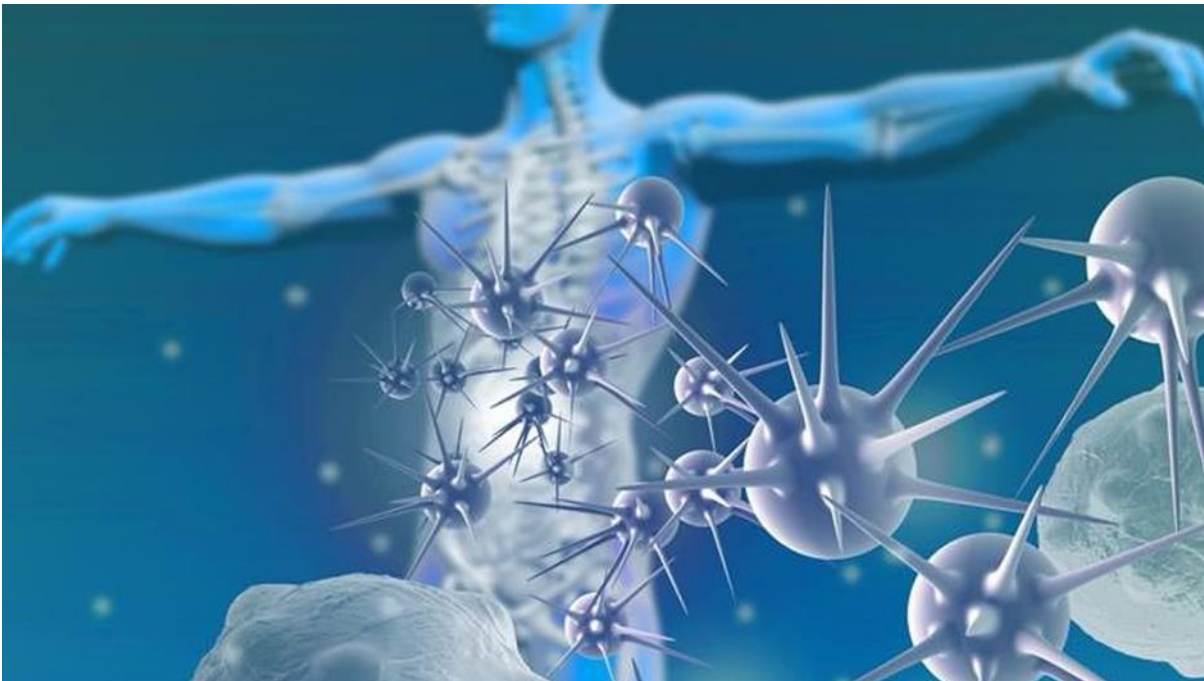


# **Strategic Analysis & Valuation of Genmab**



**Copenhagen Business School**

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## Executive Summary

The objective with my thesis was to make a valuation of Genmab the 22 of February 2017, and challenge the market value of this date.

Genmab are a small Danish biotech company, specializing in the development of human antibodies, used within cancer treatments. Until 2015, Genmab only had one drug on the market, marketed through its collaborating partner Novartis. The success of this drug has been mixed, but has decreased over the last couple of years. Ever since the introduction of Darzalex, things have changed around for Genmab, and they are now a profitable biotech with a potential blockbuster drug in their portfolio.

Some of the things I discovered through my strategic analysis was, that the markets Genmab operates in at the moment are small markets which are in the need of better treatments. These markets are driven by special regulatory designations which helps bring new therapies to patients. These regulatory designations also increase the competition within these markets. The expected competition is judged to be increasing in the coming years, which Genmab needs to face in the future. Further the industry is seeing increased price pressure from political side, which can decrease the future profit margin for Genmab.

I also found out that Genmab are heavily relying on its collaborating partners, in order to bring their drugs to the market. Both of Genmabs marketed drugs are marketed through Novartis and Janssen Biotech Inc. This means that Genmab are relying on these collaborating partners effort in selling Genmabs drugs. Further Genmabs focused strategy seems to pay of relative to other small biotech companies, which are one of Genmabs strong sides.

In my valuation of Genmab, I have chosen to use the DCF model and the RI model. Both yields an enterprise value of 68,648.827 million, as of 22 of February 2017. The stock price was estimated to be DKK 1137.5, which is well under the quoted price of DKK 1415. But this value is highly sensitive to the cost of capital used and the input parameters used to calculate the Cost of Capital. The lowest share price found through my sensitivity analysis was DKK 898, while the highest share price was DKK 1524.

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## Chapter 1- Introduction

Cancer is the second leading cause of death globally. According to WHO, 8.8 million people died from the disease worldwide. Cancer has a huge economic impact globally, and the estimated cost of cancer was approximately USD 1.16 trillion in 2010<sup>1</sup>. Cancer is not just affecting the economy, but also the patients and relatives struck by this awful disease. People who get cancer will have to go through a long treatment process which will turn their life's upside down, both economically but also through very severe side-effects from the disease and the treatment itself.

There has been a growing awareness of the impact of the disease, and special awareness days have been introduced like the World's Cancer Day and Movember. This both helps bring awareness to cancer, but also serves as charity events to raise funds which can be used in research.

In 2015, the global market spending on cancer drugs was estimated to be USD 107 billion, and is expected to increase to USD 150 billion in 2020<sup>2</sup>. This increase is partly driven by the introduction of new types of therapies like antibodies and other immunotherapeutic drugs, which has shown significant improvement in the treatment of cancer above the usual chemotherapeutic approach.

Genmab is a relatively small biotech company, specialising in the discovery and development of antibodies targeting cancer forms which is hard to treat by already existing treatments. Ever since Genmab was founded in 1999, it has been struggling to make profits for its shareholders and it's only in recent years that Genmab has achieved this. This is highly driven by their newly introduction of Darzalex, which is marketed by its collaborating partner Janssen Biotech Inc.

Ever since, Genmab has been a very hot topic in the media's and amongst investors, and Genmab's stock has sky-rocketed within a short span of time. This is also the reason why I have chosen to perform a valuation of Genmab. I therefore wish to challenge the market value of Genmab's stock through my own valuation of Genmab.

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<sup>1</sup> <http://www.who.int/cancer/en/> [25/05 2017]

<sup>2</sup> <http://www.nbcnews.com/health/cancer/global-cancer-drug-market-grows-107-billion-n584481> [25/05 2017]

## 1.1 Problem statement

The goal of this thesis is to make a strategic analysis and valuation of Genmab on the 22.02.17.

Further I want to compare with the quoted share price at that date, to see if my result differ from the market price. This leads to the following main question as stated below:

*What is the estimated fair-value of Genmab on the 22.02.17, and how does this compared to the markets share price?*

To answer this, I will find answers to the following sub questions:

### Valuation models

What are the valuation methods used, and which valuation model should I use to value Genmab?

### Strategic analysis

*What macro- and industry specific factors, has influence on Genmabs future value creation?*

*What are the internal value drivers of Genmab?*

### Financial analysis

What are Genmabs sources of Income?

How are Genmabs financial performance compared to peer companies?

### Forecasting

*Based on the strategic analysis, how will Genmabs expected future revenue be?*

*Based on the strategic analysis and financial analysis, how does Genmabs pro forma statement look like?*

### Valuation

*What is the estimated cost of capital for Genmab?*

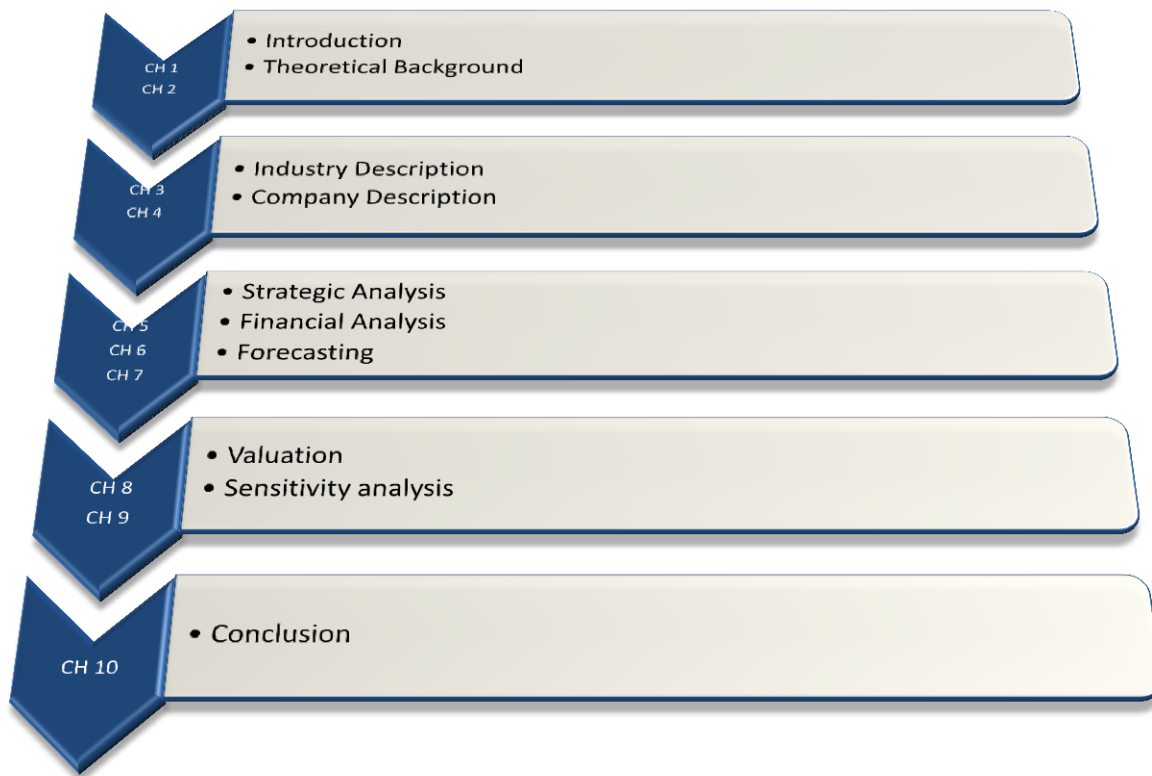
*What is the estimated fair value of Genmab?*

*What is the estimated share price of Genmab?*

### Sensitivity

*How sensitive is the estimated share price?*

## 1.2 Structure



Source: Authors own Creation

### Theoretical Background

This section will give a description of relevant theories relating to my thesis. Further I will argument for my choice of theories used in my thesis.

### Industry description

The industry description will give an overview of the Pharma and Biotech industry in general. The intention is to give a general understanding of the industry and what the main characteristics is of this type of business. The topics I will describe is the difference between chemical and biological drugs, the patent process and the discovery and development.

### Company description

In the company description, I will introduce Genmab where some of the following topics will be described: Genmabs History, stock information, what their marketed drugs is, technologies and some of their pipeline drugs.

### Strategic Analysis

This section is divided into macro, industry and internal analysis of the factors that can influence Genmabs' future value creation. To analyse the macro environment I have chosen to use the SLEPT model. To describe the industry factors I have chosen to use Porters Five Forces. To describe the internal factors, I will make an analysis of the company's physical, human, financial and immaterial resources.

### Financial Analysis

In the financial section, I will both be doing an analysis of Genmabs sources of Revenue, and the development in these, which serves as preparation to the pro forma statements. Further I will be analysing Genmabs financial value drivers, and compare these to peers in order to assess Genmabs performance.

### Forecasting

Based on the results from the strategic and financial analysis, I will be forecasting Genmabs pro forma statement.

### Valuation

This section starts out by estimating the input parameters necessary to estimate Genmabs Cost of Capital. Further I will be estimating Genmabs enterprise value and its share price.

### Sensitivity analysis

With the sensitivity analysis, I will see how sensitive Genmabs share price are by changing relevant input parameters.

### Conclusion and discussion

In this section I will be answering my problem statement, and discuss the results found.



### **1.3 Choice and critic of data**

To answer the problem statement I make use of secondary data, which can be acquired through Genmabs annual reports, scientific articles, news media, homepages, databases etc. The reason for this is that in a typical valuation with the goal of stock investing, an analyst would not have access to primary data from the company and its employees.

In the thesis I will make use of both qualitative and quantitative data. The information about Genmab and its drugs is mainly based from its webpage and yearly reports. The reliability of these data is estimated to be high, even though that Genmab might have an interest in presenting the company in a more positive way.

To gather information about the diseases and other scientific areas within the field, I use organisational webpages which stems from governments and other private organisational webpages. These organisations should not have an interest in altering the truth for their own benefit. Further I make use of scientific articles which has been published. These materials are judged to be very reliable.

Other gathering of material and data, are done through a judgemental process where I always try and assess the validity and reliability of these sources.

The theories and models which are used in my thesis have a long track record and are custom within the valuation framework. These theories and models are judged to be reliable.

Overall, the data which my thesis are based upon is judged to be reliable.

### **1.4 Delimitation**

The main focus in this thesis will be on the market in the US and in Europe since these accounts for the majority of the sales revenue.

Even though that Genmab with its collaborating partner Janssen Biotech Inc is looking to expand to the Asian market, I will not go through this in my Thesis.

Genmab has multiple drugs in its pipeline, I will only give a short description of the drugs which are in Trial 3 phases.

My valuation is on the day of the 22 February, so all information after this date will not be considered in my thesis.

There will be a natural weight on Darzalex, because this drug offers the biggest and most important value creation for Genmab at this point of time.

Due to Genmab restructuring and the dramatic increase in profitability, the historical period is ranging from 2013-2016. I have chosen this period because this best represent Genmab today, and should be the best representation of Genmabs performance in the future.

Genmab makes use of warrants, for their employees. These warrants will not be considered in my thesis.

There are two disease targets which are in phase 3 clinical trials, Multiple Sclerosis and Follicular Lymphoma. But after analysing the market, I have chosen to remove the Treatment of Follicular Lymphoma. This is due to the decreasing market, according to Genmabs Annual Report 2016, and that Rituxan from Roche is already in use for this disease. Looking at the effect that Rituxan has had in the treatment of Chronic lymphocytic lymphoma, I do not think that Arzerra will have any positive results in this market. This is of course hard to say, when the drug has not yet been finally tested, but the two drugs are belonging to the same class of drugs, which are monoclonal antibodies aimed at the CD20 antibody.

The valuation of Genmab is based on the assumption that Genmab is being a going concern, and that it will be operational for eternity. Further the company are valued on a stand-alone basis, where synergies from a merger will not be considered.

The punctuation style for numbers is written as English punctuation. This does not include dates.

## Chapter 2- Theory

This section will give an overview of the relevant theories used in my thesis. It will give a description of the different assumptions used, and what their drawbacks is. Moreover I will argument for the choice of valuation model.

### 2.1 Strategic analyses

#### 2.1.1 Macro analysis

To analyse what macro factors that influences the value creation of Genmab, I have chosen a variation of the PESTLE model, known as the SLEPT model. The SLEPT model put emphasis on Social, Legal, Economic, Political and Technological factors<sup>3</sup>. I have chosen this variation because it includes factors that are judged important in analysing Genmab.

#### 2.1.2 Industry analysis

To analyse the industry, I will use Porters Five Forces, which looks at five industry factors which influences the company's ability to create value for its stock holders. The five forces in an industry that influences the company's value creation are; Threat of Entrants, Bargaining power of suppliers, Threat of substitutes, Bargaining power of Buyers, And Rivalry among existing competitors(Porter, 2008). I have chosen this model, because it enables me to separate the most important influencing factors in the industry, and serves the purpose of the Industry analysis well.

#### 2.1.3 Internal analysis

For the internal analysis, I have chosen to divided Genmabs' resources into Physical, Human, Financial and Intangible resources according to Petersen and Plenborg(2012). This seems appropriate, when assessing Genmabs resource base.

I could have chosen to use Porters a value chain analysis, but this seem to be irrelevant when taking into account, that the value chain of Genmab mainly consist of its R&D.

### 2.2 Present value approaches

When using present value approaches, you can both do a valuation of the enterprise value or the value of the Equity. The difference between the two is that if you value the enterprise, you need

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<sup>3</sup> <http://www.mbaskool.com/business-concepts/marketing-and-strategy-terms/8377-slept-analysis.html> [25/03 2017]

to subtract the Net interest bearing Debt (NIBD) to get the value of Equity. Moreover you will use the Weighted Average Cost of Capital (WACC) as the discount rate. Genmab does not have any debt financing, and therefore I will go through the valuation models from an Equity valuation approach.

### 2.2.1 Dividend Discount Model

The dividend discount model, also called Gordons Growth model, is the basis of the other present value Approaches. The dividend discount model values a company's equity by discounting its expected future dividend payments with the required rate of return on equity. Below the formula for the two stage model are shown:

**Formula 1: Dividend Discount Model**

$$\text{Market value of equity}_{y_0} = \sum_{t=1}^n \frac{\text{Dividend}_t}{(1+r_e)^t} + \frac{\text{Dividend}_{n+1}}{(r_e+g)} * \frac{1}{(1+r_e)^n}$$

Source: Petersen & Plenborg (2012), pp 214

Where n is the number of periods with extraordinary growth rates, and g is the long term stable growth rate.

In the two-stage dividend model, the market value of equity is divided into two stages, where the first stage is the forecast horizon, and the second stage is the terminal period, with a constant growth rate which is usually the long term growth rate of the economy which the company operates in.

The Dividend discount model, is relying on easy accessible and understandable information, which can make this model seem as an attractive model to use in valuation (Sørensen, 2011).

Some of the shortcomings with the Dividend Discount Model are that the model does not offer any intuitive explanations between the difference of the book value of equity, and the estimated market value. Moreover, dividends are seen as a distribution of value and do not tell anything about how value is created in (Petersen & Plenborg, 2012). Other shortcomings are that dividend policies is usually a complex matter determined by the board of directors in a company, and it is

most suitable for companies which pays out dividends (Sørensen, 2011). Genmab does not pay dividends to its shareholder, and therefore I will not be using this model.

