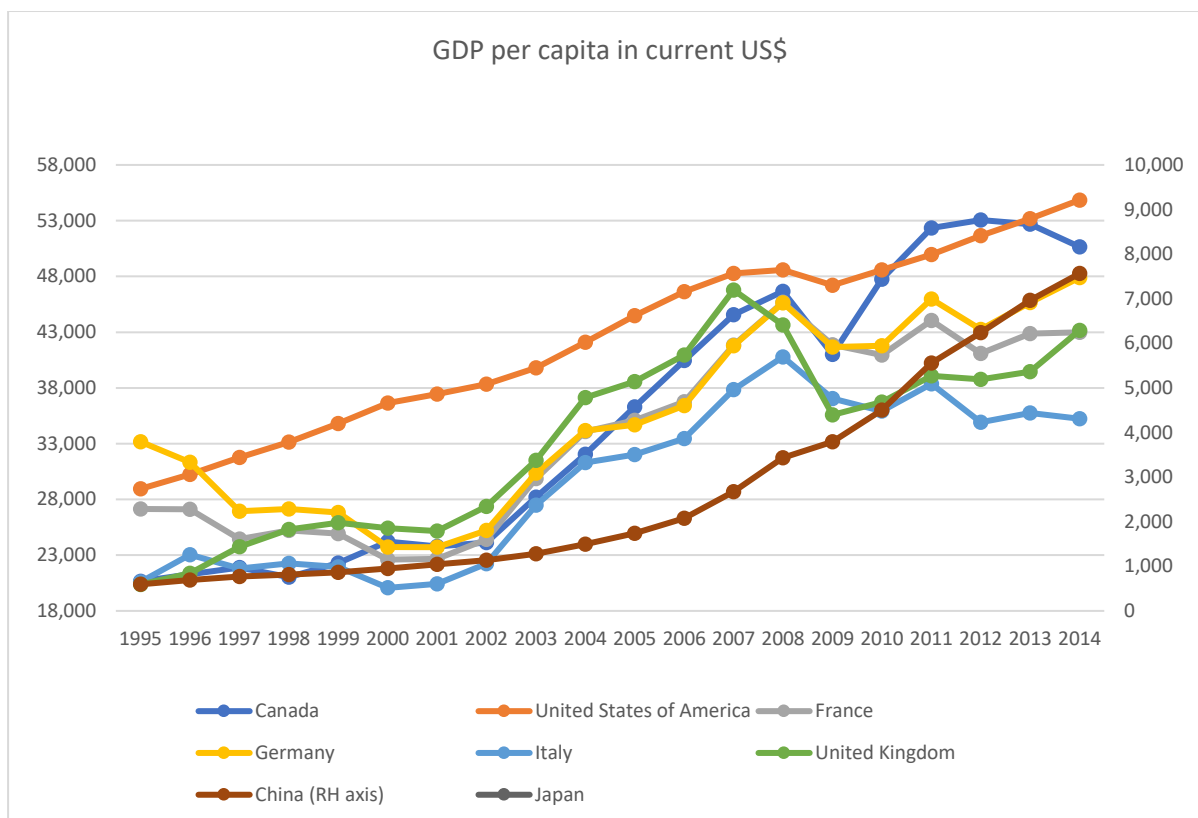


Figure 11: Inflation-adjusted GDP per capita in current US dollars. Compiled by authors. Source: OECD, 2016

Germany, France, Canada and Italy experienced severe declines in their real GDPs as well, whereas their health care expenditure per capita only decreased moderately.

Furthermore, Novo Nordisk has been able to expand their top line substantially every year since 2006 and through the 2008-2009 recession and onwards far outperforming the real GDP growth of the major G7 countries and China.

Thus, while a severe economic downturn could prompt adverse developments in consumer preferences, evidence suggests that pharmaceutical companies such as Novo Nordisk should be largely unaffected by business cycles. However, biosimilars were not available during previous economic downturns, so we cannot rule out a shift in consumer preferences towards cheaper alternatives in case of a future economic downturn.

### Exchange rate fluctuations

Foreign exchange risk is the principal financial risk for Novo Nordisk (Novo Nordisk Annual Report, 2016, p. 83). Novo is a global multinational corporation with over 99% of its total sales occurring

outside Denmark. Thus, it incurs significant exchange rate risks with the USD being the major risk currency. Novo is also exposed to risk in the EUR, CNY, JPY, GBP and CAD.

Due to the fixed exchange rate regime in Denmark, risk towards EUR is considered low. For the remaining currencies, Novo employs continual risk management by hedging the exchange rate risk through forwards and options to minimize total exchange rate risk (Novo Nordisk Annual Report, 2016, p. 83).

The overall policy of Novo Nordisk is to hedge 75% of total currency exposure (Novo Nordisk Annual Report, 2016, p. 85). Thus, for the year 2016 an aggregate move of 5% increase in other currencies against EUR and DKK would impact net after-tax income by approximately 2.4 billion DKK. As Novo will continue to manage exchange rate risk through 2017, the net impact of exchange rate fluctuations is expected to be largely the same for 2017. Novo does not hedge currency risks towards emerging markets currencies (Novo Nordisk Annual Report, 2016, p. 83).

The stated policy of Novo Nordisk to actively manage currency risks by continually hedging currency exposure in future cash flows is considered an adequate risk management strategy, and thus exchange rate risk can be disregarded in the valuation.

#### *Counterparty and credit risk*

Being a large multinational engaged in transactions in different currencies, Novo will encounter many counterparties in many different parts of the world. Thus, it incurs significant credit and counterparty risks. Novo is mitigating credit and counterparty risk through a clearly defined credit policy (Novo Nordisk Annual Report, 2016, p. 84 & 85).

Novo only enters derivative financial contracts and money market deposits with counterparties possessing a solid long-term credit rating and invests its surplus cash in highly-rated fixed income securities trading on a liquid market (Novo Nordisk Annual Report, 2016, p. 84 & 85). In 2016, 98.7% of Novo's cash and fixed-income investments were held in A to AAA instruments with the majority being held in cash. Thus, the credit risk of Novo Nordisk is assessed to be low.

#### *Interest rate risk*

At the end of 2016, a 1 percentage point increase in interest rate levels would everything else equal result in a decrease in the fair value of Novo's financial instruments of 3 million DKK (Novo Nordisk

Annual Report, 2016, p. 84). As Novo Nordisk is funded exclusively through equity (FactSet, 2017), interest rate risk is considered insignificant in this context.

## Political

Main takeaways:

- Increasing threat from biosimilar products as legislative environment becomes more favorable towards biosimilar
- Unlikely that US health care policy will be subject to major reform

As Novo Nordisk conducts the major proportion of its business in the United States, we find that it is highly relevant to assess the political environment surrounding Novo Nordisk in the United States. As opposed to most of the European markets, the US does not have a centralized single-payer system of drug purchase. This means that the likelihood of significant changes in the purchasing policies of payers in RoW is limited (Novo Nordisk Annual Report, 2016, p. 33). Furthermore, the single-payer systems in RoW have been in place for a long time with broad political backing, so the potential for any radical changes that could impact Novo is assessed to be very limited. The primary risk of significant developments with the potential to impact Novo Nordisk is in the US market, so the primary focus of this analysis will be the United States political environment.

Currently, the United States holds a clear first place in total health care expenditure per capita in the world when combining both private and governmental expenditure (WHO, 2016). Government and compulsory contributions health care expenditure is the second highest among the OECD countries adjusted for Purchasing Power Parity (PPP) (OECD, 2016). There is a growing perception in the US population that the health care system could be improved, and as concern in the population grows, so does the political interest in the topic. Thus, the political element will remain a factor in determining future revenue growth.

Already during the 1990s, the public started to become aware of the consequences of increasing drug prices as neither insurers nor the government was willing to bear the increasing costs of drugs. In the recent presidential campaign in 2016, a great deal of criticism was raised towards drug prices in the United States, and Novo Nordisk was mentioned specifically by - among others - the Democrat presidential candidate Bernie Sanders, who called for an investigation of whether Novo and Eli Lilly colluded on the pricing of insulin products (Friis & Kongskov, 2016). Having raised list prices on insulin

products by more than 450% since 1996, the criticism and subsequent debate in the media were associated with adverse developments in the Novo Nordisk share price. (Ritzau, 2017)

The introduction of the The Patient Protection and Affordable Care Act - also known as ObamaCare – in 2010 contributed significantly to increased price pressure in the insulin market as it provided the legal groundwork for an abbreviated approval process for biosimilar products on the US market (US Food and Drug Administration, 2016). Thus, the act has allowed the introduction of the first biosimilar basal insulin in the US ever, Basaglar from Eli Lilly that became available for purchase in December 2016 (Hoskins & Tenderich, 2016). Basaglar was developed based on an original product from Sanofi that initially sued for infringement only to settle the lawsuit with Eli Lilly later. As of writing, Merck has also developed a biosimilar insulin product that is currently pending approval at the FDA. If successful, the drug could be launched to the market by 2018.

Current president Donald Trump has still not succeeded in repealing ObamaCare - partially due to internal conflict on the stance on ObamaCare within the Republican Party (GOP), which prompted the withdrawal of a floor vote on a repeal bill in congress (Vladimorov, 2017). Vice President Mike Pence has repeated the confidence of the current administration in the repeal of ObamaCare, but centrist parts of the GOP are still pushing against a repeal citing increases in insurance premiums as a major concern (Marcos, 2017).

In our view, the successful implementation of Obamacare, the subsequent introduction of a biosimilar and the current sentiment in the GOP represents a significant change in American health care policy, which will have politicians leaning relatively more towards implementing policies that make it easier for competitors to introduce competing products such as biosimilars in the future. Combined with increased demand for cheaper alternatives to branded name drugs such as those marketed by Novo Nordisk (Hoskins & Tenderich, 2016), the current trend in the political environment could result in increased price pressure.

However, we must also be aware that the changes brought about by Obamacare was many years underway. The presidency of Obama lasted 8 years, so the change in legislation was underway for a very long time. Thus, the apparent “success” of Obamacare can hardly be interpreted as a beginning of a major reform of US health care policy and drug purchasing practices in the market. The political and congressional gridlock currently prevents any drastic overhauls of US health care policy, and if any



such initiatives would be initiated, lobbying efforts and internal disagreements in the parties would drastically slow down such process (Kesselheim, et al., 2016).

Kesselheim, et al. (2016) cites market exclusivity, constrained negotiating powers of payers, physician prescribing choices and the political willingness to pay higher prices for drugs to support R&D spending by pharmaceutical firms as causes for the high drug prices in the US. The study suggests that these factors allow firms in the pharmaceutical industry to apply a price-setting behavior akin to a monopoly. While Obamacare with its abbreviated approval process for biosimilars was a step in the right direction, Kesselheim et al. (2016) considers the causes they identified to be difficult to remedy in both the short and long-term.

In RoW, Novo Nordisk is facing significant price and competitive pressures as governments seek to bring down health care costs and further introduction of new biosimilars is expected (Novo Nordisk Annual reports). Novo expects these trends to continue in the future, which will have a negative impact on price development.

### Technological analysis

#### Main takeaways:

- External technological developments could have a major impact on the financial results of Novo
- Technological pressure incites Novo Nordisk to engage more actively with external firms
- New M&A strategy opens the door for acquisition of new technology

As one of the leading pharmaceutical firms in the world, technology plays a key role in Novo's long-term success. Failure to introduce new products to the marketplace before current patents expire could have profound impacts on the financial results of Novo, and thus the firm is sensitive to changes in external technological developments.

A common way for pharmaceutical firms to protect themselves against external technological developments is to engage in M&A (Torsoli & Kitamura, 2015), with firms in the American healthcare industry spending \$7.9 billion on M&A in Q1 2017 (PwC, 2017). The M&A activity consists both of acquisitions, with large firms acquiring smaller firms with innovative technologies, and mergers between large firms.

Historically, Novo has insisted on developing new technologies internally and expand capabilities as the markets expanded, and generally refrain from larger acquisitions that could not be funded with Novo's own cash flow (Torsoli & Kitamura, 2015). Despite this, Novo acquired two "biopharmaceutical research companies", which would help Novo to develop better drugs for diabetes and obesity (Genetic Engineering & Biotechnology News, 2015).

With the new CEO Lars Fruergaard Jørgensen, there has been a distinct change of tone with regards to M&A strategy. Fruergaard has noted that Novo will have to operate more like other big drug makers, which includes growing its revenues and acquiring new technology through acquisitions (Hirschler, 2017). Previously, Novo's acquisitions have been of a small scale, such as their acquisition of biopharmaceutical research firms Calibrium LLC and MB2 LLC in 2015 (Novo Nordisk, 2015). Lars Fruergaard acknowledges that the technological pressure in the industry has reached a point where Novo's internal development capabilities may not be enough for the firm to remain competitive. Recently, Novo has approached Global Blood Therapeutics, a U.S. biotech company focused on blood disorders valued at 1.5\$ billion to discuss a potential take-over (Hirschler, 2017).

In conclusion, as an innovator firm, Novo is entirely reliant on staying at the forefront of technological development. While Novo's internal capabilities historically have allowed the firm to grow into the market-leading position it is in today, the firm may be required to engage increasingly with external firms in order to maintain its technological edge. In particular, this pertains to a more active M&A policy, but may also extend to strategic alliances or joint-ventures.

## Porter's Five Forces

### Introduction and industry definition

To gain a better understanding of the attractiveness of Novo's industry, and the firm's position within it, we apply the Five Forces framework developed by Porter (Porter, 1979).

The first step is to construct a definition of the industry. We do this to provide a more targeted analysis of the competitive field, as well as potential substitutes. Novo Nordisk is clearly a pharmaceutical firm, but the pharmaceutical industry is too broadly defined, so we need a stricter definition to delimitate the analysis.

Instead, we view Novo's industry as consisting of products that buyers would consider substitutes to Novo Nordisk's products, and we use this concept of substitutability to define the market that Novo

Nordisk operates in. Many conditions can be managed in multiple ways. For Novo Nordisk, exercise and a healthy diet can vastly improve the conditions for diabetics, as well as alleviate obesity. However, it would of course be wrong to suggest that fitness centers or providers of healthy food, are competitors to Novo Nordisk. Instead, we narrow down our definition to:

**Producers of prescription drugs seeking to pharmacologically treat the same conditions as Novo Nordisk**

With this definition, we limit ourselves to firms that are similar to Novo Nordisk in terms of product, development process and market access. However, apart from obesity and type 2 diabetes, there is relatively little overlap between the conditions that Novo Nordisk aims to treat. Where necessary, such as when assessing competitive pressure, we will discuss each of the four industries separately.

**Threat of new entrants**

**Main takeaways:**

- Capital requirements are high for R&D, manufacturing and sales
- Incumbents have little to no cost advantage on raw materials, but do have cost advantages due to economies of learning
- Costs to meet legal requirements are high because of patents and extensive approval processes
- Scale economies are present in both manufacturing and R&D
- High barriers to entry, ensuring high profit rates

The limitations on new entrants to the industry in terms of entrance and exit barriers have a direct impact on the ability of incumbent firms to earn abnormal returns. All else equal, high entry and exit barriers cause firms in the industry to generate higher returns (Porter, 1979). In this case, we are analyzing the threat of new entrants and not the entries themselves, since the threat of entry itself should provoke a reaction from incumbent firms in the form of innovation in products and lower prices to ward against new competitors entering the market. High exit costs similarly dissuade new entrants, as large-scale pharmaceutical operations require highly specialized assets that are difficult to repurpose.

We evaluate the threat of new entrants based on the following variables: capital requirements, cost advantages, legal barriers and economies of scale.

### *Capital requirements – High development cost and long time-to-market*

As we have mentioned in previous sections, the average development time of a new pharmaceutical product is approximately 12 years (Holland, 2013). Furthermore, out of 10,000 potential compounds, only 5 make it to clinical testing, and only 1 of the 5 will receive approval and enter the market (Stevens, 2016). As medicine generates no cash flow before it reaches the market, it is a reasonable assumption that any potential entrant will operate with negative cash flows for the first 12 on average.

Furthermore, the average cost of developing a single new medicine is an estimated \$1.2 billion, with some estimations reaching higher (Holland, 2013). Apart from developing costs being inflated by the high failure rate in development, manufacturing, sales and other operations are necessary in order to market the drug and generate cash flows. Due to high costs, long time-to-market and complexity of operations, we conclude that capital requirements are high.

### *Cost advantages – No advantage in raw materials but highly dependent on proprietary knowledge*

The raw materials used in manufacturing of pharmaceutical products – even advanced biologicals like insulin – are not particularly rare (Gebel, 2013). As such, there is little that suggests that incumbent firms would have an advantage over new entrants in terms of raw material costs. However, the industry is highly dependent on knowledge, which in biological products is extended to knowledge of production methods. As such, there may be some merit to the argument that knowledge barriers can prevent new entrants from reaching the same cost per unit as the incumbents.

### *Legal barriers – Highly regulated industry*

As we noted in the industry description and SLEPT-analysis, patents are a key component in the industry. Incumbents have their products protected by patents, and due to rapid advances and product innovation, a drug is often inferior by the time it goes off-patent. As such, by the time a product is not covered by legal restrictions, it is significantly less valuable. Because of this, any new competitor to Novo Nordisk would have to develop their own compound, which as mentioned takes years and can cost more than \$1 billion. If they instead attempt to develop a biosimilar, they will still be subject to an extensive review process, although somewhat less than if they had developed their own (US Food and Drug Administration, 2015). In summation, new entrants would either have to spend significant resources on developing a new product, or begin to compete with a less modern product while still being subject to a significant approval process. We therefore conclude that the legal barriers to entry are high.

### *Scale economies – High scale necessary to operate competitively*

Novo Nordisk's focus areas are all chronic illnesses that require constant, recurring treatment and has little to no seasonal fluctuation. Because of this, and the aforementioned high capital requirements, Novo Nordisk's products are manufactured and sold in very high volumes, servicing a significant share of the total market on a global scale. Any new entrant would have to compare on a global scale in order to justify the significant entry costs, but a significant investment is necessary in order to reach the necessary scale.

Additionally, a new entrant would face difficulties when their product goes off-patent if they do not have a new generation of drugs ready. Large pharmaceutical firms like Novo Nordisk can justify their significant investments in manufacturing by virtue of their large R&D pipeline ensuring a constant flow of new products. A new entrant would have difficulties balancing between over- and underinvesting in production unless they have the resources to develop an extensive R&D pipeline.

Apart from manufacturing and commercial activities, scale economies are also present in the development phase. Research indicates that while small and medium sized firms are able to remain competitive during phase-1 trials (that are performed on a small number of volunteers), large firms have a significant advantage in phase 2 and 3 trials in which their large, international network provide them with better opportunities to establish trials on large groups of people (Danzon, 2006). As a small firm, it may be difficult to meet the demands of regulatory agencies in trials, creating a demand for scale well before a product even reaches the market.

An example of the large capital requirements in trials can be given by Adocia, a French firm that has developed an ultra-fast acting version of Eli Lilly's Humalog (Adocia, 2017a) and has partnered with Eli Lilly in order to use the company's resources for clinical trials. In January 2017, Eli Lilly terminated the partnership (Adocia, 2017b), which put the development of their new drug on indefinite hold until they are able to find a new partner to help them continue with phase 3 trials.

### *Conclusion on threat of new entrants*

In our analysis on the threat of new entrants to Novo Nordisk's industries, we find that capital requirements are high, incumbent firms have an advantage due to economies of learning, legal barriers are high and a large-scale operation is all but necessary to even develop a product.

We therefore conclude that the overall barriers to entry are high, providing a competitive environment which is conducive to high profits. While the entry barriers are very high for newly-

started firms, the high capital requirements and demands for a complex organization are less troublesome for another large pharmaceutical company. As such, it will be possible for other similarly-sized organizations to enter Novo Nordisk's markets, and as we will see in the next section, that is already happening.

#### Threat of substitutes

##### Main takeaways:

- First biosimilar has reached the market in December 2016
- Biosimilars are priced at a 10-30% discount compared to reference products
- Patients, physicians and PBMs have all expressed interest in exploring biosimilar insulins further
- Biosimilars could potentially open up for new markets, attracting diabetics who have previously been without treatment
- Novo Nordisk is unlikely to pursue biosimilar within diabetes but have previously used them to enter other markets
- The full impact of biosimilars on the insulin market is difficult to gauge, but we expect the biosimilars to develop a significant market share
- Lastly, Novo's ability to increase prices in the future is expected to be impacted by PBMs and patients having access to cheaper versions of successful products

As mentioned, we operate under the assumption that none of the conditions that Novo Nordisk treats will be cured. While diabetes could be cured eventually, a wide-scale cure is unlikely to happen within our forecast period. This assumption, combined with the previously found high entry barriers leads us to conclude that the most likely substitutes will come from either existing large-scale pharmaceutical firms, most likely ones that are present within the industries already, or from biosimilars. Existing competition will be analyzed in a later part of this section, so the following will focus on the threat of biosimilars.

#### Diabetes

Until recently, biosimilar insulins have been non-existent, as all major insulins were still under patent protection. Within recent years however, several firms have announced upcoming biosimilars of popular insulins. On December 15, 2016, the first biosimilar insulin was released in the United States (Hoskins & Tenderich, 2016). Basaglar, produced by Eli Lilly in partnership with Boehringer Ingelheim,

is a biosimilar version of Sanofi's successful long-acting basal insulin Lantus. Other biosimilars that are expected to reach the market in the coming years include:

- Merck's MK-1293, which is also based on Lantus and could potentially be approved in the first half of 2017 (Hoskins & Tenderich, 2016)
- Biocon is partnering with Mylan to develop and market three biosimilar insulins: One based on Lantus, one based on Eli Lilly's Humalog and one based on Novo's NovoRapid. The Lantus biosimilar has already been submitted in Europe (Mylan, 2016) while the two fast-acting biosimilars are in early stages of trials

It should be noted that these biosimilars are all developed either by firms already in the industry or by other major pharmaceutical firms. As such, our conclusion in the previous section holds true, as no small-scale firms are attempting to enter the industry.

Basaglar is priced at \$315.85 for a pack of 5 pens, which represents a 15% discount over Lantus and Toujeo, a 21% discount to Levimir and a 28% discount to Tresiba. This relatively modest discount comes as no surprise, as biosimilars require significantly larger capital investments than generics. A biosimilar drug costs between \$30-150 million to develop and approve, compared to \$1-2 million for a chemical generic (Rotenstein, et al., 2012). Manufacturing costs are also significantly higher for insulin, costing \$50-75 per gram compared to approx. \$5 per gram for chemical drugs. The high development costs combined with production costs that are near-identical to their reference product means that biosimilars are unlikely to ever be able to underprice significantly compared to their reference products. Within all industries any biosimilar that have been approved in the US have been priced at a sub-30% discount compared to their reference product, and we see no reason why insulin should be different. CVS Health Chief Medical Officer Troyen A. Brennan suggests a biosimilar pricing of 10-15% below the reference product (Dennis, 2016).

Since biosimilars are developed to resemble their reference drug as closely as possible, they cannot compete on any other parameter but price. Additionally, since biosimilars are only possible for off-patent products, they will by definition always be lagging behind at least one generation. This, combined with the 15-30% discount, means that it is unlikely to have the same impact on drug sales as generics do for synthetics. Due to the cost of diabetes, it is however not unlikely that a significant share of patients will consider lower-priced options.

It could be argued that insulin has reached a level of sophistication so that new generations only represent a meager advantage over the previous, which could lead some patients to consider lower-

priced options. A previous study asked 1,637 American insulin-dependent diabetics whether they would use “a less-expensive generic version of their insulin (a biosimilar)” if it was available and approved by their healthcare provider (Rotenstein, et al., 2012). 30% answered that they definitely would, while 37% said that they would be likely to. Similarly, 415 diabetes educators were asked whether they would recommend biosimilar insulins, with 41% saying a definitive yes and 42% saying that they would likely recommend them. This suggests that there is at least some interest among users and physicians to switch to biosimilar insulin when it becomes more broadly available. In the US, the PBMs have also shown interest in the potential of biosimilars, with CVS excluding the branded Lantus from their 2017 formulary in favor of the new biosimilar Basaglar (CVS Health, 2016).

It seems evident that there is a level of interest in biosimilars among all three primary customer groups (patients, physicians and payers), but they have all expressed concerns about biosimilar’s reliability compared to the tried-and-true reference products. As such, it is likely that a significant shift to biosimilar insulin is still some ways off. The impact of biosimilars on sales is challenging to gauge accurately, due to the modest price difference and concerns over efficacy (as biosimilars are not completely identical to their reference product).

Another point that should be mentioned is whether biosimilars will manage to steal a significant share from the current market, or instead expand the market by opening up treatment options for previously untreated diabetics that were unwilling or unable to purchase the original drugs at higher prices.

The impact is also not likely to be uniform across countries, due to differences in payment models. In Europe, where the states will cover most to all expenses associated with diabetes treatment, it is likely that most patients and caregivers will choose the most efficient option and therefore stay with the newest forms of insulin. In the US and other countries where patient expenses vary wildly depending on insurance, many may choose the cheaper option if it is allowed by their insurance. Especially diabetics with poor or no insurance is likely to weigh cost concerns heavily when choosing insulin. However, as international payers are also looking to reduce their spending on healthcare, it can be assumed that they will also consider the possibilities of switching patients to biosimilar insulins.

So far, Lantus has been the primary target for biosimilars. Biocon and Mylan are partnering to develop a biosimilar of NovoRapid, but it is still in early stages and will most likely not receive approval before 2018 at the earliest. The impact of this as-of-yet unnamed product on the sale of NovoRapid largely



depends on whether Novo can manage to move patients from NovoRapid to their new fast-acting Fiasp.

Lastly, we also need to take into the account the potential for Novo Nordisk to develop their own biosimilars. While Novo could potentially copy Eli Lilly's strategy and produce their own version of Lantus, we do not find it very likely. Novo Nordisk currently has strong positions in all three primary insulin segments<sup>13</sup>, so there is little reason for Novo to start undercutting their own products by producing cheaper biosimilars. Eli Lilly's situation is different as they have previously been without a contender on the long-acting market, making a biosimilar version of Lantus a much more enticing prospect for them.

### *Biopharmaceuticals*

Biosimilars have existed in the biopharmaceutical industries where Novo operates for years. Within Haemophilia, NovoSeven received its first biosimilar competition following the launch of AryoSeven in 2015 (AdisInsight, 2017), but the biosimilar has failed to make a significant impact on NovoSeven's sales. In 2014, Novo entered the haemophilia A market with its own biosimilar NovoEight but has similarly not made a significant impact in the highly competitive market. Multiple biosimilars also exist within growth hormone therapy. Within these segments, competition is centered around other factors than the pure efficacy of the drugs, and biosimilars therefore have less of an impact as they lack the convenience or patient care programs that are associated with the original products. Biosimilars are a cost-effective way to enter a new segment (as demonstrated by NovoEight), but have not had the same level of impact that is expected in diabetes.

### *Conclusion on substitutes*

In conclusion, the only relevant substitute that can threaten Novo Nordisk's products are new biosimilars that are in development. They come either from existing competition or from other large pharmaceutical firms. Due to high costs of development and production, biosimilars are only priced at a 10-30% discount compared to their reference product. As the first biosimilar reached the market in December 2016, we have little data on sales figures yet but initial interest is present from patients, physicians and PBMs. Even though none of Novo's products have been copied yet, based on the growth of Basaglar so far, it is likely that biosimilars will have a significant impact on the insulin market. We expect that PBMs will seek to leverage the new opportunities given to them by biosimilars to pressure pharmaceutical firms into lowering prices or risk being locked out, as we have already seen

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<sup>13</sup> Long-acting, fast-acting and premix

happen to Lantus (CVS Health, 2016). Sanofi has already lost significant market share due to CVS' choice of locking out Lantus from their 2017 formulary, and Novo may face the same pressures when Biocon and Mylan's version of NovoRapid reaches the market. Regardless, we expect the fact that payers and patients now have access to cheaper versions of successful products to put pressure on Novo's ability to increase its prices in the future.

#### Bargaining power of suppliers

Main takeaways:

- Bargaining power of suppliers is generally low
- Raw materials are simple and easily available
- Novo Nordisk closely monitors its supply chain, and has back-ups available

The raw ingredients to produce insulin consists of easily available substances like water, sugar, and a number of organic and inorganic chemicals (Gebel, 2013). There are no particularly rare components necessary to produce insulin. Instead, the complexity of the products stem from the production methods and the knowledge-intensive nature of both development and production. This means that Novo Nordisk's suppliers are relatively easily interchangeable, as long as they are committed to following Novo Nordisk's high ethical standards (Novo Nordisk Annual Report, 2016, p. 12). Novo performs annual audits of their suppliers to ensure that standards within ethics and quality are met.

Due to the high regulatory demands, Novo Nordisk continually monitors their supply chain. They regularly scan for alternative supply sites and have multiple back-up facilities in place (Novo Nordisk Annual Report, 2016, p. 42). Because of this we do not believe that an individual supplier has much bargaining power, nor do we expect that to change in the future.

#### Bargaining power of buyers

Main takeaways:

- Patients and doctors have little bargaining power
- PBMs have significant bargaining power in the US
- US government has little to no bargaining power and is unlikely to change under Trump
- RoW: Most buyers outside of US are governments that looks to decrease healthcare spending
- RoW: Government bargaining power suggests constant or decreasing future prices

A buyer group has high bargaining power if the group is concentrated or individually buys in large volumes (Porter, 1979, p. 141). As we discussed in the industry overview, buyers consist of three

overall segments: patients, doctors and payers. We will divide the following analysis in order to process each segment.

#### *Patients and doctors*

The medical conditions that Novo Nordisk treats range from seriously debilitating to life-threatening. As such, we consider treatment for these conditions to be absolutely necessary for the majority of patients, and they will have no choice not to receive treatment. Their only option therefore consists of choosing between different treatment options available from Novo or its competitors. Additionally, patients are single persons and thus do not individually represent a large share of sales. As such, we do not consider patients to have any significant buying power compared to Novo Nordisk.

Doctors' primary goal is to find the most effective treatment for their patients' conditions. To this end, they should not be economically incentivized to pick one drug over others. While pharmaceutical firms spend significant resources in marketing themselves to physicians, each individual doctor holds little bargaining power. Due to their independence and focus on optimal treatment, we also do not consider doctors to have significant bargaining power over Novo Nordisk.

#### *US Government as a buyer*

In the following sections, we have chosen to divide the United States from the rest of the world. We argue that this contributes to a better analysis, as the US is a major market for Novo Nordisk and has a vastly different healthcare system than the rest of the world.

In the United States, 67.2% of the population is privately insured, either through their employer or by direct-purchase (US Census, 2016). Approx. 9% of the US population is uninsured while the remaining is insured through public programs such as Medicare, Medicaid and military health care. In recent years, ObamaCare has significantly affected the insurance coverage of Americans, reducing the ratio of uninsured individuals from 16% in 2010 to 8.6% by the first quarter of 2016 (Mangan, 2016) by moving many uninsured individuals to the Medicare and Medicaid programs.

While combining previously uninsured individuals under large organizations such as Medicare and Medicaid would intuitively increase their bargaining power, in practice it has had a relatively minor impact on Novo's ability to set their prices in the US. While Medicaid receives a mandated discount, Medicare is prohibited from negotiating with drug companies (The Economist, 2016) and is instead forced to purchase drugs at a price agreed upon by private insurers. Thus, the largest US payer has no

bargaining power. Instead, one could even argue that it benefits the pharmaceutical firms, since the largest government payer is forced to purchase at a price negotiated with third parties. Novo Nordisk also mentions in their 2015 Annual Report (p. 78) that the new rules implemented under the Affordable Care Act “does not have a material impact on Novo Nordisk’s financial position, operating profit or cash flow for the period”.

This reality is unlikely to change in the near future. While Donald Trump has been receptive to the idea of allowing Medicare to negotiate drug prices, it will have no effect unless Medicare is allowed to refuse drugs, which is an idea that has not been suggested (The Economist, 2016). Additionally, the US pharmaceutical industry is a major contributor to the American economy and a major lobbyist. As the current government has suggested no initiatives that would provide increased bargaining power to government healthcare, we do not believe that it is likely to change in the near future.

#### *Pharmacy Benefits Managers*

In the United States, Pharmacy Benefits Managers (PBMs) are responsible for maintaining the formulary, contracts with pharmacies and negotiate discounts and rebates with drug manufacturers (Gryta, 2011). Novo Nordisk negotiates with PBMs in order to secure access for its products and provide rebates (Novo Nordisk Annual Report, 2016, p. 1). PBMs are the main purchasers of medicine in the US.

In recent years, a number of mergers and acquisitions have heightened the concentration of the PBM landscape. Recent deals include Express Script’s \$29.1B acquisition of Medco in 2012 and UnitedHealth’s \$12.8B acquisition of Catamaran (Breese, 2016). As a result, the industry is now highly consolidated, with just three players being responsible for roughly 82% of all prescriptions in the US (See Figure 12).

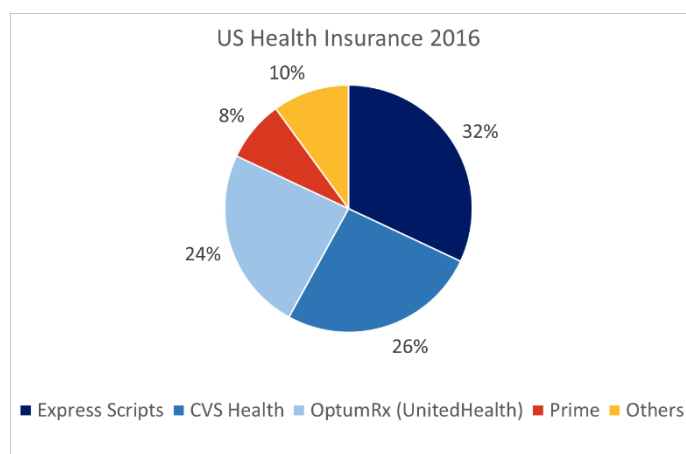


Figure 12: Market share of PBMs in the US. Compiled by authors.  
Source: Novo Annual Report 2016, p. 65

Novo has felt the impact of this increased consolidation. Due to the larger size of the individual PBMs, they carry a higher bargaining power (as per Porter’s argument). In order to continue their business

with the major PBMs, Novo has had to renegotiate their contracts and has significantly increased the rebates offered. As we mentioned in the section on substitutes, CVS has dropped Lantus from their formulary completely. PBMs are exploiting their increased size and the opportunities brought by the new biosimilars to pressure pharmaceutical firms to increase their rebates or risk losing the contract (Dennis, 2016) (Novo Nordisk Annual Report, 2016, p. 40). Also, PBMs are now adopting exclusive contracts which potentially lock out pharmaceutical firms from specific PBMs, as has happened to Sanofi with CVS and Novo with Express Scripts (Paton, 2016).

These increased rebates have had a significant effect on Novo Nordisk's net revenues (see Figure 13)<sup>14</sup>. The firm has been forced to increase its rebates as a response to the increased bargaining power from PBMs. The firm mentions its

<b>Gross-to-net sales reconciliation</b>			
<b>DKKm</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Gross sales	198,924	182,779	131,841
US Managed Care and Medicare	(40,874)	(33,235)	(17,522)
US wholesaler charge-backs	(25,416)	(22,030)	(12,858)
US Medicaid rebates	(10,862)	(9,838)	(5,578)
Other US discounts and sales returns	(5,147)	(4,685)	(2,972)
Non-US discounts and sales returns	(4,845)	(5,064)	(4,105)
Total gross-to-net sales adjustments	(87,144)	(74,852)	(43,035)
<b>Net sales</b>	<b>111,780</b>	<b>107,927</b>	<b>88,806</b>
- Rebates as % of gross sales	43.81%	40.95%	32.64%

Figure 13: Rebates' impact on sales. Compiled by authors. Source: Novo Nordisk annual report 2016, p. 66

challenges with PBMs in its 2016 annual report (page 1, 2, 32), confirming the impact on its operations.

Whether further consolidation in PBMs is possible is uncertain – a number of proposed acquisitions have been blocked by the US Department of Justice on antitrust grounds (Breese, 2016), so it is possible that the concentration in large PBMs will not develop further.

Even so, the significant bargaining power that PBMs have in the US has had a material impact on Novo's operations, and that is likely to continue as PBMs explore opportunities to pressure pharmaceutical companies further by leveraging the appearance of new biosimilars. Thus, in conclusion it is unlikely that Novo Nordisk will be able to increase future prices to the same degree as in the past. A more likely scenario is a further increase in rebates to counter the increased bargaining power of PBMs combined with the impact of biosimilars. As price increases have represented a

<sup>14</sup> As can be seen from the graph, rebates to governmental organizations (Medicare and Medicaid) significantly increased over the period. That does not disprove our point made in the previous section, as these increases are primarily a result of Novo Nordisk's negotiations with private insurance firms resulting in increased rebates.

considerable share of the sales growth for insulin makers (Hirsch, 2016) a suppression in future prices is likely to impact Novo's revenue growth significantly.

#### *RoW buyers*

Much of the world operate with single-payer systems in which the vast majority of medical expenses are covered by the government. Governments across the world are experiencing pressure to optimize their healthcare systems and control expenditures (Novo Nordisk Annual Report, 2016, p. 37). This pressure has caused multiple countries to implement austerity measures to control their healthcare spending, directly affecting pharmaceutical firms. Several European countries have imposed significant price restrictions on drugs in order to optimize healthcare systems in response to the slowing economic growth and the aging population.

Additionally, China's recent economic slowdown has caused the government to provide increased pressure on pharmaceutical firms to reduce prices. Similar themes are present in many countries globally, and Novo expects this trend to continue in the future (Novo Nordisk Annual Report, 2016, p. 38). As governments in single-payer countries are responsible for the vast majority of purchases in that given country, they have major bargaining power as per Porter's reasoning. Due to their power, and the focus on cost optimization, we do not expect that Novo will be able to generate substantial sales growth through price increases in other countries.

#### *Summary on buyers' bargaining power*

We do not expect that the US government will be able to force any price decreases, as they do not possess any negotiating power and we have no expectations of that to change. However, Pharmacy Benefits Managers in the US have consolidated in recent years, providing them with significant bargaining power. The introduction of biosimilars also provide an alternative for patients, and we expect PBMs to leverage this opportunity to pressure pharmaceutical firms into lower prices. Outside of the US, many countries are under pressure to optimize their healthcare system in the face of slowing economic growth and aging populations. Thus, we do not expect Novo Nordisk to be able to increase future prices to the same degree as in the past.

#### *Competitive rivalry between existing companies*

As we mentioned in the introduction to this analysis, Novo Nordisk is active in four different industries: diabetes, obesity, hemophilia and growth disorders. For the optimal analysis, we have divided the

following section in order to focus on each segment individually. We will provide a summary of all the points made in this section in appendix 1.

## *Diabetes*

Main takeaways:

- GLP-1
  - GLP-1 market is rapidly growing in both US and RoW
  - Novo no longer has the superior product
  - Victoza will continue to lose market share
  - Launch of Semaglutide in 2018 will stabilize Novo market share
- Long-acting
  - First biosimilar reached the market in December 2016 and has quickly gained market share
  - Novo's future growth is dependent on the success of Tresiba
  - Long-term market is likely split between new-generation insulins and biosimilars
- Fast-acting
  - Current competition primarily between NovoRapid and Lilly's Humalog
  - Novo is first on the RoW market with effective ultra-fast acting, still awaiting FDA
  - Biosimilars have not entered the market yet, but are likely to do so in the future
  - Long-term market is likely split between new-generation insulins and biosimilars
- Pre-mix
  - Historically a relatively stable segment
  - New GLP-1/long-acting combos open up for new opportunities
- Obesity
  - Saxenda has little direct competition, with most other products being pills of varying effectiveness
  - Primary challenge for Novo is not to beat the competition but rather to grow the market

Due to the size and complexity of the diabetes treatment industry as well as its importance to Novo Nordisk, we will segment this part by treatment type: GLP-1, long-acting, fast-acting, premix and others. This mirrors the structure we followed in the company description.

## GLP-1 agonists

The market for GLP-1 agonists is relatively young. The first product on the market was Byetta in 2005 (Drugs.com, 2005), manufactured by Amylin Pharmaceuticals and marketed by Eli Lilly. Following the acquisition of Amylin Pharmaceuticals by Bristol-Myers Squibb in 2012, AstraZeneca (AstraZeneca, 2012) gained the rights to market the product.

Novo Nordisk entered the market with an EU launch in July 2009 (Staton, 2013b) and a US launch in February 2010. Since entering the market, Victoza has gained significant market shares (see Figure 14) and is now the leading product within the GLP-1 segment.

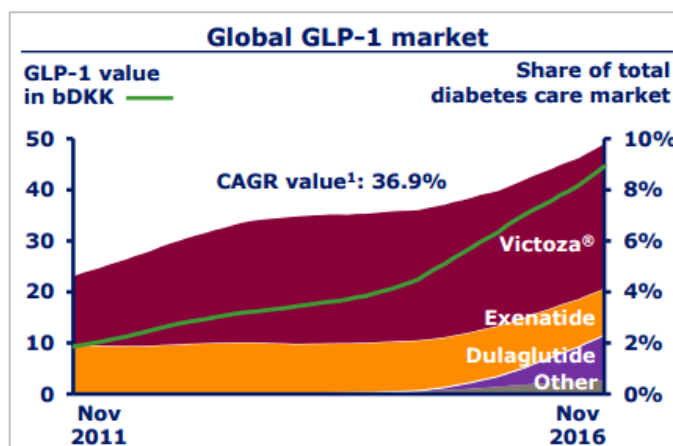


Figure 14: GLP-1 as part of total diabetes care market. Source: Novo Nordisk Investor Presentation Full Year 2016, p. 58

The primary competition for Novo Nordisk has been the aforementioned Byetta (Exenatide), marketed by Eli Lilly and since

AstraZeneca. AstraZeneca launched an improved version of Byetta in 2014, named Bydureon, intended to be injected just once-weekly as opposed to once-daily (AstraZeneca, 2014). Since then, Eli Lilly has reentered the market with an introduction of their product Trulicity (Dulaglutide) in November 2014 (Diatribes, 2014a) and its market share has climbed rapidly, reaching 25% in the US by the end of 2016 (Novo Nordisk Investor Presentation: Full Year, 2016, p. 14).







Product	Victoza	Byetta	Bydureon	Trulicity	Tanzeum	Semaglutide
Manufacturer					 GlaxoSmithKline	
US volume market share	50%	5%	13%	25%	7%	TBA
EU/US launch	2009/2010	2005/2005	2012/2012	2015/2014	2014/2014	TBA
Frequency	Once-daily	Once-daily	Once-weekly	Once-weekly	Once-weekly	Once-weekly
Ready-to-use	Yes	No	No	Yes	No	Yes
Price (USD)	920.60	820.39	738.53	757.11	588.32	TBA

Figure 15: Summary of key characteristics of major GLP-1 agonists. Compiled by authors.



The products differ in several ways as summarized in Figure 15<sup>15</sup>. Victoza is immediately ready for use, does not require additional steps to prepare the injection (Victoza.com, 2017) and is to be taken once a day. The two types of Exenatide made by AstraZeneca, the once-daily Byetta and the once-weekly Bydureon previously required the user to transfer the medication between a vial and the syringe (Diatribе, 2014b). This inconvenience was somewhat alleviated in 2014 with the introduction of a new type of pen which allows the user to inject themselves without the previous mixing. Even so, Exenatide still requires the user to mix the ingredients by tapping the pen firmly against the palm of their hand at least 80 times before injecting (Diatribе, 2014b). Eli Lilly's once-weekly GLP-1 agonist Trulicity (Dulaglutide) comes ready-to-use with no requirements for premixing. Tanzeum is manufactured by GlaxoSmithKline and is similarly a once-weekly injection, but requires a mixing time of at least 15 minutes before it is ready for injection (Tanzeum, 2017).

As can be deduced from the previous, the market for GLP-1 agonists is highly competitive with multiple firms competing, and several new products being launched in recent years. While Victoza is still the current market leader, the number of competing products that are objectively better in one or more respects puts pressure on Victoza, whose US market share has been gradually declining in the past 3 years. In particular, Trulicity has been well-received by the market, gaining a 25% market share in the US in just 2 years (see Figure 16). The product sets itself apart by combining the ready-to-use nature of Victoza while only requiring a once-weekly injection.

The apparent superiority of Victoza's competition has had a clear impact on its market share, falling from almost 65% to 50% in the US since 2013. While Novo's competitive position has worsened in the past three years, the total market for GLP-1 agonists has increased significantly (see Figure 14), causing Victoza to still contribute with a significant share of Novo's total revenue growth.

Key drivers for Novo to maintain its leadership position within GLP-1 agonists, are: Improvements to Victoza and Semaglutide, a product yet to reach the market.

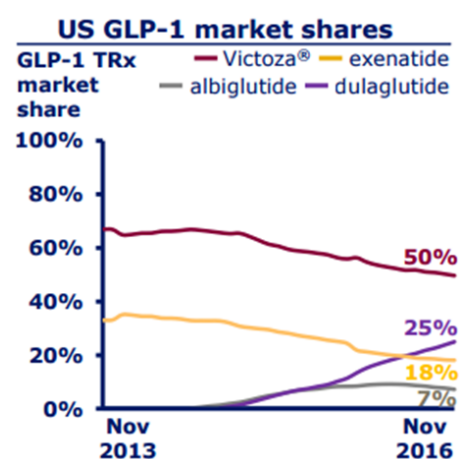


Figure 16: US GLP-1 market shares, split between Victoza, exenatide (AstraZeneca), albiglutide (GlaxoSmithKline) and dulaglutide (Eli Lilly). Source: Novo Nordisk Investor Presentation Full Year 2016, p. 14

<sup>15</sup> Market share data is based on Novo Nordisk investor presentation 2016. The term Ready-to-use covers whether additional steps are needed to prepare the compound before injection. US prices are the average retail prices according to <https://www.goodrx.com/>. Depending on insurance these prices may vary.

In October 2016, Novo Nordisk filed a supplemental New Drug Approval form to the FDA in order for their product label to include the results from their new LEADER trial, which showed a statistically significant 22% reduction in cardiovascular deaths among patients treated with Victoza (The Pharma Letter, 2016). This product label update is highly important, as being able to prove the medical benefits of Victoza gives Novo Nordisk leverage in negotiating with PBMs and governments, and previous studies and label updates have played a key role in Victoza reaching the market leader position in the first place (Apple, 2012). A decision on Victoza's label claim is expected during 2017 and an approval from FDA will help greatly in being able to resist the competition from Trulicity. Despite requiring daily injections, Victoza is still seen as a strong contender due to its potential for lowering A1C levels<sup>16</sup> and potential for weight-loss (Apple, 2012). With the added proven benefit of lowering the risk of cardiovascular death (of which Victoza is the only GLP-1 agonist to do), it is possible that Victoza can stave off, or at least lessen, the impact of more convenient competitors.

Even so, it is likely that Victoza will gradually lose market share due to the increased competition. As we stated in the previous section on Novo's R&D pipeline, Semaglutide is positioned to become Novo's next primary product within the GLP-1 segment. Similarly to Victoza, Semaglutide is ready-to-use and does not require any preparation before injection. Additionally, Semaglutide is only needed once a week as opposed to Victoza's daily injections.

This would initially seem to simply level the playing field, putting Novo at no advantage over Eli Lilly's Trulicity. However, the trials that Novo has performed on Semaglutide shows some promising results that may put it at an advantage over its competitor. It has already proven superiority<sup>17</sup> over AstraZeneca's Bydureon, and Merck's DPP-4 Januvia (not a GLP-1 agonist) as well as improved HbA1c control compared to Lantus. In their SUSTAIN 6 trials, which were presented in September 2016, Semaglutide was found to significantly reduce cardiovascular problems, with a 39% reduction in strokes and a 26% reduction in heart attacks (Staton, 2016a).

There are only 2 other diabetes treatments that have proven benefits to the cardiovascular system: Victoza and Eli Lilly/Boehringer Ingelheim's SGLT2 drug Jardiance, which is a different class of drug. Since type 2 diabetics are often at increased risk of cardiovascular problems, having a proven benefit to the heart can prove to be a major selling point for Semaglutide. Novo is counting on clinical tests to prove its superiority over the already established once-weekly competitors and has begun trials

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<sup>16</sup> HBA1C provides a measure for a person's average blood sugar levels over the previous 8-12 weeks

<sup>17</sup> In tests with HbA1c levels as primary focus, and body weight and hypoglycemic events (dangerously low blood sugars) as secondary goals

putting Semaglutide against Jardiance, which despite being a different type of drug has effects that are largely similar to GLP-1 agonists.

Thus, while Novo's Semaglutide stands to become the fourth once-weekly product to enter the market, it has a key advantage in its cardiovascular profile that is likely to allow it to win shares against the other GLP-1 agonists. Novo filed for FDA approval in December 2016 (Staton, 2017), and if approved it is likely to reach the market in late 2017 or early 2018. We expect Novo to lose market share in 2017, although the growth of the GLP-1 market should still lead to a growth in revenue for Victoza.

#### Oral GLP-1 agonists

Novo is developing an oral form of Semaglutide, intended to be taken daily. It is currently in phase 3 of trials and has shown promising results so far, with effects consistent with the once-weekly Semaglutide. The oral administration adds increased convenience and is likely to expand the market if it is approved. Being the first on the market with an oral treatment could turn Semaglutide into a blockbuster, but Novo is not the only firm developing an oral GLP-1 agonist. Oramed Pharmaceuticals is beginning phase 2 trials of their own oral GLP-1 product in 2017 (di Stefano, 2017), so it is currently unknown if Novo will manage to reach the market first.

Concerns standing in the way of an oral GLP-1 include the impact that the patient's diet may have on the absorption of the product, as well as the effect on people with delayed gastric emptying. Otherwise, the oral version has similar HbA1c and weight loss effects, and no additional safety or tolerability issues compared to the subcutaneous Semaglutide. Lastly, doses for the oral version is significantly higher than the subcutaneous version, needing 10-40 times as much to achieve the same effect (Freed & Joffe, 2016). This is likely to have an impact on production costs and therefore profit margins.

In conclusion, oral substitutes are still several years from reaching the market, and there are a few factors that are likely to prohibit them from overtaking the market completely. In particular, the significantly higher dosage will result in either a considerably higher price or a lower margin for Novo Nordisk. Because of this, we do not consider the oral GLP-1 agonist to be capable of replacing the subcutaneous ones in the near future.

## Long-acting

The long-acting insulin market has traditionally been dominated by Sanofi's Lantus (insulin glargine) with Novo's Levemir in second place with roughly 20% of the global market (Novo Nordisk Investor Presentation: Full Year, 2016, p. 46).

Recently, both products have begun to slide, with Lantus declining almost 10% in revenue in 2016 (Sanofi Annual Report, 2016, p. 4) while Levemir declined by 6.7% (Novo Nordisk Annual Report, 2016, p. 67). Apart from pricing concerns, the reason for the fall in revenues comes largely as a result of the launch of a new biosimilar, and the sales of Tresiba and Toujeo, two modern insulins intended as successors to Levemir and Lantus, respectively.

After Lantus lost its patent in 2015, competing pharmaceutical firms quickly started development of a biosimilar version (see section on substitutes for more). The first biosimilar insulin was released in December 2016 when Eli Lilly and Boehringer Ingelheim launched Basaglar, a biosimilar version of Lantus. Priced at a 15% discount compared to Lantus, Basaglar quickly made waves in the market, capturing 9% of new-to-brand subscriptions in the US (see Figure 17). In 2017,

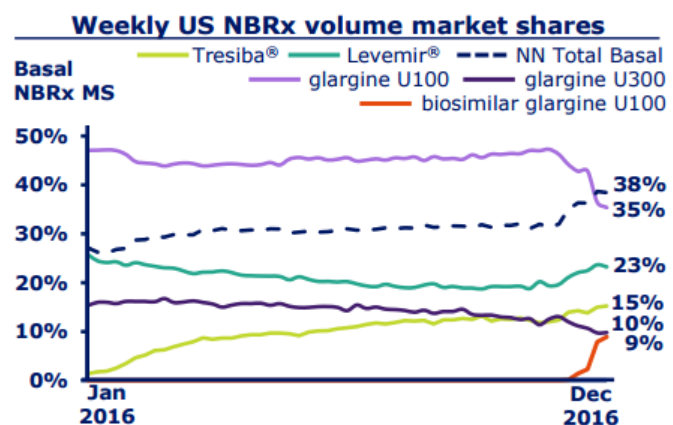


Figure 17: New-to-brand subscriptions of long-acting insulin in the US. Source: Novo Nordisk Investor Presentation Full Year 2016, p. 13. Note: Numbers do not add up to 100% due to the exclusion of NPH (human) insulins

the trend does not look better for Lantus, as CVS Health has decided to exclude Lantus from its 2017 formulary in favor of Basaglar. Looking at Figure 17, it would seem that the launch of Basaglar has so far primarily had an impact on the sales of Lantus and Toujeo, with Novo's products both gaining market share in December. However, as patients seek to move from Levemir/Lantus to newer generation insulin, some may be enticed to instead move to Basaglar due to save on costs. Novo mentions the new biosimilar as a concern in their 2016 annual report (p. 32) and acknowledges the impact it has on the bargaining power of payers and corresponding pressure on pricing. PBMs are using the threat of biosimilars as leverage to negotiate higher rebates. Express Scripts have stated that they consider the benefits of Tresiba to be "not convincing enough" compared to the previous generation of insulin, and considered an exclusive contract with Lilly's Basaglar to be "always an option" depending on whether they could reach an agreement with Novo and the other insulin makers (Kitamura & Torsoli, 2016).

Lantus lost its patent protection in 2015 (Staton, 2015) and Levemir is due to lose its protection in 2018/19 in the EU/US. Both firms have already launched their replacements however. Sanofi launched Toujeo (glargine U300) in 2015 (Saxena, 2015). Toujeo is not a completely new type of insulin, but is instead a version of Lantus with a 3 times higher concentration, leading to a more prolonged effect. Novo launched Tresiba in Europe in 2013, and after gaining FDA approval in 2015, the product was launched in the beginning of 2016 in the US. Tresiba is a new compound, providing a more stable glucose reduction for the patient.

Few head-to-head trials between Tresiba and Toujeo have been published yet, and preliminary results are inconclusive. Toujeo has been shown to have a more stable profile<sup>18</sup> compared to Lantus, causing fewer hypoglycemic events and lower weight gain (Cavaola, 2015). Similarly, Tresiba is shown to significantly reduce hypoglycemic events compared to Lantus. Novo announced the completion of a head-to-head study between Tresiba and Toujeo in 2016 (Børsen, 2016) in which Tresiba was shown to provide a significantly more effective glucose-control than Toujeo among type 1 diabetics. However, Sanofi has completed a similar study, indicating a more stable profile for Toujeo. Sanofi is currently working on a larger trial involving 920 patients, and the results of this trial is expected in November 2017. Until then, our working assumption based on the clinical trials so far is that they are equally effective. Thus, the market shares of the two new drugs will largely depend on the commercial operations of Novo and Sanofi.

In the future, it is likely that the primary three competitors will be Tresiba, Toujeo and Basaglar. The first two are “new generation” ultra-long-acting insulins with a more stable profile than the previous generation and will seek to emphasize their superior medical performance compared to their predecessors. Basaglar is identical to Lantus in performance and will instead seek to compete on its lower price. We expect market shares of Lantus and Levemir to gradually decline, with Lantus declining faster due to the direct competition by a biosimilar. With the focus on pricing among both US and RoW payers, we expect Basaglar to be able to achieve a significant market share at the expense of Lantus and Levemir. Both Tresiba and Toujeo is likely to be affected by the biosimilar, but as Toujeo is essentially a more concentrated Lantus, we expect Toujeo to be affected to a larger degree than Tresiba.

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<sup>18</sup> Meaning a more even performance throughout the day, rather than peaking early and then fading out. See Novo Nordisk Investor Presentation Full Year 2026, page 40 for an illustration on action profiles of different insulin types.

## Fast-acting

In the fast-acting insulin segment, Novo Nordisk's NovoRapid is the market leader with approx. 40% of global sales (Novo Nordisk Investor Presentation: Full Year, 2016, p. 46). Its two main competitors are Eli Lilly's Humalog and Sanofi's Apidra. The patent for NovoRapid (Novo Nordisk Annual Report, 2016, p. 101) and Humalog expires in 2017 (Fiercepharma, 2012) and Apidra loses protection in 2018 (Monson, 2017). Thus, competition in the future is largely going to center around a new generation of products.

Novo has gained approval for its new ultra-fast-acting insulin Fiasp in most non-US countries, and has already launched in Canada and several EU countries and is expecting a wider launch during H1 2017. After initially being declined, Fiasp was resubmitted to the FDA in April 2017 (Runge, 2017), with a decision expected in late-2017, most likely meaning an early-2018 launch for Fiasp in the US.

The only ultra-fast acting insulin currently on the market is Afrezza, the result of a partnership between Sanofi and MannKind. Afrezza sets itself apart by being the only inhaled insulin on the market (afrezza.com, 2017). Other pharmaceutical firms have previously attempted to develop oral insulins, but none have succeeded. Pfizer's Exubera was discontinued in 2007, citing safety concerns with patients' lungs and ended up costing Pfizer \$2.8 billion (Vieira, 2016).

Unfortunately, despite the obvious convenience of an inhaled insulin, Afrezza has performed extremely poorly on the market. Both patients and doctors are hesitant to try it, and patients who are willing to try have been reluctant to stay on it (Osborne, 2016a). Afrezza can only be dosed in increments of 4 or 8 units<sup>19</sup> as opposed to subcutaneous insulins that can be dosed in individual units. This is a concern for patients who find themselves taking either too much or too little insulin. Additionally, the FDA requires patients to take a long function test before starting Afrezza. The drug has not been popular among payers either, resulting in little-to-no rebates for the drug, making the cost significantly higher than competing insulins. Sanofi terminated the partnership with MannKind in January 2016 (Vieira, 2016) after which MannKind established a 70-person committed salesforce to market the product themselves. Despite the efforts, Afrezza has failed miserably, with weekly prescriptions of 300 by late 2016, and MannKind's share price has fallen to less than \$1, down from \$30 in the beginning of 2015 when the product was launched (Nasdaq, 2017). With low cash flows and

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<sup>19</sup> 1 Insulin Unit is the biological equivalent of 34.7 microgram of pure crystalline insulin. It is the industry standard unit of measurement

high debt, it is unlikely that MannKind will be able to turn the product around, and we expect market shares of Afrezza to remain negligible.