### 2.2.2 The discounted cash flow model

The discounted cash flow model (DCF), is one of the most widely used model in valuation context. The DCF model relies on the estimated cash flows to the equity owners, discounted with the investors required rate of return to equity holders. Below the formula for the two-stage model is presented:

#### **Formula 2: Discounted Cash Flow Model**

$$\text{Market value of equity}_0 = \sum_{t=1}^n \frac{FCFE_t}{(1+r_e)^t} + \frac{FCFE_{n+1}}{r_e - g} * \frac{1}{(1+r_e)^n}$$

Source: Petersen & Plenborg (2012), pp 217

Where  $FCFE_t$  are the cash flow to the equity owners in time period t, and  $r_e$  is the investors required rate of return.

The DCF model rest on the assumption that cash surpluses is either paid out as dividends or reinvested in zero NPV projects. If this assumption is not violated, the model gives an unbiased valuation.

Some of the shortcomings of the model are that this model does not offer any explanation of the differences in book value of equity and the estimated value of equity (Petersen & Plenborg, 2012). Further, the FCFE is not easily accessible and needs to be estimated by the analyst. This usually demands a deep knowledge of the company to be valued (Sørensen, 2011).

### 2.2.3 Residual Income Model

The Residual Income (RI) is an excess return approach, which is relying on accrual accounting data instead of cash-flow based data. The formula for the two-stage RI model is shown below:

#### **Formula 3: Residual Income Model**

$$\text{Market value of equity}_0 = \text{Book value of equity}_0 + \sum_{t=1}^n \frac{RI_t}{(1+r_e)^t} + \frac{RI_{n+1}}{R_e - g} * \frac{1}{(1+r_e)^n}$$

Source: Petersen & Plenborg (2012), pp 221

Where  $RI_t$  is the residual income in time period t. The calculation of the residual income is shown below:

**Formula 4: Residual Income**

$$RI_t = \text{Book value of equity}_{t-1} * (\text{return on equity}_t - r_e)$$

Source: Petersen & Plenborg (2012), pp 221

The RI model relies on the assumption of clean-surplus, which means that all revenues, expenses, gains and losses in the forecast period are recognised in the income statement. If this assumption is violated, it will lead to a biased valuation (Petersen & Plenborg, 2012).

Some of the positive attributes of this model is that the terminal value weighs less than in the other two models. Second it builds on accessible accounting data (Sørensen, 2011). This valuation approach is easier to understand, because it offers an explanation to the differences in the book value of equity and the estimated market value of equity. In computational terms, the same inputs needs to be done as in the DCF model, and is therefore just as time-consuming (Petersen & Plenborg, 2012).

Some of the shortcomings of this model are that it builds on heavy accounting conventions, and that it is sensitive to accounting manipulation (Sørensen, 2011).

The DCF valuation model is relatively easy to use, and easy to understand model, which is why I have chosen to use this model in my valuation. I will also use the RI model, to access the quality of my DCF valuation. The two models should be leading to the same Estimate, unless something is wrong.

## 2.3 The relative valuation approach

The relative valuation approach, or Multiples approach, are another way to calculate a company's value. This approach is also a way of test the value calculated from the discounted value approaches. The usual multiples used are for example P/E, EV/EBIT or EV/Revenue. These multiples are calculated from comparable peers who are in the same industry. This model may seem simple to use, but it is not because you need to put an effort in finding the right peer

companies to use. The peer companies should be identical in performance amongst other things (Petersen & Plenborg, 2012).

Due to Genmabs positioning as a growth company, I choose not to use the multiples approach since this will most likely lead to wrong estimates due to lack of relevant peer companies.

## **Chapter 3 - Industry description**

The purpose of this section is to give an overview of how the Pharma-and Biotech industry works. A more focused analysis of some of the implications that this industry can face will be part of the strategic analysis. The section will start with an introduction to chemical and biological drugs. Moreover there will be an elaboration of the drugs life-cycle, including patent rights, and special regulatory designations.

### **3.1 Biological drugs versus chemical drugs**

#### **3.1.1 Biological**

A biological drug is usually manufactured in living cells, such as human or animal cells. The molecules in biologics are very large and complex, compared to that of chemical drugs. The production is much more complex, where the process is of high importance in order to make a consistent drug. Small changes in the manufacturing process can change the way the biological drug functions in the body. So there need to be a very tight control of the manufacturing process when producing a biological drug. This is a type of drug which is not easily replicated because small changes in the production, can change the effect of the drug (Morrow & Felcone, 2004). Genmab produces drugs composed of antibodies, and is thus a biological drug.

#### **3.1.2 Chemical**

Chemical drugs are manufactured through chemical synthesis. This means that you combine different chemicals in an ordered process. The manufacturing process of chemical drugs is much simpler and usually cheaper than for biological drugs. It is possible to analyse the various components in a chemical drug in a lab, which makes it easier to reproduce (Morrow & Felcone, 2004).

### 3.2 Product life-cycle

The introduction of a new drug to the market is a very long and costly affair to engage in, with a high risk of a drug not entering the market, either due to lack of efficacy, high degree of risk for patients, or that the drug is not economically sufficient when it is brought to market. According to the California Biomedical Research Association, it takes on average 12 years from the research phase till the drug reaches market, and the average cost is USD 359 million<sup>4</sup>. But this cost varies a lot, and depends on whether you include the cost of failures, size of the company etc. Due to the high cost of the development process, the cost is brought on to the patients, which makes these drugs very expensive to purchase. This is also why these drugs are protected by patents, and other regulatory ways of extending the time on the market for a drug.

In figure 1 below, is shown the process of discovery and development for Genmab. The process consists of a pre-clinical phase and a clinical phase. In the pre-clinical phase, Genmab discovers and test the properties of antibody candidates. Once the specific antibodies have been discovered, they will perform in vitro and in vivo test, to test for efficacy and safety before entering into the human trials. This has to be performed, before Genmab can apply for human trials.

Once the drug reaches human trials, there are 3 phases which the drug will go through. The first phase and second phase is to test for safety in a small number of healthy volunteers, and a small number of patients. Once the drug has proven safe, they will enter into phase 3, where they start testing for efficacy. This is done with a large number of patients to establish significance in efficacy and safety (Keegan, 2008).

Once the drug has been approved for marketing, it will enter a Post-marketing surveillance which intends to monitor the ongoing safety and efficacy of the drug (Keegan, 2008). It might be the case that there are some severe side-effects which was not discovered in the trial phases, which can change the label of the drug.

#### ***Figure 1: Genmabs Discovery and Development process***

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<sup>4</sup> <http://www.ca-biomed.org/pdf/media-kit/fact-sheets/CBRADrugDevelop.pdf> [05/03 2017]





Source: Genmab Annual Report 2016, pp 14

### 3.3 Patent rights

As can be seen above, the length of time that it takes to develop a new drug and market it, is very long. Fortunately the company have some protection of its drug through patent rights. A new patent right usually last for 20 years, where no other company can replicate the compound of the drug. Once the patent runs out, other companies can replicate the drug and produce what is called generic drugs or biosimilars, which only cost a fraction of what the original drug costed. Generic drugs and biosimilars shorten the life-cycle of the original drug (Keegan, 2008).

Even though that the patent last for 20 years, the drugs life-cycle will usually not last that long, because that the company will be filing for patent rights long before the drug is marketed.

According to (Keegan, 2008), the drug is only protected for 7-12 years from entering the market to the patent runs out.

Due to these factors there exist patent extensions, which increase the patent protection period with a certain amount of years. In the US, it is called "Patent term Restoration", which can extend the patent protection with up to 5 years, as long as the total number of years does not exceed 14 years from the marketing date<sup>5</sup>. In Europe a company can apply for a "Supplementary Protection

<sup>5</sup> <https://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069959.htm> [17/05 2017]

certificate”, which extends the life of the patent with the maximum of 5 years<sup>6</sup>. A company can also try and extend the drugs life cycle, by applying for patents that cover other uses of the drug. In extension to patent extensions, there exist special designations granted from FDA and EMA to drugs which treat rare and life-threatening diseases, which will be described below.

### **3.4 Special FDA and EMA designations**

#### **3.4.1 Breakthrough Therapy Designation**

The breakthrough therapy designation is granted by the FDA, in order to quicken the time it takes to review a drug application. If a drug is designated as a breakthrough therapy, FDA will review the marketing application within 60 days from the granted designation.

The breakthrough therapy designation is granted if a drug is meant to treat a serious or life-threatening disease or if there is early evidence that the drug can offer an improvement in the treatment of a disease over other already existing drugs<sup>7</sup>.

#### **3.4.2 European Conditional Marketing Authorization**

The European Conditional marketing Authorization(CMA) helps to speed up the access to drugs for patients with unmet medical needs. This is typically patients who are suffering from debilitating or life-threatening diseases.

The EMA grants the CMA if it is proved that the benefit of immediate availability to patients, outweighs the risk that the drug offers. The CMA is valid for 1 year, where the company is obligated to conduct further studies, which is reviewed annually by EMA, with intention of renewing the CMA<sup>8</sup>.

#### **3.4.3 Orphan Drug designation**

[FDA orphan drug designation:](#)

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<sup>6</sup> [https://ec.europa.eu/growth/industry/intellectual-property/patents/supplementary-protection-certificates\\_da](https://ec.europa.eu/growth/industry/intellectual-property/patents/supplementary-protection-certificates_da) [17/05 2017]

<sup>7</sup> <https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDASIA/ucm329491.htm> [05/03 2017]

<sup>8</sup> [http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2017/01/news\\_detail\\_002680.jsp&id=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/01/news_detail_002680.jsp&id=WC0b01ac058004d5c1) [04/03 2017]

The orphan drug designation (ODD) is for drugs used to treat rare diseases, where it is expected that the applying company, will not recover the cost of developing the drug from sales in the US.

On FDA's webpage, a rare disease is defined as<sup>9</sup>:

“

1. *It affects less than 200.000 individuals in the US*
2. *Or it affects more than 200.000 individuals in the US, without it being possible to cover the cost of development and distribution by sales in the US.*

“

**Source:** [www.fda.gov](http://www.fda.gov) (See footnote 9 below for direct reference)

If a drug is granted ODD, it will get tax credits on clinical trials, 7 years of market exclusivity and fast track procedures amongst other things.

#### EMA orphan drug designation:

The EMA ODD is inspired by the FDA ODD, and is therefore very similar. For a drug to receive orphan drug status its must meet the following criteria<sup>10</sup>:

“

1. *It must be intended as treatment for a life-threatening disease or a chronically debilitating disease.*
2. *The prevalence of the disease in EU must not exceed 5 in 10.000, or it must be unlikely that marketing generates sufficient returns to cover its development cost.*
3. *There exist no satisfactory method of treatment, or the drug must be of significant benefit for the patient.*

“

**Source:** [www.ema.europa.eu](http://www.ema.europa.eu) ( See footnote 10 for direct reference)

The benefits from receiving the ODD are that the company will receive protocol assistance, 10-years of market exclusivity, and a reduction in fees related to EMA.

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<sup>9</sup>

<https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/ucm364750.htm> [04/03 2017]

<sup>10</sup>

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000029.jsp&mid=WC0b01ac0580b18a41](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000029.jsp&mid=WC0b01ac0580b18a41) [04/03 2017]

## Chapter 4 – Company Description

### 4.1 Introduction to Genmab

Genmab is an international biotech company, specializing in the creation and development of antibodies used to treat certain types of cancer. Genmab was founded in 1999 in Copenhagen, and was listed on the Copenhagen and Frankfurt stock exchange through an IPO. Genmab Raised DKK 1.56 billion, which was a European Biotech record at that time. In 2002 they announced their ofatumumab program, which their first marketed drug, Arzerra, is built on. In 2009 Arzerra was granted accelerated approval by the FDA to treat certain lines of therapy in patients with CLL, and was later that year launched for sale by Genmabs collaborating partner, GSK. The following year, Arzerra was approved in EU for the treatment of certain lines of therapy in patients with CLL. In 2012, Genmab entered into a worldwide agreement with Janssen Biotech Inc, for their daratumumab program. Darzalex(daratumumab), receives Breakthrough Therapy Designation by the FDA in 2015, which is approved for use in certain lines of therapy for patients with Multiple myeloma. And in 2016 it received a Conditional Marketing Authorization by the EU for certain lines of treatment in patients with Multiple Myeloma<sup>11</sup>. Since the collaboration with Janssen, and the introduction of Darzalex, Genmabs revenue has increased drastically.

Genmab has its headquarters and clinical development team in Denmark. Moreover, Genmab has its research and development laboratory in the Netherlands, and administrative functions in the USA. As can be seen in figure 2, Genmab A/S runs its foreign operations through its subsidiaries which are 100% owned by Genmab A/S directly or indirectly. In 2015 Genmab created a new subsidiary which is a holding company, who owns Genmab B.V in the Netherlands<sup>12</sup>. Genmab is employing 205 people distributed amongst the 3 countries.

Genmab currently has two drugs on the market, Arzerra and Darzalex, which is marketed through their collaborating partners, Novartis and Janssen Biotech Inc. Besides the two marketed drugs, Genmab has 9 drugs in clinical development, spanning from early stage development to late stage development. Further, they also have two proprietary technologies for antibody development,

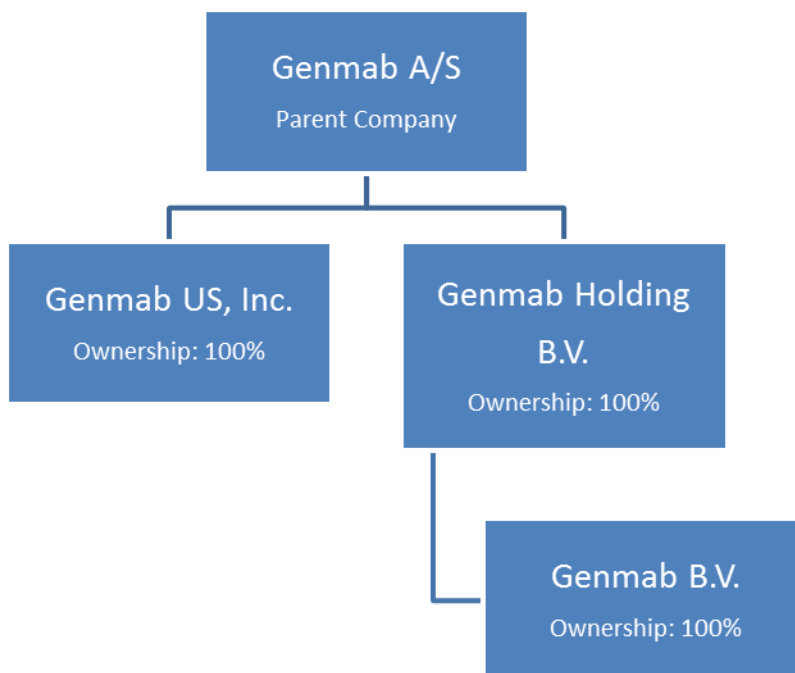
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<sup>11</sup> <http://www.genmab.com/about-us/history> [01/03 2017]

<sup>12</sup> Genmab: Annual Report 2016, pp 114

which are both used in the production of antibodies, as well as out-licensing to other biotech companies<sup>13</sup>.

**Figure 2: Genmabs Company Structure**



Source: Authors own creation

#### 4.1.1 Stock and shareholder information

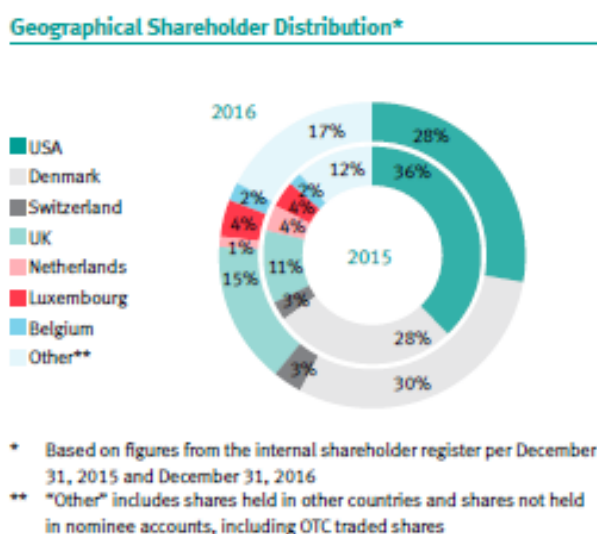
Genmab is publicly traded on the Copenhagen Nasdaq and is also traded under an ADR-program in USA. Since 2013 Genmab has been included in the Danish OMXC 20 Index. Genmab has 64,692 registered shareholders, with a geographical distribution as can be seen in Figure 3 below<sup>14</sup>. The share capital is comprised of 60,350,056 shares with a nominal value of 1 DKK, where each share has one vote<sup>15</sup>.

<sup>13</sup> Genmab Annual Report 2016, pp 4

<sup>14</sup> Genmab Annual report 2016, pp 56

<sup>15</sup> Genmab Annual report 2016, pp 103

**Figure 3:Geographical Shareholder distribution**



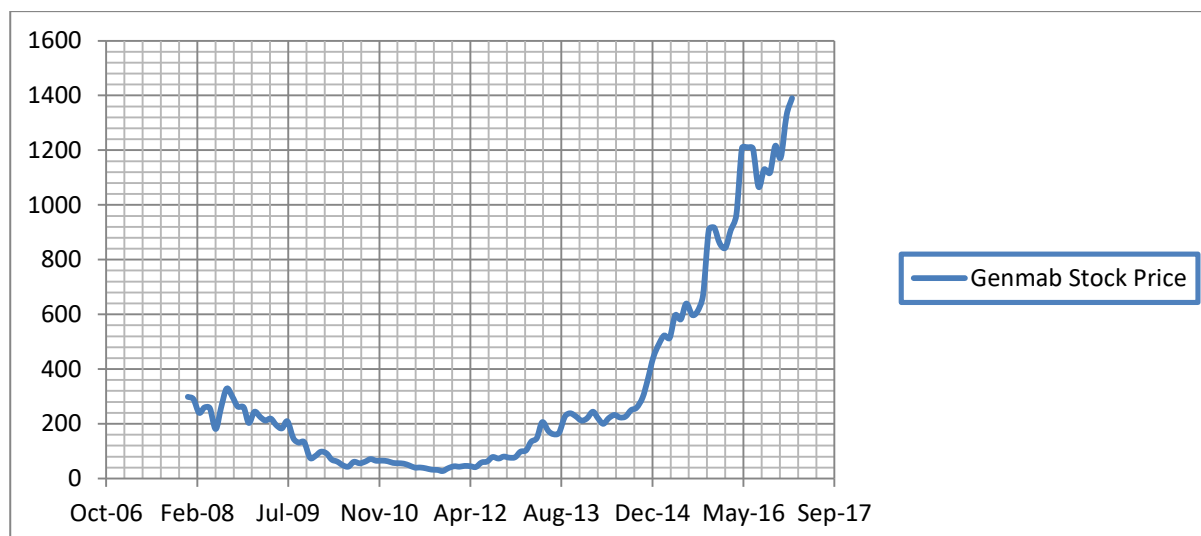
Source: Genmab Yearly Reports 2016, pp 56

#### 4.1.2 Stock Performance

As can be seen from the figure 4 below, Genmabs stock has been on the rise since 2012. In 2011 the stock was at its lowest in the chosen period, going from a low of approximately 27 DKK in 2011, to a high of 1390 DKK in Jan-2017. This corresponds to an increase of the stock price of around 5000 %. In 2014, the stock price starts to increase sharply, which can partly be explained by the approval of Arzerra for new lines of indication in CLL patients, in both the US and in EU. Same year, Genmab raised around DKK 1 billion through private placements<sup>16</sup>. In 2015 the stock takes an even sharper rise, when Darzalex is approved in the US.