Another product currently in development is BioChaperone Lispro by Adocia, an accelerated version of Eli Lilly's Humalog (Adocia, 2017a). Results in clinical trials have so far been encouraging, showing a faster rate of absorption compared to Humalog, while retaining the same safety profile (Morales, 2017). These clinical trials indicate that BioChaperone would be approx. equivalent to Novo's Fiasp in effect, making it a relevant competitor. On January 27, Eli Lilly announced the termination of their partnership (Adocia, 2017b). The decision came as a surprise to Adocia, stating that "We are extremely disappointed and surprised by Lilly's decision to terminate the collaboration on our product". Lilly issued no statement to explain their reasoning, but Adocia is currently looking for a new partner to help with phase 3 trials.

Apart from next-generation ultra-fast-acting insulins, a few biosimilars are also in development. Biocon and Mylan are partnering to develop biosimilar versions of both Humalog and NovoRapid. Both drugs are in phase I stages of clinical trials, so they are not expected to reach the market for another several years (Hoskins & Tenderich, 2016). Sanofi is in phase 3 clinical trials of SAR342434, a biosimilar version of Humalog. In October 2016, they completed a trial with positive results and they filed for approval in Europe in November 2016 (Schofield, 2016). Depending on the EMA's decision, Sanofi could launch its biosimilar in early 2018 in Europe. As they have not yet filed with the FDA, we expect a late 2018 launch at the earliest. If the biosimilars are successfully developed and approved, they would likely be priced at approx. 15% discount compared to their reference drugs, putting them in similar competitive positions as Basaglar is in the long-acting segment.

Regardless, Novo Nordisk is currently positioned with the best product on the market. This presents an opportunity for Novo Nordisk to increase its market share across all markets. We expect Novo to slightly increase its market share in all non-US markets in 2017, and similarly in the US following the expected launch of Fiasp in the US in primo 2018. A launch of a biosimilar in RoW in 2018 is likely to have an impact on NovoRapid's market share, and we expect the biosimilars to capture approx. 30% of the market in the long run.

#### Premix

The premix segment has traditionally consisted of products mixing long-acting and fast-acting insulins. NovoMix' market share has been relatively stable at approx. 33% in the past 5 years (Novo Nordisk

Investor Presentation: Full Year, 2016, p. 46). As the patent for NovoMix has expired, Novo has developed two replacements: Ryzodeg, a mix of Tresiba and NovoRapid and Xultophy, a mix of Tresiba and Victoza.

Ryzodeg was launched in Mexico in 2014 and is now on the market in 10 countries. Results are positive so far, but the total value of the long-acting + fast-acting market is relatively minor, and the sales of Ryzodeg in 2016 amounted to approx. 403 million DKK (Novo Nordisk Annual Report, 2016, p. 6).

Instead, the potential major blockbuster is Novo's other new premix product Xultophy. Results from trials have been very positive, with Xultophy providing a 2% improvement in HbA1c while also providing the cardiovascular benefits of Victoza. Novo filed for FDA approval and was approved on November 21, 2016, but Novo has hesitated to launch the product until their sales force is sufficiently prepared. Expected launch of Xultophy is early May 2017 (Helfand, 2017). In the meantime, Sanofi released Soliqua, a mix of Lantus and their GLP-1 agonist Adlyxin in January 2017. Sanofi is aggressively marketing the product, seeking to exploit its window of exclusivity in the new premix/GLP-1 segment by offering \$0 co-pays, reimbursement help and connections to other resources such as transportation and nutritional supplements (Helfand, 2017).

We expect that Sanofi's headstart will allow it to develop a significant market share in early 2017. However, Xultophy seems to be the superior product, owing to a better cardiovascular profile. Additionally, Novo has stated a willingness to aggressively price Xultophy at a 20% discount relative to its drug components (Helfand, 2017). Because of this, we expect Novo to be able to regain market share in the premix segment following the launch of Xultophy.

### *Obesity*

Obesity is a growing epidemic, with 600 million living with clinical obesity (Novo Nordisk Annual Report, 2016, p. 4). Despite this, only about 3% of obese Americans are treated pharmacologically. The market is growing fast (see Figure 18) and Novo's plans are highly ambitious.



Despite only launching in 2015, Novo's anti-obesity medication Saxenda has already reached market leadership, with a 56% value market share of branded AOM<sup>20</sup> in the US. Sales grew to 1,577 DKKm in 2016, up from DKK 460m in 2015.

Novo's main competition in the AOM segment consists of three oral treatments: Contrave, manufactured by Orexigen Therapeutics was approved by the FDA in 2014 (Keshavan, 2016)

but has not performed very well, with sales flatlining in 2016 and the company verging on a Nasdaq delisting. Similar results are seen in Vivus' Qsymia, with sales down 22% in Q2 2016 (Osborne, 2016b) and Arena Pharmaceutical's Belviq's declining by 38% (Osborne, 2016c). All three competitors have quarterly sales in the range of \$3-12 million, so sales are significantly lower than for Novo.

Novo notes that most of the competition in AOM seem to be reducing their promotional efforts (Novo Nordisk Investor Presentation: Full Year, 2016, p. 87), which could allow Novo to win further market shares. However, the primary concern within this segment does not seem to be competition, as they are all much smaller players with significant cash-flow issues. Instead, the primary concern for Novo's obesity division is to convince the three consumer groups<sup>21</sup> that anti-obesity medicine is worthwhile. Consumers are hesitant to try AOM, partly due to reluctance to see obesity as disease and partly due to fears of a repeat of the diet-pill "horror stories" of the 1990s in which some pills were associated with severe heart problems (Keshavan, 2016). Novo itself acknowledges this issue, stating that one of their primary concerns is to work with stakeholders to increase recognition of obesity as a chronic disease (Novo Nordisk Annual Report, 2016, p. 17). As such, Novo is less concerned with competition and more concerned about growing the market.

Whether Novo can succeed in their lofty ambitions within AOM is difficult to predict. Sales have grown at a steady pace, although at much lower rates than what analysts first predicted. Novo does not seem particularly concerned however (Dalskov, 2015), stating that it is likely to take many years for Saxenda to reach blockbuster status. It seems certain that Saxenda will remain as market leader in the anti-

#### **AOM Market Value has grown quickly in recent years, fuelled by branded treatment uptake**

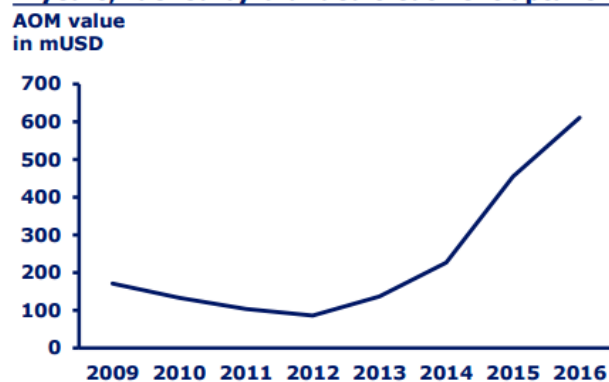


Figure 18: Market value of anti-obesity medication in the US. Source: Novo Nordisk Investor Presentation Full Year 2016, p. 86

<sup>20</sup> Anti-obesity medication

<sup>21</sup> Patients, doctors and payers

obesity medicine segment, but whether they can manage to grow the market depends on their ability to affect the demand of consumers to adopt AOM. As the market was barely existent before Saxenda, predicting its growth is challenging. Consensus estimates suggest a sales growth of approx. 1 billion DKK annually until 2019 (ABG Sundal Collier, 2017). Taking the previous growth rate and the prevalence of obesity into account, we find the consensus estimates reasonable, and predict growth rates to remain in the double digits until the mid-2020s.

### *Biopharmaceuticals*

Main takeaways:

- Haemophilia
  - NovoSeven has had no competition for most of its lifetime
  - Trials of competitor product ACE910 is affecting Novo's sales
  - ACE910 is likely to capture significant market share in the inhibitor segment until Novo's replacement finishes development
  - NovoEight is unlikely to capture relevant market share in Haemophilia A
  - N8-GP is a non-superior product in a highly competitive market and unlikely to become market leader
  - N9-GP is expected to be the second-best product on the market
- Growth disorders
  - Little difference between products, instead competition is centered around convenience and support programs
  - Novo is leader in this segment and we expect that to continue

### *Haemophilia*

As mentioned in the company description, the haemophilia market is comprised of three segments: A, B and inhibitors.

### *Inhibitors*

In the market for inhibitors, NovoSeven has no direct competitors (Paton, et al., 2016). The only other product currently on the market is AryoSeven (AdisInsight, 2017), a biosimilar version of NovoSeven. After launching in mid-2015, AryoSeven has been unable to significantly impact the sales of NovoSeven (see Figure 19).

The main competition is looking to come from the Swiss firm Roche in the form of ACE910 which is currently in phase 3 of clinical trials (Børsen, 2016b). Despite the fact that the drug is not yet on the

market, the low number of patients means that a late-stage clinical trial has had a major impact on sales of NovoSeven which declined by 593 DKKm in 2016 (Novo Nordisk Investor Presentation: Full Year, 2016, p. 7). If ACE910 is approved and reaches the market, it is likely to affect Novo's sales significantly as it is a superior product requiring fewer and shorter injections. ACE910 has had a few stumbles in its trials. In the latest trials, several people

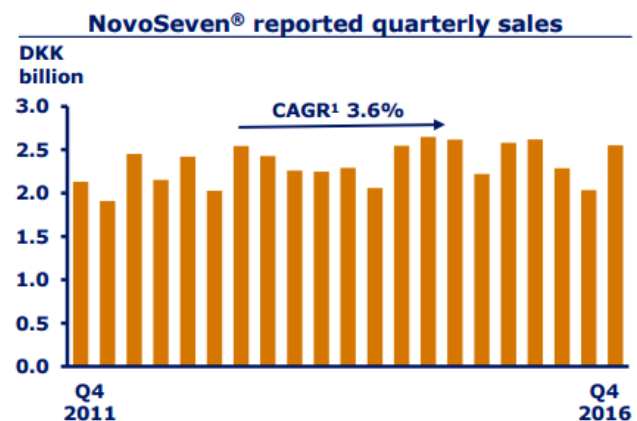


Figure 19: Quarterly sale of NovoSeven. Source: Novo Nordisk Investor Presentation Full Year 2016, p. 96

suffered severe side effects, with one patient dying of a severe rectal hemorrhage (Carroll, 2017). Despite the side-effects, the drug still met all of its primary and secondary endpoints. Whether ACE910 played a role in the patient's death is still unclear, but it is likely to delay the launch until all side-effects are mapped out.

The fate of NovoSeven is thus somewhat uncertain. While Roche has stated that the delay will be minimal, it is likely that the FDA will require additional information before approving ACE910 to ascertain the safety of the product. We expect a launch in 2019, after which the product will severely impact the sales of NovoSeven. There is however some uncertainty due to the clinical trials, and if the side-effects continue to be severe, it could mean the termination of ACE910, allowing NovoSeven to keep its status as market leader. Even so, we expect a decline in the sales of NovoSeven in the near future due to trials of ACE910 as well as continued pressure from biosimilars. Novo is currently in phase I trials of their product Concizumab which will serve the inhibitor segment. However, as Concizumab is still in the early stages, a launch before 2025 is unlikely, and we expect Novo's market share to decline until then.

#### Haemophilia A

The market is worth approx. 42 billion DKK in 2016 (Baxter Investor Conference - Hematology, 2015). Novo launched NovoEight in 2014, making their entry into the wider haemophilia market (Novo Nordisk Annual Report, 2016, p. 17). The treatment for haemophilia type A is highly competitive, with the market leader being Shire's Advate with almost 50% of the market after they bought Baxalta (Dabney, 2016).

NovoEight is a biosimilar of Advate and was never expected to conquer the market, but instead to open up for Novo's once-weekly product N8-GP which is currently in phase 3 trials and is expected to be filed for approval in 2018 (Campbell, 2017). As a once-weekly to twice-weekly treatment, it will be competing against the twice-weekly Eloctate from Bioverativ, Shire's twice-weekly Adyvonate, Bayer's twice-weekly Kovaltry and CSLBehring's twice-weekly Afstylä, all of which have already reached the market.

Novo will enter a highly competitive market without a first-mover advantage. The results from trials so far suggest that N8-GP might need less frequent injections than its competitors, which is a definite advantage. As the difference is uncertain and relatively minor however (studies show that N8-GP might need injection every 4 days, compared to every 3-5 days for Eloctate), we do not expect Novo to make a significant impact on the market, especially not as they are going against experienced firms with many years of experience in treating type A haemophilia. If the trials succeed, Novo expects to file for approval in 2018 which would enable a 2019 launch. The fact that N8-GP is at least comparable to competitors should allow it to capture a part of the market, but due to the market's competitiveness and N8-GP's non-superiority, we do not expect N8-GP's market share to exceed 10%.

#### Haemophilia B

Novo is yet to enter the haemophilia B market which was worth approx. 12 billion DKK in 2016 (Baxter Investor Conference - Hematology, 2015), but has recently filed for approval of their N9-GP product, a once-weekly drug.

N9-GP will compete against Alprolix by Bioverativ and CSLBehring's Idelvion which was launched in 2016. Alprolix can be dosed at 10-day intervals, and Idelvion can be administered in 7, 10 or 14 day intervals.

Currently, CSLBehring's Idelvion is leading the market for new-generation haemophilia B medicine, with Bioverativ's Alprolix in second place (Campbell, 2017). The efficacy of all three drugs are relatively similar, with median annual bleeding rates on prophylactic treatment of 1.0 for N9-GPe (Novo Nordisk Investor Presentation: Full Year, 2016, p. 100), 2.3 for Alprolix (Bioverativ, 2017) and between 0.0 and 1.08 for Idelvion depending on either 7 or 14-day treatments (CSLBehring, 2016). No patients have developed inhibitors using any of the drugs during trials. Idelvion was launched in 2016 and little information on sales has been released so far. Alprolix had sales of \$333.7 million in 2016, corresponding to a market share of approx. 18%.

Having already filed for approval, we expect a launch in 2018 for Novo's N9-GP. We do not expect N9-GP to take over Idelvion's leadership position, as CSL's product has the potential to last longer while remaining as efficient. It is likely that N9-GP will perform somewhere between Alprolix and Idelvion, corresponding to a long-run market share of 25%.

### Growth disorders

The market for growth hormones has 6 relevant players, with Novo Nordisk in a solid leadership position with 30% of the market based on volume (see Figure 20), and 37% based on value.

A major competitive driver in growth hormone therapy is not related to the efficacy of the product itself, but rather the convenience of using the product. The most important features include reliability, ease of use, lack of pain during injection, safety in use and

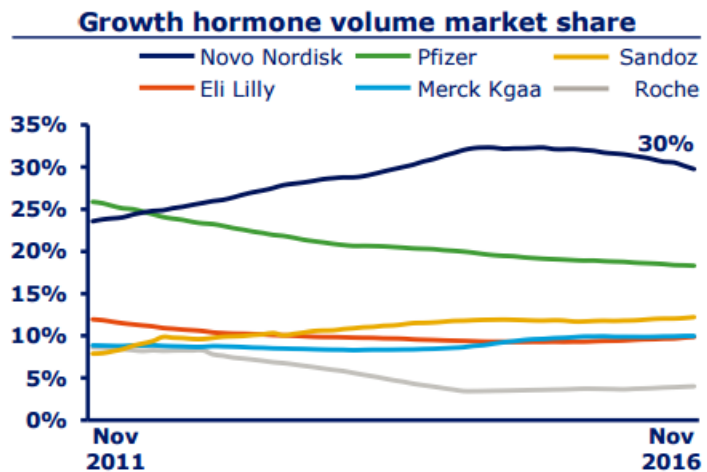


Figure 20: Growth hormone market share. Source: Novo Nordisk Investor Presentation Full Year 2016, p. 102

storage, and the number of steps needed before and after use (Hooker, 2013). Novo's Norditropin has a number of advantages in these categories. In the UK, a study showed<sup>22</sup> that the majority (92%) of endocrinologists consider the different growth hormone products identical, but that preferences may arise due to differences in the aforementioned features. Other studies have shown that patients prefer Novo's offering due to better services offered, as well as less pain during injection, ease of preparation, measuring doses and administration. Similarly, a blind study among nurses concluded that the time spent administering Norditropin products was significantly less than others.

These advantages in convenience and support programs have led Novo Nordisk to become the market leader in GHT<sup>23</sup>. The patent for Norditropin is due to expire in 2017, but no biosimilar is expected to reach the market soon. As mentioned, competition in the industry revolves around value-adding characteristics and services rather than the drug itself. In 2006, Sandoz received approval for the first and only biosimilar GHT, a version of Pfizer's Genotropin, but initially failed to sufficiently penetrate

<sup>22</sup> See Hooker, 2013 for an overview of all the studies mentioned in this section

<sup>23</sup> Growth Hormone Therapy

the market (GlobalData, 2015) despite pricing its new product at a 30% discount compared to its reference product. Only after introducing improved delivery options and a new formulation were they able to gradually gain market share, but as we can see in Figure 20, Sandoz is only the third largest player on the market today. This indicates that in order to compete in the GHT market, copying a successful patent is far from enough. Additional investments in development of delivery systems and support programs puts the cost of a biosimilar GHT product close to that of their originator. We therefore do not expect biosimilars to play a significant role in the competitive pressure in GHT.

Novo's next product in GHT is currently in phase 3 trials with positive results so far. The new product, dubbed Somapacitan is a once-weekly treatment instead of once-daily, providing obvious convenience. One of the big issues with current generation of treatments is non-compliance (Ascendis Pharma, 2016) in which patients do not take the prescribed treatment which has a negative impact on the demand for the product. A less frequent dosage has been shown to drastically reduce non-compliance among patients with growth hormone disorders (Global industry Analysts, 2012), and thus the competition in the future is likely to center around once-weekly treatments. With Somapacitan in phase 3 trials, a launch could happen as early as late-2018, although a 2019 launch is more likely.

Currently, the only once-weekly product on the market is LG's Eutropin (LG, 2017) but it is only on the market in Georgia, South Korea and Thailand (Drugs.com, 2017b). Very little information is available regarding this drug and it does not seem to be a relevant player except in South Korea, with no information about FDA filings to be found. The other competitor with potential to release before Novo was Pfizer/Opko health's hGH-CTP which failed to meet its endpoints in phase 3 trials. As such, it is likely that Novo Nordisk will be the first major player on the market with a once-weekly growth hormone.

In conclusion, high efficacy is assumed in all growth hormone therapy products and competition instead centers around convenience. We expect Novo Nordisk's advantages in delivery systems and patient care programs to continue into the new generation. Thus, we expect a relatively constant market share of Norditropin until the launch of Somapacitan. By being the first major once-weekly product on the market, Somapacitan is likely to capture a share of the potential market that the less convenient options have failed to consistently attract. We expect a 2019 launch of Somapacitan, after which Novo will be able to gradually grow its market share from 37% to 40%.

## Internal resources and capabilities

Main takeaways:

- Resources
  - Novo and its two primary competitors are similar in most aspects
  - All are international firms with good financial strength, production capabilities and are well-regarded by their internal and external environments
- Capabilities
  - Novo differs from its competitors by its sole focus on protein-based products for a small range of conditions
  - This has caused Novo to have a more focused R&D and production setup, leading to significantly lower costs compared to Sanofi and Lilly
  - We believe this advantage is sustainable, as Sanofi and Lilly are unlikely to narrow their focus. Novo may broaden their efforts however, which may lead to a slight dilution of this advantage

In the internal analysis, we aim to develop an understanding of Novo Nordisk's resources and capabilities. Resources are the productive assets, as defined in (Barney, 1991) and capabilities are the firm's ability to mobilize these resources in order to improve productivity (Makadok, 2001).

As mentioned, Novo operates within four different industries. As we have shown in the Porter's Five Forces analysis, Novo's main competition differs between industries. However, by taking the relative importance of Novo's four industries into account, we would argue that Sanofi and Eli Lilly, based on their strengths in diabetes treatment are Novo's primary competitors. We will therefore use these two firms as reference points in our analysis of Novo's internal resources and capabilities.

### Resources

#### *Production facilities and distribution network*

Novo is a highly international organization, with R&D, production and distribution spread out over the world. Novo has R&D facilities in Europe, North America and China and production sites in Europe, North & South America, Asia and North Africa (Novo Nordisk Annual Report, 2016, p. 95). Novo has previously had only a single manufacturing plant in each country, but from 2018 to 2020, Novo expects to open several new production facilities in the US and Denmark. (Novo Nordisk Annual Report, 2016, p. 75)

Eli Lilly has research facilities in 6 different countries and manufacturing plants in 13 countries, including the US/Puerto Rico, China and multiple countries in Europe (Lilly.com, 2017). Similarly, Sanofi has manufacturing plants in 40 countries on all continents except Australia, and R&D in North America, Europe and China (Sanofi, 2017).

In distribution, all three firms are also spread out globally, with particular focus on North America, Europe and Asia. As distribution seems to be localized in largely the same countries, no firm has an advantage due to lower labor costs or better market access.

As such, it does not seem like any of the three competitors have any particular advantage within R&D, production or distribution. They are largely placed in the same areas, close to their markets, with a natural bias towards their respective countries of origin.

#### *Financial strength*

There is no major difference in the credit rating of the three companies, with all being placed solidly in investment grade. Novo has very little debt and is rated A1 and stable by Moody's, compared to Sanofi's A1 stable and Eli Lilly A2 stable. (Moody's, 2016) (Sanofi, 2017b). They all have positive cash flows per share and pay dividends out to investors.

We consider all firms stable enough that they should be able to finance future projects, either through retained cash or borrowing. Thus, we do not consider any of the firms to have a competitive advantage due to their financial strengths. It could be argued that Novo has a slight edge in flexibility, as they are the only one out of the three with more cash than debt (Williams, 2017). While this is unlikely to affect operations, it could give Novo a potential advantage in large-scale projects such as M&A. However, this flexibility can only be considered an advantage if Novo is willing to engage in major acquisitions, which they have so far been hesitant to.

#### *Intellectual property*

The pharmaceutical industry is heavily dependent on their patents in order to recoup the enormous up-front costs of successfully developing a drug. The impact of generics on off-patent drugs is a clear example of how important patent protection is to the pharmaceutical industry. However, we would argue that patents are a necessity and never a source of competitive advantage.



A patent functions by securing exclusivity for the product in question. This can potentially be very valuable, but is highly reliant on the underlying product being valuable in the first place. Thus, the source of a patented product's competitive advantage lies with the product and not the patent. Novo has some very valuable patents, and so do the two others, but their value lies with the products, which we have analyzed in the Porter's Five Forces section. Thus, we consider patents to be a necessity in order to function, but not a source of competitive advantage for either of the firms.

### *Support functions*

Novo, Lilly and Sanofi all rely on a wealth of supportive functions, such as legal, finance, corporate and administrative departments. Like patents, these are necessary in order for any major firm to operate, but we do not find them to be the source of any competitive advantages.

### *Human relations and public relations*

Like any research and technology-focused industry, pharmaceuticals are highly dependent on the quality of their workforce. Novo, Lilly, Sanofi and others rely on highly educated people to develop their products, but also on individuals to support the firms in sales, legal, HR and other functions. Since human labor is by law mobile, keeping qualified individuals within the firm is paramount to competitiveness in the long term. A firm that is able to attract and keep the most talented individuals may therefore be able to build a competitive advantage over its competitors.

"The Novo Nordisk Way" defines Novo's approach to corporate culture and is a series of goals that Novo aims to follow with respect to its employees (Novo Nordisk Annual Report, 2016, p. 19). How successfully this approach is implemented is scored with an annual employee survey. The score ranges from 1-5, with 5 being highest, and in 2016 Novo scored 4.4, up from 4.3 in 2015. The target is 4.0 (see Figure 21) and Novo has consistently scored higher, reflecting a successful adherence to the company's cultural values. Similar scoring systems cannot be found within Sanofi or Eli Lilly.

On the Fortune list of the 100 best places to work, Novo is ranked as number 73 in 2016 (Fortune, 2017), while neither Sanofi nor Eli Lilly is ranked in top 100. In Glassdoor's ranking system, Novo has an average of 3.6/5.0 based on 545 reviews,

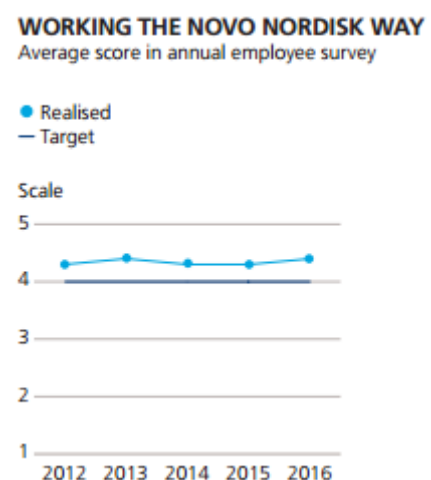


Figure 21: Score in the Novo Nordisk annual employee survey. Source: Novo Nordisk Annual Report 2016, p. 12

while Sanofi and Lilly scores 3.5 and 4.0, respectively. It would thus seem that all three firms are highly regarded among their employees, and it is difficult to argue that Novo has a strong competitive advantage in this area.

Among customers in developed countries, all three firms are also well regarded. Reputation Institute conducted a survey among 23,000 respondents and ranked firms based on their reputation in several categories, including governance, citizenship, products & performance and leadership (Strauss, 2016). In pharmaceuticals, Novo ranked number 3 overall, only beaten by Bayer and Abbott. Novo scored the highest in citizenship, governance and innovation among all firms. Sanofi ranked as number 6 and Eli Lilly as number 9. Thus, even though Novo was the highest scoring of the two, it is difficult to state definitively that they have a superior reputation than the other two firms. In conclusion, all three firms are highly regarded by both internal and external stakeholders, and no competitive advantage can be drawn from either.

Novo's choice of M&A policy may have had a positive impact on their corporate culture. Under the leadership of Lars Rebien, Novo has historically chosen to stay away from mergers and acquisitions, which are frequent among other participants in the industry, with Rebien being quoted saying "As long as I have anything to do with the company, we are not going to get involved in M&A" (Torsoli & Kitamura, 2015). Lack of cultural fit is associated with significant value destruction in M&A (Engert, et al., 2010), so refraining from acquisitions may have helped Novo keep its cultural coherence. While Novo's new CEO Lars Fruergaard has stated a willingness to engage in M&A (Hirschler, 2017), it is assumed that these deals will only happen if the targets are closely aligned with Novo's way of operating. We therefore do not expect any changes, whether positive or negative, to Novo's cultural coherence in the near future.

## Internal capabilities

### *Research and development*

As with all innovators within pharmaceuticals, their primary tool in order to compete is the efforts of their R&D departments. By consistently developing new high quality medications, Novo has managed to grow organically into one of the largest pharmaceutical firms in the world. However, this is no different than Sanofi and Eli Lilly and as our previous analysis shows, all three firms have proven capable of consistently developing competitive products.

For knowledge-heavy industries like pharmaceuticals and biotech, R&D expenses are often a good predictor of future profits (Petersen & Plenborg, 2012, p. 310). Comparing R&D expenses between the firms, (see Table 1) we do not find that any of the three firms are particular outliers. Instead, R&D expenses remain relatively constant across time for all three firms,

Research and development costs as percentage of sales					
	2012	2013	2014	2015	2016
Novo Nordisk	14.0%	14.0%	15.5%	12.6%	13.0%
Sanofi	14.0%	14.5%	14.3%	14.9%	15.3%
Eli Lilly	23.4%	23.9%	24.1%	24.0%	24.7%

*Table 1: R&D-to-sales for Novo, Sanofi and Lilly. Compiled by authors. Source: Company annual reports 2012-2016*

suggesting that none of them are making any additional efforts compared to their historical levels.

One key difference between Novo Nordisk and its competitors is its focus. Since 2007, Novo has solely been focused on protein-based biological products (Novo Nordisk Annual Report, 2016, p. 16). In contrast, Eli Lilly and Sanofi treats a much wider range of conditions, including depression, drug addiction, erectile dysfunction and cancer (Sanofi, 2017c) (Eli Lilly, 2017). The fact that Novo Nordisk concentrates almost all of their resources on a select few areas reduce the complexity of the organization and allow them to only allocate its resources to areas where they are demonstrably strong. Thus, one could argue that Novo has a competitive advantage within protein-based products, as Novo is entirely focused on this type of drugs.

This advantage is sustainable as it is unlikely that Sanofi or Eli Lilly would make a wholesale switch to protein-based drugs. As we have previously established, entry from new competitors is also highly unlikely, unless the entrant is another major pharmaceutical firm. Thus, we consider this competitive advantage sustainable.