<sup>16</sup> <http://www.genmab.com/about-us/history> [05/03 2017]

**Figure 4: Genmabs stock performance 2008-2017**



Source: Authors own creation

#### 4.1.3 Business model and Strategy

In order to get their drugs to market, Genmab make use of strategic collaborations with big pharmaceuticals and biotech companies, which has the resources within commercialization, distribution and research capabilities. Genmabs 2 marketed drugs, has been developed and commercialized in collaboration with Novartis and Janssen Biotech Inc., from where Genmab receives milestone payments and royalties from sales and regulatory approvals.

Genmab makes use of in-licensing as well as out-licensing of technologies to help support its business operations<sup>17</sup>. From out-licensing Genmab receives upfront payments, milestone payments and potential royalties, if the drug which is built on Genmabs technology, makes it to the market.

Genmab uses a focused strategy within discovery and development of differentiated antibodies. Their main focus are on disease targets with high commercial potential, where they can offer better efficacy, or be the first-in-class with their antibodies. Moreover they are building up a strong capital position, from which they can invest in the continuing business development<sup>18</sup>.

<sup>17</sup> <http://www.genmab.com/partnering/our-approach> [05/03 2017]

<sup>18</sup> <http://www.genmab.com/about-us/strategy> [26/02 2017]

## 4.2 Products and Technologies

### 4.2.1 Introduction to antibodies

Antibodies are a type of proteins produced by the immune system to help fight viruses and other diseases. The way they work is by attaching to antigens in the body where they are able to recruit the immune system to attack and destroy the cell which contains the antigen. It is possible to design the antibodies to attach to a specific antigen, which exist in the cancer cell. When researchers discover a specific antibody for a certain type of cancer, they will produce many of these antibodies in the lab. These antibodies are called monoclonal antibodies<sup>19</sup>.

There are different types of antibody drugs used for cancer which will be described below:

- Naked monoclonal antibodies: These are the most common type of antibodies. The reason they are called naked monoclonal antibodies, is because that there are no drugs or radioactive materials attached to them<sup>20</sup>.
- Conjugated monoclonal antibodies: These are antibodies which are attached to a chemotherapeutic drug or a radioactive particle. It works by taking the attached drug or particle directly into the cancer cell. There are two types of conjugated monoclonal antibodies, *Radiolabeled antibodies* which has small radioactive particles attached to them. And then there are *Chemolabeled antibodies*, which are attached to a strong chemotherapy drug. These are also called *antibody-drug conjugates(ADC's)*<sup>21</sup>.
- Bispecific monoclonal antibodies: These antibodies are designed to attach to two different antigens. For example they can be designed to attach to a cancer cell, and the immune systems t-cell<sup>22</sup>.

### 4.2.2 Marketed drugs

#### 4.2.2.1 Arzerra (ofatumumab)

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<sup>19</sup> <http://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/monoclonal-antibodies.html> [08/01 2017]

<sup>20</sup> <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/monoclonal-antibodies.html> [08/01 2017]

<sup>21</sup> <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/monoclonal-antibodies.html> [08/01 2017]

<sup>22</sup> <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/monoclonal-antibodies.html> [08/01 2017]



Arzerra is Genmabs first marketed antibody drug, which are used to treat Chronic Lymphocytic Leukemia (CLL). Arzerra was approved for sale in the US in 2009 and in EU in 2010. Arzerra is a human antibody which targets a protein on the cancer cell, called CD20<sup>23</sup>.

Approved indications as written in Genmabs annual report of 2016<sup>24</sup>:

“

1. *First line CLL in combination with Chlorambucil in the US.*
2. *First-line CLL in combination with Chlorambucil or bendamustine in the EU.*
3. *As a monotherapy for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive CLL in the US.*
4. *Relapsed CLL in combination with FC in the US and EU.*
5. *As monotherapy for CLL refractory to floundabine and alemtuzumab.* “ Source:

**Taken from Genmabs Annual Report 2016, pp 17**

### Chronic Lymphocytic Leukemia (CLL)

CLL is a type of cancer which exists in the bone marrow of patients, where the bone-marrow produces too many white blood cells. It is the most common type of cancer in the western world, and there exist no cure for this cancer yet. But the 5 year-survival rate is relatively good, with a 64%-83% survival rate in the US and in 5 major EU markets<sup>25</sup>.

In 2015, the reported incidents in US and 5 major EU markets were approximately 39,295 new incidents, and it is estimated that the number of new incidents will increase to 45,683 in 2023. The branded sales of CLL was 1.4 billion in 2013, and is estimated to increase to 3.6 billion in 2018, for the US and the 5 major European markets<sup>26</sup>.

### Partners

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<sup>23</sup> Genmab Annual Report 2016, pp 26

<sup>24</sup> Genmab Annual Report 2016, pp 17

<sup>25</sup> Genmab Annual Report 2015, pp 26

<sup>26</sup> Genmab Annual Report 2015, pp 26

In 2006, Genmab and GlaxoSmithKline (GSK) entered into a co-development and collaboration agreement for ofatumumab. In 2015, Novartis received the full rights to ofatumumab from GSK, and is now fully responsible for the development and commercialization of ofatumumab, including all cost associated with this. Genmab receives milestone payments and royalties for sales related to ofatumumab and regulatory approvals<sup>27</sup>.

#### Other disease targets in clinical phases:

- Follicular Lymphoma(phase III)
- Relapsing multiple Sclerosis(Phase III)

#### Multiple Sclerosis (MS)

Multiple sclerosis is a disease in the body's Central Nervous System, where the body's immune system mistakenly attacks the myelin in the central nervous system. This causes the forming of scar tissue in the myelin, which is why it is called Sclerosis. MS damages the nerve fibers which interrupts the nerve signals travelling through the central nervous system<sup>28</sup>. The effect of this is a wide variety of symptoms like fatigue, walking difficulties, spasticity and vision problems amongst other symptoms<sup>29</sup>.

According to Genmabs annual report, there are around 2.5 million people suffering from MS worldwide. And there will be an estimated number of new incidents of MS in US and 5 major European markets of 37,718. The market for MS were estimated to be worth 16.8 billion in 2016, and are expected to increase to USD 20.3 billion in the USA and 5 major European markets<sup>30</sup>.

#### 4.2.2.2 Darzalex (daratumumab)

Darzalex is Genmabs second marketed drug, which is currently being a huge success, and offers great potential of high revenues for Genmab. It was first approved for sale in the US in 2015, and in 2016 it was approved in EU<sup>31</sup>. Darzalex is a first-in-class human antibody, treating Multiple Myeloma. Daratumumab is a human antibody called IgG1K, which binds to a molecule called CD38

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<sup>27</sup> Genmab Annual Report 2015, pp 21

<sup>28</sup> <http://www.nationalmssociety.org/What-is-MS/Definition-of-MS> [08/06 2017]

<sup>29</sup> <http://www.nationalmssociety.org/Symptoms-Diagnosis/MS-Symptoms> [08/06 2017]

<sup>30</sup> Genmab Annual Report 2016, pp 27

<sup>31</sup> <http://www.genmab.com/about-us/history> [03/03 2017]

which is very distinct on the surface of MM cells. Darzalex can therefore lead to death of the cancer cells<sup>32</sup>.

Approved indications as written in Genmabs Annual Report of 2016<sup>33</sup>:

“

1. *Approved in the US in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma (MM) who has received at least one prior therapy.*
2. *Approved in the US as monotherapy for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a PI and an immunomodulatory agent or who are double refractory to a PI and an immunomodulatory agent in the US.*
3. *Approved in the EU as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapies including a PI and an immunomodulatory agent, and who have demonstrated disease progression on the last therapy.*

“

**Source: Taken from Genmab Annual Report 2016, pp 17**

Darzalex has been granted two fast track and breakthrough designations by the FDA. The first was received in 2013, and the second in 2016. Further it has been given orphan drug status by both the FDA and the EMA<sup>34</sup>

In 2013 Darzalex received the fast track designation and Breakthrough therapy designation from the FDA, for the treatment of patients with multiple myeloma who has received 3 prior lines of therapy. Again in 2016, Darzalex received the fast track designation and breakthrough therapy designation in combination with lenalidomide and dexamethasone, or with bortezomib and dexamethasone, for patients who has received at least one prior therapy<sup>35</sup>.

### Multiple Myeloma (MM)

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<sup>32</sup> Genmab Annual Report 2016, pp 21

<sup>33</sup> Genmab Annual Report 2016, pp 17

<sup>34</sup> <http://www.genmab.com/product-pipeline/products-in-development/daratumumab> [06/03 2017]

<sup>35</sup> <http://www.genmab.com/product-pipeline/products-in-development/daratumumab> [17/05 2017]

Multiple Myeloma is a blood cancer, and are the third most common type of blood cancer in the US<sup>36</sup> and the second most common in Europe. MM only counts for approximately 1 % of all cancers types found in patients<sup>37</sup>.

There exists no cure for multiple myeloma at the moment, so the treatment of this disease is based on some uncertainty. The 5 year survival rate lies at around 46.6% in the US, which are relatively low compared to other cancer types. In 2016 the number of new incidents was approximately 30,330 in the US. In 2015 the number of new incidents globally was approximately 124,225<sup>38</sup>.

According to Genmabs annual report, the global market for multiple myeloma was USD 12.8 billion in 2016, and is expected to increase to USD 22.4 in 2023<sup>39</sup>.

### Partners

In 2012, Genmab granted Janssen Biotech Inc., exclusive worldwide license to develop, manufacture and commercialize daratumumab. From this licence, Genmab received an upfront fee of USD 55 million. Further Janssen invested USD 80 million in new Genmab shares. Janssen is fully responsible to all cost associated with development, manufacturing and commercialization of daratumumab<sup>40</sup>.

### Other disease target in clinical development<sup>41</sup>:

- Non-Hodgins Lymphoma(Phase II)
- Natural Killer/ T-Cell Lymphoma(Phase II)
- Solid Tumours(Phase I/II)

### 4.2.2.3 Technologies

#### DuoBody

The DuoBody platform is one of Genmabs proprietary technologies which are used within discovery and development of antibodies. The Duobody program discovers antibodies, which can

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<sup>36</sup> <https://www.cancer.gov/research/progress/snapshots/myeloma> [06/03 2017]

<sup>37</sup> <http://www.mpeurope.org/about-myeloma/introduction-to-myeloma/> [06/03 2017]

<sup>38</sup> Genmab Annual Report 2016, pp 22

<sup>39</sup> Genmab Annual Report 2016, pp 22

<sup>40</sup> Genmab Annual Report 2015, pp 17

<sup>41</sup> Genmab Annual Report 2016, pp 18

bind together to enhance the effect of the antibody. The Duobody program can be used for other than cancer related diseases as well, namely autoimmune, infectious and central nervous system diseases<sup>42</sup>.

Genmab has multiple commercial collaborations for the Duobody platform, from which it receives license fees and milestone payments. The collaborations are with Janssen, Novartis, Aduro Biotech Europe, BioNTech and Novo Nordisk. Further Genmab have multiple research collaborations, for the further development of the Duobody program<sup>43</sup>.

### Hexabody

Hexabody is another technological platform, which is designed to enhance the power of the antibodies when targeting diseases. This platform can be used together with the Duobody platform, or other antibody platforms. Genmab has currently research collaborations with Humabs BioMed, Agenus and Gilead Sciences<sup>44</sup>

## **Chapter 5 - Strategic Analysis**

The goal of the strategic analysis is to find factors which can influence Genmabs future ability to create value for its shareholders. The section is divided into a macro analysis, industry analysis and internal analysis, where the models described under the theory will be applied. The section will end with an S.W.O.T analysis, bringing it all together, where Genmabs Strength, Weaknesses, Opportunities and Threats will be listed.

### **5.1 Macro analysis**

As mentioned in the theory section, I have chosen to use a variation of the PESTEL analysis, referred to as SLEPT. SLEPT divides the macro environment into Social, Legal, Economic, Political and technological factors. I will be giving a description of what is judged to be most important factors to Genmabs future ability to create value. In most circumstances, it will be Threats and opportunities to Genmab as a whole, but whenever needed the macro analysis will be divided into the disease areas where Genmab operates in.

#### **5.1.1 Social**

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<sup>42</sup> Genmab Annual Report 2015, pp 29

<sup>43</sup> Genmab Annual Report 2015, pp 29

<sup>44</sup> Genmab Annual Report 2015, pp 32

### Chronic Lymphocytic Leukemia:

Getting CLL is not a life-style disease, therefore the development of CLL cannot be linked to trends in the populations' lifestyle. The average age of people getting diagnosed with CLL is people in the group of 65-74, with a median age of diagnosis of 71<sup>45</sup>. So the probability of getting diagnosed with CLL increases with age. There is other risk -factors which increases the probability of being diagnosed with CLL, including race, ancestry and sex. There has also been found a link between CLL and radon in homes, but this has not been proven yet<sup>46</sup>.

For the last 10 years, there has been a fall of yearly new incidents of CLL, of an average of 1.3% in the United States<sup>47</sup>. But this has to be seen in connection with a sudden sharp rise in new incidents from the year 2000, as can be seen below in figure 5<sup>48</sup>. What causes this sudden rise in the new incidents is unknown, and there might be some sought of generation effect occurring. Prior to the year 2000, there is a slow rise of new incidents, with a mean value of 4.5 new incidents per 100.000. From the year 2000 till 2013<sup>49</sup>, the mean value of new incidents rises to 5.3 in the US. Taking the average from the whole period, gives an average of new incidents from 1975-2013 of 4.7. As CLL is linked to age, I will establish the expected trend in CLL in a separate section going over the age trends.

#### ***Figure 5: New cases of CLL in the US***

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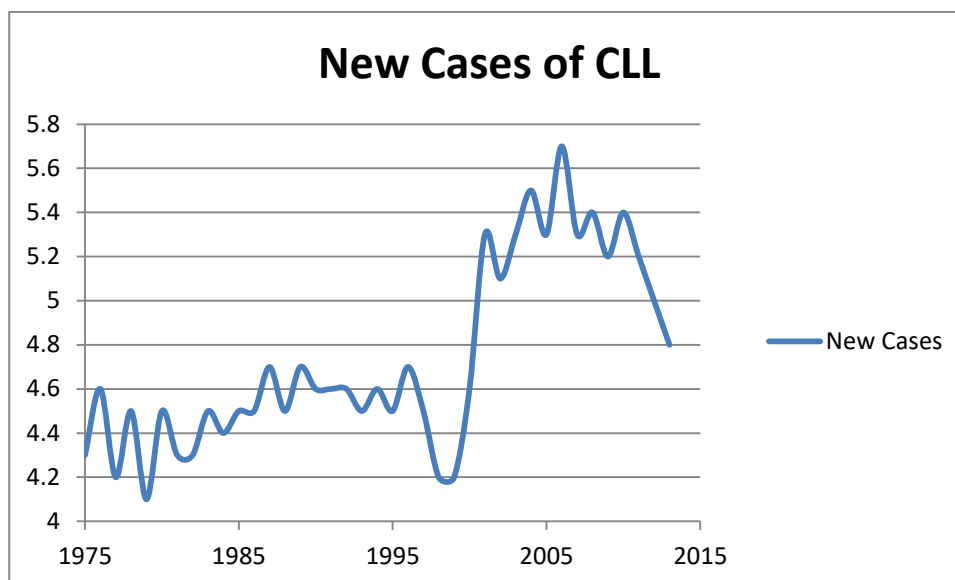
<sup>45</sup> <https://seer.cancer.gov/statfacts/html/clyl.html> [06/03 2017]

<sup>46</sup> <http://www.futuremedicine.com/doi/pdf/10.2217/fon.15.275> [08/01 2017]

<sup>47</sup> <https://seer.cancer.gov/statfacts/html/clyl.html> [08/01 2017]

<sup>48</sup> I have not been able to find statistical data for Europe. Stats are usually divided by country. But approximately the same trend is expected in Europe.

<sup>49</sup> The Data from seer.cancer.gov is only available till 2013



Number of new cases per 100.000

Source: Authors own Work/Data from [www.seer.cancer.gov](http://www.seer.cancer.gov)

### Multiple Myeloma:

Since 1975 there has been a yearly increase of nearly 1 % in total incidents of multiple myeloma<sup>50</sup>. MM is not a lifestyle disease, meaning that people's choice of living has no direct effect on whether you will get MM during your lifetime. The average age of diagnosis is 69<sup>51</sup>, so the change of getting diagnosed with CLL increases with age. Other risk factors mentioned are if you are male, if you are African-American, if you have been exposed to radiation or certain chemicals, and if you have had MGUS<sup>52</sup>, or isolated Plasmacytoma<sup>53, 54</sup>.