It should be noted that Novo's extreme focus also carries with it a degree of risk: if treatment of diabetes or haemophilia ceases to be as profitable, Novo is affected much more severely than the others. However, since no cure has reached anything more than early stage trials we do not expect a severe loss in profitability in any of Novo's business areas in the near future.

### Manufacturing

The advantage we identified in the previous section has a measurable impact on the costs of manufacturing.

Cost of goods sold as percentage of sales					
	2012	2013	2014	2015	2016
Novo Nordisk	17.3%	16.9%	16.4%	15.0%	15.4%
Sanofi	31.8%	33.0%	32.7%	32.1%	31.6%
Eli Lilly	21.2%	21.2%	25.1%	25.2%	26.6%

Table 2: COGS-to-sales for Novo, Sanofi and Lilly. Compiled by authors. Source: Company annual reports 2012-2016

Due to Novo's focus on protein-based drugs, the firm is able to streamline its production, resulting in lower costs of goods sold relative to sales. As can be seen in Table 2, the difference is rather significant, and Novo has also managed to lower the COGS/sales over the period.

As was the case with R&D, we consider this advantage to be sustainable. While Sanofi or Lilly could replicate Novo's strategy if they wished, we consider it highly unlikely that Sanofi or Eli Lilly would choose to abandon their other product segments and focus exclusively on protein-based drugs.

### Performance of commercial operations

From the analysis on rivalry within the industry, we have established that the performance of the product is not the only determinant of market share. As an example, despite being seemingly equal, Lantus' market share is significantly higher than that of Levemir, and NovoRapid is the market leader in fast-acting despite being equal in efficiency to Lilly's Humalog (Drugs.com, 2016). It is likely that being first on the market can explain some of these differences, but as Humalog reached the market before NovoRapid did, it is unlikely to explain the entire difference.

Sales and marketing efforts in pharmaceuticals are major parts of the firms' operations, and differences in sales efforts could be an explanation for the difference in market performance. We cannot directly compare sales costs, as they are combined with distribution costs in the firms' annual reports. However, current evidence suggests that Novo at the very least has commercial operations that are fully capable of competing with Lilly and Sanofi. In 2015, following major gains by Levemir against Lantus in the US, Sanofi reorganized its US operations, replacing 1/3 of sales managers. Sanofi claims that Levemir "has nothing to offer compared to Lantus"<sup>24</sup> (Torsoli & Bennett, 2015). It is likely that superior sales operations were responsible for Levemir's success, as Novo offered better prices with higher rebates. However, following the restructuring of their commercial operations, it is difficult

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<sup>24</sup> As this statement comes from Sanofi, it is obviously biased and should not be taken as evidence of Lantus' superiority

to assess whether Novo's sales efforts are superior to their competitors. But, at the very least it seems justified to conclude that they are not at a disadvantage in their commercial capabilities.

#### *Conclusion on resources, capabilities and sustainable competitive advantage*

In most aspects, Novo, Sanofi and Eli Lilly are very similar firms, with a competent workforce, good reputation, solid financial capabilities and more. The primary difference between the firms, and one we believe contribute to a competitive advantage for Novo, is that Novo is entirely focused on protein-based medication, and only within a few select areas. We believe that the choice to only focus on a few conditions and a specific type of drug leads Novo to be an expert in its field, rather than a generalist that excels in no area. This is manifested in a lower cost of sales and more focused R&D efforts. We consider the advantage to be sustainable, as Sanofi and Lilly are unlikely to copy Novo's narrow focus. However, Novo's new CEO Lars Fruergaard has stated that the firm may change its policies on M&A and branch out more (Christensen, 2017), which may erode some of the advantage Novo has enjoyed due to its focus. Despite this, we do not expect Novo to become a "general" pharmaceutical firm like Eli Lilly or Sanofi without our forecast period.

## SWOT analysis

To conclude our company presentation and strategic analysis, we present the issues discussed in a SWOT matrix in compliance with the framework for analysis suggested by Petersen and Plenborg (2012).

INTERNAL		Strengths	Weaknesses		
		<ul style="list-style-type: none"><li>• Focused organization with in-depth knowledge of protein-based medicine</li><li>• Highly developed delivery systems, patient care programs and other support systems</li><li>• Efficiency in manufacturing due to strategic focus</li><li>• High employee satisfaction and good corporate reputation</li><li>• Superior products in several categories</li><li>• Strong R&amp;D pipeline that covers the entire diabetes market</li><li>• Little risk of external entrants</li><li>• Strong financial position</li><li>• Life-saving products make Novo largely independent of business cycles</li><li>• Strong commercial operations</li><li>• Potential new treatment form in oral GLP-1 agonist</li></ul>	<ul style="list-style-type: none"><li>• Lack of flexibility due to strategic focus</li><li>• Within some segment, such as haemophilia inhibitors, Novo's R&amp;D pipeline is inadequate to respond to competitors on time</li><li>• Delay of Fiasp launch in the US due to FDA</li><li>• Heavily reliant on the success of future drug Semaglutide in GLP-1</li></ul>		
		EXTERNAL		Opportunities	Threats
				<ul style="list-style-type: none"><li>• Population growth</li><li>• Growth in global obesity and prevalence of diabetes</li><li>• Global economic growth enable higher rates of diagnosis and treatment</li><li>• Potential for market development in obesity and haemophilia</li><li>• Increase global awareness of diabetes, improving the "rule of halves"</li></ul>	<ul style="list-style-type: none"><li>• Small risk of major healthcare policy reform in the US</li><li>• Consolidation among payers in the US increasing bargaining power</li><li>• Governments in RoW seeking to lower healthcare costs</li><li>• Biosimilars entering the diabetes market</li><li>• Potential development and approval of ACE910</li><li>• Threat of industry disruption due to technological innovations from competitors</li></ul>

## Valuation

### Estimating the cost of capital

To provide a valuation of Novo, we will use the classic weighted average cost of capital (WACC) as the discount rate for future cash flows.

$$WACC = \frac{MV \text{ of equity}}{Enterprise \text{ value}} * r_e + \frac{MV \text{ of debt}}{Enterprise \text{ value}} * r_d * (1 - Tax)$$

As Novo is effectively debt-free save very minor debt incurred as part of ongoing operations, we omit the debt factor in the WACC calculation, so the final WACC effectively becomes the required return on equity ( $r_e$ ):

$$WACC = r_e$$

To calculate the required rate of return on equity, we use the Capital Asset Pricing Model (CAPM) which calculates the return based on the risk-free rate of return, firm beta and the applicable equity risk premium:

$$r_e = r_f + \beta * ERP$$

### Estimating the risk-free rate

We estimate the risk-free rate based on the guidelines in Aswath Damodaran's paper "Estimating Risk Free Rates" (Damodaran, 2016), which states that several requirements need to be fulfilled for an asset to be considered risk-free.

First, the asset should have no risk of default. Second, the asset should have no reinvestment risk.

Novo, being an international corporation with the US constituting its largest market by far, can be considered an American corporation in a valuation context. As such, we have chosen to apply an American risk-free rate to this valuation. The United States currently holds an AAA rating from all major rating agencies apart from S&P who rate it AA+ (Tradingeconomics, 2017), and thus the creditworthiness of the United States government is considered "as good as it gets", when it comes to a sovereign issuer of government debt.

Optimally, each cash flow estimated should be discounted with the relevant risk free rate for that specific point in time. However, this practice is considered impractical for “well-behaved” term structures with only minor deviations between different maturities (Damodaran, 2016). Currently, the United States term structure can be considered “well-behaved”, and thus this paper will refrain from determining individual rates, but focus on determining a single risk-free rate.

The current low interest rates have led some analysts to try to “normalize” risk-free rates by determining the average 10-year yield over the past 30 years. (Damodaran, 2016b) discourages this practice, citing that current rates are reflective of the economic environment and accurately reflect the alternative risk-free return available to investors. Thus, we will not normalize the risk-free rate based on historical averages.

(Petersen & Plenborg, 2012) suggests the use of the 10 or 30-year government bond yield for the risk-free rate. As the terminal value of the valuation is placed at year 2030, we find that the most viable risk-free rate is the United States 10-year yield on government bonds, which currently (April 2016) is **2.3%** (Bloomberg, 2016).

#### Estimation of equity beta

Equity beta,  $\beta_e$ , measures systemic risk of stocks relative to the market. More precisely, it measures the correlation between returns of the asset in question and the market portfolio’s returns. According to CAPM, only systemic risk is compensated as idiosyncratic risk can be diversified away (Petersen & Plenborg, 2012).

Initially assessing the available beta estimates for Novo Nordisk, we find that there are significant differences in beta estimates depending on the source. (Petersen & Plenborg, 2012). Hence, to determine a suitable beta for Novo Nordisk, we will use the method of triangulation and apply two different methods of beta estimation to determine the appropriate beta for Novo Nordisk:  $\beta_e$  estimation via regression, rolling  $\beta_e$  estimation and  $\beta_e$  estimation via comparable companies.

#### *$\beta_e$ estimation from regression*

When estimating beta through regression, it is necessary to determine the optimal applicable market portfolio, historical time period and return interval for the regression (Damodaran, 1999).



Novo Nordisk is listed on Nasdaq OMX Copenhagen and as an ADR on the New York Stock exchange where the majority of the turnover in the share takes place. Novo Nordisk is a large international corporation with a strong American focus deriving the biggest proportion of its revenues from the US market. Furthermore, Novo's investor base comprises many international investors. According to Damodaran (1999), the choice of market portfolio for determining the equity risk premium should reflect the alternative market portfolio of the marginal investor in the market. Based on the aforementioned observations, we consider the optimal proxy for the market portfolio to be the S&P 500.

For more liquid assets, it can be of value to consider shorter return intervals to obtain a better estimate of market beta. The average daily turnover of Novo suggests that the stock is highly liquid, and thus, we will regress the returns of Novo Nordisk on the market portfolio returns on both weekly and monthly return data.

For the choice of time period, Damodaran (1999) states that the time period used should run sufficiently far back in time to provide a useful estimate, but not so far that the company is vastly different from how it is today and how it is expected to become in the future.

Many professional practitioners of investment analysis use from 2 to 5 years of data when calculating beta (Damodaran, 1999), while (Koller, et al., 2010) suggests 3 years of price data as a suitable period. Novo's business model incorporates both long-term and shorter term elements. It is constantly innovating and releasing new products gradually, but its focus on especially insulin has remained for many years. Thus, a compromise between 2 and 5 years is warranted, and as Novo's business model can be considered relatively stable in the long-term, a 3-year period of returns is selected. To assess potential differences and the quality of the estimate derived from regression, rolling beta calculations on 2, 3 and 5 years of historical data will be presented as well.

Following (Damodaran, 1999) we get the following regression equation:

$$R_j = \alpha + \beta R_m$$

where  $R_j$  is the return of Novo Nordisk,  $R_m$  is the return on the market portfolio (S&P500) and  $\alpha$  and  $\beta$  are the parameters estimated.

The results of the regression on both weekly and monthly returns are summarized below in Table 3.

Return interval	Estimated beta	Standard Error	CI_95 lower	CI_95 upper
<b>Weekly</b>	0.85	0.16	0.54	1.15
<b>Monthly</b>	0.5	0.38	-0.27	1.28

Table 3: Overview of  $\beta$  estimations, standard errors and confidence intervals. Compiled by authors.

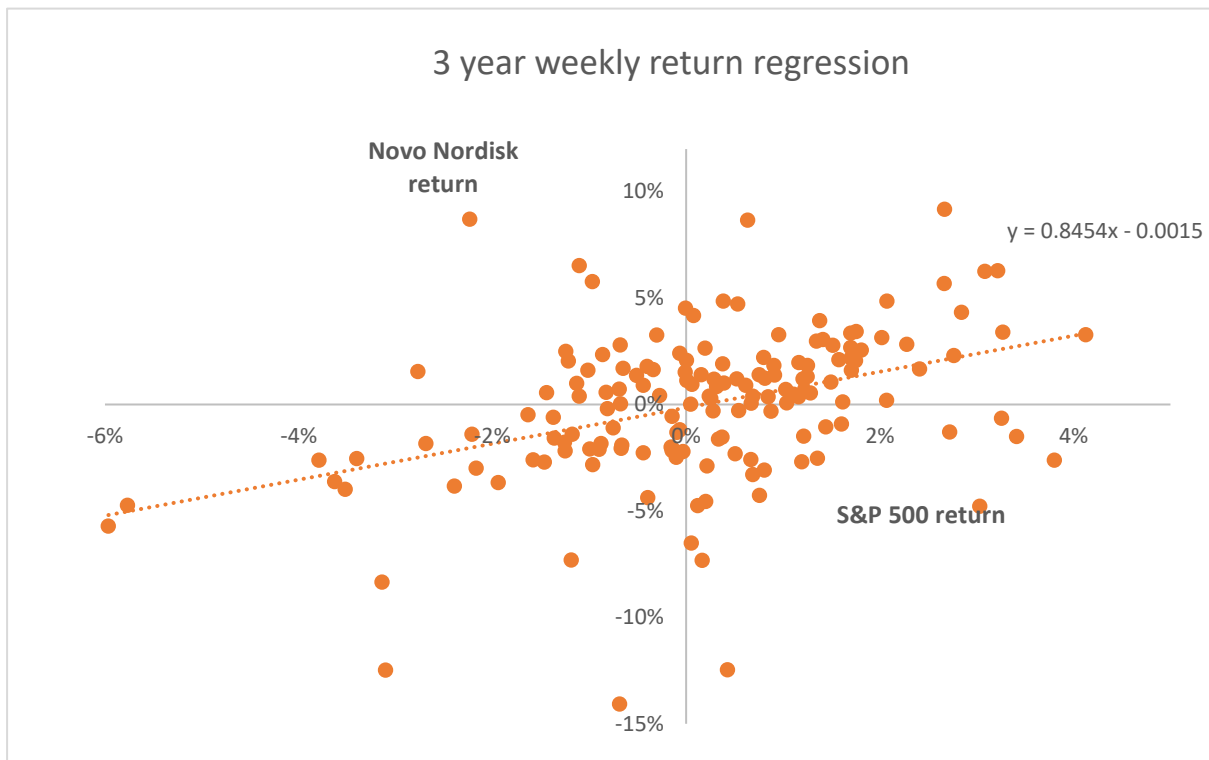


Figure 22: 3-year weekly return regression. Compiled by authors. Data source: Yahoo Finance

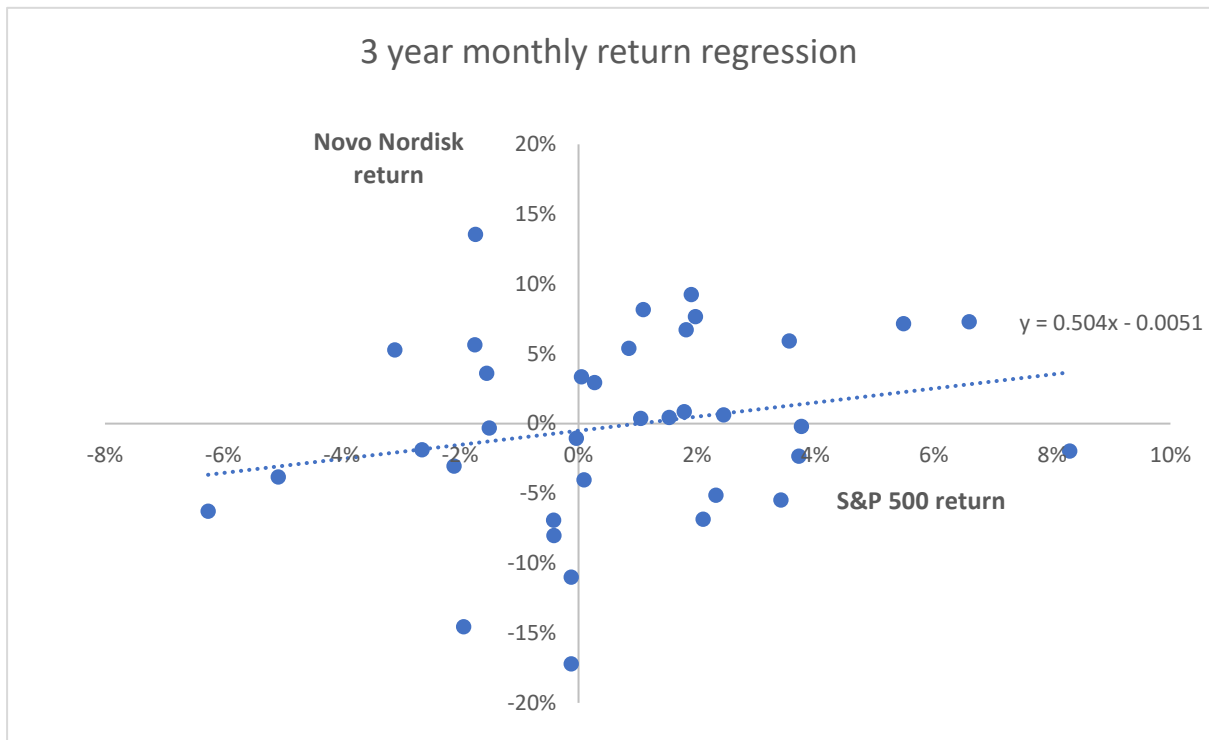


Figure 23: 3-year monthly return regression. Compiled by authors. Data source: Yahoo Finance

As weekly beta shows the smallest standard error by far and provides a tighter 95% confidence interval, we assess that this estimation of beta is more precise than the beta value obtained from monthly data.

Thus, the result of the regression is a beta value of **0.85**.

#### *Rolling $\beta$ estimates*

To assess the historical values of  $\beta$ , and to investigate any effects of business cycles, we calculate and illustrate the rolling 2,3 and 5 year  $\beta$  based on weekly returns.

Rolling beta will be calculated based on the definition in Larsen (2015):

$$\beta = \frac{Cov(NVO, SP500)}{Var(SP500)}$$

Where the numerator is the covariance of returns on Novo Nordisk and the market portfolio (S&P500) over the period assessed, and the denominator is the variance of the market portfolio in the same period.

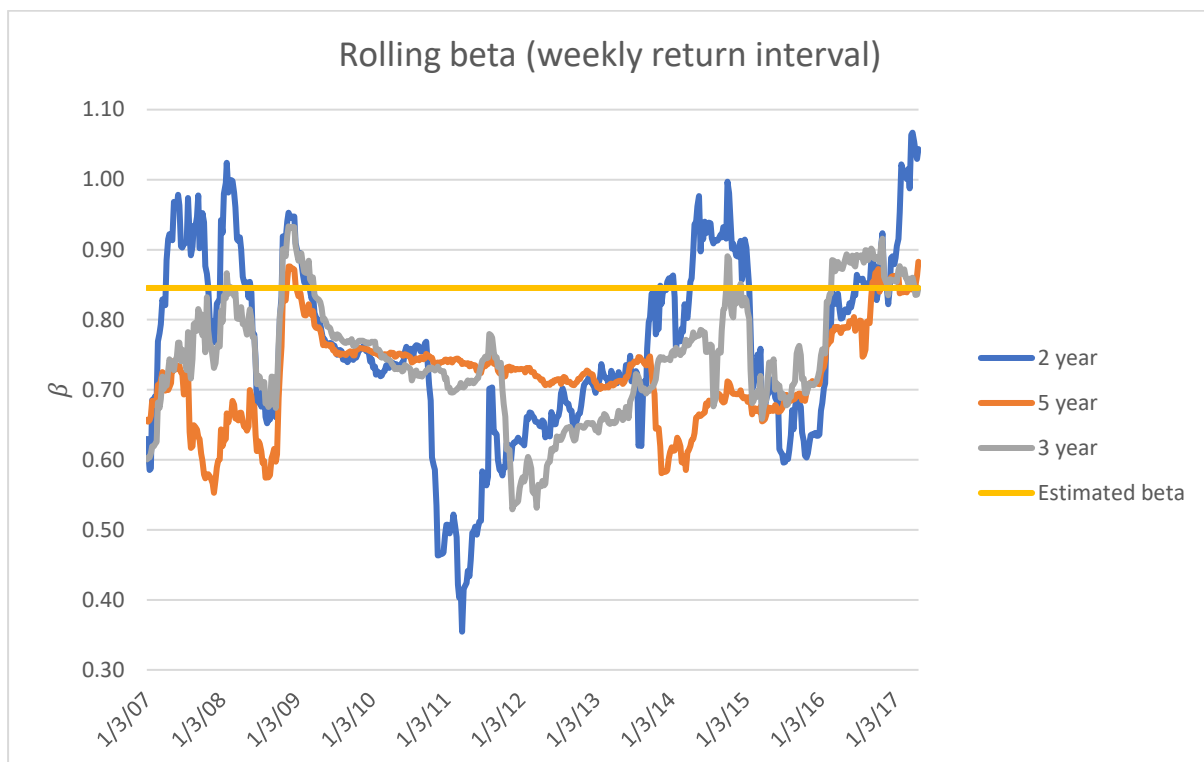


Figure 24: Rolling  $\beta$  estimations based on 2, 3 and 5 years of historical data. Compiled by authors. Data source: Yahoo Finance

As can be seen from Figure 24, the  $\beta$  estimated from the regression on weekly returns is in the upper part of the historical rolling betas in the time periods assessed. Also, historical regressions have shown beta values that are both higher and lower than the estimated beta both before and after the recession of 2008-2009. There appears to be some mean-reversion in play, but given the uptrend in all rolling betas since the start of 2016, we find no reason to question the result of the regression presented above.

#### *Estimating equity beta from industry beta and comparable companies*

Novo Nordisk A/S is a part of the industry sector “Drugs (pharmaceutical)” on Damodaran online (Damodaran, 2017), and so are its main competitors on the diabetes care market, Eli Lilly and Sanofi. Thus, the average unlevered industry beta of this sector is considered as comparable to the beta estimate of Novo.

Currently, the industry sector unlevered beta for Drugs (pharmaceuticals) is **0.93** (Damodaran, 2017).

#### *Final equity beta applied*

Based on the evidence available, we do not believe the overall industry beta for comparable companies accurately reflects the real beta of Novo Nordisk.

As Novo Nordisk primarily targets the diabetes care market and thus is heavily focused on one market, it is reasonable to expect that Novo Nordisk carries unique risks associated with the diabetes care market that is not carried by other competitors in the industry. Even though Novo has hinted that it will enter other markets in the future (Reuters, 2017), the very specific exposure to the diabetes care market that Novo Nordisk has is unlikely to shift for a long time.

Based on statements from CEO Lars Fruergaard (Reuters, 2017), we find it reasonable to expect that Novo Nordisk will enter other markets gradually and thus diversify its revenue sources, but in our assessment and especially considering the current R&D pipeline of Novo Nordisk, this change will be very gradual and unlikely to significantly change the risk profile of Novo Nordisk. We conclude that Novo Nordisk is still exposed to very specific risks pertaining to developments in the diabetes care market, and that this specific focus will prevail in the future. Thus, the beta obtained from the regression is more likely to be the correct beta than the industry average, as the regressed beta reflects Novo Nordisk and its business specifically.

The equity beta obtained from regression on 3 years of historical data is in the upper historical range of the rolling beta estimates both on the 2, 3 and 5 year periods, which might reflect market expectations for a more diversified revenue base in the future and/or convergence to growth rates that reflect the overall economic development in Novo Nordisk's markets.

Based on these circumstances, we find that adopting the beta obtained from regression is the best estimate of equity beta at the day of the valuation.

Thus, the final equity beta is **0.85**.

#### *Expected capital structure*

Novo currently holds no long term interest-bearing debt – in fact, it has negative net interest-bearing debt, and it is currently undertaking a large share repurchase program to distribute profits from operations to shareholders (Novo Nordisk Annual Report, 2016). The program follows years of excellent total returns to shareholders, where Novo has managed to realize financial results and profit

margins that are unparalleled by its two primary competitors, Eli Lilly and Sanofi (FactSet, 2017) (Novo Nordisk Annual Reports, 2016). With negative interest-bearing debt, one could argue that the debt factor of the WACC calculation should be included in the final calculation. However, as Novo does not retain cash as part of a capital structure strategy and has a clear policy of returning all excess cash to shareholders (Novo Nordisk Annual report, 2016, p. 44), we do not find grounds to include debt in the WACC calculation.

CEO Lars Fruergaard has hinted that Novo will need to “increasingly look for external innovation” (Reuters, 2017) , which means that Novo might need to commit larger sums of capital to acquisitions in the future. Competitors Sanofi and Eli Lilly have been more actively engaged in M&A, and both competitors have chosen debt as partial funding source for the expansion (Sanofi Annual Report, 2016) (Eli Lilly, 2017). Also, the industry average debt-to-equity funding ratio stands at 14.02% as of writing (Damodaran, 2017a).

Hence, it is necessary to consider the possibility of a change in the capital structure of Novo Nordisk in the future. The new CEO, Fruergaard Jorgensen, has stated that optimal acquisitions are in the “single-digit billion-dollar range” with an “optimal” acquisition target being 1-3 billion USD (Danske Bank Markets, 2017). Currently, it seems likely that Novo will be able to fund such acquisitions through its free cash flow directly. In 2016, Novo achieved 41.5 billion DKK (approximately 6 billion USD) in free cash flow, and we expect Novo’s free cash flow to be well above the 1-3 billion USD range in all years in the future.

Based on the communication of the new CEO and the free cash flows of Novo, we expect that Novo will be able to grow without adding debt to its capital structure, but it might have to halt or alter its share repurchase program to retain more cash for investments. Even if Novo was to acquire some debt, we can reasonably expect this debt to comprise a very minor proportion of Novo’s total capital structure as the long-term debt-to-equity ratio of the industry is very low. Any slight addition of debt would then only have a very miniscule influence on WACC.

Thus, the valuation will be conducted assuming that Novo will be 100% equity-financed both now and in the future.

### Equity risk premium

The current equity risk premium for the S&P 500 market portfolio is obtained from Damodaran online (Damodaran, 2017b) and it currently stands at **5.69%**.

### Estimated WACC of Novo Nordisk

Putting it all together, the estimated WACC of Novo Nordisk is calculated as

$$WACC_{NVO} = r_f + \beta * ERP_{SP500} = 2.3\% + 0.85 * 5.69\% = \mathbf{7.11\%}$$

### Analytical income statements and balance sheets

To accurately assess a firm's profitability and financial performance, it is necessary to restate its financial statements to analytical statements (Petersen & Plenborg, 2012), so that operating and financing items are separated. We have restated the financial statements of Novo Nordisk, Sanofi and Eli Lilly according to the approach in Petersen & Plenborg (2012)

As all three companies include depreciation and amortization as part of their operating expenses, it was necessary to add a line item reversing the depreciation and amortization expensed as operating costs to calculate EBITDA for each company. The depreciation and amortization item is based on the reported non-cash depreciation and amortization in each company's annual report.

Operating under the same accounting standards defined in IFRS, the financial statements of Novo Nordisk and Sanofi can be considered highly comparable. Eli Lilly reports according to US GAAP, which is different from IFRS. Especially relevant for the pharmaceutical industry, notable differences include differential treatment of carrying values of intangible assets (such as goodwill from M&A activity), property, plant and equipment and general impairment, depreciation and amortization practices (KPMG, 2015). Thus, it is not realistic to expect exact comparable numbers between the three competitors. However, we find that comparing profitability measures and other financial ratios from the three firms in spite of accounting differences will still add value to the valuation, as it allows us to compare the development of the companies over time.

Novo Nordisk A/S reports their figures in DKK, whereas Sanofi reports in EUR. Due to the prevailing EURDKK fixed-exchange rate regime, the historical figures presented can be considered comparable. As Eli Lilly reports in USD, there is an added element of uncertainty, but given the status of all

currencies as being stable currencies, the difference in currencies do not rule out the value of comparing the three firms.

The re-statement of all financial statements has been conducted in accordance with the framework in Petersen & Plenborg (2012). Invested capital (net operating assets) are defined as working capital plus intangible and tangible assets. According to Petersen & Plenborg (2012), working capital is defined as current assets less current liabilities, but to make the forecast and pro forma statements comparable to other information from Novo Nordisk, we have chosen to adopt the definition of working capital that Novo uses itself and states in its annual report. Thus, working capital for Novo Nordisk is defined as Inventories, Trade receivables, Other receivables and prepayments less Trade payables and Other liabilities (Novo Nordisk Annual Report, 2016, p. 84). Lilly and Sanofi do not state their method of calculating NWC in their reports, so the definitions in Petersen & Plenborg (2012) will be used to calculate NWC and tangible and intangible assets for Eli Lilly and Sanofi.

Petersen & Plenborg (2012) states several accounting items that need extra scrutiny to be defined correctly as either related to operating activities or financing activities. We will go through the items on Novo Nordisk's financial statements that require extra careful consideration according to Petersen & Plenborg (2012, p. 75) and justify their categorization as either a financing or operating item.

The item "Marketable securities", which represents short-maturity investment grade bonds in the A to AAA range (Novo Nordisk Annual Report, 2016), and "Cash at bank and on hand" are both categorized as financing items. Novo Nordisk continually distributes almost all its free cash flow, and as the items appear on the balance sheets for each year consequently, we interpret the holdings as excess cash in accordance with the guidelines in Petersen & Plenborg (2012).