As stated above the average age when people are getting diagnosed with MM is 69, so it seems fair to conclude that in order to determine if one can expect a rise in future incidents of MM, I will have to find out if the population is expected to grow. I could also look into the growth in the other risk factors mentioned, but these risk-factors do not stand as clear as the age dependence. So in determining if it can be expected that there will be a rise in MM in the future, it should be

<sup>50</sup> <https://www.cancer.gov/research/progress/snapshots/myeloma> [20/12 2016]

<sup>51</sup> <https://seer.cancer.gov/statfacts/html/mulmy.html> [06/03 2017]

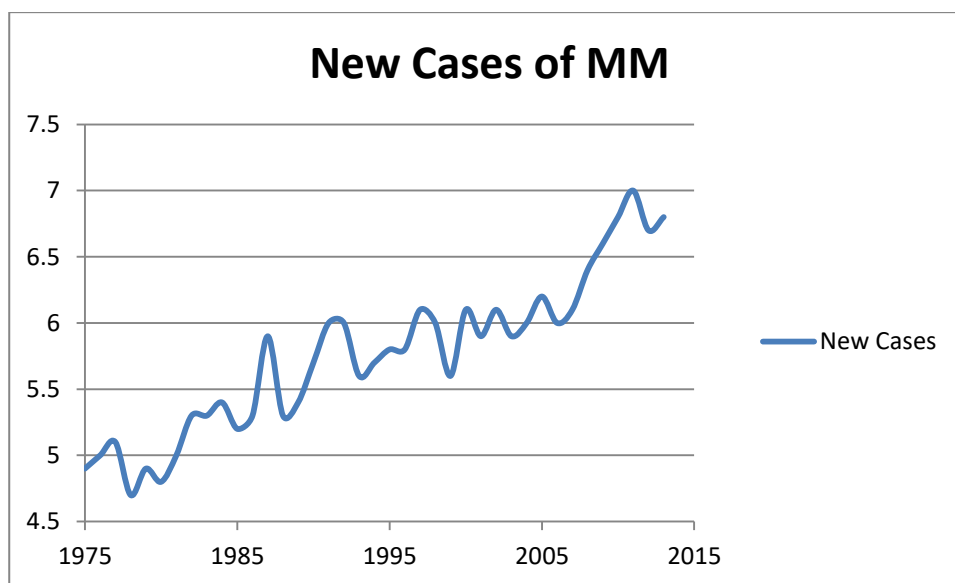
<sup>52</sup> Monoclonal Gammopathy of Undetermined Significance: A condition where there is a higher level of a protein called M in the blood. It increases the chance of getting cancer.

<sup>53</sup> A type of cancer that begins in the bone.

<sup>54</sup> <https://www.cancer.gov/research/progress/snapshots/myeloma> [20/12 2016]

enough to look at expected growth in the population. Looking at Figure 6 below, which shows yearly new cases of MM per 100.000 in the US<sup>55</sup>, the growth in new MM incidents has been steadily rising since 1975, and seems to continue into the future.

**Figure 6: New Incidents of MM in US**



New cases per 100.000    Source: Authors own work/ Data from [www.seer.cancer.gov](http://www.seer.cancer.gov)

#### Age trends:

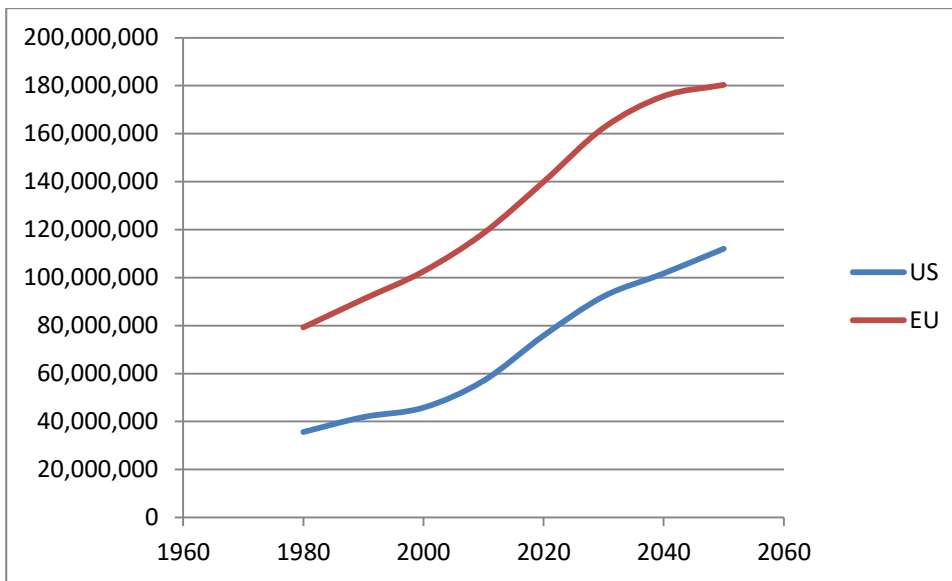
Since both disease targets, relates to age, it seems fair to assume that new incidents of both diseases will depend on the development of age. Below is a graph of the estimated development in age from 60+ for the US and the European Union.

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<sup>55</sup> I have not been capable of finding statistics for incidents in Europe, but it is expected to behave in the same way.



**Figure 7: Projected growth in population Age 60+**



Source: Authors own Creation/ Data extract: [https://aoa.acl.gov/Aging\\_Statistics/future\\_growth/future\\_growth.aspx](https://aoa.acl.gov/Aging_Statistics/future_growth/future_growth.aspx) and [www.worldbank.org](http://www.worldbank.org)

As can be seen from the figure, the growth in the population of 60+ is expected to rise. The population of 60+ in the US, is expected to double from 56,986,401 in 2010 to 112,037,396 in 2050. And for the European Union, the number is expected to increase about 52 % for the same years. Linking this to both diseases, I expect the market to grow in the future.

### Multiple Sclerosis:

The reasons people get MS are still not known, but there are a variety of theories of what causes MS. They have found for example that populations further away of equator are more exposed to getting MS, and scientist believe this might be related to D-Vitamins. There has also been found link to genetics, where people who has relatives with MS are more exposed of getting MS. Again the causes are not really known, only theoretical based causes which are ongoing<sup>56</sup>. Most people

<sup>56</sup> <http://www.nationalmssociety.org/What-is-MS/What-Causes-MS> [08/06 2017]

who get diagnosed with MS are between 20 and 50, but MS occurs in all ages<sup>57</sup>. So as the population are expected to grow<sup>58</sup>, the numbers of new incidents are also expected to grow.

### 5.1.2 Legal

The biotech industry is highly sensitive to the legal environment. First of all, both the FDA and EMA will have to give permission for a biotech company to make human trials, which will only be done when thoroughly conducted experiments has been made. Further the company will then have to conduct trials on humans, to test for risk and efficiency, before they can apply for marketing rights for the drug. If then, the company wants to preside on testing the drug on other diseases, they will have to go through the trial phases again. This can be a very time consuming process, which causes the launch of a new drug to be a long and costly process. Thus any changes in the legal framework for the approval of new drugs might be of a concern for Genmab, due to the increased cost that they will incur in the development process<sup>59</sup>.

Genmab is protected by its patent rights that it has on its drugs, which help protect the life-cycle of its drugs. To extend the life-cycle of its already marketed drugs, it can apply for new patents when they find other diseases for which the drug can be used for. Further, as described in the industry section, there are special regulatory approvals which Genmab can benefit from when entering markets which are relatively small. For example the Orphan Drug Designation that gives Genmab or its strategic partners marketing exclusivity for 7-10 years, on each disease target it applies for.

Genmab is also at risk of being sued by competitors, due to patents infringement<sup>60</sup>. There is currently a lawsuit filed against Genmab by its competitor, Morphosys. The reason for this is that they claim that they are entitled to royalties, because they have a patent on antibodies targeting the CD38 molecule which Darzalex also targets<sup>61</sup>. If Morphosys wins the case, it will be very costly for Genmab and its partner Janssen, both in royalty payments and the economic consequences of the law suit.

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<sup>57</sup> <http://www.nationalmssociety.org/What-is-MS/Who-Gets-MS> [08/06 2017]

<sup>58</sup> <https://www.census.gov/population/international/data/idb/worldpopgraph.php> [08/06 2017]

<sup>59</sup> Genmab Annual Report 2015, pp 39

<sup>60</sup> Genmab Annual Report 2015, pp 39

<sup>61</sup> [http://medwatch.dk.esc-web.lib.cbs.dk/Medicinal\\_Biotek/article9367273.ece](http://medwatch.dk.esc-web.lib.cbs.dk/Medicinal_Biotek/article9367273.ece) [06/03 2017]

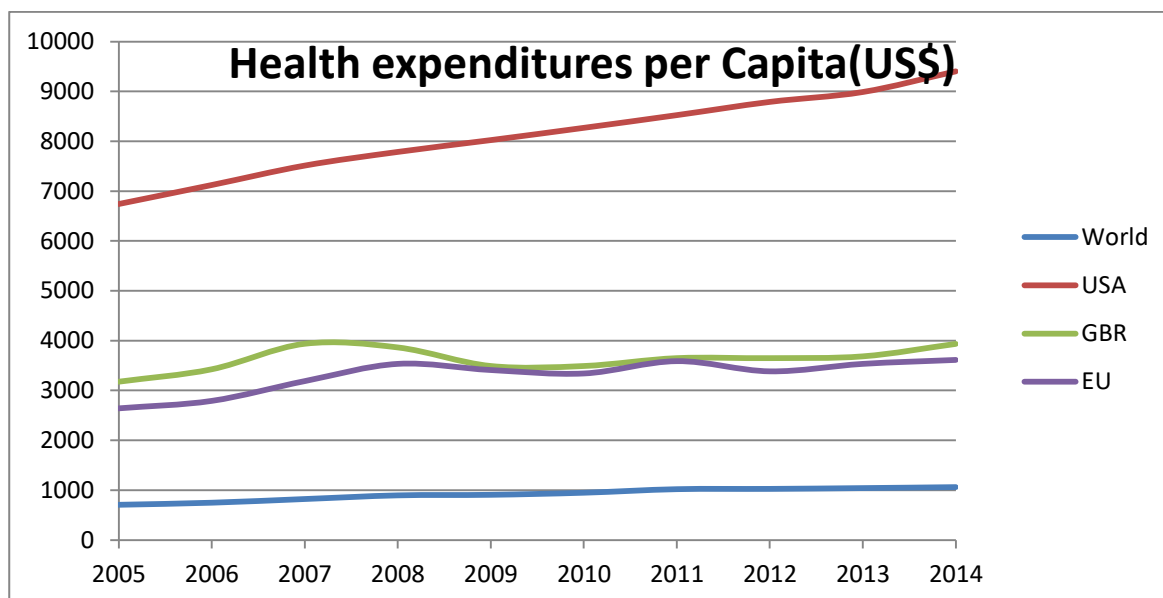
### 5.1.3 ECONOMIC

The first thing I will try to establish in this section is how sensitive Genmab is to the economic cycles. I will not be doing a thoroughly statistical analysis, but I will be drawing upon relevant literature and using graphs to establish the sensitivity to economic cycles. The section will also be looking at other economic factors which can have an influence on Genmab.

First of all the sales of Genmab's drugs depends on public health care programs, and of private health insurance. Due to this, it seems fair to assume that the sensitivity to economic downturns depends on whether a country's health care expenditures decline in economic downturns.

(Cleeren et al., 2016) has been investigating this problem, by testing the link between a Country's GDP and their public health care expenditures across 32 countries. His findings suggest that this is dependent on whether the system of the country is tax-based or insurance based. The tax-based system seems to be more cyclical than for the insurance based systems. This seems as a reasonable conclusion, which can also be back up by the figure 8 and 9 below, showing the link between health care expenditures and a country's GDB.

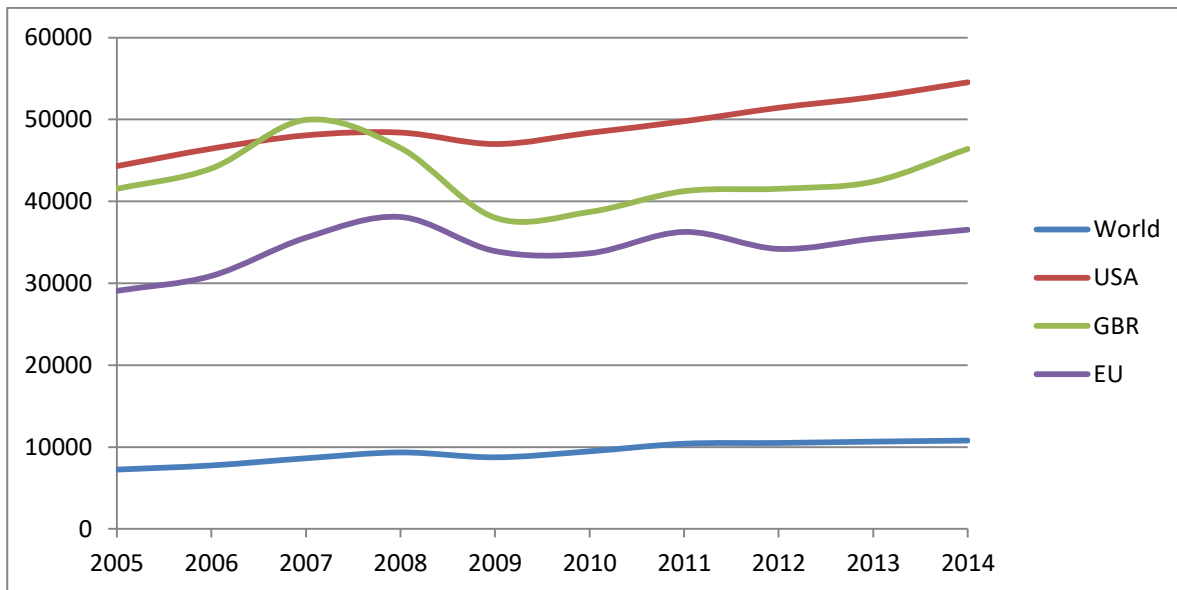
**Figure 8: Health expenditures per Capita (US \$)**



Health care expenditures per capita

Source: Authors own creation/ [www.worldbank.org](http://www.worldbank.org)

**Figure 9: GDP per Capita**



**GDP per Capita (Annual)** Source: Authors own creation/ [www.worldbank.org](http://www.worldbank.org)

When looking at figure 9, you will see that for the United States, the health care expenditures is more or less rising through the whole period. This stems with the result which (Cleeren et al, 2016), found in their article, that insurance based systems spend more on health care during economic downturns. Further the implementation of Obamacare, which included more people into the public health care program, can have had an effect on this increase. Looking at Europe and Great Britain, the picture changes around 2008 where the financial crisis started. The public health care expenditures decreased, and the health care spending has just recently reached the level of pre-crisis.

Summing up, the sensitivity to economic cycles depends on the system that each country keeps, which varies across countries. In the US it is an insurance based system, while for example it is a tax based system in Denmark.

So one of the things that can put pressure on Genmab, are price pressure on its drugs due to the economic cycles, which depends on what policy the countries lead. In countries where they keep a more tax-based system, will probably lead to increased price pressure from the governments in economic downturns.

### Financial Risk

There are mainly 3 types of financial risk Genmab faces within its operations. These are credit risk, Currency risk and interest rate risk. I will go through these 3 types of risk below, and explain how Genmab deals with these risk exposures.

#### *Credit Risk:*

Genmabs credit risk mainly comes from their marketable securities and bank deposits, where changes in the interest rate can lead to losses<sup>62</sup>. Genmab does not hold any long term debt.

#### *Currency Risk:*

Since Genmab operates in different countries, they cannot avoid having currency risk related to their operations. The main currencies which it operates in, is DKK, EUR, USD and GBP. Genmab has its functional currency in DKK, where increases or decreases in the other currencies, will have an impact on Genmabs result in either a positively or negatively way. For changes in EUR, this is not a concern due to the Danish currency commitment to the EUR, where the Danish Krone will be frozen to 7.46 across EUR.

To manage the currency risk, Genmab mainly match income and expenses in the same currency. Other than that they keep large cash positions in the major currencies that they operate in. Genmab also uses hedging instruments such as derivatives and futures<sup>63</sup>.

As of March 2015, the collaboration with GSK were transferred to Novartis, which resulted in that Genmab is no longer responsible of any development cost, which decreases their currency exposure to the GBP<sup>64</sup>.

#### *Interest rate risk:*

The interest rate risk that Genmab is exposed to is related to their marketable securities. They have large holdings of marketable securities, which is sensitive to fluctuations in the interest rate. They mainly hold government Bonds from the main markets that they operate in, namely DKK, USD, EUR and GBP, where the biggest portfolio is in DKK. They keep their marketable securities

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<sup>62</sup> Genmab Annual Report 2015, pp 79

<sup>63</sup> Genmab Annual Report 2015, pp 79

<sup>64</sup> Genmab Annual Report 2015, pp 80

with short maturities, where the duration for 2015 is 1.7 years and there is no marketable security with a duration longer than 8 years<sup>65</sup>.

Therefore, Genmabs credit risk, currency risk and interest risk seems to be of less importance compared to the rest of the business operations.

#### 5.1.4 Political

One of the more obvious political threats is changes in the tax rate. Genmab pays taxes in Denmark, where the Danish tax rate of 22% applies. The Danish tax rate has been falling in recent years, which lowers the tax payment per krone of income.

Other political risks, is increased price pressure on pharmaceuticals, which are a continuing threat to the pharmaceutical- and biotech companies. Like the newly elected American president, Donald Trump, who have stated that he wants to bring down prices on pharmaceuticals<sup>66</sup>. Whether this will happen is not clear, but stands as a potential threat for Genmab and their collaborating partners. In Europe there is also a continuing political threat on pharmaceutical prices<sup>67</sup>.

In extension, more drastic changes in the political environment stand as a potential threat. Donald Trump has stated that he wants to remove or make drastic changes to what is known as "Obamacare". This could lead to less people being part of the public health care system in the US, which is an important market for Genmabs drugs.

#### 5.1.5 Technological

Genmab being a biotech company, is very dependent and sensitive to technological changes.

First of all, in the production of their antibodies, they make use of licensed technology from other companies in assisting in the development of new antibodies. Like for example the new ADC technology from Seattle Genetics Inc. These are used in collaboration with their own technologies (Hexabody and Duobody). In the future, there may open up new technologies that Genmab can make use of, in the development of new drugs or improvements on already existing drugs.

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<sup>65</sup> Genmab Annual Report 2015, pp 80

<sup>66</sup> <http://edition.cnn.com/2017/01/31/politics/donald-trump-pharma-meeting/> [26/05 2017]

<sup>67</sup> <http://www.pwc.com/il/en/pharmaceuticals/pricing-pressures-shrinking-margins.html> [26/05 2017]

As the rapid change of technology can create opportunities for Genmab, it can also create threats for Genmab. Genmab might not gain access to new technologies, which their competitors might be able to get license for. Further, new drugs may be developed which will be ground breaking in the treatment of cancer. This will of course make Genmabs drugs insufficient and they will lose market share<sup>68</sup>.

So technological changes both offer opportunities and potential threats, depending on how well Genmab can be able to monitor new technologies.

### 5.1.6 Summing up the macro analysis

In this section I will make a short summation of the most important findings in the macro analysis. First of all, the market for MM, CLL and MS is expected to increase in the future, due to increases in the population. Further, any changes in the legal framework possess a threat for Genmab, because this may lead to increased cost in the development process of their drugs. Also, Genmab is constantly under threat for being sued due to patent infringement, which would be a high cost for Genmab if lost. There is also increased price pressure from Governments who wish to make drugs far less expensive, due to the high cost they possess on the public health care. Genmab is also very sensitive to the technology surrounding them, which can both pose as a potential threat, but it also can give rise to opportunities. The biggest threat is technological breakthroughs in the treatment of MM, CLL and MS, which can make Genmabs drugs worthless.

## 5.2 Industry Analysis

To analyse the industry, I have chosen Porters Five Forces. Porters five forces consist of five forces which helps determine the potential for a company in an industry. Porters Five Forces consist of threat of new entrants, threat of substitutes, bargaining power of suppliers, bargaining power of buyers and rivalry between existing competitors (Sørensen, 2011).

### 5.2.1 Treats of new entrants:

The biotech industry is very R&D intensive and therefore very knowledge intensive, where in order to discover and develop a new drug you need experts on the field. To get success in the discovery

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<sup>68</sup> Genmab Annual Report 2015, pp 38

and development of a new drug, you will need field experts who have a long education and experience behind them.

Further, as mentioned earlier under the industry description, the time it takes to develop a new drug is very long, hence there is a high amount of risk involved when entering into the Biotech industry. A company might discover a new drug which shows signs of potential in the early phases, but later on prove to be ineffective or dangerous for patients. This would lead to huge losses for the company since it has not yet received any cash inflows from the sales of their drugs. Secondly, they do not know in advance if they are having a blockbuster drug which can generate enough cash-flows, or they will have to terminate the project before the drug is launched (Bogdan & Villiger, 2010).

Another important entry barrier is the cost of developing a new drug. As mentioned, the Biotech industry is very R&D intensive where the biggest expenses are in the R&D phase. According to a paper by (Dimasi et al., 2003), the cost outlay in the discovery and development phase is on average USD 800 million including the cost of failures. For a small biotech company, these of course needs to be raised from investors willing to take the risk of investing in a drug which is not yet ready for sale.

So due to high entry barriers in the form of Knowledge, high cost and a high amount of risk involved in the development of a new drug, the threat of new entrants seems to be relatively low.

### 5.2.2 Threat of substitutes

Analysing “Threat of Substitutes” aims at trying to find out how sensitive the industry is to the development of new products or technologies (Sørensen, 2011).

Since there are two different marketed drugs, I will split this section CLL, MM and MS. The therapies mentioned below is judged to be a substitute to Genmabs drugs, which goes under the category of treating MM and CLL. Most of these different types of therapies are increasingly being used as a combination drug.

#### Arzerra (CLL):

- Chemotherapy: As described under Darzalex above.



- Stem Cell transplant: As described under Darzalex above.
- Targeted Therapy: Targeted therapy is a newer form of drug, which can target specific proteins in the cancer cells, and limit their ability to grow. The positive thing about the use of targeted therapy is that it is usually only the cancer cells getting hit, and not the healthy cells<sup>69</sup>.

As can be seen, there are many different types of therapies which can be used to treat MM. Under each type of therapy, there are relatively many different drugs, all which has both positive and negative effects (Side effects etc.). The use of these drugs in combination with other drugs, also seem to increase the threat because already existing drugs can increase its advantages when combined with other drugs. There are also increasing technological advantages within the different therapies, which can quickly make the existing drugs less attractive.

There are not as many different therapies for the treatment of CLL, but still the threat of substitutes, does seem high, when you think of the many types of drugs that exist, and will be developed over time.

Another important substitutional product is the treat from biosimilars which Genmab will face in the future<sup>70</sup>. But how big of a threat they are, is hard to say because that biosimilars and the approval of such, are in its early stages. Biosimilars are harder to produce, because difference in the production can change the effect of a biosimilar, where for generics is just a reproduction of a chemical compound as described in the industry description.

### Multiple Myeloma (Darzalex)

There are as mention earlier no cure for multiple myeloma, and therefore there exist only treatments. Within treatments, there exist numerous ways of treating Multiple Myeloma, and the success rate depends on numerous factors. Below I will describe the different types of therapies that are available for patients with MM, which serves as a substitute for Darzalex. The focus will be on the technologies, and not on competitors, which will come under the section “Rivalry between established competitors”.

<sup>69</sup> <http://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/targeted-therapy/what-is.html>  
[28/12 2016]

<sup>70</sup> Genmab Annual Report 2016, pp 49

- Chemotherapy: This is the traditional way of treating patients with cancer. When, taken (Orally or injected through the vein), it enters the bloodstream and reaches all areas of the body. This makes chemotherapy a good treatment for MM, because it has a tendency to spread throughout the body. But with chemotherapy, you are not only targeting the cancer cells, but also the healthy cells in the body and can therefore do long term damage to the body<sup>71</sup>.
- Proteasome Inhibitors: They work by stopping what is called enzyme complexes, which breaks down certain proteins in the cells, which are important for keeping cell division under control. . There exist drugs which can be injected through the vein, under the skin or orally through a capsule<sup>72</sup>.
- Histone deacetylase(Hdac) inhibitors: They work by effecting which genes are active inside the cells, by interacting with chromosomes called histones<sup>73</sup>.
- Immunomodulating agents: These drugs work by regulating the body's immune response to a desired level. These drugs will decrease the growth in cancer cells while the body will start attacking the cancer cells<sup>74</sup>.
- Stem cell transplant: Stem cells are immature cells, which can transform into other forms of blood cells. When using stem cells for treatment, you will receive high doses of chemotherapy, to kill the cancer cells. Then the stem cells are transplanted, which will make sure that new red and white blood cells are formed. Using stem cells from a donor can potentially cure MM, but this can be very risky, and there are no certainties that it will actually cure MM<sup>75</sup>.

### Arzerra(MS):

There are numerous drugs being used in the treatment of MS patients. The most common are those of the type interferon beta-1a and interferon beta 1b. Other than that, there are numerous of different compounds of drugs, which cannot be classified in the same way as with the cancer

<sup>71</sup> <http://www.cancer.org/cancer/multiple-myeloma/treating/chemotherapy.html> [28/12 2016]

<sup>72</sup> <http://www.cancer.org/cancer/multiple-myeloma/treating/chemotherapy.html> [28/12 2016]

<sup>73</sup> <http://www.cancer.org/cancer/multiple-myeloma/treating/chemotherapy.html> [28/12 2016]

<sup>74</sup> <https://www.cancer.dk/myelomatose-knoglemarvskraeft/behandling-myelomatose/behandling-rettet-mod-myelomatosecellerne/myelomatose-immunmodulerende-behandling/> [27/05 2017]

<sup>75</sup> <http://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/stem-cell-transplant/why-stem-cell-transplants-are-used.html> [28/12 2016]

drugs because they are chemical drugs<sup>76</sup>. Other than the approved drugs, off label drugs are also used in treating patient with MS<sup>77</sup>. Then there are alternative medications like for example cannabis. There have been some signs of increasing efficacy by stem cell transplant, but this is still ongoing<sup>78</sup>. The substitutes to Arzerra are judged to be very scattered, where there is a need for better treatments.

If Arzerra are effective, the closest substitutes will be other drugs in the same class. And if the stem cell transplants are effective, these will also be classified as a substitute.

### 5.2.3 Bargaining power of suppliers

Some of the things that increases the suppliers bargaining power are, if the size of the cost are a relatively big proportion of a company's total cost, if there are many suppliers and how the access to substitutional services or products are for the company(Sørensen, 2011).

Genmab is outsourcing manufacturing and clinical research to organisations which perform these services. These organisations need to comply with specific rules and regulations. If Genmab would have to change to other organisations, this could lead to delays which can be very costly<sup>79</sup>.

Genmab is also relying on their partnerships with big pharmaceuticals and biotech companies to develop and commercialize their drugs. If these partnerships are terminated, or they are not as engaged in their collaboration with Genmab, Genmab will suffer from this, due to Genmabs size<sup>80</sup>.

Genmab depends on human knowledge in order to keep being able to develop drugs which has competitive advantages. For this, Genmab needs to be a working place that attracts new employees that are experts on their field. So the bargaining power from their employees is relatively big, where Genmab has to continue to strive to attract new employees and to keep existing employees.

To be an attractive workplace for employees, they use merit-based bonus and salary review programs, where they grant their employees warrants. They also have paid holidays, health

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<sup>76</sup> <http://www.nationalmssociety.org/Treating-MS/Medications> [08/06 2017]

<sup>77</sup> <http://www.nationalmssociety.org/Treating-MS/Medications> [08/06 2017]

<sup>78</sup> <http://www.nationalmssociety.org/Research/Research-News-Progress/Stem-Cells-in-MS> [08/06 2017]

<sup>79</sup> Genmab Annual Report 2016, pp 49

<sup>80</sup> Genmab Annual Report 2016, pp 49

benefits etc. Further they have recognition and service programs, which aims to celebrate the successes and commitment from their employees<sup>81</sup>.

Altogether, the bargaining power of suppliers seems to be medium to high, due to Genmabs dependence of these.

#### 5.2.4 Bargaining power of buyers

If the bargaining power of buyers is low, the company stands stronger, and can get a higher price for its products. The bargaining power of buyers increases if it is easy to shift supplier, there are many substitutes or if there are low cost associated with shifting supplier (Sørensen, 2011).

Genmab depends on hospitals and physicians to use their drugs when treating patients. The price of the drug is passed on to the patients, which then depends on public and private health insurance to pay for the high cost of the drug. Further there are costs associated with the drug, because Genmabs drugs are given at the hospitals by healthcare personal. If the patient cannot get price reimbursement, the patient will probably stop the treatment. Therefore Genmab are dependent on the reimbursement from public and private health care providers, which can negotiate on the price on Genmabs drugs. Further, there is not any high economic switching cost associated with shifting to different drug.

Secondly there are many drugs on the market, which are able to treat cancer, which increases the bargaining power of the buyer. In order for a company to gain some advantages in selling their drugs, they need to be able to have a drug that's able to treat cancer with better efficiency than existing drugs. This is either in higher efficacy, or lower side-effects from using the drug, and lower cost associated with the drug.

So the bargaining power of buyers seems to be medium to high, which depends on the efficiency of the drug. There is an overall tendency, that the industry is seeing increased price pressure from political side.

#### 5.2.5 Rivalry between established competitors

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<sup>81</sup> <http://www.genmab.com/careers/benefits> [10/03 2017]

Some factors that can influence the intensity in an industry is a high amount of competitors, if they are roughly equal in size, industry growth is small or the exit barriers is high or there is high fixed cost (Porter, 2008).

The pharma-and biotech industry within cancer treatments is characterized by a relatively few number of big pharmaceuticals which operates across geographical areas. Moreover there is a vast amount of smaller biotech companies which is more focused on R&D, due to their size. It is usual within the industry, that the big pharmaceuticals acquire licences to promising drugs, which they bring to market. Other ways is through M&A which is custom in the industry.

Some of the biggest vendors operating in the same markets as Genmab are currently Roche, Abbvie, Novartis, Johnson & Johnson, Teva Pharmaceuticals, Gilead Sciences and Takeda Pharmaceuticals.

Due to the evolvement of new therapeutics, the market for cancer treatment is expanding rapidly. Many cancer forms like MM and CLL, has no cure, which drives the market intensity because the new therapeutically drugs offers better treatment for patients, and increases the overall survival rates. Due to these factors, these types of cancer areas are very lucrative if a company can get its drugs to the market. This is also what helps drive the rivalry amongst existing competitors, which is intensifying, and is driven by capturing market shares by expanding the line of indications which a drug is approved for. This can be done, if the drug is capable of increasing the efficacy of the treatment, while maintaining a sound risk-profile.

Other factors that drives the rivalry amongst competitors, is regulatory initiatives as mentioned earlier, which offers benefits for the companies that can offer potential drug candidates to the market. This has helped Genmab expedite the introduction of its drugs, can decrease the R&D cost associated with the trial phases which are very lengthy.

Ever since the introduction of new therapeutic drugs, there has been an increased use of combination drugs. This can improve the treatment of patients, and improve the efficacy of a drug. This offers potential for new and existing drugs.

#### 5.2.5.1 Chronic Lymphocytic Lymphoma (Arzerra)

The competitive environment is characterized by strong competitiveness amongst competitors, and it would also be characterized as an Oligopolistic competition.

The key competitors in the market for CLL are Roche, Abbvie, Gilead Sciences, and Teva Pharmaceuticals. Roche is the market leader within the treatment of CLL, with numerous marketed drugs. Its key drug is Rituxan, which is co-marketed with Johnson & Johnson in the US, and Johnson & Johnson has the marketing rights in the EU.

Arzerra has had trouble gaining market penetration, and is struggling from the increased competition. Especially the introduction of Imbruvica from Abbvie has had a negative effect on the sales of Arzerra<sup>82</sup>. The sales of Arzerra are in the low end relative to its peers. But Arzerra has recently been approved in a new line of patients which may improve their sales, though it seems very unlikely looking at their recent performance.

#### 5.2.5.2 Phase 3 diseases for Arzerra

In this section I will give a short description of the rivalry amongst competitors and the potential for Arzerra in the market for Multiple Sclerosis, which Arzerra is being tested against in phase 3 studies.

##### Multiple Sclerosis (MS):

There is no effective cure or treatment of multiple sclerosis, but there are numerous drugs to ease the symptoms and shortening the relapse time of outbreaks. The market for Multiple Sclerosis is relatively big, if new drugs prove to be more effective or are a best in class drug<sup>83</sup>. According to Genmabs Annual Report 2016, the market is of approximately USD 16.8 Billion in the US and 5 major European markets, and is expected to increase to USD 20.3 Billion in 2023. So this market offers huge potential for Genmab if Arzerra can improve the treatment of MS patients<sup>84</sup>.

#### 5.2.5.3 Multiple Myeloma ( Darzalex)

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<sup>82</sup> Genmab Annual Report 2016, pp 52

<sup>83</sup> <http://www.nationalmssociety.org/Treating-MS/Medications> [ 29/05 2017]

<sup>84</sup> Genmab Annual Report 2016, pp 27

The market for multiple myeloma is also expected to increase rapidly. This is partly due to increases in the population, but also driven by new combination therapies which can increase the market size.

Darzalex has already had a great start, even though it has only been on the market for around a year. Within that year, it has been approved as a second line therapy in combination with other drugs. So it seems that Darzalex is gaining momentum with sales of USD 572 million in 2016.

The market for MM is dominated by a few big players, Celgene which has Revlimid, Pomalyst and Thalomid on the market. Celgene is the most prominent player on the market. Other dominant market players are, Amgen, Novartis, Johnson & Johnson and Takeda Pharmaceuticals.

The competition is expected to increase in the coming years, due to other big players entering the market. And the market landscape does seem to have change in these last couple of years, with the introduction of new drugs like Darzalex, Kyprolis(Amgen) and Ninlaro(Takeda). Again, the market is driven by combinational drugs which shows increasing efficiency against cancer, and can clear the way for already existing drugs. Further, these new therapies like antibodies and proteasome inhibitors helps changing the market.

Altogether, there is an increasing competition between existing competitors. This is driven by both special designations by regulatory authorities, the introduction of new therapeutics and the increasing use of combination therapies. The industry in general is characterised by a few very big market players, who either, develop, acquire licenses or gain access to new technologies through M&A.

#### 5.2.6 Summing up Porters 5 forces

The threat of new entrants into the market of cancer therapy in general, seems to be very low, due to the high cost and risk involved. The general development time is very lengthy, and there is a very low change of success. The threat of substitutes seems to be medium to high, due to the evolvement of technology within the new therapeutic areas, which shows improved efficacy compared to already existing drugs. The bargaining power of Genmabs suppliers is medium to high. They are highly dependent on their collaborating partners, in order to develop and launch a new drug. The Bargaining power of buyers are medium to high. There are a high number of

different therapies and the switching cost are low. Further Genmab depends on their patients being able to get reimbursements from governments and private health care providers. The Rivalry amongst already existing competitors, are intensifying, and in order to gain market share, a drug needs to show high efficacy while being low in price.

### **5.3 Internal Analysis**

The internal analysis tries to identify company specific resources which can help the company gain a competitive advantage over its peers. The companys' resources can be divided into physical, Human, Financial and intangible resources (Petersen & Plenborg, 2012).

In going through Genmabs Internal resources, I will be making comparisons to relevant peer companies, to see if Genmab have any competitive advantages over its competitors. These peer companies will also serve as comparison when going over the financial analysis. I have chosen two companies, which are in opposite sites of the spectre. The first company I have chosen is Morphosys, which as mentioned earlier are suing Genmab for patent infringement. I have chosen this company as a peer company, because that it resembles Genmab, both because it is approximately the same size, and they are also developing antibodies. The other company I have chosen are Roche, which are much bigger and well established. They also develop antibodies amongst other things. I have chosen Roche as a peer company, to see how a more mature company perform. They are a major player within cancer treatments, so it seems reasonable to compare Genmab with Roche in order to see how Genmab perform.

Both Roche and Morphosys are reporting under the IFRS, which makes comparisons to Genmab better due to same measurement of assets and liabilities. The annual reports that I use are from the period 2013-2015, since their annual reports for 2016 has not come out yet. So I will not be able to make comparisons for 2016.