"Derivative financial instruments" relate to the exchange rate hedges employed by Novo to ensure the exchange rate of future cash flows other than DKK. Both realized and unrealized gains and losses on these contracts are recognized as either financing income or expenses in the income statement. The decision to hedge future exchange rates is not related directly to the operations of Novo as that decision could be replicated easily by other firms. Novo also recognizes profit and losses from the currency hedges as financing income and expenses. Thus, the items are categorized as financing items.

"Retirement benefit obligations" are also categorized as financing items as they relate to pension obligations that are adjusted each year according to their actuarially calculated present value. The



present value represents future liabilities discounted to their present value, for which reason the item is considered interest-bearing, which makes it a financing item.

To ensure optimal comparability between the companies, the same approach to items that need extra consideration has been applied to the analytical financial statements of Sanofi and Eli Lilly. For example, cash reserves have been defined as financing items across all three balance sheets to ensure optimal comparability. This, however, creates a challenge as the resulting net working capital figure for Eli Lilly is negative for some of the historical years assessed. As Eli Lilly do not provide additional information on, for example, the purpose of holding cash and short-term investments, which could be used as working capital (refer to Appendix 2), we will stick to the calculations based on the recommendations in Petersen & Plenborg (2012) to maintain optimal comparability.

We acknowledge that applying the same approach to categorizing the items that need extra consideration across firms can lead to an understatement of invested capital (net operating assets) for Eli Lilly and Sanofi, but the understatement is likely to be very limited relative to total invested capital for both Eli Lilly and Sanofi.

Petersen & Plenborg (2012) works mostly with historical data going back four your years. The optimal historical period to be assessed mainly depends on the value it adds to the forecast. As we have outlined in our forecasts of the future market value and expected revenue growth of Novo Nordisk, the future expected markets for Novo Nordisk are likely to be vastly different from the markets back in 2011 and beyond. For example, we are forecasting none to only very modest growth in revenues for Novo in 2017. Thus, we follow the example of Petersen & Plenborg (2012), p. 178, and consider analytical financial statements for the years 2012-2016, both years included.

The historical analytical financial statements of the three companies are available in Appendix 2.

### Profitability analysis

The profitability of a company is important to its survival and its relationships with customers, (potential) lenders and shareholders. The historical profitability of a company is also an important element in defining the future expectations for a company, and the profitability of a company should be compared with its competitors (Petersen & Plenborg, 2012). The profitability analysis will follow the Du Pont model described in Petersen & Plenborg (2012).

As we expect that Novo Nordisk will be fully equity-financed in the future as well, the analysis will not analyze the effects of financial leverage.

#### Overall profitability: Return on invested capital (ROIC)

Petersen & Plenborg (2012) presents two measures of ROIC, one taking taxes into consideration and one that does not. Taxes are one of the value drivers mentioned in Petersen & Plenborg (2012), and thus we consider it necessary to include taxes when comparing ROIC across companies. The after-tax ROIC should thus serve as the primary profitability measure, but the pre-tax ROIC might illuminate differences in operational effectiveness that are “masked” by higher tax rates. Thus, we compare both ROIC measures across all three companies.

After-tax ROIC is defined as

$$ROIC = \frac{\text{Net operating profit after tax (NOPAT)}}{\text{Invested capital (net operating assets)}}$$

Whereas pre-tax ROIC is defined as

$$ROIC = \frac{EBIT}{\text{Invested capital (net operating assets)}}$$

The historical ROIC of Novo Nordisk, Sanofi and Eli Lilly are summarized in Table 4.

ROIC		2012	2013	2014	2015	2016
Novo Nordisk	Pre-tax (EBIT)	119%	117%	124%	173%	180%
	After-tax (NOPAT)	92%	91%	96%	139%	143%
Sanofi	Pre-tax (EBIT)	10%	8%	10%	9%	11%
	After-tax (NOPAT)	8%	7%	8%	8%	8%
Eli Lilly	Pre-tax (EBIT)	37%	34%	23%	16%	19%
	After-tax (NOPAT)	28%	27%	18%	13%	15%

Table 4: Historical pre and after-tax ROIC of Novo Nordisk, Sanofi and Eli Lilly. Compiled by authors. Data source: Annual reports.

Remarkably, Novo is showing a significantly larger ROIC than its competitors in all years assessed. Novo has further been able to increase its ROIC over time, where Sanofi has shown a stable development, and Eli Lilly has shown a decreasing ROIC over time.

The profitability achieved by Novo Nordisk is impressive, and the large difference between the firms warrants a further discussion of the results obtained in Table 4.

First, as can be seen from the analytical balance sheets in Appendix 2, both Sanofi and Eli Lilly carry a significant amount of goodwill and intangible assets on their balance sheets. These items have been accumulated from M&A activity and external purchases of intangible assets (Eli Lilly Annual Report, 2016 & Sanofi Annual Report, 2016). Novo has primarily developed their organizational know-how, internal resources and capabilities internally, which means that the value of the intangible assets are not carried on the balance sheet to the same extent as they generally are on the balance sheets of Sanofi and Eli Lilly.

Secondly, Novo Nordisk has been able to increase its top line quite significantly, from approximately 78 billion DKK in 2012 to 111.8 billion DKK in 2016, a 43% increase without increasing its asset base proportionally. Contrast to Eli and Sanofi that have seen their revenues decline slightly in the same period. Furthermore, Eli Lilly has expanded its invested capital base, and Sanofi has decreased its invested capital base. All firms appear to be following a regular depreciation schedule with not much variability in depreciation, but Novo Nordisk is the only firm that has managed to increase its top line so significantly.

Thus, rapid top line growth without a proportional growth in invested capital appears to be the primary source of the increase in ROIC observed for Novo Nordisk as opposed to accounting differences or significant differences in depreciation and amortization schedules. This is further backed by Novo's ability to increase its ROIC in a period, where competitors were barely able to sustain their ROIC. Even if the "real" value of the invested capital base of Novo were to be higher due to unrecognized internally developed intangible assets, the ROIC would still be exceptionally high compared to that of Eli Lilly and Sanofi.

Critics would point to the high ROIC numbers of Novo Nordisk and argue that the exceptionally high ROIC is not sustainable, as it could be driven mainly by products that are now at the mature stage of the product life cycle illustrated in Figure 25. This implies that these products should now be bound to enter the decline phase, which would be reflected in the future ROIC of Novo Nordisk. Hence, we will also provide a forecast of the future ROIC of Novo Nordisk to assess the expected long-term profitability of Novo Nordisk.

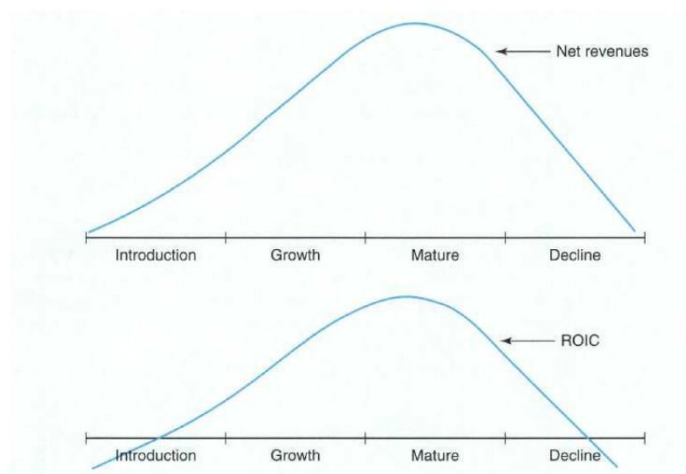


Figure 5.6 Return on invested capital at different stages of the product lifecycle

Figure 25: Expected profitability throughout a normal product life cycle.  
Source: Petersen & Plenborg (2012)

To further evaluate the results and determine whether the superior ROIC of Novo is driven by a better revenue and expense relation or improved capital utilization, a decomposition of the ROIC into profit margins and turnover rate of invested capital is warranted.

#### Decomposing ROIC: Margin and turnover rate analysis

ROIC can be decomposed into profit margin and the turnover rate of capital to assess the specific drivers of ROIC, where ROIC is:

$$ROIC = Profit\ margin * Turnover\ rate\ of\ capital$$

Profit margin and turnover rate of capital are defined as:

$$Profit\ margin = \frac{EBITDA}{Net\ revenues}$$

$$Turnover\ rate\ of\ invested\ capital = \frac{Net\ revenues}{Invested\ capital}$$

To gain a better understanding of margins and alleviate any differences in the depreciation and amortization schedules of the companies, we will assess profit margins at both the EBITDA and EBIT level.

<b>Profit margins</b>		<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
<b>Novo Nordisk</b>	EBITDA margin	41%	41%	43%	49%	46%
	EBIT margin	38%	38%	39%	46%	43%
<b>Sanofi</b>	EBITDA / Revenue	32%	32%	28%	29%	29%
	EBIT / Revenue	18%	15%	18%	17%	19%
<b>Eli Lilly</b>	EBITDA / Revenue	31%	32%	22%	22%	23%
	EBIT / Revenue	24%	26%	15%	14%	16%

Table 5: Historical profit margins at the EBIT and EBITDA level for Novo Nordisk, Sanofi and Eli Lilly

As can be seen, Novo has managed to increase its margins throughout the period assessed and thus better its income-expense ratio, both at the EBIT and EBITDA margin levels.

<b>Turnover rate of invested capital</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
<b>Novo Nordisk</b>	3.16	3.10	3.19	3.79	4.15
<b>Sanofi</b>	0.53	0.52	0.53	0.56	0.56
<b>Eli Lilly</b>	1.55	1.32	1.48	1.09	1.17

Table 6: Turnover rate of invested capital for Novo Nordisk, Sanofi and Eli Lilly

Table 6 shows the historical development of the turnover rate of invested capital, and again we observe the same pattern as with ROIC and profit margins. Novo has shown significant increases and has been very successful in utilizing its invested capital with remarkable turnover rates compared to competitors. Sanofi has shown a slight increase in its turnover rate, whereas Eli Lilly has seen its turnover rate decline slightly.

### Conclusion on profitability analysis

Novo Nordisk has achieved a remarkable ROIC backed by historically sustainable high turnover rates of capital and large profit margins. The decomposition of ROIC shows that the ROIC figures have been achieved by improving both components. For a pharmaceutical company, we would usually expect to see relatively high margins as their products are highly important for patients, and low turnover rates as pharmaceuticals tend to continually invest in new technology (Petersen & Plenborg, 2012, p. 108). Notably, Novo has achieved superior margins and incredible turnover rates unparalleled by its competitors in the pharmaceutical industry.

The profitability analysis confirms the conclusion of the strategic analysis and analysis of Novo's internal capabilities and resources. We established that Novo has a sustainable competitive advantage due to their expertise in biological medicine, as we believe that the high profitability is a direct result of Novo's singular focus on this high-margin segment.

## The valuation model

### Choice of forecast horizon

Petersen & Plenborg (2012) states that the choice of forecast horizon depends on the analyst's assessment of when the firm in question reaches a "steady state". In the steady state, it is assumed that the firm's value drivers remain constant (Petersen & Plenborg, 2012, p. 177) while any or all of the value drivers can change on a yearly basis until then.

We have chosen to explicitly forecast Novo Nordisk's value drivers until the year 2030 as we do not expect a steady state until this year. After this date, we assume a steady state. For most value drivers, we assume a steady state after 2027. Our reasoning is that we can develop a general idea of Novo's product launches for the next decade based on their R&D pipeline (see our sections on R&D and product launches in the Company Description and the Porter's Five Forces for our view on Novo's pipeline). In the pharmaceutical industry, the average time from drug discovery to market is 12 years (Holland, 2013), and it is therefore expected that all drugs currently in Novo's pipeline will have been either launched or terminated by 2027. We therefore consider an attempt to explicitly forecast Novo's performance in diabetes care, obesity and most biopharmaceuticals past 2027 would be an exercise in guesswork and add no value to our analysis.

However, consider it necessary to explicitly forecast Novo's performance in its hemophilia inhibitors division for a few years beyond 2027. The reason is due to the expected launch of Roche's ACE910 which we expect to impact Novo's market share significantly. Novo is developing Concizumab, but is still in the earliest stage of clinical trials and we do not expect a launch until around 2025. Because Novo's market share is expected to fall significantly following the launch of ACE910, and they only have the opportunity to gain it back after 2025, we did not feel justified in declaring the inhibitors segment to be in a steady state already after 2027. As such, we have chosen to explicitly forecast Novo's performance in inhibitors until 2030. However, for all other segments, we feel justified in declaring them in a steady state after 2027, so the changes in Novo's value drivers after this year is relatively minor.

## Market growth rates

### Diabetes and obesity care

As the United States differs in both growth rates and price levels from the rest of the world, we have decided to split our revenue forecasts within the diabetes segment between the US and RoW.

#### *GLP-1*

The GLP-1 segment has historically grown at a very rapid pace, with a growth of approx. 30% and 22% in 2016 in the US and ROW, respectively. Analysts expect the market to grow by 12.4% CAGR until 2025 (Staton, 2016b). We find this expectation reasonable, but do not expect a flat growth rate. We predict a gradual slowdown in growth, starting with 27% and 20.6% in US/ROW and gradually slowing down each year in correspondence with the long-term expected CAGR of 12.4% until 2025.

#### *Insulin*

Both long-acting and fast-acting insulin has historically grown at roughly the same pace, with a CAGR of 6.0% and 5.1%, respectively. We therefore have chosen to apply the same growth rate to both segments. We expect a lower than historical market growth rate for insulin in the future, due to pressure from payers to reduce prices, as well as increased competition from biosimilars, in particular in the United States. As such, we expect a modest value growth of 2% in 2017, based on an expected 4-5% price decrease (ABG Sundal Collier, 2017) offset by an increase in volume of products sold. A slightly higher growth rate of 4% is expected internationally, as the increase in price pressure from international payers is less intense. We expect this price pressure to continue until reaching a stable level in 2019, after which the growth rate in insulin will increase to 4% and gradually decline until reaching the steady state.

#### *Obesity*

Currently, Saxenda is the only product of its class with clinically-proven results of weight loss, and it only faces competition from less effective pills. As such, the big barrier to Saxenda's growth is whether Novo Nordisk can succeed in growing the market as a whole. This to a large extent comes down to whether Novo Nordisk and interest groups will succeed in gaining global approval for obesity as a clinical disease (Novo Nordisk Annual Report, 2016, p. 29). Both Novo Nordisk management and external analysts expect a significant growth in Saxenda's sales and predict sales in the range of \$1 billion by 2021 (Christensen, 2014). In our assessment, given the results of Saxenda that have been proved clinically, Saxenda as a product has major advantages over potential competitors. Also, Novo Nordisk will be able to utilize its already established commercial operations to market Saxenda. Thus,

we find the assumption about the future growth prospects of Saxenda reasonable, and expect sales of Saxenda to grow by a CAGR of approx. 36% until 2021 with a continually declining rate until the terminal period.

#### *Human insulin*

Novo's sales of human insulin has been constant in the past 5 years (Novo Nordisk Investor Presentation: Full Year, 2016, p. 44). Human insulin is primarily intended as a low-cost option for diabetics in developing countries, and no new development takes place in this segment. We therefore see no reason why the growth of the human insulin segment should change significantly, and assume a modest value growth rate of 0.3% annually.

#### *Other diabetes and obesity care*

Other diabetes and obesity care mainly covers needles and other supplementary items. There has been no significant change in sales in this segment<sup>25</sup> and we expect this to continue. We therefore apply a 2% growth rate annually.

### *Biopharmaceuticals*

#### *Inhibitors*

We expect the market for inhibitors, in which Novo has close to monopoly-status, to decline by approx. 6.5% in 2017 due to trials of ACE910. The number of patients with inhibitors is relatively small at approx. 4,000 people worldwide, and has experienced lower market growth than the other haemophilia segments historically (Baxter Investor Conference - Hematology, 2015). As new treatments for haemophilia A and B includes a lower risk of the patient developing inhibitors, we expect the future market growth of haemophilia to be a modest 2% in the forecast period, falling to 1.5% in the terminal period. We believe that a lower terminal growth is warranted, as newer treatments for haemophilia A and B has a lower risk of developing inhibitors and we therefore can expect the patient growth to be lower in the long term.

#### *Haemophilia A*

The market is worth approx. 42 billion DKK in 2016 and is expected to grow by a CAGR of approx. 6% until 2020 (Baxter Investor Conference - Hematology, 2015), with haemophilia A growing at a slightly slower rate than haemophilia B. We therefore expect a growth rate of 5.4% annually in haemophilia

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<sup>25</sup> Adjusting for the sales of Saxenda, which Novo currently includes as part of "Others"



A until 2020, gradually tapering off until the terminal period. As an inherited disease, we expect the growth of haemophilia to approximately follow the economic development thus we assume a 2% terminal growth rate.

### *Haemophilia B*

The haemophilia B market is worth approx. 12 billion DKK in 2016. Similar conditions are present for haemophilia B, where we predict a marginally higher initial growth rate of 6%, gradually declining until the terminal period.

### *Growth disorders*

Growth disorders have grown by a CAGR of 1.9% in the past 5 years (Novo Nordisk Investor Presentation: Full Year, 2016, p. 102). As the condition is inherited and the growth rate is close to the growth of the economy, we expect the growth to be a stable 1.9% annually. Novo's sales are expected to decline in 2017 compared to the previous year due to the positive impact of an adjustment to sales rebates in 2016, but as it is a one-off adjustment, we expect sales to pick back up in 2018, followed by a slight boost after the launch of Somapacitan which we expect in 2019.

### *Other biopharmaceuticals*

This segment primarily consists of hormone replacement therapy-related products and Novo's sales is expected to decline due to the launch of a generic copy of Vagifem (Novo Nordisk Annual Report, 2016, p. 9). We expect sales in the segment to decline slightly in the years following the generic launch, after which it will stabilize at 2% annually.

## Budget and revenue forecasts

### *Financial value drivers*

In constructing the pro forma financial statements, we follow the approach in Petersen & Plenborg (2012), where we focus on forecasting the items that are important and refrain from forecasting items, where we are unlikely to forecast with a high level of precision.

We forecast the following value drivers based on the strategic analysis and Novo's historical levels:

- Revenue growth
- EBITDA margin
- Depreciation as a percentage of tangible and intangible assets
- Effective tax rate

- CAPEX as a % of net sales
- Net working capital as a percentage of revenues

#### Revenue growth

Our forecasting of Novo Nordisk's revenues is primarily based on the strategic analysis of both Novo Nordisk's products and the future outlook of Novo's markets. We apply the top-down approach described in Petersen & Plenborg (2012) in which we derive the revenue forecast as a function of the expected growth rates in Novo's markets, and Novo's market share within these markets.

The section titled 'Market growth rates' details our expectations for the growth of each of Novo's markets and is based on our findings in the SLEPT and Porter's analyses. The development of Novo's market share within them is largely based on our evaluation of Novo's products compared to its competition, which we outlined in the Porter's Five Forces analysis.

We show our forecasts of market sizes and Novo's market shares in key industries in appendix 3. Also included in appendix 3 is the overall revenue forecast for all of Novo's business units and the sum of these is our expected revenue growth in the forecast.

#### EBITDA margin

In the past 5 years, Novo has realized an average EBITDA margin of 44% with the highest level being in 2015 with a margin of 49%, and the lowest in 2012 with a margin of 41%. The estimation of the long-term EBITDA margin has been conducted in accordance with the framework in Peterson & Plenborg (2012) that recommends having margins converge to industry standards in the long-term.

For 2017, we expect margins to remain the same as in 2016 driven by increased market shares for high margin products such as Tresiba and Fiasp. Increased price pressure from payers in general and the introduction of biosimilars are expected to influence margins negatively, so we predict the net effect on margins to be zero. Moving further out on the forecasting horizon, we expect decreasing EBITDA margins as biosimilars gain market share and payers, especially in the United States, are expected to exert additional pressure for price reductions. Furthermore, we expect increased spending on R&D as competition in Novo's core market for diabetes care increases putting further demands on product innovation. Also, with the goal of expanding secondary business segments or entering new ones as proposed by the new CEO, we assess that Novo will need to invest further resources into R&D to ensure future growth.

While we forecast significant increases in the global market for diabetes care, we expect the value growth to be driven primarily by volume as opposed to price increases in the future. As volume grows disproportionately with prices, manufacturing costs as a percentage of revenues are expected to increase, everything else equal. This will also put pressure on margins going forward.

Given the abovementioned circumstances, we find the proposition that margins will move towards long-term industry standards over the longer periods reasonable. At the current time, it is difficult to assess whether the EBITDA margin has reached a longer-term peak because of the factors presented above, but given the developments in the market and our strategic analysis, we believe this peak in margins will be seen sooner rather than later.

Thus, we go with the more conservative approach and expect decreasing EBITDA margins already from 2018 and onwards until 2027, where we expect it to stabilize at 36%. This is still above the EBITDA margins achieved by Sanofi and Eli Lilly. Currently, we do not see threats that are severe enough so that Novo's competitive edge should completely disappear. Thus, we expect Novo's margins to decrease, but not completely to the level of its competitors as we expect Novo to maintain their expertise in diabetes care and biological products.

#### Depreciation as a percentage of intangible and tangible assets

For the past 5 years, we have seen depreciation as a percentage of operating assets increase, while operating assets as a percentage of total revenues have been decreasing.

For 2017, Novo expects depreciation of DKK 3 billion, which is approximately 17.5% of its expected tangible and intangible assets. This figure is in the lower end of the historical depreciation as a percentage of assets in the years assessed, so in accordance with the framework in Petersen & Plenborg (2012), we expect the ratio to move towards industry standards in the long run.

Comparing with Sanofi and Lilly provides little value in the exact estimate of the future depreciation as both carry a significant amount of goodwill from M&A activity, which is not the case for Novo. However, the competitors are valuable proxies for a mature company operating within the pharmaceutical sector, so they can provide an indication of the trend in depreciation and operating assets relative to net sales, assuming Novo will move more towards being a "normal" pharmaceutical

company. Sanofi and Eli expense from 5% to 9% in depreciation and amortization, significantly lower than Novo Nordisk.

Providing that Novo Nordisk will need to act more like a “normal” pharmaceutical company, we expect that Novo will increase its operating assets in the future, which will cause depreciation and amortization to decrease relative to operating assets

The depreciation rate of 17.5% of tangible and intangible assets is realized in a year, where Novo increases its asset base significantly, and considering the low depreciation rates of competitors, the estimate of 17.5% should be a conservative estimate for the long term. Based on the guidelines of Novo Nordisk, we expect depreciation of **17.5%** as a percentage of tangible and intangible assets throughout the forecasting period.

#### Effective tax rate

Novo Nordisk expects an effective tax rate of between 21% and 23%, which is consistent with the Danish corporate tax rate of 22% (Skatteministeriet, 2017). Novo Nordisk will pay the majority of its corporate taxes in Denmark, so the best estimate of the future effective tax rate is **22%**.

#### Capex as a % net sales

To forecast future CAPEX as a % of net sales, we started out by forecasting future tangible and intangible assets as a % of net sales.

For the past 5 years, we have seen operating assets as a percentage of total revenues decrease resulting in a remarkable turnover rate of invested capital for Novo Nordisk.

Petersen & Plenborg (2012) suggests that for long term forecasts, financial value drivers should move towards longer term industry standards, and we find that this assumption is applicable to this value driver as well. Comparing with Sanofi and Eli Lilly, we see that both competitors both have a very large asset base relative to net sales. This is mostly due to M&A activity. Novo has not engaged in considerable M&A activity, but this might change in the future. The current sentiment of the new CEO suggests that future M&A activity will be limited to the “single-digit billion dollar range”. Thus, we do not find grounds to provide for larger increases in tangible and intangible asset as a % of revenues. Instead, we will forecast based on the expectation that the ratio will move toward long-term industry averages, but we do not expect the ratio for Novo to reach industry standards.

Novo has already stated that it expects CAPEX of approximately DKK 10 billion in 2017. As CAPEX is a consequence of internal decisions, we consider Novo's own assessment of CAPEX in 2017 to be reliable, and we will adopt this expectation in the forecast.

Following the 2017 forecast, we follow the expected convergence to industry standards of tangible and intangible assets relative to revenues. In the years 2015 and 2016, assets relative to net sales fluctuated wildly, whereas the ratio was relatively stable around 20% in 2013-2014. The expected CAPEX of 2017 is large compared to the prior 5 years, so following 2017, we expect CAPEX to reflect a more stable growth in tangible and intangible assets relative to net sales in accordance with the expectations of convergence to industry standards. We expect tangible and intangible assets as a percentage of net sales to have reached 20% in 2027, and we expect an increase of 0.5 percentage points each year from the 2017 value of 15%. The historical observations have fluctuated, but for the years 2012-2014, the ratio has only deviated by 1 percentage point. Thus, for the forecast we expect that the long-run changes in the ratio will move gradually by 0.5 percentage points each year. The exact CAPEX figures forecast are based on the forecast of tangible and intangible assets relative to net sales and both are available in Appendix 4. We expect CAPEX relative to net sales to reach 4.6% in the terminal period, which is significantly lower than the industry standard of Capex/Sales, which is 9.64% (Damodaran, 2017b), but higher than Novo's historical average of 2.1% in the past 5 years. The expected figure is in alignment with the strategic analysis, and we expect that Novo's competitive advantage within biological medicine will allow the firm to grow its revenue from a smaller asset-base than more diversified competitors.

#### Net working capital as a percentage of revenues

Assessing the historical Net Working Capital of Novo Nordisk, we see that it has fluctuated between 12% and 15% of total net sales. We have no reason to expect that to change materially in the future, for which reason we will use the average NWC for the past 5 years, **12.5%**, for the forecast.

#### Terminal growth rate

We expect the growth rate of revenues to converge to the long-term growth rate of the economy. As discussed in the SLEPT analysis, we expect increasing prevalence rates of diabetes and obesity until 2040 as well as general population growth. At this point, the visibility regarding these developments is not sufficiently granular to warrant an adjustment of the long-term terminal growth rate of the economy that is usually used for the terminal horizon (Petersen & Plenborg, 2012). Petersen &

Plenborg (2012) suggests a terminal growth rate of between 2% and 3%, consistent with the growth in the overall economy. Based on the SLEPT analysis, we expect long-term growth rates of 3% within the diabetes and obesity segments and lower growth rates for the biopharmaceutical divisions that treat inherited conditions. Overall, we expect a terminal growth rate of 2.6%.

#### Net borrowing costs and financial income

We do not forecast net borrowing costs in the pro forma statements. In the historical period, financial income and expenses were mainly a result of gains and losses from the currency hedges employed by Novo. Historically, Novo has realized both gains and losses with no predictable pattern. As we will not predict future exchange rate fluctuations and as we forecast that Novo will be fully equity-financed in the future, we find that the best forecast of future net financial income is simply 0.

#### Net interest-bearing debt

Novo has negative interest-bearing debt. We expect Novo to be fully equity financed, and we forecast no net financial income. Thus, forecasting future net-interest-bearing debt will not add any value to the valuation, so we simply forecast constant net-interest-bearing debt equivalent to the level observed by end of year in 2016.

#### DCF valuation

As stated in the methodology, we aim to estimate Novo's value by applying a discounted cash flow analysis to the cash flows we have forecast. The model returns the estimated fair enterprise value of the firm, which we adjust for the net interest bearing debt to arrive at the equity value. Novo's equity value is then divided by the number of shares outstanding to arrive at the share price. The shares outstanding after dilution is 2,525,161,000.

As we aim to value Novo Nordisk on April 24, 2017, we adjust for the value of the share to this date<sup>26</sup>. After this adjustment, our DCF analysis returns the following estimated base case values:

- Enterprise value: 767,801 million DKK
- Equity value: 786,159 million DKK
- Share price: 311.3 DKK
- Estimated fair value share price on April 24, 2017: 318.0 DKK

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<sup>26</sup> Share price \*  $(1 + WACC)^{113/365}$

Present value of FCFF in forecast horizon	340,713
Present value of FCFF in terminal period	427,088
Estimated value of firm (enterprise value) mDKK	767,801
Net interest bearing debt mDKK	-18,358
Estimated market value of equity mDKK	786,159
Implied share price	311.33
Factor adjustment to the valuation date (113 days)	1.0215
Estimated enterprise value April 24, 2017	784,302
<b>Fair share price April 24, 2017</b>	<b>318.0</b>

Figure 26: Output from valuation model. Compiled by authors.

Appendix 4 shows an overview of our predicted development in value drivers that form the basis of this valuation. Appendix 5 contains the DCF valuation itself.

### Sensitivity analysis through Monte Carlo simulation

Forecasting of a company's future operations will, regardless of the quality of the analysis, always be subject to a significant degree of uncertainty. In an attempt to accommodate some of the inherent uncertainty associated with our forecast, we have decided to run a series of scenarios in a Monte Carlo simulation. In the simulation, we let the values of the following growth drivers change:

- Revenue growth
- EBITDA margin
- Effective tax rate
- CAPEX as % of sales
- Net working capital as % of sales
- WACC

The forecast values have formed the basis for the mean values in the simulation, whereas our expected standard deviations come from a combination of Novo's historical levels, the levels of the firm's peers and our expectations for Novo's future development based on the strategic analysis.