#### **5.3.1 Physical Resources**

##### **5.3.1.1 Property, Plant and Equipment**

Genmab has facilities in 3 different countries, with different functions. Genmab has its headquarters and clinical development team in Denmark, R&D facility in the Netherlands, and an



office in the U.S for administration purposes<sup>85</sup>. Genmab outsources its manufacturing and clinical research to 3-parties, which increases Genmabs' focus on R&D<sup>86</sup>. In the past it made a restructuring of its company, where it decided to sell of its manufacturing plant in the US, which came through in 2013. Besides selling the plant, Genmab also laid off 300 of their employees. This was done, to ensure a tight cost-control and to fully focus on R&D<sup>87</sup>.

With these implementations Genmab has succeeded in lowering its cost, while increasing its revenue. This has led to increasing profits in recent years. This has also increased Genmabs risk, because it is relying on collaborating partners, contract manufactures etc.

### 5.3.2 Technologies

Genmab is heavily dependent on its technologies in the discovery and development process of antibodies. Genmab has a broad portfolio of technologies, including proprietary technologies and in-licences of technologies.

As mentioned earlier in the thesis, Genmab has developed the Duobody and Hexabody platforms, which it uses in its own discovery and development of antibodies. Both technologies are designed to increase the efficacy and potency of the antibodies developed.

In 2014, Genmab entered into a commercial license and collaboration agreement with Seattle Genetics Inc., to utilize Seattle Genetics ADC technology on its Humax-TF antibody<sup>88</sup>. As mentioned earlier, the ADC technology is able to combine an antibody with a toxic agent.

Genmab also utilises other technologies, which it has in-licensed from partnering companies. These are UltiMAB transgenic mouse technology, OmniAb transgenic mouse and rat platforms, and MAB Discovery's rabbit antibody platform<sup>89</sup>.

In comparing with the chosen peers, Roche and Genmab is focusing on the same type of technological platforms, although Roche has access to a broader portfolio of technologies, which

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<sup>85</sup> <http://www.genmab.com/about-us/company-overview> [05/03 2017]

<sup>86</sup> Genmab Annual Report 2016, pp 49

<sup>87</sup> [http://files.shareholder.com/downloads/AMDA-KPIBN/3067578399x0x534155/9920154F-D248-41E8-8B45-C7195CD60AA8/41\\_reorganization\\_051109\\_uk.pdf](http://files.shareholder.com/downloads/AMDA-KPIBN/3067578399x0x534155/9920154F-D248-41E8-8B45-C7195CD60AA8/41_reorganization_051109_uk.pdf) [05/03 2017] [Genmab stock exchange release no.41/2009]

<sup>88</sup> Genmab Annual Report 2016, pp 31

<sup>89</sup> Genmab Annual Report 2016, pp 37

would be expected for such a large company<sup>90</sup>. If we look at Morphosys, it does not seem as they are utilizing the same type of technologies. Compared to the size of the company, which is around the same as Genmab, they have plenty of technologies, but they focus on different technologies<sup>91</sup>. The difference between Genmab and Morphosys, is that Genmab has 2 marketed drugs, where one has become very successful, and Morphosys has none on the market at the moment. So Genmab's focused strategy, and its selection of technology seems to pay off, compared to Morphosys.

### 5.3.3 Human Resources

Because Genmab is an R&D intensive company, it seems like the most obvious choice to be looking at the distribution of education and experience within the pharmaceutical and biotech industry, in order to assess Genmab's relative strength within human Resources. I will both be looking at employment level as well as the management level.

#### Employees

Genmab is a relatively small company with only 205 employees in total. 86% of the employees are working within research and development. 50 % of these employees has an advanced degree (Ph.D, Doctoral or Master degree). And 78 % of the employees have more than 5 years of experience within pharmaceutical and biotech industry<sup>92</sup>.

#### Board of Directors

The board of directors consist of 9 individuals, which oversee the operations of Genmab. Out of the 9 elected board members, 67% of have experience within the pharmaceutical and biotech Industry, where Genmab uses the term "Extensive" experience in many cases to describe the level of experience. There are 33% holding a Ph.D, and 22% holding an M.D<sup>93</sup>.

#### Senior leadership

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<sup>90</sup> [http://www.roche.com/research\\_and\\_development/what\\_we\\_are\\_working\\_on/research\\_technologies/protein-related\\_technologies.htm](http://www.roche.com/research_and_development/what_we_are_working_on/research_technologies/protein-related_technologies.htm) [13/03 2017]

<sup>91</sup> <https://www.morphosys.com/science/drug-development-capabilities#technologies> [13/03 2017]

<sup>92</sup> Genmab Annual Report 2016, pp 46

<sup>93</sup> Genmab Annual Report 2016, pp 62-66

The senior leadership comprises of 9 individuals, where 78% of these has experience within pharmaceutical and biotech Industry. And 44% holds a PHd, and 10% holds an M.D.

Comparing the educational level and experience with the chosen peer companies, there is no obvious competitive advantage for Genmab. The peer companies also consist of high skilled employees and management. Further a company like Roche will most likely be able to attract a great amount of skilled employees due to its huge size.

#### 5.3.4 Financial Resources

##### Profit

Genmabs ability to create profit in the past has been very poor. This is not unusual for small biotech companies, because of the time it takes to develop new drugs. As mentioned earlier, Genmab restructured its business, cutting cost and increased focus on innovation and the development of its drugs. These changes seem to have paid off, since Genmab for the last 4 years has had increasing profits, especially after its introduction of Darzalex. The increases in profit helps Genmab invest in its pipeline drugs, which in turn can help Genmab bring more drugs into the market in the future. Further this profitability will help Genmab to start marketing their own drugs, which is one of the company goals.

So after a rough start, it seems as if Genmab has turned its business around into a more profitable company. This can be confirmed if I look at Genmabs 3 year EBIT-margin from the last 3 years, and compare these with Morphosys and Roche.

**Figure 10: EBIT-Margin**

EBIT-Margin %	2013	2014	2015
Genmab	10%	31%	64%
Morphosys	13%	-9%	16%
Roche	34%	28%	27%

Source: Authors own creation

Comparing Genmab to Morphosys, the EBIT margin is increasing in all years, while Morphosys is negative in 2014, and there is a slight increase from 2013 to 2015. In general it is low compared to

Roche, which is a mature company in the industry. Genmabs EBIT Margin is surpassing Roche's in both 2014 and 2015.

### Cash position

Genmab has a large cash position of 3,992 million at year end of 2016, which are comprised of bank deposits and marketable securities. Their marketable securities are fairly liquid securities with an average duration of approximately 1.4 years<sup>94</sup>. Their large cash-position strengthens the company, and helps Genmab continue making investments in its pipeline candidates<sup>95</sup>.

### Debt

Genmab has currently no long term or short term debt obligations, and support its operations through its revenue and equity financing. This is usual in the biotech industry because equity financing is cheaper, and it is usually hard for a small biotech to obtain debt financing, due to the high uncertainty in the business.

### **5.3.5 Immaterial resources**

One of Genmabs key immaterial resource is its strategic collaborations with other pharmaceutical and biotechnological companies. Genmab uses these strategic collaborations to help fund its projects, share knowledge, leverage capabilities and to bring drugs to the market<sup>96</sup>. Some of the key strategic collaborations are the collaboration with Janssen, which has helped bring their drug Darzalex to the market. Through its collaboration agreement, Janssen will be responsible for all future cost associated with Darzalex, including manufacturing and development cost in other indications. The success of Darzalex and the related royalties and milestone payments, can help Genmab to achieve its goals.

Another important strategic collaboration for Genmab is its collaboration with Novartis, for their ofatumumab program, where Novartis is also responsible for all cost, development and commercialisation of ofatumumab<sup>97</sup>. Although the success of their drug Arzerra has been mixed,

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<sup>94</sup> Genmab Annual Report 2016, pp 95

<sup>95</sup> Genmab Annual Report 2016, pp 50

<sup>96</sup> Genmab Annual Report 2016, pp 5

<sup>97</sup> Genmab Annual Report 2016, pp 28

there is potential in other indications like multiple sclerosis, which has entered into phase 3 clinical trials

Comparing Genmab to Morphosys, it seems as if Genmab is better at utilising its know-how, and utilizing its strategic collaborations to bring drugs to the market. Although Genmabs pipeline is small compared to Morphosys, they have succeeded in bringing 2 drugs to the market, where one has the potential to become a blockbuster drug.

#### **5.3.6 Summing up the internal analysis**

Genmabs success seems to be highly dependent on its focused strategy, which has helped Genmab into bringing 2 drugs into the market, which seems to be an achievement compared to Morphosys. Further, they are better at utilising its strategic collaborations, which seems to help Genmab to achieve its goals in the future. But Genmab are also dependant on these. They also have a strong cash position and no debt. They are also turning profitable, with increasing EBIT margins.

## 5.4 S.W.O.T

S.W.O.T ANALYSIS	
Strength	Weaknesses
Focused Strategy	Small company
Good at bringing strong drugs to market	Only 2 marketed drugs
Strategic collaborations	Dependence on strategic collaborations
Strong Cash Position	
Opportunities	Threats
Increasing markets within disease targets	Sensitive to the legal environment
Darzalex is seeing a strong penetration	Patent infringement
Increased use of combination therapies	Increasing price pressure
Regulatory designations	Rapid technology development
	Increasing rivalry amongst competitors

## Chapter 6- Financial Analysis

The purpose of this section is to learn more about how Genmab is making their profits, and how the value creation is from Genmabs core operations. The section will start by transforming the income statements and balance sheets into an analytical income and balance sheet. Then I will move on to analyse the composition of the revenue streams, and how it has evolve through time. The section will then move on to a profitability analysis.

I have chosen to use Genmabs annual reports from the period 2013-2016. This is done because of the change in Genmabs profitability, and that the company has been through a restructuring process. Furthermore, Genmab has introduced its new drug Darzalex, which has change Genmabs situation in recent years. Therefore this period seems to be best at describing Genmabs financial evolvment.

Genmabs financial statements have been prepared according to the IFRS accounting policies and additional to the Danish regulation for listed companies for all of the chosen years<sup>98</sup>. There has been no change in accounting policies for the chosen accounting period, which has had an effect on Genmabs recognition and measurement of assets and liabilities<sup>99</sup>

### 6.1 Analytical Income statement and balance sheet

The analytical income and balance sheet is done to segregate operating Items and financing items, in order to determine the value creation of the company's core operations. The reason for this is, that the company's core operations is the driving force of the company's value creation and therefore makes the company unique, where the financial items is much easier to replicate(Petersen & Plenborg, 2012).

#### 6.1.1 The analytical Income Statement

##### Transitory Items

In March 2015 the agreement to transfer GSKs' ofatumumab collaboration to Novartis became effective. This meant that Genmab was not required to pay the deferred funding liability of DKK

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<sup>98</sup> Genmab Annual Report 2016, pp 73

<sup>99</sup> Genmab Annual Report 2016, pp 75

176 million<sup>100</sup>. So this was reversed, and recognised as other income in the income statement. This is not an insignificant part of the revenue, and I consider this as transitory in nature, which is why this item is removed from the core operations.

### Taxes

Due to Genmabs' prior losses, it has unrecognised tax losses, from which it can get tax income from. Due to this, and that I want to see how Genmabs' value creation is historically and estimate the future potential value creation from Genmab, I have chosen to calculate Genmabs' actually tax payments from their result, using the Danish tax rate, from the years 2013-2016. This will give me a much better picture at how profitable Genmab is. The tax used can be seen in the appendix.

### **6.1.2 The analytical Balance Sheet**

#### Cash and cash equivalents

According to (Petersen & Plenborg, 2012) cash and cash equivalents are considered as excess cash used to pay out dividends or repaying debt, except for the cash which are needed in day-to-day operations. This would usually be 0.5-1% of cash and cash equivalents (Sørensen, 2011). Looking at Genmabs annual report, all of Genmabs cash and cash equivalence is comprised of bank deposits which is interest bearing in nature. Therefore cash and cash equivalents are treated as a financial asset.

#### Lease Liabilities

According to Sørensen(2011), lease liabilities is a financial obligation, so lease liabilities is recorded as interest bearing debt in the analytical balance sheet.

## **6.2 Revenue**

In this section I will first look at the growth in revenue. Moreover I will try and establish how Genmabs revenue is composed, and what the development of these components is. This will help me determined, what the best way is to forecast Genmabs revenue.

### **6.2.1 Revenue Growth**

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<sup>100</sup> Genmab Annual Report 2016, pp 74



As can be seen in figure 11 below, the revenue has been rising constantly through all of the years. The average growth rate has been around 40% for the period. From 2015 to 2016, the growth rate was an impressive 60%. But just looking at the numbers, I get little information about the composition of the revenue. So I want to break down the revenue in order to get a better picture.

**Figure 11: Revenue and Revenue Growth**

Revenue Calculation	2013	2014	2015	2016
Revenue	663,570	850,385	1,133,041	1,816,122
Growth %	37%	28%	33%	60%

*Source: Authors Own Creation*

## 6.2.2 Revenue split by type of Income

In figure 12 below, the Revenue has been divided by their type. This gives a much better picture of where the growth in revenue comes from. As can be seen, Royalty Income has been falling from 2013 till 2015. But in 2016 it rises sharply, which is driven by royalty income related to sales of Darzalex, as the revenue from Arzerra is decreasing in all years.

Looking at the milestone payments, they have been rising in all years, and are the biggest contributor to growth in revenue. The increases in milestone payments are mainly related to sales and approvals of new indications for Darzalex<sup>101</sup>.

Deferred revenue has been relatively constant for all years, except in 2016 where it drops. This is due to deferred revenue related to Genmabs strategic partner Novartis and their Ofatumumab program, which was fully amortized at 2015<sup>102</sup>. Deferred revenue is revenue which is usually attributable to research projects, from where Genmab receives revenue. Revenues from its Duobody program is under this post, where Genmab receives upfront payments which is then amortised over the period of development, and recognised on a straight line basis in the income statement over the amortisation period<sup>103</sup>.

Reimbursement income usually comes from Genmabs strategic partners due to cost which Genmab faces in its research and development projects. This has been decreasing over the years,

<sup>101</sup> Genmab Annual Report 2016, pp 52

<sup>102</sup> Genmab Annual Report 2016, pp 52

<sup>103</sup> Genmab Annual Report 2016, pp 77

because Genmabs strategic partners Janssen and Novartis, is now responsible to cost associated with clinical trials<sup>104</sup>.

**Figure 12: Revenue split by type**

Revenue Split by source	2013	2014	2015	2016
Royalties	131,186	101,427	92,381	521,075
Milestone payments	110,833	385,603	705,688	1,187,244
Deferred Revenue	296,322	284,130	292,426	92,572
Reimbursement Income	125,229	79,225	42,546	15,231
<b>Total</b>	<b>663,570</b>	<b>850,385</b>	<b>1,133,041</b>	<b>1,816,122</b>

*Source: Authors own creation*

So far I have found out that much of the growth in total revenue is related to sales of Darzalex, from where Genmab Receives royalties and milestone payments. Therefore I want to split Revenue into collaborating partners, which is found in Genmabs Annual Reports.

### 6.2.3 Revenue Split by collaborating partners

As can be seen from figure 13 below, revenues related to Janssen are by far the largest contributor of revenue for Genmab, and counts for 95% of total revenue. This on the other hand, also increases the risk for Genmab because the success of Genmab is related to one contributor, namely its daratumumab program and the collaboration with Janssen. It can also be seen that revenue from Arzerra is decreasing in all years. This is due to increased competition, especially from the newly introduced drug Imbruvica<sup>105</sup>. Other collaborating partners, only counts for 1 % of revenue, where some of this is from license income from the Duobody platform.

<sup>104</sup> Genmab Annual Report 2016, pp 52

<sup>105</sup> Genmab Annual Report 2016, pp 52

**Figure 13: Revenue split by collaborating partners**

Revenue split by partners	2013	2014	2015	2016
Janssen(Daratumumab & Duobody)	256,971	531,172	832,810	1,726,433
% of Total Revenue	39%	62%	74%	95%
Novartis/GSK(Ofatumumab)	363,474	310,013	284,269	63,589
% Of Total Revenue	55%	36%	25%	4%
Other Collaborating Partners	43,125	9,200	15,962	26,100
% of Total Revenue	6%	1%	1%	1%

**Source: Authors own Creation**

By going through the composition of revenue, there is no doubt, that the most important thing to forecast is sales related to Darzalex to estimate expected future cash flows for Genmab. The other sources of revenue, counts for a small portion of total revenue, and is therefore less relevant. How I will treat the forecasting of revenue will be explained in chapter 7.

### 6.3 Profitability analysis

The profitability analysis aims at clarifying a company's historical profitability. The profitability analysis is based on the Du Pont model, which breaks the operating profitability down to three levels starting with the overall profitability measure ROIC (Petersen & Plenborg, 2012).

#### Level 1: Return on Invested Capital(ROIC)

ROIC is a measure of the overall profitability of operations, which is calculated as NOPAT divided by the invested capital as can be seen in formula 5 below.

**Formula 5: ROIC after tax**

$$\text{ROIC} = \frac{\text{Net operating profit After tax(Nopat)}}{\text{Invested Capital}} * 100$$

**Source: Petersen & Plenborg(2012), pp 94**

ROIC can also be calculated on a before tax basis, which can be useful when comparing ROIC to peer companies operating in countries with different tax rates.

#### Formula 6: ROIC before tax

$$ROIC = \frac{EBIT}{Invested\ Capital} * 100$$

Source: Petersen & Plenborg(2012), pp 94

Due to differences in taxes between Genmab and the peer companies, I will be using ROIC on a before tax basis.

**Figure 14 : ROIC**

ROIC				
%	2013	2014	2015	2016
Genmab	-8%	-42%	-8671%	116%
Morphosys	-25%	-104%	27%	
Roche	49%	32%	30%	

Source: Authors Own Creation

Looking at the calculated ROIC for Genmab, these are for most years negative. In 2015 the calculated ROIC does not make much sense. The reason for the negative values is due to the calculated Invested Capital in the balance sheet, which was negative up till 2015, before turning positive. This is not an uncommon phenomenon when valuing early stage biotech companies, and other companies which are capital intensive in the beginning off their life-cycles. These companies have massive R&D investments for a number of years before they turn profitable (Koller et al., 2015). When dealing with young Biotech companies, (Koller et al., 2015) suggest using an alternative measure called CFROI. But this is a much more complex measure and is not as easy to understand, so I choose just to use ROIC, and looking at the development of ROIC over the years.