For sales, we expect a standard deviation of 1% which is based on Novo's own assessment of their 2017 sales, in which they expect a DKK sales growth of 1-6% (Novo Nordisk Annual Report, 2016, p. 8), corresponding to a standard deviation of approx. 1%<sup>27</sup>. We did not consider the historical levels relevant for future growth rates, as the historical standard deviation of 7% is based on a sales growth significantly higher than our expected future levels. We find that the choice of 1% was the most

<sup>27</sup> Based on a normal distribution in which 96% of cases will lie within 2 standard deviations from the mean

prudent choice, as we cannot reasonably expect Novo's sales growth to fluctuate as much as it has done in the past.

For the EBITDA margin, we expect a standard deviation of 2% based on Novo's historical standard deviation of 2.96% and Sanofi's historical standard deviation of 1.88%. We did not find that Eli Lilly was a useful point of comparison in this case, as their margin experienced a significant and abrupt decline in 2014 due to the expiration of patents on Cymbalta and Evista (Eli Lilly Annual Report, 2014) that led to an abnormally high standard deviation. Lilly's standard deviation without including the jump in 2014 is 0.7%. We therefore consider a standard deviation of Novo's future EBITDA margin of 2% to be reasonable, as it lies between Novo's historical rates and the industry average.

For the expected effective tax rate, we assume a modest standard deviation of 0.25%. We do not expect major fluctuations, as the tax rate of 22% is the statutory tax rate in Denmark, but we find that it is prudent to allow for small fluctuations.

For the CAPEX, we expect a standard deviation of 2.7% based on the historical levels. We expect the future variance to be consistent with historical levels and thus, we apply a standard deviation that allows both for years with little to no investments and for years with significant investments, such as is expected in 2017.

For net working capital, we expect a standard deviation of 1.3%, which is similar to historical levels. Novo's NWC/Sales has remained relatively stable regardless of developments in revenue, and we do not find anything in our strategic analysis that would suggest an increased volatility.

Lastly, we expect a standard deviation in the WACC of 0.91% based on the standard error of the beta estimation, 0.16, and an expected equity risk premium of 5.69% (refer to the section on cost of capital).

To reach a sufficiently high degree of reliability, we have run 100,000 simulations using Oracle's Excel add-on Crystal Ball. Based on these simulations, we obtain a mean share price of 327.1 DKK. As of April 24, 2017, Novo closed at 250.0 DKK. According to our simulations, there is a 98.19% chance that Novo was undervalued that day, as only 1.81% of our scenarios implied a share price at that level or below. Thus, we are confident in our view that Novo was undervalued on April 24, 2017.



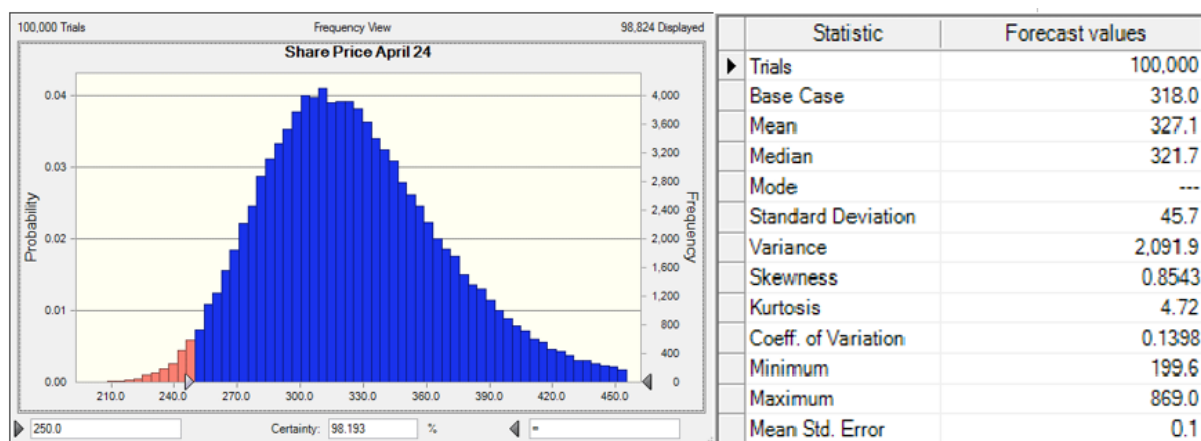


Figure 27: Distribution of results and descriptive statistics of the Monte Carlo results

Figure 27 shows the results of the Monte Carlo simulation. For a larger version of the graph, see appendix 6. The expected share price is roughly normally distributed with a mean of 327.1 DKK and a median of 321.7 DKK. Half of the results lie within the values between 295.0-353.1 DKK and 95% of the results 253.9-432.1 DKK. The high spread in values represent the uncertainties with regards to Novo's future development in sales and the other relevant value drivers. The share price of 250 on April 24 is outside the 95% confidence interval. Thus, if our inputs are correct, we can say with 95% confidence that the stock was undervalued on April 24, 2017.

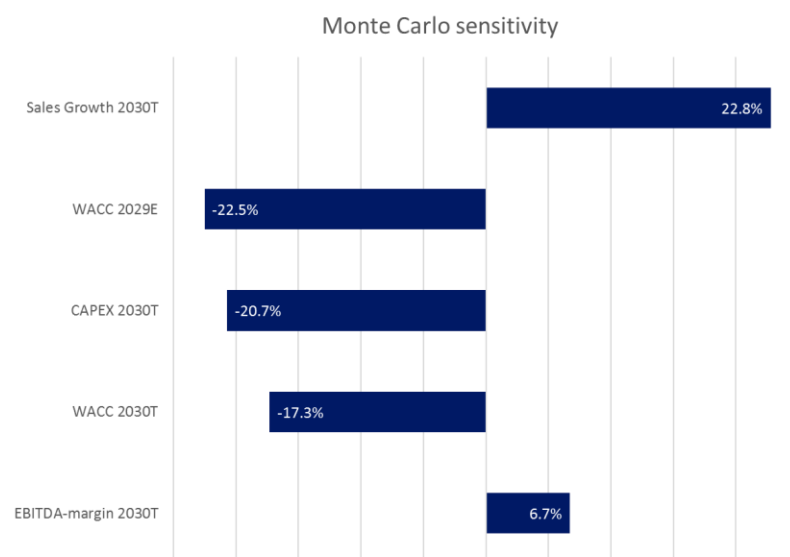


Figure 28: Monte Carlo sensitivity, showing the contribution to variance of the most important inputs. A positive value indicates a positive correlation with the share price.

Based on our estimations, the share price is most sensitive to changes in sales growth in the terminal period which contributes with 22.8% of the total variance.

This makes intuitive sense as the sales growth is a major value driver and the terminal period contributes with more

than half of the value in our valuation (see Figure 26). In fact, all of the most important inputs are related to the terminal period. The second-most important value driver is the WACC in year 2029, which makes sense mathematically, as the discount factor for the terminal period is based on the WACC for 2029. Similarly, CAPEX in the terminal period is a significant value driver as well. Overall,

there are no major surprises in the sensitivity analysis, but it underlines the importance of correctly forecasting especially future revenues and costs of capital.

## Profitability forecast

Based on the pro forma financial statements (which are available in Appendix 4), we compiled a forecast of Novo's future expected profitability (after-tax ROIC), EBITDA margin and turnover rate of invested capital illustrated in Figure 29.

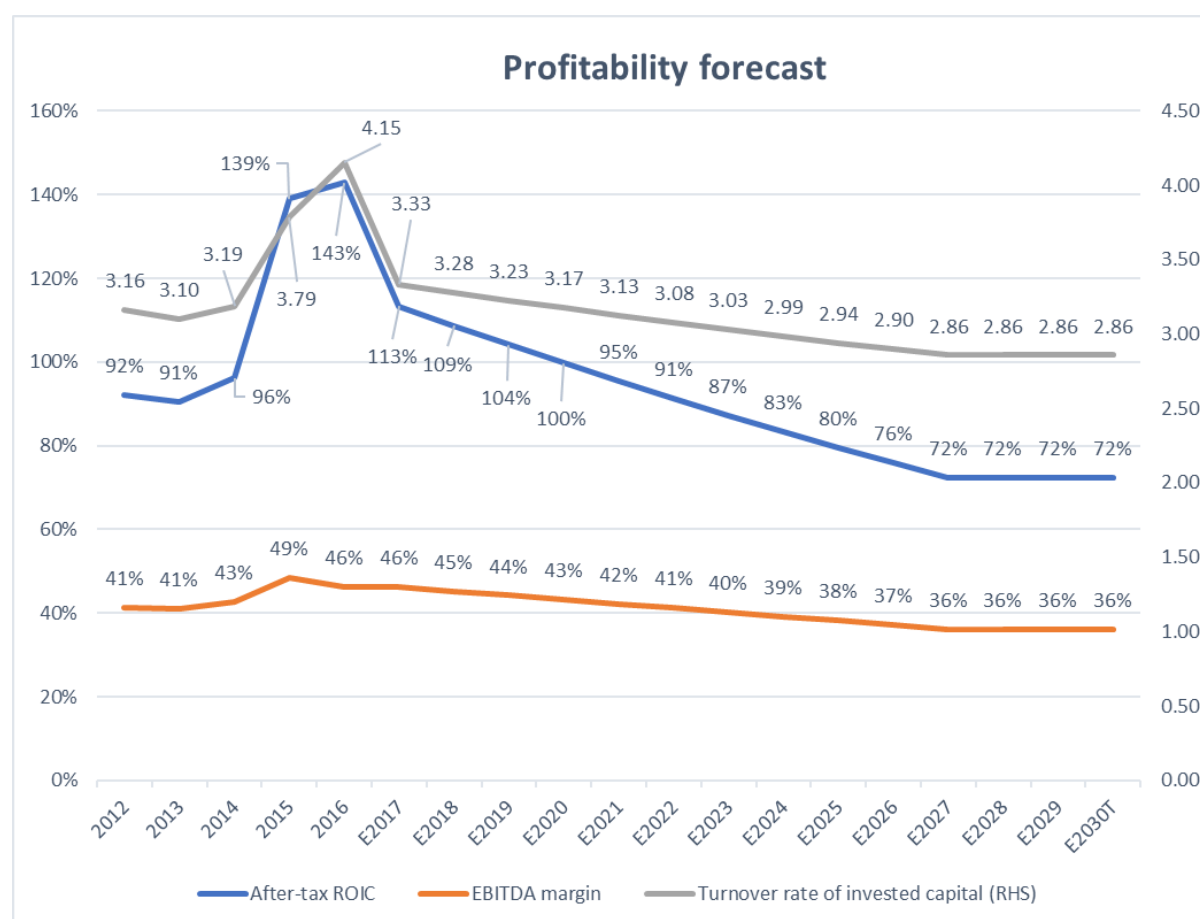


Figure 29: Profitability forecast based on pro forma financial statements. Compiled by authors.

We expect ROIC to peak already in 2016 as Novo is expected to increase tangible and intangible assets significantly in 2017. The primary driver of the expected decrease in ROIC is the turnover rate of capital, and secondly the EBITDA margin. As we forecast an increase in Novo's operating capital, the turnover rate is expected to decrease from its very high levels. Even in spite of expected decreases in profitability, Novo's forecasted profitability is still measurably better than the current profitability of Sanofi and Eli Lilly, and it is significantly larger than Novo's WACC.

## Relative valuation and multiple analysis

As a supplement to the DCF analysis, we perform a relative valuation using multiples. Again, we have chosen to compare to Eli Lilly and Sanofi, and we also compare multiples calculated based on the current share prices of the companies with the implied multiples based on the fair share price obtained in the valuation.

	Current market values			Implied
	Eli Lilly	Sanofi	Novo Nordisk	Novo Nordisk
<b>P/E</b>	32.4	22.7	16.6	21.5
<b>Forward P/E (cons.)</b>	20.4	15.3	16.8	20.2
<b>EV/EBIT</b>	26.7	17.2	12.7	16.2
<b>EV/EBITDA</b>	18.6	11.4	11.9	15.2

*Table 7: Multiple analysis of Novo Nordisk and competitors. Compiled by authors. Data source: Annual Reports and FactSet*

Petersen & Plenborg (2012) recommends the use of expected earnings, when performing multiple analysis. Unfortunately, no reliable estimates for future EBIT and EBITDA exist for Eli Lilly and Sanofi, but we have included the forward P/E multiple based on consensus expectations for earnings in 2017 (consensus data was obtained from FactSet and can be viewed in appendix 7). To account for differences in depreciation and amortization policies, both EV/EBIT and EV/EBITDA multiples have been included. The EBIT and EBITDA multiples have been calculated based on the analytical income statements and balance sheets available in Appendix 2.

Assessing Table 7: Multiple analysis of Novo Nordisk and competitors. Compiled by authors. Data source: Annual Reports and FactSet we see that Novo Nordisk is trading at a forward P/E of 16.8 compared to 15 and 20 for Sanofi and Eli Lilly respectively. The implied from valuation forward P/E is 20.2, which is in the upper part of the range. Given Novo's current and expected growth prospects, we find that a high multiple for Novo compared to peers should be justified.

At the EBITDA level, we were surprised to see that Novo is trading at a higher multiple than Sanofi. Consensus expectation for the forward earnings of Sanofi is more positive than Novo's, so the current multiple for Sanofi is probably a conservative value. At the EBIT level, Novo is currently the trading at the lowest multiple, which implies that Sanofi is expected to depreciate its assets faster than Novo. Eli Lilly stands out with the highest multiples, which could imply expectations of high future growth.

It should be noted that multiple valuation has limitations when valuing pharmaceutical companies. As the multiple valuation only provides an estimation based on a single year's financials, they cannot

adequately account for the major changes in earnings that can arise from the launch of a new pharmaceutical product, or from the patent expiry of a major product. Such developments may not be captured by a 1-year forward multiple but they still have a significant impact on the firm's total discounted cash flow. Another issue with multiple valuation is that it assumes that Novo, Sanofi and Eli Lilly are perfectly comparable. Based on our strategic and financial analysis of Novo Nordisk, it is very clear that Novo differs greatly from its closest competitors both in industry segments, competitive position and strength within those segments and financial value drivers. We therefore do not consider multiples to be as reliable a tool for valuing Novo Nordisk compared to the discounted cash flow analysis which is based on extensive research on Novo's strategic and financial position.

### Discussion on future growth drivers

As valuation involves the forecasting of growth drivers several years into the future, it is associated with a high degree of uncertainty which can only be partially remedied by our Monte Carlo simulation. This section is intended as a less formal speculation on the things that can have a severe impact on Novo's future performance but which are difficult to accurately predict. The nature of the pharmaceutical industry can be unpredictable due to its reliance on government policies and high degree of project failure. The issues mentioned in this segment have not played a direct role on the valuation, but we nevertheless consider it a useful motivator for further discussion of Novo's future performance.

#### *Failure of ACE910*

As we have mentioned, we expect the launch of ACE910 to significantly erode Novo's market share within haemophilia inhibitors. Due to the small number of patients, even the clinical trials of the product have had a measurable effect on the sales of NovoSeven. ACE910 has not had a completely trouble-free trial however, with several patients suffering severe side-effects, and the impact of ACE910 on these patients has not been clearly determined yet. Even in phase 3, drugs sometimes fail to meet their endpoints or safety requirements, leading to the termination of the project. While unlikely, the possibility exists for ACE910 to stumble in the final stretch, which would allow Novo to keep serving the inhibitor segment with no true competition until they are ready to launch Concizumab.

Similarly, it is possible for Concizumab to fail in its trials which, unless Novo develops a replacement, is likely to lead to Novo losing almost the entire market to ACE910. Sales of NovoSeven were almost 10 billion DKK in 2016, so the success or failure in this segment has a significant impact on Novo's value.

### *Growth opportunities in the obesity care segment*

As mentioned, Novo's main challenge with Saxenda is not competition, but rather hesitance from patients, doctors and payers to adopt anti-obesity treatment. Due to the high prevalence of obesity across the globe, the potential upside for Saxenda is enormous and if Novo succeeds in convincing buyers of its value, it could grow to become Novo's most profitable drug.

We find it difficult to accurately assess the impact of Saxenda on future revenue. So far, sales have grown rapidly and Saxenda has already reached more than 50% market share among branded anti-obesity drugs (Novo Nordisk Investor Presentation: Full Year, 2016, p. 87) but the challenge to reach a higher adoption rate among users remain. According to Novo's own assessment, "Obesity awareness and understanding is where type 2 diabetes was 20 years ago" (Novo Nordisk Annual Report, 2016, p. 29). Given the enormous value of the type 2 diabetes market, if Novo can help further the understanding of obesity to reach the same rate as type 2 diabetes, the potential for growth in this segment is extremely high.

### *Radical change to the payer environment in the US*

The United States differs from most of the developed world in their payer system (see our SLEPT-analysis for more). This system has inflated drug prices to a level far beyond the rest of the world, which increases the value of the market for Novo Nordisk. While unlikely to succeed, several proposals to establish a single-payer healthcare system have been made in the US, most recently the Expanded & Improved Medicare For All Act (Congress.gov, 2015). A change to a single-payer healthcare system akin to the rest of the developed world is likely to drastically reduce the price of medication, impacting Novo Nordisk's profits severely.

### *Cure for diabetes*

As we mentioned in the beginning of this thesis, we assume that the conditions that Novo Nordisk treats will not be cured within our forecast period. However, the recent major advances in medical knowledge, including research into stem cells and gene therapy may pave the way for a cure for type 1 diabetes. On May 11, 2017, researchers from the University of Miami Miller School of Medicine produced the first clinical result demonstrating that transplanting pancreatic islet cells within a tissue-engineered platform can successfully achieve insulin-independence in type 1 diabetes (Baidal, et al., 2017). The patient, a type 1 diabetic of 25 years has lived without the need for insulin injections for more than a year following the transplant. While longer trials are needed to prove the long-term safety

of the procedure, if it is proven safe the first cure for type 1 diabetes could reach the market within a decade. While the transplant would not be available to all type 1 diabetics from the start, it is not unlikely that a wide-scale cure for type 1 diabetes will be available within the next 2 decades. While type 1 diabetics only constitute approx. 10% of all diabetics, and the prevalence rate is relatively constant, a cure would most likely reduce Novo's sales in diabetes by at least 10 billion DKK annually.

## Conclusion

The aim of this thesis has been to answer the main research question: What is the fair market value of one Novo Nordisk A/S (NOVO-B) share as of April 24, 2017?

Based on a strategic and financial analysis, and discounting Novo Nordisk's cash flows using an enterprise-DCF model, we find a base case share price of 318.0 DKK. This is significantly higher than the actual closing price on April 24, 2017 of 250.0 DKK.

In the pharmaceutical industry, the primary driver of competition is having the most well-developed product at a fair price. To meet this demand, large pharmaceutical firms spend billions of DKK on developing new drugs, which typically takes more than a decade from discovery to market. Patents play a major role in the industry, and firms rely on the period of exclusivity to recoup the high costs of development.

Novo Nordisk is active in four different segments: diabetes, obesity, haemophilia and growth disorders with diabetes constituting approx. 80% of the firm's revenues. Currently, Novo Nordisk is the global market leader in diabetes care.

Novo Nordisk is the market leader in several of the segments in which it operates, supported by a strong portfolio of products, effective commercial operations and is well equipped to maintain or further its leadership through a strong R&D pipeline. However, the introduction of biosimilars, increased bargaining power of buyers, particularly in the US, and technological advances from competitors threaten to erode Novo's future profitability.

A biosimilar is a generic version of a large-molecule drug, and is generally priced at approx. 15% discount compared to the original. While this discount is significantly less than small-molecule generics, the high cost of diabetes treatment has led to interest from both patients and payers.

As a consequence of these developments, we do not expect Novo to maintain its historical profitability. Future revenue growth will primarily be driven by higher volume as opposed to price increases. The growth in volume is supported by an expected increase in the global prevalence of diabetes and obesity, economic growth and a growing population.

To support the base case valuation of 318.0 DKK, we performed a Monte Carlo simulation, with input based on Novo's historical levels and our expectations of the firm's future development. The actual closing price of 250.0 DKK on April 24, 2017 was outside the 95% confidence interval for the fair share price. This suggests that Novo Nordisk was undervalued on April 24. The valuation is most sensitive to changes in the terminal revenue growth, WACC and capital expenditure.

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## Appendices

### Appendix 1: Summary of competitive factors in Novo's industry

#### Diabetes and Obesity Care

- GLP-1
  - GLP-1 market is rapidly growing in both US and RoW
  - Novo no longer has the superior product
  - Victoza will continue to lose market share
  - Launch of Semaglutide in 2018 will stabilize Novo market share
- Long-acting
  - First biosimilar reached the market in December 2016 and has quickly gained market share
  - Novo's future growth is dependent on the success of Tresiba
  - Long-term market is likely split between new-generation insulins and biosimilars
- Fast-acting
  - Current competition primarily between NovoRapid and Lilly's Humalog
  - Novo is first on the RoW market with effective ultra-fast acting, still awaiting FDA
  - Biosimilars have not entered the market yet, but are likely to do so in the future
  - Long-term market is likely split between new-generation insulins and biosimilars
- Pre-mix
  - Historically a relatively stable segment
  - New GLP-1/long-acting combos open up for new opportunities
- Obesity
  - Saxenda has little direct competition, with most other products being pills of varying effectiveness
  - Primary challenge for Novo is not to beat the competition but rather to grow the market

#### Biopharmaceuticals

- Haemophilia
  - NovoSeven has had no competition for most of its lifetime
  - Trials of competitor product ACE910 is affecting Novo's sales
  - ACE910 is likely to capture significant market share in inhibitor segment until Novo's replacement finishes development

- NovoEight unlikely to capture relevant market share in Haemophilia A
  - N8-GP is non-superior product in a highly competitive market, unlikely to become market leader
  - N9-GP is expected to be the second-best product on the market
- Growth disorders
  - Little difference between products, instead competition is centered around convenience and support programs
  - Novo is leader in this segment and we expect that to continue

## Appendix 2: Analytical Income Statements and Balance Sheets

### Novo Nordisk - Analytical Income Statement

DKK million	2012	2013	2014	2015	2016
Net sales	78,026.0	83,572.0	88,806.0	107,927.0	111,780.0
Cost of goods sold	-13,465.0	-14,140.0	-14,562.0	-16,188.0	-17,183.0
<b>Gross profit</b>	<b>64,561.0</b>	<b>69,432.0</b>	<b>74,244.0</b>	<b>91,739.0</b>	<b>94,597.0</b>
Sales and distribution costs	-21,544.0	-23,380.0	-23,223.0	-28,312.0	-28,377.0
Research and development costs	-10,897.0	-11,733.0	-13,762.0	-13,608.0	-14,563.0
Administrative costs	-3,312.0	-3,508.0	-3,537.0	-3,857.0	-3,962.0
Other operating income, net	666.0	682.0	770.0	3,482.0	737.0
Reversal of expensed D&A under costs	2,693.0	2,799.0	3,435.0	2,959.0	3,193.0
<b>EBITDA</b>	<b>32,167.0</b>	<b>34,292.0</b>	<b>37,927.0</b>	<b>52,403.0</b>	<b>51,625.0</b>
Depreciation and Amortization	-2,693.0	-2,799.0	-3,435.0	-2,959.0	-3,193.0
<b>EBIT</b>	<b>29,474.0</b>	<b>31,493.0</b>	<b>34,492.0</b>	<b>49,444.0</b>	<b>48,432.0</b>
Tax on EBIT	-6,760.4	-7,118.6	-7,703.4	-9,805.1	-10,004.0
<b>NOPAT</b>	<b>22,713.6</b>	<b>24,374.4</b>	<b>26,788.6</b>	<b>39,638.9</b>	<b>38,428.0</b>
Financial income	125.0	1,702.0	167.0	85.0	92.0
Financial expenses	-1,788.0	-656.0	-563.0	-6,046.0	-726.0
Net financial income before taxes	-1,663.0	1,046.0	-396.0	-5,961.0	-634.0
Tax on net financial income	381.4	-236.4	88.4	1,182.1	131.0
<b>Net financial income after taxes</b>	<b>-1,281.6</b>	<b>809.6</b>	<b>-307.6</b>	<b>-4,778.9</b>	<b>-503.0</b>
<b>Profit for the year</b>	<b>21,432.0</b>	<b>25,184.0</b>	<b>26,481.0</b>	<b>34,860.0</b>	<b>37,925.0</b>

## Novo Nordisk - Analytical Balance Sheet

DKK million	2012	2013	2014	2015	2016
Intangible assets	1,495	1,615	1,378	2,158	2,714
Property, plant and equipment	21,539	21,882	23,136	25,545	30,179
Investment in associated company	0	0	0	811	809
Deferred income tax assets	2,244	4,231	5,399	6,806	2,683
<b>Total non-current operating assets</b>	<b>25,278</b>	<b>27,728</b>	<b>29,913</b>	<b>35,320</b>	<b>36,385</b>
Inventories	9,543	9,552	11,357	12,758	14,341
Trade receivables	9,639	10,907	13,041	15,485	20,234
Tax receivables	1,240	3,155	3,210	3,871	1,552
Other receivables and prepayments	2,705	2,454	2,750	2,257	2,411
<b>Total current operating assets</b>	<b>23,127</b>	<b>26,068</b>	<b>30,358</b>	<b>34,371</b>	<b>38,538</b>
Trade payables	3,859	4,092	4,950	4,927	6,011
Tax payables	593	2,222	2,771	3,777	3,976
Other liabilities	8,982	9,386	11,051	12,655	14,181
Provisions	7,656	8,310	11,590	17,059	20,461
Deferred income tax liabilities	732	672	7	6	13
Provisions	1,907	2,183	2,041	2,765	3,370
<b>Total non-interest-bearing debt (operating liabilities)</b>	<b>23,729</b>	<b>26,865</b>	<b>32,410</b>	<b>41,189</b>	<b>48,012</b>
Intangible and tangible assets	15,630	17,496	16,714	15,584	10,117
Net working capital	9,046	9,435	11,147	12,918	16,794
<b>Invested capital (net operating assets)</b>	<b>24,676</b>	<b>26,931</b>	<b>27,861</b>	<b>28,502</b>	<b>26,911</b>
Share capital	560	550	530	520	510
Treasury shares	-17	-21	-11	-10	-9
Retained earnings	39,001	41,137	41,277	46,816	46,111
Other reserves	1,088	903	-1,502	-357	-1,343
<b>Total equity</b>	<b>40,632</b>	<b>42,569</b>	<b>40,294</b>	<b>46,969</b>	<b>45,269</b>
Derivative financial instruments	48	0	2,607	1,382	2,578
Retirement benefit obligations	760	688	1,031	1,186	1,451
Current debt	500	215	720	1,073	229
<b>Interest-bearing debt</b>	<b>1,308</b>	<b>903</b>	<b>4,358</b>	<b>3,641</b>	<b>4,258</b>
Marketable securities	4,552	3,741	1,509	3,542	2,009
Cash at bank and on hand	11,553	10,728	14,396	16,923	18,690
Derivative financial instruments	931	1,521	30	304	529
Other financial assets	228	551	856	1,339	1,388
<b>Interest-bearing assets</b>	<b>17,264</b>	<b>16,541</b>	<b>16,791</b>	<b>22,108</b>	<b>22,616</b>
<b>Net interest bearing debt</b>	<b>-15,956</b>	<b>-15,638</b>	<b>-12,433</b>	<b>-18,467</b>	<b>-18,358</b>
<b>Invested capital</b>	<b>24,676</b>	<b>26,931</b>	<b>27,861</b>	<b>28,502</b>	<b>26,911</b>

## Eli Lilly - Analytical Income Statement

USD million	2012	2013	2014	2015	2016
Net sales	22,603.4	23,113.1	19,615.6	19,958.7	21,222.1
Cost of goods sold	-4,796.5	-4,908.1	-4,932.5	-5,037.2	-5,654.9
<b>Gross profit</b>	<b>17,806.9</b>	<b>18,205.0</b>	<b>14,683.1</b>	<b>14,921.5</b>	<b>15,567.2</b>
Research and development costs	-5,278.1	-5,531.3	-4,733.6	-4,796.4	-5,243.9
Marketing, selling and administrative	-7,513.5	-7,125.6	-6,620.8	-6,533.0	-6,452.0
Acquired in-process R&D	0.0	-57.1	-200.2	-535.0	-30.0
Asset impairment, restructuring and other charges	-281.0	-120.6	-468.7	-367.7	-382.5
Other operating income, net	746.8	559.3	368.3	174.8	-8.3
Reversal of D&A expensed under costs	1,462.2	1,445.6	1,379.0	1,427.7	1,496.6
<b>EBITDA</b>	<b>6,943.3</b>	<b>7,375.3</b>	<b>4,407.1</b>	<b>4,291.9</b>	<b>4,947.1</b>
Depreciation and Amortization	-1,462.2	-1,445.6	-1,379.0	-1,427.7	-1,496.6
<b>EBIT</b>	<b>5,481.1</b>	<b>5,929.7</b>	<b>3,028.1</b>	<b>2,864.2</b>	<b>3,450.5</b>
Tax on EBIT	1,337.4	1,215.6	614.7	392.4	652.1
<b>NOPAT</b>	<b>4,143.7</b>	<b>4,714.1</b>	<b>2,413.4</b>	<b>2,471.8</b>	<b>2,798.4</b>
Net financial income before taxes	-72.8	-40.4	-27.8	-74.2	-76.5
Tax on net financial income	17.8	8.3	5.6	10.2	14.5
<b>Net financial income after taxes</b>	<b>-55.0</b>	<b>-32.1</b>	<b>-22.2</b>	<b>-64.0</b>	<b>-62.0</b>
<b>Profit for the year</b>	<b>4,088.7</b>	<b>4,682.0</b>	<b>2,391.2</b>	<b>2,407.8</b>	<b>2,736.3</b>

## Eli Lilly - Analytical Balance Sheets

USD million	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
Investments	6,313	7,625	4,569	5,208	3,647
Goodwill and other intangibles - net	4,753	4,331	4,642	8,331	9,075
Other noncurrent assets	2,534	2,213	2,418	1,914	2,221
Property and equipment - net	7,760	7,976	7,964	8,253	8,054
<b>Total non-current operating assets</b>	<b>21,360</b>	<b>22,144</b>	<b>19,593</b>	<b>23,705</b>	<b>22,995</b>
Accounts receivable - net	3,336	3,434	3,235	4,029	3,513
Inventories	2,644	2,929	2,740	3,562	3,446
Other current Assets	1,374	1,344	1,378	1,472	1,163
<b>Total current operating assets</b>	<b>7,354</b>	<b>7,707</b>	<b>7,353</b>	<b>9,063</b>	<b>8,122</b>
Other current liabilities	7,189	6,785	7,391	7,700	6,885
Other noncurrent liabilities	5,716	4,491	5,215	5,371	4,777
Accounts payable	1,188	1,119	1,128	1,349	1,338
<b>Total non interest bearing debt (operating li:</b>	<b>14,094</b>	<b>12,395</b>	<b>13,734</b>	<b>14,420</b>	<b>13,000</b>
Intangible and tangible assets	15,644	17,653	14,378	18,334	18,219
New working capital	-1,023	-197	-1,166	14	-102
<b>Invested capital (net operating assets)</b>	<b>14,621</b>	<b>17,456</b>	<b>13,212</b>	<b>18,347</b>	<b>18,117</b>
<b>Total equity</b>	<b>14,774</b>	<b>17,641</b>	<b>15,388</b>	<b>14,081</b>	<b>14,590</b>
Long-term debt	5,519	4,200	5,368	8,368	7,972
Short-term borrowings	12	1,013	2,689	1,937	6
<b>Interest bearing debt</b>	<b>5,531</b>	<b>5,213</b>	<b>8,056</b>	<b>10,305</b>	<b>7,979</b>
Restricted cash	0	0	5,406	0	0
Cash and cash equivalents	4,019	3,830	3,872	4,582	3,666
Short-term investments	1,665	1,567	955	1,457	785
<b>Interest bearing assets</b>	<b>5,684</b>	<b>5,397</b>	<b>10,233</b>	<b>6,039</b>	<b>4,452</b>
<b>Net interest bearing debt</b>	<b>-153</b>	<b>-184</b>	<b>-2,176</b>	<b>4,267</b>	<b>3,527</b>
<b>Invested capital</b>	<b>14,621</b>	<b>17,456</b>	<b>13,212</b>	<b>18,347</b>	<b>18,117</b>

## Sanofi - Analytical Income Statement

€ million	2012	2013	2014	2015	2016
Net sales	34,947.0	32,951.0	33,770.0	34,060.0	33,821.0
Other revenues	1,010.0	355.0	339.0	801.0	887.0
Cost of sales	-11,098.0	-10,991.0	-11,029.0	-10,919.0	-10,702.0
<b>Gross profit</b>	<b>24,859.0</b>	<b>22,315.0</b>	<b>23,080.0</b>	<b>23,942.0</b>	<b>24,006.0</b>
Research and development expenses	-4,905.0	-4,770.0	-4,824.0	-5,082.0	-5,172.0
Selling and general expenses	-8,929.0	-8,603.0	-9,107.0	-9,382.0	-9,486.0
Other operating income	562.0	691.0	327.0	254.0	355.0
Other operating expenses	-414.0	-241.0	-163.0	-462.0	-482.0
Amortization of intangible assets	-3,291.0	-2,914.0	-2,482.0	-2,137.0	-1,692.0
Impairment of intangible assets	-117.0	-1,387.0	26.0	-767.0	-192.0
Fair value remeasurement of contingent consideration liabilities	-192.0	314.0	-303.0	53.0	-135.0
Restructuring costs and similar items	-1,141.0	-300.0	-411.0	-795.0	-879.0
Other gains and losses and litigation	0.0	0.0	0.0	0.0	211.0
Reversal of D&A expensed under costs	4,907.0	5,569.0	3,280.0	4,276.0	3,301.0
<b>EBITDA</b>	<b>11,339.0</b>	<b>10,674.0</b>	<b>9,423.0</b>	<b>9,900.0</b>	<b>9,835.0</b>
Depreciation and Amortization	-4,907.0	-5,569.0	-3,280.0	-4,276.0	-3,301.0
<b>EBIT</b>	<b>6,432.0</b>	<b>5,105.0</b>	<b>6,143.0</b>	<b>5,624.0</b>	<b>6,534.0</b>
Tax on EBIT	-1,235.4	-846.2	-1,255.2	-760.5	-1,525.9
<b>NOPAT</b>	<b>5,196.6</b>	<b>4,258.8</b>	<b>4,887.8</b>	<b>4,863.5</b>	<b>5,008.1</b>
Financial expenses	-751.0	-612.0	-605.0	-559.0	-924.0
Financial income	93.0	109.0	193.0	178.0	68.0
Net financial income before taxes	-658.0	-503.0	-412.0	-381.0	-856.0
Tax on financial income	126.4	83.4	84.2	51.5	199.9
<b>Net financial income after taxes</b>	<b>-531.6</b>	<b>-419.6</b>	<b>-327.8</b>	<b>-329.5</b>	<b>-656.1</b>
<b>Profit from core operations</b>	<b>4,665.0</b>	<b>3,839.2</b>	<b>4,560.0</b>	<b>4,534.0</b>	<b>4,352.0</b>
Share of profit/loss from associates, joint ventures and Animal Health	393.0	35.0	-51.0	-146.0	448.0
<b>Net profit for the year</b>	<b>5,058.0</b>	<b>3,874.2</b>	<b>4,509.0</b>	<b>4,388.0</b>	<b>4,800.0</b>

## Sanofi - Analytical Balance Sheets

Euro million	2012	2013	2014	2015	2016
Property, plant and equipment	10,578	10,182	10,396	9,943	10,019
Intangible assets (including goodwill)	58,265	52,529	53,740	51,583	51,166
Financial assets & investments in associates and deferred tax assets	8,665	9,428	9,819	10,115	10,379
<b>Total non-current operating assets</b>	<b>77,508</b>	<b>72,139</b>	<b>73,955</b>	<b>71,641</b>	<b>71,564</b>
Inventories, accounts receivable and other current assets	16,419	15,655	16,086	15,780	16,414
<b>Total current operating assets</b>	<b>16,419</b>	<b>15,655</b>	<b>16,086</b>	<b>15,780</b>	<b>16,414</b>
Non-current liabilities related to business combinations and interests	1,350	884	1,133	1,121	1,378
Provisions and other non-current liabilities	11,043	8,735	9,578	9,169	8,834
Deferred tax liabilities	5,932	5,060	4,105	2,895	2,292
Accounts payable & Other current liabilities	9,948	9,757	11,363	13,259	14,472
Current liabilities related to business combinations and interests	100	24	131	130	198
<b>Total non-interest-bearing debt (operating liabilities)</b>	<b>28,373</b>	<b>24,460</b>	<b>26,310</b>	<b>26,574</b>	<b>27,174</b>
Net intangible and tangible assets	59,183	57,460	59,139	58,456	59,060
Net working capital	6,371	5,874	4,592	2,391	1,744
<b>Invested capital (net operating assets)</b>	<b>65,554</b>	<b>63,334</b>	<b>63,731</b>	<b>60,847</b>	<b>60,804</b>
Equity attributable to equity holders of Sanofi	57,332	56,885	56,120	58,049	57,554
Equity attributable to non-controlling interests	134	129	148	161	170
<b>Total equity</b>	<b>57,466</b>	<b>57,014</b>	<b>56,268</b>	<b>58,210</b>	<b>57,724</b>
Liabilities related to assets held for sale or exchange	39	1	0	983	1,195
Short-term debt and current portion of long-term debt	3,812	4,176	1,538	3,436	1,764
Long-term debt	10,719	10,414	13,276	13,118	16,815
<b>Interest-bearing debt</b>	<b>14,570</b>	<b>14,591</b>	<b>14,814</b>	<b>17,537</b>	<b>19,774</b>
Assets held for sale or exchange	101	14	10	5,752	6,421
Cash and cash equivalents	6,381	8,257	7,341	9,148	10,273
<b>Interest bearing assets</b>	<b>6,482</b>	<b>8,271</b>	<b>7,351</b>	<b>14,900</b>	<b>16,694</b>
<b>Net interest bearing debt</b>	<b>8,088</b>	<b>6,320</b>	<b>7,463</b>	<b>2,637</b>	<b>3,080</b>
<b>Invested capital</b>	<b>65,554</b>	<b>63,334</b>	<b>63,731</b>	<b>60,847</b>	<b>60,804</b>



### Appendix 3: Market share and revenue forecast

	DKKm	2014A	2015A	2016A	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Diabetes	GLP-1	13,426	18,027	20,046	22,980	26,030	29,316	32,124	34,886	36,365	37,853	38,697	39,717	41,017	42,247	43,515	44,820	46,165
	y/y growth		34.3%	11.2%	14.6%	13.3%	12.6%	9.6%	8.6%	4.2%	4.1%	2.2%	2.6%	3.3%	3.0%	3.0%	3.0%	3.0%
	Fast-acting	17,818	20,720	19,945	20,795	22,004	22,865	23,264	23,619	23,925	24,181	24,385	24,566	24,725	24,861	25,607	26,375	27,166
	y/y growth		16.3%	-3.7%	4.3%	5.8%	3.9%	1.7%	1.5%	1.3%	1.1%	0.8%	0.7%	0.6%	0.5%	3.0%	3.0%	3.0%
	Long-acting	14,217	19,648	21,139	21,297	22,000	22,865	23,757	24,635	25,498	26,339	27,156	27,989	28,838	29,703	30,594	31,512	32,457
	y/y growth		38.2%	7.6%	0.7%	3.3%	3.9%	3.9%	3.7%	3.5%	3.3%	3.1%	3.1%	3.0%	3.0%	3.0%	3.0%	3.0%
	Premix	10,160	11,234	10,885	12,123	13,492	15,101	16,807	18,655	20,001	21,313	22,521	23,553	24,344	25,068	25,813	26,580	27,371
	y/y growth		10.6%	-3.1%	11.4%	11.3%	11.9%	11.3%	11.0%	7.2%	6.6%	5.7%	4.6%	3.4%	3.0%	3.0%	3.0%	3.0%
	Obesity	-	460	1,577	2,404	3,544	4,430	5,405	6,431	7,461	8,430	9,273	9,923	10,319	10,629	10,948	11,276	11,615
	y/y growth			242.8%	52.4%	47.4%	25.0%	22.0%	19.0%	16.0%	13.0%	10.0%	7.0%	4.0%	3.0%	3.0%	3.0%	3.0%
Biopharmaceuticals	Human insulin	10,298	11,231	11,090	11,123	11,157	11,190	11,224	11,257	11,291	11,325	11,359	11,393	11,427	11,462	11,496	11,530	11,565
	y/y growth		9.1%	-1.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
	Other diabetes and obesity	4,061	4,270	4,267	4,352	4,439	4,528	4,619	4,711	4,805	4,901	4,999	5,099	5,201	5,305	5,412	5,520	5,630
	y/y growth		5.1%	-0.1%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
	Inhibitors	8,924	10,047	9,492	8,844	8,919	6,471	5,644	4,781	4,379	3,959	3,521	4,119	5,387	6,044	6,445	6,860	6,962
	y/y growth		12.6%	-5.5%	-6.8%	0.8%	-27.4%	-12.8%	-15.3%	-8.4%	-9.6%	-11.1%	17.0%	30.8%	12.2%	6.6%	6.4%	1.5%
	Haemophilia Type A	380	600	980	1,254	1,415	1,974	2,586	3,236	3,919	4,627	5,351	6,082	6,204	6,328	6,454	6,583	6,715
	y/y growth		57.9%	63.3%	28.0%	12.8%	39.5%	31.0%	25.2%	21.1%	18.1%	15.7%	13.7%	2.0%	2.0%	2.0%	2.0%	2.0%
	Haemophilia Type B	-	-	-	-	416	1,169	1,842	2,326	2,836	3,280	3,735	4,192	4,648	4,741	4,836	4,933	5,031
Biopharmaceuticals	y/y growth					181.3%	57.5%	26.3%	21.9%	15.7%	13.8%	12.3%	10.9%	2.0%	2.0%	2.0%	2.0%	2.0%
	Growth Disorders	6,506	7,820	8,770	8,139	8,202	8,498	8,803	9,117	9,439	9,770	10,111	10,461	10,820	11,026	11,235	11,449	11,666
	y/y growth		20.2%	12.1%	-7.2%	0.8%	3.6%	3.6%	3.6%	3.5%	3.5%	3.5%	3.5%	3.4%	1.9%	1.9%	1.9%	1.9%
	Other biopharmaceuticals	3,016	3,870	3,589	2,184	1,966	1,867	1,867	1,905	1,943	1,982	2,021	2,062	2,103	2,145	2,188	2,232	2,276
	y/y growth		28.3%	-7.3%	-39.1%	-10.0%	-5.0%	0.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
	Novo total revenue	88,806	107,927	111,780	115,497	123,582	130,275	137,941	145,560	151,862	157,961	163,128	169,156	175,034	179,558	184,542	189,670	194,620
	y/y growth		21.5%	3.6%	3.3%	7.0%	5.4%	5.9%	5.5%	4.3%	4.0%	3.3%	3.7%	3.5%	2.6%	2.8%	2.8%	2.6%

# GLP-1 USA

	2014	2015	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Global %	12,256	19,140	24,807	31,505	38,436	45,162	51,485	57,405	62,572	66,952	70,299	73,111	75,305	77,564	79,891	82,287	84,756
Growth		56.2%	29.6%	27.0%	22.0%	17.5%	14.0%	11.5%	9.0%	7.0%	5.0%	4.0%	3.0%	3.0%	3.0%	3.0%	3.0%
Market shares																	
Victoza	70.8%	65.7%	57.0%	52%	46%	34%	24%	17%	12%	9%	6%	4%	3%	1%	1%	1%	1%
Byetta	10.0%	7.5%	4.7%	3%	2%	1%	1%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Bydureon	18.8%	17.3%	13.2%	12%	11%	10%	9%	8%	7%	6%	5%	4%	4%	4%	4%	4%	4%
Trulicity	0.0%	7.4%	21.0%	27%	30%	32%	34%	34%	35%	35%	35%	34%	32%	31%	31%	31%	31%
Tanzeum	0.5%	2.1%	4.1%	6%	8%	10%	12%	14%	16%	18%	20%	22%	24%	25%	25%	25%	25%
Semaglutide	0.0%	0.0%	0.0%	0%	3%	13%	21%	27%	30%	32%	34%	36%	37%	39%	39%	39%	39%

Global DKKm	12,256	19,140	24,807	31,505	38,436	45,162	51,485	57,405	62,572	66,952	70,299	73,111	75,305	77,564	79,891	82,287	84,756
Growth		56.2%	29.6%	27.0%	22.0%	17.5%	14.0%	11.5%	9.0%	7.0%	5.0%	4.0%	3.0%	3.0%	3.0%	3.0%	3.0%
Sales DKKm																	
Victoza	8,674	12,570	14,146	16,390	17,498	15,140	12,112	9,486	7,211	5,707	3,884	2,577	1,901	407	419	432	445
- Growth		44.9%	12.5%	15.9%	6.8%	-13.5%	-20.0%	-21.7%	-24.0%	-20.9%	-32.0%	-33.6%	-26.2%	-78.6%	3.0%	3.0%	3.0%
Byetta	1,225	1,434	1,158	882	646	455	311	208	-	-	-	-	-	-	-	-	-
- Growth		17.1%	-19.3%	-23.8%	-26.8%	-29.5%	-31.6%	-33.1%	-100.0%								
Bydureon	2,302	3,307	3,268	3,836	4,295	4,595	4,724	4,693	4,490	4,134	3,638	3,052	3,144	3,238	3,335	3,436	3,539
- Growth		43.7%	-1.2%	17.4%	12.0%	7.0%	2.8%	-0.7%	-4.3%	-7.9%	-12.0%	-16.1%	3.0%	3.0%	3.0%	3.0%	3.0%
Trulicity	-	1,425	5,207	8,461	11,714	14,519	17,274	19,399	21,998	23,537	24,714	24,972	24,215	24,166	24,891	25,637	26,406
- Growth			265.4%	62.5%	38.4%	23.9%	19.0%	12.3%	13.4%	7.0%	5.0%	1.0%	-3.0%	-0.2%	3.0%	3.0%	3.0%
Tanzeum	56	404	1,028	1,936	3,130	4,581	6,253	8,120	10,102	12,148	14,161	16,190	18,182	19,503	20,088	20,691	21,311
- Growth		620.1%	154.5%	88.3%	61.7%	46.4%	36.5%	29.9%	24.4%	20.3%	16.6%	14.3%	12.3%	7.3%	3.0%	3.0%	3.0%
Semaglutide				-	1,153	5,871	10,812	15,499	18,772	21,425	23,902	26,320	27,863	30,250	31,157	32,092	33,055
- Growth						409.2%	84.2%	43.4%	21.1%	14.1%	11.6%	10.1%	5.9%	8.6%	3.0%	3.0%	3.0%

**GLP-1 ROW**

	2014	2015	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Global %	5,947	7,155	8,700	10,490	12,545	14,877	17,419	19,872	22,175	24,189	25,783	26,836	27,909	28,747	29,609	30,497	31,412
Growth		20.3%	21.6%	20.6%	19.6%	18.6%	17.1%	14.1%	11.6%	9.1%	6.6%	4.1%	4.0%	3.0%	3.0%	3.0%	3.0%
Market shares																	
Victoza	79.9%	76.3%	67.8%	63%	55%	42%	31%	22%	16%	11%	7%	3%	2%	0%	0%	0%	0%
Byetta	13.2%	10.3%	7.3%	5%	3%	1%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Bydureon	6.8%	9.4%	9.3%	8%	7%	6%	5%	4%	3%	2%	1%	1%	1%	1%	1%	1%	1%
Trulicity	0.0%	3.9%	15.2%	22%	27%	31%	35%	37%	39%	40%	41%	41%	39%	37%	37%	37%	37%
Tanzeum	0.0%	0.1%	0.3%	1%	3%	5%	7%	9%	11%	13%	15%	17%	19%	21%	21%	21%	21%
Semaglutide	0.0%	0.0%	0.0%		4%	14%	22%	28%	31%	33%	35%	37%	38%	40%	40%	40%	40%

	2014	2015	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Global DKKm	5,947	7,155	8,700	10,490	12,545	14,877	17,419	19,872	22,175	24,189	25,783	26,836	27,909	28,747	29,609	30,497	31,412
Growth		20.3%	21.6%	20.6%	19.6%	18.6%	17.1%	14.1%	11.6%	9.1%	6.6%	4.1%	4.0%	3.0%	3.0%	3.0%	3.0%
Sales DKKm																	
Victoza	4,752	5,457	5,900	6,590	6,877	6,221	5,368	4,336	3,508	2,738	1,887	891	647	92	95	97	100
- Growth		14.8%	8.1%	11.7%	4.4%	-9.5%	-13.7%	-19.2%	-19.1%	-21.9%	-31.1%	-52.8%	-27.3%	-85.8%	3.0%	3.0%	3.0%
Byetta	788	734	635	556	414	194	-	-	-	-	-	-	-	-	-	-	-
- Growth		-6.8%	-13.5%	-12.4%	-25.5%	-53.2%	-100.0%										
Bydureon	406	672	812	874	920	942	929	861	739	564	343	357	372	383	394	406	418
- Growth		65.6%	20.7%	7.7%	5.2%	2.4%	-1.4%	-7.3%	-14.2%	-23.7%	-39.1%	4.1%	4.0%	3.0%	3.0%	3.0%	3.0%
Trulicity	-	281	1,326	2,334	3,418	4,649	6,018	7,263	8,548	9,688	10,584	11,016	10,898	10,650	10,970	11,299	11,638
- Growth			371.5%	75.9%	46.5%	36.0%	29.5%	20.7%	17.7%	13.3%	9.2%	4.1%	-1.1%	-2.3%	3.0%	3.0%	3.0%
Tanzeum	1	10	26	136	414	788	1,272	1,848	2,506	3,217	3,945	4,643	5,387	6,123	6,307	6,496	6,691
- Growth		635.7%	153.4%	422.5%	203.6%	90.5%	61.3%	45.3%	35.6%	28.4%	22.6%	17.7%	16.0%	13.7%	3.0%	3.0%	3.0%
Semaglutide	-	-	-	-	502	2,083	3,832	5,564	6,874	7,983	9,024	9,929	10,606	11,499	11,844	12,199	12,565
- Growth						315.1%	84.0%	45.2%	23.5%	16.1%	13.0%	10.0%	6.8%	8.4%	3.0%	3.0%	3.0%

## Fast Acting USA

	2014	2015	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Global %	21,182	25,426	23,809	24,285	25,013	26,014	27,055	28,069	29,051	29,996	30,896	31,822	32,777	33,760	34,773	35,816	36,891
Growth		20.0%	-6.4%	2.0%	3.0%	4.0%	4.0%	3.8%	3.5%	3.3%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
Market shares																	
NovoRapid	48.1%	47.9%	46.4%	47%	46%	43%	35%	29%	25%	19%	16%	13%	11%	9%	9%	9%	9%
Humalog	47.3%	47.8%	50.0%	50%	49%	46%	41%	38%	35%	32%	29%	26%	23%	20%	20%	20%	20%
Apidra	4.6%	4.3%	3.6%	3%	3%	2%	2%	1%	0%	0%	0%	0%	0%	0%	0%	0%	0%
BioChaperone	0.0%	0.0%	0.0%				1%	3%	5%	6%	6%	6%	6%	6%	6%	6%	6%
Fiasp	0.0%	0.0%	0.0%	0%	3%	6%	13%	18%	21%	26%	28%	30%	31%	32%	32%	32%	32%
Biosimilar	0.0%	0.0%	0.0%			3%	9%	11%	14%	17%	21%	25%	29%	33%	33%	33%	33%

	2014	2015	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Global DKKm	21,182	25,426	23,809	24,285	25,013	26,014	27,055	28,069	29,051	29,996	30,896	31,822	32,777	33,760	34,773	35,816	36,891
Growth		20.0%	-6.4%	2.0%	3.0%	4.0%	4.0%	3.8%	3.5%	3.3%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
Sales DKKm																	
NovoRapid	10,191	12,184	11,058	11,414	11,506	11,186	9,469	8,140	7,263	5,699	4,943	4,137	3,605	3,038	3,130	3,223	3,320
- Growth		19.6%	-9.2%	3.2%	0.8%	-2.8%	-15.3%	-14.0%	-10.8%	-21.5%	-13.3%	-16.3%	-12.8%	-15.7%	3.0%	3.0%	3.0%
Humalog	10,016	12,160	11,896	12,142	12,257	11,966	11,092	10,666	10,168	9,599	8,960	8,274	7,539	6,752	6,955	7,163	7,378
- Growth		21.4%	-2.2%	2.1%	0.9%	-2.4%	-7.3%	-3.8%	-4.7%	-5.6%	-6.7%	-7.7%	-8.9%	-10.4%	3.0%	3.0%	3.0%
Apidra	976	1,082	855	729	625	520	406	281	145	-	-	-	-	-	-	-	-
- Growth		10.9%	-21.0%	-14.8%	-14.2%	-16.8%	-22.0%	-30.8%	-48.3%	-100.0%							
BioChaperone	-	-	-	-	-	-	271	842	1,453	1,800	1,854	1,909	1,967	2,026	2,086	2,149	2,213
- Growth								211.3%	72.5%	23.9%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
Fiasp	-	-	-	-	750	1,561	3,517	5,052	6,101	7,799	8,651	9,547	10,161	10,803	11,127	11,461	11,805
- Growth						108.0%	125.3%	43.7%	20.8%	27.8%	10.9%	10.4%	6.4%	6.3%	3.0%	3.0%	3.0%
Biosimilar	-	-	-	-	-	780	2,300	3,088	3,922	5,099	6,488	7,956	9,505	11,141	11,475	11,819	12,174
- Growth							194.7%	34.3%	27.0%	30.0%	27.2%	22.6%	19.5%	17.2%	3.0%	3.0%	3.0%

### Fast Acting ROW

	2014	2015	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Global %	16,277	17,485	18,410	19,146	19,893	20,648	21,412	22,183	22,960	23,740	24,524	25,309	26,093	26,876	27,682	28,513	29,368
Growth		7.4%	5.3%	4.0%	3.9%	3.8%	3.7%	3.6%	3.5%	3.4%	3.3%	3.2%	3.1%	3.0%	3.0%	3.0%	3.0%
Market shares																	
NovoRapid	46.9%	48.8%	48.3%	46%	40%	36%	30%	26%	20%	18%	16%	14%	13%	11%	11%	11%	11%
Humalog	43.8%	41.3%	41.5%	40%	42%	40%	37%	34%	32%	30%	27%	24%	21%	19%	19%	19%	19%
Apidra	9.4%	9.9%	10.2%	11%	9%	8%	6%	5%	4%	3%	3%	3%	3%	3%	3%	3%	3%
BioChaperone	0.0%	0.0%	0.0%				1%	3%	5%	5%	5%	5%	5%	5%	5%	5%	5%
Fiasp	0.0%	0.0%	0.0%	3%	9%	13%	18%	21%	26%	27%	28%	29%	29%	30%	30%	30%	30%
Biosimilar	0.0%	0.0%	0.0%			3%	9%	11%	14%	17%	21%	25%	29%	32%	32%	32%	32%

	2014	2015	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Global DKKm	16,277	17,485	18,410	19,146	19,893	20,648	21,412	22,183	22,960	23,740	24,524	25,309	26,093	26,876	27,682	28,513	29,368
Growth		7.4%	5.3%	4.0%	3.9%	3.8%	3.7%	3.6%	3.5%	3.4%	3.3%	3.2%	3.1%	3.0%	3.0%	3.0%	3.0%
Sales DKKm																	
NovoRapid	7,627	8,536	8,887	8,807	7,957	7,433	6,424	5,768	4,592	4,273	3,924	3,543	3,392	2,956	3,045	3,136	3,230
- Growth		11.9%	4.1%	-0.9%	-9.7%	-6.6%	-13.6%	-10.2%	-20.4%	-6.9%	-8.2%	-9.7%	-4.3%	-12.8%	3.0%	3.0%	3.0%
Humalog	7,124	7,225	7,649	7,658	8,355	8,259	7,816	7,542	7,232	7,122	6,621	6,074	5,480	5,106	5,260	5,417	5,580
- Growth		1.4%	5.9%	0.1%	9.1%	-1.1%	-5.4%	-3.5%	-4.1%	-1.5%	-7.0%	-8.3%	-9.8%	-6.8%	3.0%	3.0%	3.0%
Apidra	1,527	1,724	1,873	2,106	1,790	1,652	1,285	1,109	918	712	736	759	783	806	830	855	881
- Growth		12.9%	8.7%	12.4%	-15.0%	-7.7%	-22.2%	-13.7%	-17.2%	-22.5%	3.3%	3.2%	3.1%	3.0%	3.0%	3.0%	3.0%
BioChaperone	-	-	-	-	-	-	214	665	1,148	1,187	1,226	1,265	1,305	1,344	1,384	1,426	1,468
- Growth								210.8%	72.5%	3.4%	3.3%	3.2%	3.1%	3.0%	3.0%	3.0%	3.0%
Fiasp	-	-	-	574	1,790	2,684	3,854	4,658	5,970	6,410	6,867	7,339	7,567	8,063	8,305	8,554	8,810
- Growth					211.7%	49.9%	43.6%	20.9%	28.1%	7.4%	7.1%	6.9%	3.1%	6.6%	3.0%	3.0%	3.0%
Biosimilar	-	-	-	-	-	619	1,820	2,440	3,100	4,036	5,150	6,327	7,567	8,600	8,858	9,124	9,398
- Growth							193.8%	34.1%	27.0%	30.2%	27.6%	22.9%	19.6%	13.7%	3.0%	3.0%	3.0%