Even though the numbers are a bit hard to interpret anything out off, I can see that ROIC turn positive in 2016 where Genmab hits record revenues.

When comparing to Morphosys the same problem with negative ROIC arrises, but this changes in 2015. This just confirms that negative ROIC for young biotech's is common. When looking at ROIC for Roche, they are having positive ROIC which are behaving more normal. So I would expect that Genmabs ROIC will level out eventually.

## Level 2 : Decomposition of ROIC

ROIC can be decomposed into profit margin (PM) and turnover rate to be able to explain what the profitability is driven by. The profit margin can be calculated on an after tax basis or a before tax basis (Petersen & Plenborg, 2012). As with ROIC, I choose to calculate the profit margin on a before tax basis.

### **Formula 7: Profit margin before tax**

$$\text{Profit margin} = \frac{\text{EBIT}}{\text{Net Revenues}} * 100$$

*Source: Petersen & Plenborg(2012), pp 107*

### **Formula 8: Turnover rate**

$$\text{Turnover Rate} = \frac{\text{Net Revenue}}{\text{Invested Capital}}$$

*Source: Petersen and Plenborg(2012), pp 107*

In many cases, companies with high profit margins, have low turnover rates, and vice versa (Petersen & Plenborg, 2012). For a company like Genmab, which has a high amount of R&D expenses, it would be expected that they have high profit margins and a low turnover rates.

As can be seen from figure 15 below, Genmab is improving its profit margin in all years. This is a combination of increased revenues in all years, while keeping a fairly constant level of operating expenses. In 2016 Genmab increases their R&D budget due to investments in their pipeline<sup>106</sup>. Altogether, they seem to have a pretty high profit margin, this of course has to be compared with peer companies, to see if this is true.

Comparing the profit margin to Morphosys, Genmab's profit margin is higher for the most years, except in 2013. Secondly Genmab's profit margin is steadily rising, where Morphosys are rising and falling through the period. Looking at Roche's profit margin, it is falling through the period, and is

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<sup>106</sup> Genmab Annual Report 2016, pp 9

on average 30%. So I would expect Genmabs profit margin to fall to a lower level eventual as the company matures.

The turnover rate can be interpreted as, for every krone invested in net operating assets, there is a sale corresponding to the turnover rate(Petersen & Plenborg, 2012). So in the beginning of the period, where the turnover rate is negative for Genmab, they are having negative sales. This seems a bit odd, but can probably be explained by the negative invested capital which Genmab has. Looking at Morphosys the same thing is occurring.

Altogether, there is a picture of Genmab turning into a profitable business, but the numbers are much shaken due to the transitioning from a biotech company being in the introduction phase, going into a growth phase.

**Figure 15 : PM and Turnover rate**

PM and turnover rate		2013	2014	2015	2016
Genmab	Profit Margin	10%	31%	49%	58%
	Turnover Rate	-0.74144	-1.3558	-177.287	2.007361
Morphosys	Profit Margin	13%	-9%	16%	-
	Turnover rate	-1.94525	-11.3024	1.646308	-
Roche	Profit Margin	34%	28%	27%	-
	Turnover rate	1.443478	1.130159	1.105717	-

*Source: Authors Own Creation*

### Level 3: Analysing the profit margin

There are two different ways, in which you can analyse the profit margin. This can be done through a common size analysis or by indexing. When using a common size analysis you use the different items on the financial statement and put them relative to revenue. When applying indexing, you choose a base year to see how the different items have evolved through time (Petersen & Plenborg, 2012). I have chosen to use a common size analysis, to see how the different items are evolving as a percentage of revenue. .

When looking at figure 16 below, you can see that Genmabs R&D expenses are decreasing through all years as a percentage of revenues. This sharp drop are not due to falling R&D expenses, but

that revenues are increasing all years, which decreases the relative portion of R&D expenses. Their General and Administrative expenses (G&A) are also decreasing relative to revenue. So even though Genmabs expenses increases, it is not at the same rate as their revenue.

Comparing to Morphosys, their R&D expenses and G&A expenses relative to revenue are higher. The most noticeable are their G&A expenses which counts for a relative large portion compared to Genmab, though it is improving in 2015. So it seems that Genmab has been better at managing their expenses in all years, which also stems with their restructuring. Not surprisingly, Genmabs EBITDA are higher than Morphosys in the last couple of years.

**Figure 16: Common Size**

	Genmab			
<b>Common Size Analysis</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
<b>Revenue</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>
Research And Development Expenses	-78%	-58%	-40%	-34%
General and administrative Expenses	-10%	-9%	-8%	-6%
<b>Operating Expenses</b>	<b>-88%</b>	<b>-67%</b>	<b>-48%</b>	<b>-40%</b>
Other Income	-	-	-	-
Other Expenses	-	-	-	-
<b>EBITDA</b>	<b>12%</b>	<b>33%</b>	<b>52%</b>	<b>60%</b>
Depreciation, Amortisation and Impairment	2%	1%	3%	2%
<b>EBIT</b>	<b>10%</b>	<b>31%</b>	<b>49%</b>	<b>58%</b>
<b>Morphosys</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
<b>Revenue</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	-
Research and development	-51%	-68%	-62%	-
General and administrative	-21%	-21%	-13%	-
<b>Operating Expenses</b>	<b>87%</b>	<b>110%</b>	<b>88%</b>	-
Other Income	1%	1%	5%	-
Other expenses	-1%	-1%	-1%	-
<b>EBITDA</b>	<b>27%</b>	<b>11%</b>	<b>29%</b>	-
Depreciation, and amortisation	15%	20%	13%	-
<b>Ebit</b>	<b>13%</b>	<b>-9%</b>	<b>16%</b>	-
<b>Roche</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	-
<b>Revenue</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	-
Cost of sales'	-25%	-27%	-31%	-
Marketing and distribution	-17%	-17%	-17%	-
Research and Development	-19%	-20%	-19%	-
General and Administration	-5%	-8%	-5%	-
<b>EBITDA</b>	<b>34%</b>	<b>28%</b>	<b>27%</b>	-
Depreciation, Amortisation	0%	0%	0%	-
<b>EBIT</b>	<b>34%</b>	<b>28%</b>	<b>27%</b>	-

**Source: Authors own creation**

Roche is considered to be a mature, which has other kinds of expenses. So it does not make much sense to compare these figures to Genmabs. But comparing to Roches EBIT can give me a picture of how Genmabs EBIT will evolve in the future. As Genmab matures, I expect their expenses to increase as well, and therefore their EBIT are expected to decrease in the future.



## Chapter 7- Forecasting

After a thorough analysis of Genmab and its environment through the strategic analysis, the time has come to make the forecasting of the different value drivers. I have chosen a forecasting period of 7 years. I could have chosen a longer period, but as the time period increases the uncertainty will as well.

### 7.1 Revenue Forecast

The composition of Genmabs revenue is quite complex which could be seen from the financial analysis. Therefore I have chosen to use different techniques in my forecasting of the expected revenue. The Revenue is split up into revenue related to sales of Darzalex, Milestone Payments, Other Income and sales of Arzerra in Multiple Sclerosis.

#### 7.1.1 Revenue from Darzalex sales

From Genmabs 2016 Capital Markets Day(CMD), Genmab reports expected sales from Darzalex(see Figure 16 below). I have chosen to use these expected sales figures, because that I find them to be reasonable based on the analysis of Darzalex.

**Figure 16: Revenue forecast from Darzalex sales**

Revenue Forecast '000	2016	2017	2018	2019	2020	2021	2022	2023
Darzalex sales	572000	1000000	2000000	3000000	4000000	4666666.7	5055555.6	5266204
Growth %	-	75%	100%	50%	33%	17%	8%	4%
Royalties USD	Rate = 16%	160000	320000	480000	640000	746666.67	808888.89	842592.6
USD Rate	7.04							
Royalties DKK	458000	1126400	2252800	3379200	4505600	5256533.3	5694577.8	5931852

*Source: Sales figures (2017-2020) from Genmab CMD Presentation 10 November 2016/ Calculations  
Authors Own creation*

Genmab report royalties from Darzalex sales, of between 12-20 %. Thus I have used the average royalty rate which is 16%, as they do not report the conditions of the royalty payments. The USD currency rate I have chosen is from 15/02/17, which were DKK 7.04 per dollar<sup>107</sup>.

#### 7.1.2 Revenue from Arzerra sales in Multiple Sclerosis

<sup>107</sup> [www.nationalbanken.dk](http://www.nationalbanken.dk) [14/06 2017]

As mentioned earlier, Arzerra is in phase 3 trial for the treatment of multiple Sclerosis. According to Genmabs annual report from 2016, they are expecting the results to come in 2019<sup>108</sup>. I have made the assumption that this is also the year that Arzerra will be approved for treating patients with multiple sclerosis.

In order to calculate the expected sales from Arzerra, I have been inspired by decision tree analysis. Therefore there will be 3 scenarios, each with an attached probability assigned to it.

The chosen probabilities are roughly the same as (Kellogg & Charnes, 2000) use in there article, with some modifications. They use 5 different scenarios which are: Dog, Below average, Average, Above Average and Breakthrough. Average is assigned 60% probability, while the rest of the scenarios are assigned 10 % probability each. Instead of 5 scenarios I have three which is: Best case, Base case and Worst case. The base case scenario is given a probability of 60 %, while the two other scenarios are given a probability of 20% each.

To calculate the expected sales of each scenario, I use a top-down approach suggested by (Keegan, 2008). With this approach I can use the expected market size times the expected market share. I choose this method due to the complexity of these calculations, and that the data availability is very poor. So this method seems to be the best way to overcome this problem. The expected market for multiple sclerosis is taken from a report from Technavio<sup>109</sup>, who publishes forecasting reports for different disease targets amongst other things.

**Figure 17: Best case Scenario, Sales of Arzerra in MS**

Best Case '000	2019	2020	2021	2022	2023
Sales Arzerra MS	822,384.91	1,418,177.82	2,698,893.11	3,900,863.27	5,089,933.76
Royalties USD	131,581.58	226,908.45	431,822.90	624,138.12	814,389.40
Royalties DKK	926,334.36	1,597,435.50	3,040,033.20	4,393,932.38	5,733,301.38

*Source: Authors own creation*

The best case scenario rest on the assumption, that Arzerra are a best in class drug for the treatment of MS. Whether this will be the case is hard to say at the moment, since Arzerra are still

<sup>108</sup> Genmab Annual Report 2016, pp 8

<sup>109</sup> Technavio: Global Central Nervous System Disorders Therapeutics Market 2016-2020

in phase 3 studies for MS. Phase two studies has suggested improvement in the condition, but information are still not clear. Darzalex had a very good introduction into the market, so I have used Darzalex's market share and expected market share, as a proxy for the market share that Arzerra will have in its best case scenario. Since the information Arzerra are in the treatment of MS are very scarce, this seems as the best estimate so far.

**Figure 18: Base Case Scenario, Sales of Arzerra in MS**

Base Case '000	2019	2020	2021	2022	2023
Sales Arzerra MS	521,005.38	648,798.67	862,491.36	927,758.13	661,030.80
Royalties USD	83,360.86	103,807.79	137,998.62	148,441.30	105,764.93
Royalties DKK	586,860.46	730,806.83	971,510.27	1,045,026.75	744,585.10

*Source: Authors own creation*

To calculate the base case scenario, I have used the market share which Arzerra has already made on the market for CLL. This seems as a reasonable assumption, because it is based on Arzerra's past performance. Again, the information about MS is scarce, and there are no effective treatments at the moment. Other drugs similar to Arzerra are being tested, so if Arzerra are effective, there will be other competitors coming around the same time.

**Figure 19: Worst Case Scenario, Sales of Arzerra in MS**

Worst Case '000	2019	2020	2021	2022	2023
Sales Arzerra MS	0	0	0	0	0
Royalties USD	0	0	0	0	0
Royalties DKK	0	0	0	0	0

*Source: Authors own Creation*

The worst case scenario is if the drug is not approved as a treatment for MS patients. If so, the sales and expected royalties are zero.

### 7.1.3 Milestone Payments

The information about their milestone payments and what to expect in the future are very scarce. I can see from the annual report that there are multiple trials related to Darzalex, plus trials from

other drugs as well. In the past years, the growth has been high due to Darzalex and its approved line of indications etc., but this high growth rate should be expected to wear off. Therefore I have decreased the yearly growth rate over the years as can be seen from the appendix.

#### **7.1.4 Other Revenue**

Other Revenue is comprised of sales from Arzerra in the CLL market, deferred income and reimbursement income. These have all been decreasing over the years, and are expected to do so in the future.

The sales from Arzerra in the CLL market have been falling rapidly the last 3 years, both due to low market penetration and increased competition. So I see no reasons that this should not continue in the future.

Deferred income is also expected to fall, as reported in the annual report.

Reimbursement income was mainly driven from cost associated with the development from Arzerra and Darzalex, but these costs have been passed on to their collaborating partners. So this is also set to decrease into the future.

#### **7.1.5 Financial Income/Expenses**

Both financial income and expenses are related to Genmabs investment in marketable securities and other derivatives. I have chosen to make the assumption that the financial income equals the financial expenses in the forecasting horizon. This has been chosen due to the nature of derivatives, which seems to be very hard to predict in the future.

### **7.2 Forecasting Expenses**

#### **7.2.1 R&D**

R&D as a percentage of revenue has been decreasing over the years, but this has to be seen in connection to increases in revenue. The R&D as a percentage of revenue was 34% last year, and is therefore set to this for 2017. Looking at Roche R&D as percentage of revenue is far lower, but Roche's expenses are comprised differently than for Genmab. So after 2017, the R&D expenses are set at 30% for the rest of the forecasting horizon. I expect that Genmab will continue to invest in its pipeline, in order to achieve its goals in the future.

### 7.2.2 G&A

Historically, Genmabs G&A expenses has on average been 2% of revenue. So for the forecasting period, G&A will be set at 2%. Genmab has managed to keep their cost low, but it will be expected to increase as the company increases. This can also be seen in the rise of G&A expenses for 2016, and the hiring of new employees.

## 7.3 Forecasting Balance sheet Items

### 7.3.1 Intangible and tangible Assets

Intangible and tangible assets as a percentage of revenue has been increasing until 2016 where it drops to 12%. The historical average is also 12 % of revenue, so I have chosen 12% of revenue for the rest of the forecast period.

### 7.3.2 NWC

The biggest contributor to net working capital is receivables, which has increased drastically in 2016. In 2016 NWC is 61% of revenue compared to 16 % in 2015. Some of this can be explained by timing of royalty payments and milestone payment. The average NWC as percentage of revenue are 28 %, which are chosen as the target for NWC. So I have chosen to decrease NWC over the years until it hits the average of 28%. There is little information about this post in the annual report, plus that this post has been much lower historically. So this seems to be the best way to estimate it, with the assumption that the timing of these payments gets better.

## 7.4 Taxes

It is assumed that the current Danish tax rate of 22% is the tax rate in all of the years in the forecast horizon.

## Chapter 8-Valuation

Before I can do my valuation of Genmab, I will first have to calculate the cost of capital for Genmab. When this is done, I can finally calculate the value of Genmabs stock based on the forecasting of Genmabs FCFE.

## 8.1 Estimating the cost of capital

The usual way of estimating the cost of Capital for a company is to use the Weighted Average Cost of Capital(WACC).

### **Formula 9: WACC**

$$WACC = \frac{NIBD}{(NIBD+E)} * r_d * (1-t) + \frac{E}{(NIBD+E)} * r_e$$

**Source: Petersen and Plenborg(2012), pp 246**

Where NIBD is the market value of net interest bearing debt, E is the market value of Equity,  $r_d$  is the required rate of return on NIBD,  $r_e$  is the required rate of return on equity, and t is the tax rate.

Due to Genmabs Capital structure, which consists mainly of Equity, I have chosen to use the required rate of return on equity alone, which will be estimated using the CAPM model.

### **Formula 10: Required rate of return to equity holders (Cost of Capital)**

$$CAPM: r_e = r_f + \beta_e * (r_m - r_f)$$

**Source: Petersen and Plenborg(2012),pp249**

Where,  $\beta_e$  is the systematic risk on Equity,  $r_m$  is the return on the market portfolio, and  $r_f$  is the Risk-Free interest rate.

There are other ways of determining the required rate of return, like the Fama-French Factor model, and there is an ongoing discussion on which is the best at estimating the required rate of return on equity. The decision on which model is the best, is beyond the scope of this thesis, and I have decided to use the CAPM model due to its relative simplicity.

Below I will Estimate each of the parameters used in the CAPM model, in order to Estimate the required rate of return on Genmab.

### 8.1.1 Estimation of the risk-free interest rate ( $r_f$ )

The risk-free interest rate is the return an investor can earn on a portfolio without any risk. In theory, you would construct a zero-Beta portfolio, in order to determine the risk-free rate. But this

is very problematic to use in reality, which is why you usually use the yield of a 10-year or 30-year government bond as the risk-free interest rate. These are usually seen as risk-free due to the probability of default is very low in most cases, although this is not always the case (Petersen & Plenborg, 2012).

I have chosen to use the 10-year Danish government bond, as a proxy for the risk-free interest rate<sup>110</sup>. Further I have used the average rate for the last 12 months to even out small fluctuations. The average interest rate for a 10-year government bond was 0.26 %.

### 8.1.2 Estimation of systematic risk ( $\beta_e$ )

The systematic risk component, Beta, is the part of risk, which cannot be diversified away by diversification. Beta tells us what the sensitivity of the stock return is to the market return (Petersen & Plenborg, 2012). The beta coefficient can be calculated directly by using formula 11 below, or by excel's regression analysis. Both lead to the same result, but the regression output can be useful in determining the usefulness of the beta estimate.