## Long Acting USA

	2014	2015	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Global %	40,552	43,953	44,337	45,224	46,580	48,444	50,381	52,271	54,100	55,858	57,534	59,260	61,038	62,869	64,755	66,698	68,699
Growth		8.4%	0.9%	2.0%	3.0%	4.0%	4.0%	3.8%	3.5%	3.3%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
Market shares																	
Levemir	22.4%	29.5%	27.6%	25%	22%	17%	15%	13%	11%	9%	7%	5%	3%	0%	0%	0%	0%
Lantus	77.6%	68.3%	59.2%	54%	48%	42%	36%	30%	24%	20%	15%	10%	5%	1%	1%	1%	1%
Tresiba	0.0%	0.0%	4.6%	7%	10%	15%	17%	19%	21%	23%	25%	27%	29%	31%	31%	31%	31%
Toujeo	0.0%	2.2%	8.0%	10%	12%	14%	16%	18%	20%	22%	24%	26%	28%	29%	29%	29%	29%
Biosimilar	0.0%	0.0%	0.7%	5%	9%	13%	17%	21%	25%	27%	30%	33%	36%	39%	39%	39%	39%

	2014	2015	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Global DKKm	40,552	43,953	44,337	45,224	46,580	48,444	50,381	52,271	54,100	55,858	57,534	59,260	61,038	62,869	64,755	66,698	68,699
Growth		8.4%	0.9%	2.0%	3.0%	4.0%	4.0%	3.8%	3.5%	3.3%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
Sales DKKm																	
Levemir	9,088	12,982	12,247	11,185	10,123	8,106	7,423	6,656	5,807	4,878	3,874	2,805	1,668	-	-	-	-
- Growth		42.8%	-5.7%	-8.7%	-9.5%	-19.9%	-8.4%	-10.3%	-12.8%	-16.0%	-20.6%	-27.6%	-40.5%				
Lantus	31,464	30,024	26,227	24,491	22,430	20,421	18,215	15,762	13,068	10,979	8,719	6,017	3,146	726	747	770	793
- Growth		-4.6%	-12.6%	-6.6%	-8.4%	-9.0%	-10.8%	-13.5%	-17.1%	-16.0%	-20.6%	-31.0%	-47.7%	-76.9%	3.0%	3.0%	3.0%
Tresiba	-	-	2,028	2,973	4,460	7,060	8,350	9,709	11,131	12,609	14,138	15,748	17,441	19,682	20,273	20,881	21,508
- Growth				46.6%	50.0%	58.3%	18.3%	16.3%	14.6%	13.3%	12.1%	11.4%	10.8%	12.9%	3.0%	3.0%	3.0%
Toujeo	-	948	3,531	4,506	5,573	6,765	8,043	9,390	10,801	12,269	13,788	15,387	17,069	18,210	18,756	19,319	19,898
- Growth								16.7%	15.0%	13.6%	12.4%	11.6%	10.9%	6.7%	3.0%	3.0%	3.0%
Biosimilar	-	-	304	2,069	3,994	6,091	8,350	10,754	13,295	15,123	17,015	19,303	21,714	24,251	24,979	25,728	26,500
- Growth					93.1%	52.5%	37.1%	28.8%	23.6%	13.8%	12.5%	13.4%	12.5%	11.7%	3.0%	3.0%	3.0%

## Long Acting ROW

	2014	2015	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Global %	20,909	24,609	24,712	25,700	26,702	27,717	28,743	29,777	30,820	31,868	32,919	33,973	35,026	36,076	37,159	38,274	39,422
Growth		17.7%	0.4%	4.0%	3.9%	3.8%	3.7%	3.6%	3.5%	3.4%	3.3%	3.2%	3.1%	3.0%	3.0%	3.0%	3.0%
Market shares																	
Levemir	24.5%	21.6%	19.6%	18%	16%	14%	12%	10%	8%	6%	4%	2%	1%	0%	0%	0%	0%
Lantus	75.5%	71.8%	65.8%	61%	55%	49%	42%	36%	29%	23%	17%	14%	11%	8%	8%	8%	8%
Tresiba	0.0%	5.5%	8.2%	10%	12%	14%	16%	18%	20%	22%	24%	26%	27%	28%	28%	28%	28%
Toujeo	0.0%	0.8%	5.2%	7%	9%	11%	14%	16%	19%	21%	24%	25%	26%	27%	27%	27%	27%
Biosimilar	0.0%	0.3%	1.2%	4%	8%	12%	16%	20%	24%	28%	31%	33%	35%	37%	37%	37%	37%

	2014	2015	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Global DKKm	20,909	24,609	24,712	25,700	26,702	27,717	28,743	29,777	30,820	31,868	32,919	33,973	35,026	36,076	37,159	38,274	39,422
Growth		17.7%	0.4%	4.0%	3.9%	3.8%	3.7%	3.6%	3.5%	3.4%	3.3%	3.2%	3.1%	3.0%	3.0%	3.0%	3.0%
Sales DKKm																	
Levemir	5,129	5,318	4,836	4,515	4,157	3,761	3,325	2,850	2,333	1,775	1,175	533	272	-	-	-	-
- Growth		3.7%	-9.1%	-6.6%	-7.9%	-9.5%	-11.6%	-14.3%	-18.1%	-23.9%	-33.8%	-54.6%	-49.0%				
Lantus	15,780	17,665	16,251	15,616	14,623	13,515	12,147	10,649	9,018	7,253	5,682	4,845	3,944	2,980	3,070	3,162	3,257
- Growth		11.9%	-8.0%	-3.9%	-6.4%	-7.6%	-10.1%	-12.3%	-15.3%	-19.6%	-21.7%	-14.7%	-18.6%	-24.4%	3.0%	3.0%	3.0%
Tresiba	-	1,348	2,028	2,623	3,259	3,938	4,658	5,421	6,228	7,077	7,969	8,903	9,457	10,021	10,321	10,631	10,950
- Growth				29.3%	24.3%	20.8%	18.3%	16.4%	14.9%	13.6%	12.6%	11.7%	6.2%	6.0%	3.0%	3.0%	3.0%
Toujeo	-	202	1,294	1,859	2,466	3,114	3,948	4,834	5,774	6,767	7,813	8,403	9,014	9,645	9,934	10,232	10,539
- Growth								22.5%	19.4%	17.2%	15.5%	7.5%	7.3%	7.0%	3.0%	3.0%	3.0%
Biosimilar	-	76	304	1,087	2,197	3,389	4,664	6,023	7,467	8,996	10,280	11,288	12,339	13,431	13,834	14,249	14,676
- Growth					102.2%	54.3%	37.6%	29.1%	24.0%	20.5%	14.3%	9.8%	9.3%	8.8%	3.0%	3.0%	3.0%

## Haemophilia Inhibitors

	2014	2015	2016	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030T
Global market - DKKm	9,549	10,927	9,742.00	9,118	9,195	9,379	9,566	9,758	9,953	10,152	10,355	10,562	10,773	10,989	11,208	11,433	11,604
Growth		14.4%	-10.8%	-6.4%	0.8%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	1.5%
Market shares																	
NovoSeven	97%	97%	97%	97%	97%	69%	59%	49%	44%	39%	34%	19%	15%	10%	3%	0%	0%
ACE910						25%	35%	45%	50%	55%	60%	55%	45%	40%	38%	35%	35%
Concizumab												20%	35%	45%	55%	60%	60%
Biosimilars/Others	3%	3%	3%	5%	6%	6%	6%	6%	6%	6%	6%	6%	5%	5%	5%	5%	5%
Global sales																	
NovoSeven	8,924	10,047	9,492	8,844	8,919	6,471	5,644	4,781	4,379	3,959	3,521	2,007	1,616	1,099	280	-	-
- growth		12.6%	-5.5%	-6.8%	0.8%	-27.4%	-12.8%	-15.3%	-8.4%	-9.6%	-11.1%	-43.0%	-19.5%	-32.0%	-74.5%	-100.0%	
ACE910	-	-	-	-	-	2,345	3,348	4,391	4,976	5,584	6,213	5,809	4,848	4,395	4,203	4,001	4,061
- growth							42.8%	31.1%	13.3%	12.2%	11.3%	-6.5%	-16.5%	-9.3%	-4.4%	-4.8%	1%
Concizumab	-	-	-	-	-	-	-	-	-	-	-	2,112	3,771	4,945	6,165	6,860	6,962
- growth														31.1%	24.7%	11.3%	1%
Biosimilars/Others	286	328	292	456	552	563	574	585	597	609	621	634	539	549	560	572	580
- growth		14.4%	-10.8%	56.0%	21.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	-15.0%	2.0%	2.0%	2.0%	1%



## Appendix 4: Forecast of value drivers and pro forma statements

### Value driver forecast

	E2017	E2018	E2019	E2020	E2021	E2022	E2023	E2024	E2025	E2026	E2027	E2028	E2029	E2030T
Revenue growth	3.3%	7.0%	5.4%	5.9%	5.5%	4.3%	4.0%	3.3%	3.7%	3.5%	2.6%	2.8%	2.8%	2.6%
EBITDA-margin	46.2%	45.2%	44.2%	43.2%	42.2%	41.2%	40.2%	39.2%	38.2%	37.2%	36.2%	36.2%	36.2%	36.2%
Efficient tax rate	22.0%	22.0%	22.0%	22.0%	22.0%	22.0%	22.0%	22.0%	22.0%	22.0%	22.0%	22.0%	22.0%	22.0%
Depreciation as % of intangible and tangible assets subject to dep. an	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%	17.5%
CAPEX as % of revenue	8.8%	4.2%	4.2%	4.3%	4.4%	4.3%	4.4%	4.4%	4.6%	4.6%	4.6%	4.6%	4.6%	4.6%
Intangible and tangible assets as % of revenue	15.0%	15.5%	16.0%	16.5%	17.0%	17.5%	18.0%	18.5%	19.0%	19.5%	20.0%	20.0%	20.0%	20.0%
Net working capital as % of revenue	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%

### Pro forma analytical income statement

DKK millions	E2017	E2018	E2019	E2020	E2021	E2022	E2023	E2024	E2025	E2026	E2027	E2028	E2029	E2030T
<b>Revenue</b>	<b>115,497</b>	<b>123,582</b>	<b>130,275</b>	<b>137,941</b>	<b>145,560</b>	<b>151,862</b>	<b>157,961</b>	<b>163,128</b>	<b>169,156</b>	<b>175,034</b>	<b>179,558</b>	<b>184,542</b>	<b>189,670</b>	<b>194,620</b>
y/y revenue growth	3.3%	7.0%	5.4%	5.9%	5.5%	4.3%	4.0%	3.3%	3.7%	3.5%	2.6%	2.8%	2.8%	2.6%
<b>EBITDA</b>	<b>53,342</b>	<b>55,840</b>	<b>57,561</b>	<b>59,569</b>	<b>61,404</b>	<b>62,544</b>	<b>63,476</b>	<b>63,921</b>	<b>64,591</b>	<b>65,086</b>	<b>64,972</b>	<b>66,776</b>	<b>68,631</b>	<b>70,422</b>
EBITDA margin	46.2%	45.2%	44.2%	43.2%	42.2%	41.2%	40.2%	39.2%	38.2%	37.2%	36.2%	36.2%	36.2%	36.2%
<b>EBIT</b>	<b>50,310</b>	<b>52,488</b>	<b>53,914</b>	<b>55,586</b>	<b>57,073</b>	<b>57,893</b>	<b>58,500</b>	<b>58,640</b>	<b>58,967</b>	<b>59,112</b>	<b>58,688</b>	<b>60,317</b>	<b>61,993</b>	<b>63,610</b>
EBIT margin	43.6%	42.5%	41.4%	40.3%	39.2%	38.1%	37.0%	35.9%	34.9%	33.8%	32.7%	32.7%	32.7%	32.7%
Tax	(11,068)	(11,547)	(11,861)	(12,229)	(12,556)	(12,736)	(12,870)	(12,901)	(12,973)	(13,005)	(12,911)	(13,270)	(13,638)	(13,994)
<b>NOPAT</b>	<b>39,242</b>	<b>40,941</b>	<b>42,053</b>	<b>43,357</b>	<b>44,517</b>	<b>45,156</b>	<b>45,630</b>	<b>45,739</b>	<b>45,994</b>	<b>46,108</b>	<b>45,776</b>	<b>47,047</b>	<b>48,354</b>	<b>49,616</b>
Net financial income after tax	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>Profit for the year</b>	<b>39,242</b>	<b>40,941</b>	<b>42,053</b>	<b>43,357</b>	<b>44,517</b>	<b>45,156</b>	<b>45,630</b>	<b>45,739</b>	<b>45,994</b>	<b>46,108</b>	<b>45,776</b>	<b>47,047</b>	<b>48,354</b>	<b>49,616</b>

### Pro forma analytical balance sheet

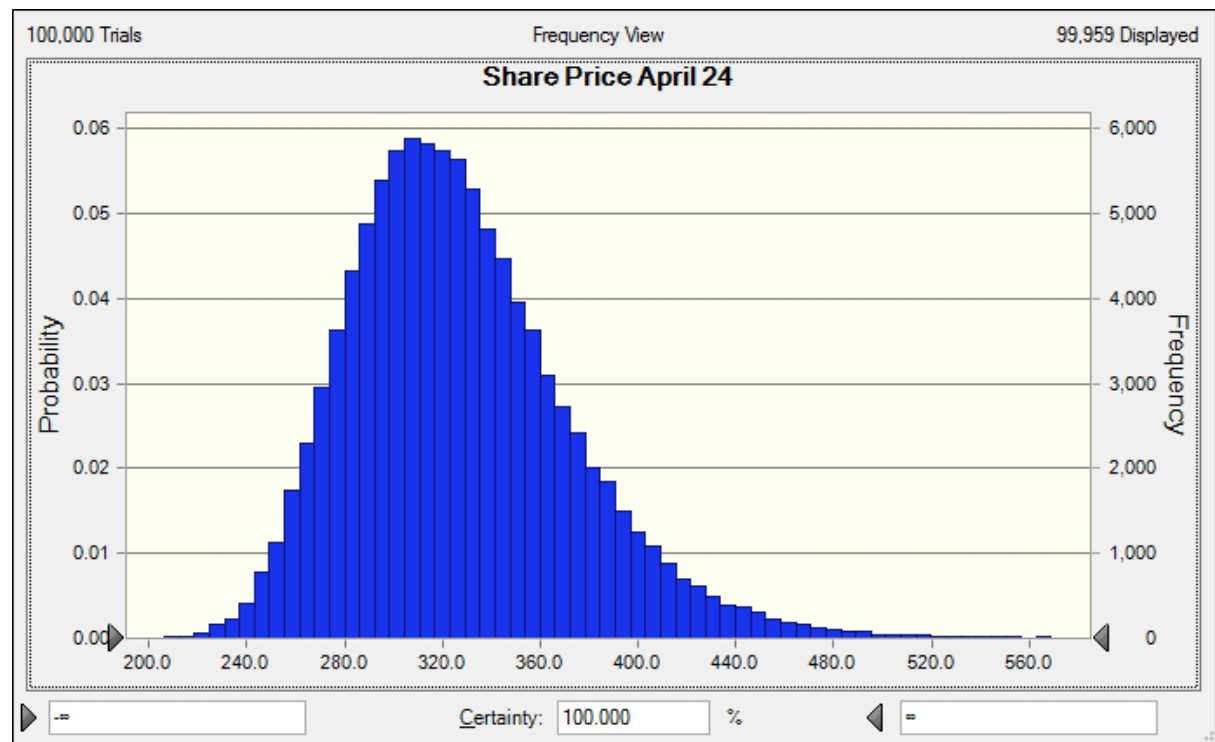
DKK million	E2017	E2018	E2019	E2020	E2021	E2022	E2023	E2024	E2025	E2026	E2027	E2028	E2029	E2030T
Intangible and tangible assets	17,325	19,155	20,844	22,760	24,745	26,576	28,433	30,179	32,140	34,132	35,912	36,908	37,934	38,924
Net working capital	14,437	15,448	16,284	17,243	18,195	18,983	19,745	20,391	21,145	21,879	22,445	23,068	23,709	24,327
<b>Invested capital (net operating assets)</b>	<b>31,762</b>	<b>34,603</b>	<b>37,128</b>	<b>40,003</b>	<b>42,940</b>	<b>45,559</b>	<b>48,178</b>	<b>50,570</b>	<b>53,284</b>	<b>56,011</b>	<b>58,357</b>	<b>59,976</b>	<b>61,643</b>	<b>63,251</b>
Equity, beginning of period	45,269	50,097	52,972	55,625	58,576	61,594	64,295	67,002	69,490	72,323	75,187	77,652	80,226	82,873
Net income	39,242	40,941	42,053	43,357	44,517	45,156	45,630	45,739	45,994	46,108	45,776	47,047	48,354	49,616
Dividends	(34,414)	(38,065)	(39,399)	(40,406)	(41,499)	(42,456)	(42,923)	(43,251)	(43,162)	(43,244)	(43,312)	(44,472)	(45,707)	(46,939)
<b>Total equity</b>	<b>50,097</b>	<b>52,972</b>	<b>55,625</b>	<b>58,576</b>	<b>61,594</b>	<b>64,295</b>	<b>67,002</b>	<b>69,490</b>	<b>72,323</b>	<b>75,187</b>	<b>77,652</b>	<b>80,226</b>	<b>82,873</b>	<b>85,550</b>
Net-interest-bearing debt	(18,358)	(18,358)	(18,358)	(18,358)	(18,358)	(18,358)	(18,358)	(18,358)	(18,358)	(18,358)	(18,358)	(18,358)	(18,358)	(18,358)
<b>Invested capital</b>	<b>31,762</b>	<b>34,603</b>	<b>37,128</b>	<b>40,003</b>	<b>42,940</b>	<b>45,559</b>	<b>48,178</b>	<b>50,570</b>	<b>53,284</b>	<b>56,011</b>	<b>58,357</b>	<b>59,976</b>	<b>61,643</b>	<b>63,251</b>

## Appendix 5: DCF Valuation

DKK million	E2017	E2018	E2019	E2020	E2021	E2022	E2023	E2024	E2025	E2026	E2027	E2028	E2029	E2030T
NOPAT	39,242	40,941	42,053	43,357	44,517	45,156	45,630	45,739	45,994	46,108	45,776	47,047	48,354	49,616
Depreciation	3,032	3,352	3,648	3,983	4,330	4,651	4,976	5,281	5,624	5,973	6,285	6,459	6,638	6,812
Δ Net working capital	2,357	(1,011)	(837)	(958)	(952)	(788)	(762)	(646)	(754)	(735)	(566)	(623)	(641)	(619)
Capital Expenditures	(10,217)	(5,217)	(5,464)	(5,976)	(6,396)	(6,563)	(6,921)	(7,124)	(7,703)	(8,103)	(8,183)	(8,411)	(8,644)	(8,870)
<b>Free cash flows to the firm (FCFF)</b>	<b>34,414</b>	<b>38,065</b>	<b>39,399</b>	<b>40,406</b>	<b>41,499</b>	<b>42,456</b>	<b>42,923</b>	<b>43,251</b>	<b>43,162</b>	<b>43,244</b>	<b>43,312</b>	<b>44,472</b>	<b>45,707</b>	<b>46,939</b>
WACC	7.11%	7.11%	7.11%	7.11%	7.11%	7.11%	7.11%	7.11%	7.11%	7.11%	7.11%	7.11%	7.11%	7.11%
Discount factor	0.934	0.872	0.814	0.760	0.709	0.662	0.618	0.577	0.539	0.503	0.470	0.439	0.409	
Present value of FCFF	32,129	33,179	32,063	30,699	29,437	28,116	26,539	24,966	23,261	21,758	20,346	19,504	18,715	
Present value of FCFF in forecast horizon	340,713													
Present value of FCFF in terminal period	427,088													
Estimated value of firm (enterprise value) mDKK	767,801													
Net interest bearing debt mDKK	-18,358													
Estimated market value of equity mDKK	786,159													
Implied share price	311.33													
Factor adjustment to the valuation date (113 days)	1.0215													
Estimated enterprise value April 24, 2017	784,302													
<b>Fair share price April 24, 2017</b>	<b>318.0</b>													

## Appendix 6: Results from Monte Carlo simulation

### Share Price April 24



Statistic	Forecast values
► Trials	100,000
Base Case	318.0
Mean	327.1
Median	321.7
Mode	---
Standard Deviation	45.7
Variance	2,091.9
Skewness	0.8543
Kurtosis	4.72
Coeff. of Variation	0.1398
Minimum	199.6
Maximum	869.0
Mean Std. Error	0.1

## Appendix 7: Consensus Estimates for Novo and competitors

### Novo Nordisk

Profit and Loss (DKKm)								
Fiscal Year (Year end: 31-dec)	2012	2013	2014	2015	2016	2017E	2018E	2019E
Revenue	78.026	83.572	88.806	107.927	111.780	116.220	121.667	128.271
Growth	n.a.	7,1%	6,3%	21,5%	3,6%	4,0%	4,7%	5,4%
Cost of goods sold	-11.475	-12.059	-12.316	-14.053	-15.045	-18.417	-19.742	-21.037
Gross profit	66.551	71.513	76.490	93.874	96.735	97.803	101.926	107.234
Margin	85,3%	85,6%	86,1%	87,0%	86,5%	84,2%	83,8%	83,6%
Selling, general & administrati...	-35.141	-38.018	-39.459	-44.987	-45.860	-44.446	-46.020	-47.727
Other operating costs	0	0	-639	0	0	n.a.	n.a.	n.a.
EBITDA	31.410	33.495	36.392	48.887	50.875	53.357	55.905	59.507
Margin	40,3%	40,1%	41,0%	45,3%	45,5%	45,9%	45,9%	46,4%
Depreciation	-2.413	-2.489	-2.653	-2.470	-2.432	-3.138	-3.502	-4.097
EBITA	28.997	31.006	33.739	46.417	48.443	n.a.	n.a.	n.a.
Margin	37,2%	37,1%	38,0%	43,0%	43,3%	n.a.	n.a.	n.a.
Amortisation	-160	-166	-143	-149	-219	n.a.	n.a.	n.a.
EBIT	28.837	30.840	33.596	46.268	48.224	50.219	52.403	55.410
Margin	37,0%	36,9%	37,8%	42,9%	43,1%	43,2%	43,1%	43,2%
Associated income	0	0	0	n.a.	n.a.	n.a.	n.a.	n.a.
Financial income	125	71	101	56	52	n.a.	n.a.	n.a.
Financial costs	-58	-55	-150	-148	-150	n.a.	n.a.	n.a.
Other financial items	-1.093	1.683	549	-2.707	-352	n.a.	n.a.	n.a.
Pretax profit	27.811	32.539	34.096	43.469	47.774	48.418	52.202	55.492
Margin	35,6%	38,9%	38,4%	40,3%	42,7%	41,7%	42,9%	43,3%
Extra ordinary items	0	0	0	14	24	n.a.	n.a.	n.a.
Tax	-6.379	-7.355	-7.615	-8.623	-9.873	-10.415	-11.202	-12.045
Net profit	21.432	25.184	26.481	34.860	37.925	38.003	41.000	43.447
Margin	27,5%	30,1%	29,8%	32,3%	33,9%	32,7%	33,7%	33,9%
Minority interests	0	0	0	0	0	n.a.	n.a.	n.a.
Net profit after minorities	21.432	25.184	26.481	34.860	37.925	n.a.	n.a.	n.a.
EPS (DKK)	7,9	9,5	10,2	13,7	15,1	15,2	16,4	17,3
Diluted EPS (DKK)	7,8	9,3	10,1	13,5	15,0	15,0	16,2	17,1
DPS (DKK)	3,6	4,5	5,0	6,4	7,6	7,5	8,5	9,2

## Sanofi

Profit and Loss (EURm)								
Fiscal Year (Year end: 31-dec)	2012	2013	2014	2015	2016	2017E	2018E	2019E
Revenue	34.947	32.951	33.770	34.542	33.821	36.627	37.641	39.269
Growth	n.a.	-5,7%	2,5%	2,3%	-2,1%	8,3%	2,8%	4,3%
Cost of goods sold	-9.890	-9.825	-9.886	-9.659	-9.500	-11.119	-11.317	-11.731
Gross profit	25.057	23.126	23.884	24.883	24.321	25.508	26.324	27.539
Margin	71,7%	70,2%	70,7%	72,0%	71,9%	69,6%	69,9%	70,1%
Selling, general & administrati...	-13.795	-13.301	-13.859	-14.399	-14.586	-13.820	-14.313	-14.829
Other operating costs	-225	-241	0	0	-9	n.a.	n.a.	n.a.
EBITDA	11.037	9.584	10.025	10.484	9.726	11.688	12.011	12.710
Margin	31,6%	29,1%	29,7%	30,4%	28,8%	31,9%	31,9%	32,4%
Depreciation	-1.201	-1.141	-1.174	-1.235	-1.174	-1.924	-1.812	-1.928
EBITA	9.836	8.443	8.851	9.249	8.552	n.a.	n.a.	n.a.
Margin	28,1%	25,6%	26,2%	26,8%	25,3%	n.a.	n.a.	n.a.
Amortisation	-3.396	-3.010	-2.574	-2.759	-1.816	n.a.	n.a.	n.a.
EBIT	6.440	5.433	6.277	6.490	6.736	9.764	10.199	10.782
Margin	18,4%	16,5%	18,6%	18,8%	19,9%	26,7%	27,1%	27,5%
Associated income	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Financial income	68	49	103	57	56	n.a.	n.a.	n.a.
Financial costs	-496	-457	-445	-416	-379	n.a.	n.a.	n.a.
Other financial items	-135	-422	-204	-888	-735	n.a.	n.a.	n.a.
Pretax profit	5.877	4.603	5.731	5.243	5.678	9.395	9.261	9.983
Margin	16,8%	14,0%	17,0%	15,2%	16,8%	25,7%	24,6%	25,4%
Extra ordinary items	393	35	-51	-146	448	n.a.	n.a.	n.a.
Tax	-1.134	-763	-1.171	-709	-1.326	-2.223	-1.773	-2.007
Net profit	5.136	3.875	4.509	4.388	4.800	7.173	7.489	7.976
Margin	14,7%	11,8%	13,4%	12,7%	14,2%	19,6%	19,9%	20,3%
Minority interests	-169	-158	-119	-101	-91	n.a.	n.a.	n.a.
Net profit after minorities	4.967	3.717	4.390	4.287	4.709	n.a.	n.a.	n.a.
EPS (EUR)	3,9	2,9	3,4	3,4	3,8	5,7	6,0	6,4
Diluted EPS (EUR)	3,9	2,9	3,4	3,3	3,7	5,5	5,8	6,2
DPS (EUR)	2,8	2,8	2,9	2,9	3,0	3,1	3,2	3,4

## Eli Lilly

Profit and Loss (USDm)								
Fiscal Year (Year end: 31-dec)	2012	2013	2014	2015	2016	2017E	2018E	2019E
Revenue	22.603	23.113	19.616	19.959	21.222	22.085	22.268	23.310
Growth	n.a.	2,3%	-15,1%	1,7%	6,3%	4,1%	0,8%	4,7%
Cost of goods sold	-3.334	-3.463	-3.554	-3.610	-4.158	-4.993	-5.144	-5.299
Gross profit	19.269	19.651	16.062	16.349	17.064	17.092	17.124	18.010
Margin	85,2%	85,0%	81,9%	81,9%	80,4%	77,4%	76,9%	77,3%
Selling, general & administrati...	-12.792	-12.657	-11.354	-11.329	-11.696	-10.801	-10.378	-10.586
EBITDA	6.478	6.994	4.708	5.020	5.368	6.292	6.745	7.424
Margin	28,7%	30,3%	24,0%	25,2%	25,3%	28,5%	30,3%	31,9%
Depreciation	-754	-891	-843	-796	-809	-808	-937	-891
EBITA	5.724	6.103	3.865	4.224	4.559	n.a.	n.a.	n.a.
Margin	25,3%	26,4%	19,7%	21,2%	21,5%	n.a.	n.a.	n.a.
Amortisation	-708	-555	-536	-632	-688	n.a.	n.a.	n.a.
EBIT	5.015	5.548	3.329	3.592	3.871	5.484	5.808	6.533
Margin	22,2%	24,0%	17,0%	18,0%	18,2%	24,8%	26,1%	28,0%
Associated income	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Financial income	105	120	121	87	109	n.a.	n.a.	n.a.
Financial costs	-178	-160	-149	-161	-185	n.a.	n.a.	n.a.
Other financial items	466	382	-301	-728	-421	n.a.	n.a.	n.a.
Pretax profit	5.408	5.889	3.000	2.790	3.374	5.498	5.898	6.602
Margin	23,9%	25,5%	15,3%	14,0%	15,9%	24,9%	26,5%	28,3%
Extra ordinary items	0	0	0	0	0	n.a.	n.a.	n.a.
Tax	-1.320	-1.205	-610	-382	-636	-1.159	-1.283	-1.455
Net profit	4.089	4.685	2.391	2.408	2.738	4.339	4.614	5.147
Margin	18,1%	20,3%	12,2%	12,1%	12,9%	19,6%	20,7%	22,1%
Minority interests	0	0	0	0	0	n.a.	n.a.	n.a.
Net profit after minorities	4.089	4.685	2.391	2.408	2.738	n.a.	n.a.	n.a.
EPS (USD)	3,6	4,2	2,2	2,2	2,5	3,9	4,2	4,7
Diluted EPS (USD)	3,7	4,3	2,2	2,3	2,6	4,1	4,3	4,8
DPS (USD)	2,0	2,0	2,0	2,0	2,0	2,1	2,2	2,3

Source: FactSet Research. Retrieved on April 24, 2017