#### **Formula 11: Beta**

$$\beta = \frac{\text{Covariance}(\text{Market return}, \text{Stock return})}{\text{Variance}(\text{Market return})}$$

**Source: Benninga (2014), pp 91**

The true market portfolio is not observable, so you will usually use a proxy. According to (Koller et al., 2015), a local portfolio of assets should not be used as this may be too small or might be too heavily weighted within certain industries. Due to this, I will not be using the Danish C20 Index due to the factors mentioned above. (Koller et al., 2015) suggest using the S&P500 or the MSCI World index as a proxy for the market portfolio. The difference between using one over the other should not be significant because that they have a highly correlation.

Therefore I have chosen to use the MSCI world, but I also choose to use the MSCI EUROPE Index<sup>111</sup>, to see which beta estimate seems more appropriate. The time period used should not be less than 5 years of return, and preferably monthly returns. The problem by using smaller time

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<sup>110</sup> Found on [www.danmarksstatistik.dk](http://www.danmarksstatistik.dk) [01/06 2017]

<sup>111</sup> Found on [www.msci.com](http://www.msci.com) [01/06 2017]

frames is if the stocks return are illiquid which can lead to zero returns in some periods (Koller et al, 2015). Genmabs stock 5 years ago were more illiquid than today, so it makes sense to just stick with the monthly returns. Further I have been using returns from the period 2012-2016 which equals five years of data.

By using the MSCI World Index I have come to an estimated 5 year beta of 1.88. Looking at the T-stat and the P-value (see appendix), they show that the estimated beta is significant at a 5 % significance level, and even at a 1 % level. By using the MSCI Europe Index, the calculated 5-year beta is -0.17, with a p-value of 0.67 which is extremely high.

Comparing the to beta values, I choose to use the MSCI World index as proxy for the market portfolio, and the corresponding beta of 1.88. But the beta value seems to be a bit high, which is probably explained by the high volatility of Genmabs stock price in recent years. To overcome such issues (Koller et al., 2015) suggest to use beta smoothing, which adjust the beta closer to 1. There are mentioned different techniques, but I have chosen to use a simple smoothing technique which is used by Bloomberg(Koller et al, 2015), see formula 12 below.

**Formula 12: Adjusted Beta**

$$\text{Adjusted Beta} = 0.33 + 0.67 * (\text{Raw beta})$$

*Source: Koller et al (2015), pp299*

By using the formula above, the adjusted beta are 1.59. This estimate seems more appropriate, so I will be using this beta instead of 1.88 which was the raw beta. The beta still seems high, but this estimate seems much better. To make a sanity check I have found beta-values calculated from financial pages which can be seen from figure 20 below.

**Figure 20: Beta Collections**

	Beta
Financial Times	1.148
Reuters	1.15
Yahoo Finance	0.2

*Source: Authors own Creation*



Compared to the calculated betas from other sources, my beta estimate does seem high, and can have an effect on my valuation. But the differences in beta estimates should be captured in the sensitivity analysis.

### 8.1.3 Estimation of market portfolio risk-premium ( $r_m - r_f$ )

According to (Petersen and Plenborg, 2012), there is two ways of estimating the market risk premium. The Ex-post approach and the ex-ante approach. The ex-ante approach uses the historical differences between the market return and the return on the risk-free investment. The ex-ante approach try to infer the market portfolios implicit risk, by using analysts' consensus earnings forecast.

There is no clear way, of which method is the right one, nor is there any agreement amongst practitioners about the right market risk-premium. In many cases the market risk premium is taken from books and research articles (Petersen & Plenborg, 2012), which is what I have chosen to do.

(Fernandez et al., 2016), have ask practitioners in 71 countries around the world, of which market risk-premium they used. In Denmark the Average market risk premium used by practitioners was 5.3%, with a standard deviation of 1.7%. So I have chosen to use the average market risk premium of 5.3 %.

In another article from (Damoradan, 2015), he quotes a Market Risk premium for Denmark of 5.81%, which are a bit higher than the estimate from (Fernandez et al., 2016). Because the numbers from (Fernandez et al., 2016) are the most recent numbers, I choose to use his.

### 8.1.4 Estimating the required rate of return on Equity ( $r_e$ )

Based on my findings above, I am now ready to calculate the required rate of return through CAPM:

$$r_e = 0.26\% + 1.59 * (5.3\%) = 8.7\%$$

So the estimated required rate of return or Genmab which I will use in my valuation is 8.7 %.

### 8.1.5 Estimating the terminal growth rate

In order to calculate the terminal value, which accounts for the largest part of a company's value, one must calculate the expected growth rate in the terminal value. In the terminal period the company's growth is assumed to have reached a steady state of constant growth. Usually you use the growth in the economy, which can be measured by the growth in BNP (Sørensen, 2011). Therefore I have chosen to use the expected 5 year European growth rate in BNP, which is 1.8%<sup>112</sup>.

Through the strategic analysis, I found that there are a lot of uncertainties, like the dependants on the sales of Darzalex, dependants of its collaborating partners, and increased competition. Therefore I feel that because Genmab is in its early growth phase, it seems reasonable to keep a conservative estimate of the growth in the terminal value.

## **8.2 Valuing Genmabs share price**

### **8.2.1 Valuation using DCF**

As mentioned in the theory section the valuation of Genmabs Equity is based on the FCFE, and has been calculated as can be seen from the appendix. The market value of Genmabs Equity, or enterprise value, has been calculated to be DKK 68,865.501 million on the 22/02/17.

To calculate on a per share basis, I will have to divide by the number of outstanding shares, which was stated in Genmabs Annual report 2016 to be 60.350 million shares. This gives a share value of DKK 1137.5 on the 22/02/17

### **8.2.2 Valuation using RI**

When applying the RI valuation model, one needs to calculate RI instead of FCFE. RI is calculated as the difference between NOPAT and Invested Capital in the budgeting period. Further you have to add the Invested Capital to the sum of the PV of RI in the forecasting period and the PV of the RI in the terminal period. Despite the differences in the inputs, it should theoretically give the same result as when using the DCF valuation model.

This has also been the case, as the market value of Equity was estimated to be DKK 68,865.501 million, and the share price was thus DKK 1137.5 per share.

### **8.2.3 Comparing with the market value**

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<sup>112</sup> [https://www.ecb.europa.eu/stats/prices/indic/forecast/html/table\\_hist\\_hicp.en.html](https://www.ecb.europa.eu/stats/prices/indic/forecast/html/table_hist_hicp.en.html) [07/06 2017]

Genmabs share price at 22/02/17 was quoted at DKK 1415<sup>113</sup>, which is above my estimated share price of 1137.5 per share. So if my estimates are the true value, the price is clearly overvalued, and I would recommend to sell the stocks rather to buy. But the calculated share price is depending on a lot of inputs, which is why I will be performing a sensitivity analysis to see how sensitive my share price is to different inputs. This is done in the next chapter below.

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<sup>113</sup> <https://finance.yahoo.com/quote/GEN.CO/history?p=GEN.CO> [07/06 2017]

## Chapter 9- Sensitivity Analysis

It is recommended to perform a sensitivity analysis of the valuation to see how sensitive the result is to changes in important value drivers. I have chosen to perform a sensitivity analysis of how sensitive the Cost of Capital is to changes in beta and in the market risk-premium. Both my “Raw beta” and adjusted beta was relatively high, especially when comparing to beta’s found on financial webpages. So it seems to be a good starting point when performing this sensitivity analysis.

**Figure 21: Sensitivity of Cost of Capital**

R(.e)	Beta				
MRP	1.19	1.39	1.59	1.79	1.99
4.90%	6.09%	7.07%	8.05%	9.03%	10.01%
5.10%	6.33%	7.35%	8.37%	9.39%	10.41%
5.30%	6.57%	7.63%	8.69%	9.75%	10.81%
5.50%	6.81%	7.91%	9.01%	10.11%	11.21%
5.70%	7.04%	8.18%	9.32%	10.46%	11.60%

**Source: Authors own Creation**

I have chosen to use vary the beta with 0.2, and the Market Risk premium with 0.2%. As you can see from the figure above, this changes the Cost of Capital a great deal. The cost of capital ranges from 6.09% at its lowest to 11.60 % as the highest, just by changing beta and the Market Risk Premium by a small amount. This tells me that the Cost of Capital are very sensitive to changes in the two input variables.

Due to the sensitivity of the cost of capital to its inputs, it seems fair to test the effect this has on the stock price. Further I will test how sensitive the stock price is to the Growth rate. I have chosen the variation in Cost of Capital from the calculations above, which are closest to the cost of capital I have used. The Growth rate is in steps of 0.2%.

**Figure 22: Sensitivity of the Stock price**

Stock Price	Growth				
r(.e)	1.40%	1.60%	1.80%	2.00%	2.20%
7.35%	1359.826	1396.646	1436.12	1478.544	1524.264
8.37%	1145.521	1170.746	1197.506	1225.946	1256.23
8.69%	1091.166	1113.806	<b>1137.761</b>	1163.149	1190.101
9.75%	940.4432	956.665	973.7031	1053.989	1010.488
10.11%	898.0088	912.6206	927.936	944.0071	960.8913

**Source: Authors Own Creation**

Looking at the figure above, the estimated price of the stock is very sensitive to the cost of capital and the growth rate. This is especially the case when changing the cost of capital. Changing the cost of capital with 1 percentage point can change the value of the stock with almost DKK 300. The stock price ranges from DKK 898 to DKK 1524, which is a large span.

Based on the sensitivity analysis, the cost of capital and the price of the stock are very sensitive to its input parameters. So differences in my estimated price and the quoted market price might be to differences in cost of capital, beta or the expected growth rate.

## Chapter 10- Conclusion

The goal of this thesis was to estimate the fair price of Genmabs share price on the 22/02/17, through a strategic and financial analysis. This has been a challenging job because Genmab has positioned itself as a strong growth company, which made past performance irrelevant, because it tells nothing about Genmabs expected future performance. Therefore the selected time period of analysis was only from 2013-2016, with emphasis on the last year. In my valuation, I decided to use the DCF model and RI model, because these seemed suitable for the job. Using multiples were discarded because these would be too simple for a growth company like Genmab.

Genmab focuses on the development of antibodies for the treatment of cancer types where other drugs are inefficient. These markets are driven by special designations from the FDA and EMA, which offers opportunities for Genmabs drugs if these are capable of offering better efficacy than already existing drugs. But with relatively small markets, and increasing competition, this can challenge Genmabs drug Darzalex in the future, as has been seen with their other drug Arzerra. Further the industry is seeing increased price pressure from political side. The treat of substitutes is relatively high, due to the wide variety of useful therapies, which is undergoing rapidly technological changes which can possess a threat to Genmab in the future. There are also a increased use of combination drugs, which drives the market growth.

Due to Genmab being a small biotech company, it is relying on its collaborating partners to help develop, manufacture and distributed its drug. This increases Genmabs risk, if their collaborating partners don't put the time and effort in Genmabs drugs. Further Genmab only has two drugs on the market, where the sales of Arzerra are decreasing. Genmabs other marketed drug, Darzalex has had a very good start, and sales has been very good this past year. But Darzalex is also what will drive Genmabs growth in the near future.

Genmabs main sources of revenue are milestone payments and royalties related to sales of its drugs. The only source of revenue growth at the moment is milestone payments and royalties related to sales and line of approvals from Darzalex, which are expected to be a blockbuster drug. As a consequence, Genmabs financial performance have changed drastically in recent years, and are now being a profitable biotech company. The sales of Darzalex and further approvals hereof, are also expected to drive revenue growth in the future. Further the approval of Arzerra in the

treatment of MS patients, which should be expected in 2019, should also increase Genmabs revenue growth, but this are coupled with high uncertainty.

Based on the strategic and financial analysis, I reached an enterprise value of DKK 68,648.827 million and a share price at 22/02/17 of DKK 1137.5, which is below the quoted share price of DKK 1415. This suggests that the share price is overvalued, according to my estimates and an investor should sell the stock, or wait to by till the price reverses.

The result above is based on a Cost of Capital of 8.69% and a growth rate of 1.8%. Through my sensitivity analysis, I found both that my cost of capital are sensitive to its input parameters, but also that the share price are very sensitive in variations of the cost of capital and the selected growth rate. Through changes in these variables, I found the share price to span from DKK 898 to DKK 1524 per share, by small incremental changes in the parameters. So my result is coupled with a high degree of uncertainty.

## 10.1 Discussion

In this section I will briefly discuss the effect of some of the assumptions which I have made through my thesis. Further I will make a brief discussion on my beta value which was a bit high.

In my valuation I have made some assumptions in order to ease my calculations. This of course has an effect on the result, which I feel also needs to be addressed. One of my assumptions was concerning Genmabs Tax loss carry forwards, which I did not incorporate in my Valuation. By including these would have Increased NOPAT, due to a lower effective tax rate.

Another assumption I made, was that Genmabs Financial income and expenses was the same and therefore equals zero in the forecasting period. This is probably a bold assumption, but as explained these are mainly comprised of gains and losses from marketable securities and other derivatives which will fluctuate in the future. Further these are not Genmabs main source of Income. Even though, the net financial income was around DKK 76 million in 2016, and accounted for approximately 10 % of its net result. Including some estimate of the financial income, at least in the first couple of years in the forecasting horizon would have increased the estimated value of Genmabs share price.

My beta estimate was a bit high, especially when comparing to the beta estimates from Reuters and Financial times. So I could have tried to use other indexes like the S&P500 as the market proxy. I could also have tried other more advanced smoothing techniques to see if this would lower my estimated beta value. As seen from the sensitivity analysis, the value of the share price was very sensitive to the calculated cost of capital, so with a lower estimated beta value, would have decreased the cost of capital, and in turn have increased the estimated share price, which could have changed my conclusion.

## **10.2 Perspective**

In my valuation of Genmab it could have been relevant to include Real options. Both (Keegan, 2008) and (Bogdan & Villiger, 2010) suggest the use of Real option when valuating Biotech companies. This is because this method can capture the uncertainty and management decision process correlated with the development of a new drug. By including real-options I could have estimated some of Genmabs other drugs, which are in their trial phases, which could have given a different estimate.



## References

### Company Reports:

#### Genmab

Genmab Annual Report 2013

Genmab Annual Report 2014

Genmab Annual Report 2015

Genmab Annual Report 2016

Genmab Stock Exchange Release no.41/2009

Genmab 2016 Capital Markets Day: Building Innovation Powerhouse. Nov.16. 2016

#### Roche

Roche Annual Report 2013

Roche Annual Report 2014

Roche Annual Report 2015

#### Morphosys

Morphosys Annual Report 2013

Morphosys Annual Report 2014

Morphosys Annual Report 2015

#### Others

Technavio: Global Central Nervous System Disorders Therapeutics Market 2016-2020

### Articles & Books:

Benninga, S.(2014). Financial Modelling(4<sup>th</sup> ed.). Cambridge MA. Massachusetts Institute of Technology. The MIT Press.

Bogdan, B. & Villiger, R. (2010). Valuation in Life Sciences: A practical Guide(3<sup>rd</sup> Edition). Springer

Cleeren, K., Lamey, L., Meyer, J-H., Ruyter, K. (2016). How Business Cycles affect the healthcare sector: A cross country investigation. Health Economics. 25: 787-800

Damodaran, A. (2015). Country Risk: Determinants, Measures and Implications-The 2015 Edition. Stern School of Business

DiMasi JA, Hansen RW, Grabowski HG. 2003. The price of innovation: new estimates of drug development costs. Journal of Health Economics 22(3): 141–185.

Fernandez, P., Ortiz, A. Acin, I.F. ( 2016). Market Risk Premium used in 71 countries in 2016: a survey with 6,932 answers. IESE Business School. University of Navarra

Finans, R. & Jensen, L.W.(15.02.17). Analytiker: Udvidelse af patentsag rører ikke Genmab. [www.medwatch.dk](http://www.medwatch.dk)

Keegan, D. K. (2008). Biotechnology valuation: An introductory Guide(1'st Edition). John Wiley and Sons, LTD., Publication

Kellogg, D. & Charnes, J.M.(2000). Real-options valuation for a Biotechnology company. Financial Analyst Journal, Vol.56, NO. 3(May-Jun, 2000), pp. 76-84

Koller, T. Goedhart, M & Wessels,D. (2015). Valuation: Measuring and Managing the Value of Companies. (McKinsey & Company(6.th Edition)). Wiley

Landers, E. (31.01.17). Trump pledges to work with Big Pharma to lower drug prices. [www.edition.cnn.com](http://www.edition.cnn.com)

Morrow, T.,& Felcone, L. H. (2004).Defining the difference: What makes biologics unique. Biotechnology healthcare, Sep:1(4), pp 24-26, 28-29

Petersen, C.V. & Plenborg, T. (2012). Financial statement analysis: Valuation; Credit analysis; Executive compensation. Prentice Hall

Porter, M. (2008). The five forces that shape strategy. Harvard Business Review, 86(1), 78-93

Sørensen, O. (2011), Regnskabsanalyse og værdiansættelse - En praktisk tilgang( 3'rd Edition).Gjellerup

#### **Webpages:**

[www.aoa.acl.gov](http://www.aoa.acl.gov)

[www.ca-biomed.org](http://www.ca-biomed.org)

[www.cancer.org](http://www.cancer.org)

[www.cancer.gov](http://www.cancer.gov)  
[www.census.gov](http://www.census.gov)  
[www.cancer.dk](http://www.cancer.dk)  
[www.danmarksstatistik.dk](http://www.danmarksstatistik.dk)  
[www.ec.europa.eu](http://www.ec.europa.eu)  
[www.ecb.europa.eu](http://www.ecb.europa.eu)  
[www.edition.cnn.com](http://www.edition.cnn.com)  
[www.ema.europa.eu](http://www.ema.europa.eu)  
[www.fda.gov](http://www.fda.gov)  
[www.ft.com](http://www.ft.com)  
[www.futuremedicine.com](http://www.futuremedicine.com)  
[www.genmab.com](http://www.genmab.com)  
[www.mbaschool.com](http://www.mbaschool.com)  
[www.medwatch.dk](http://www.medwatch.dk)  
[www.meurope.org](http://www.meurope.org)  
[www.morphosys.com](http://www.morphosys.com)  
[www.msci.com](http://www.msci.com)  
[www.nationalbanken.dk](http://www.nationalbanken.dk)  
[www.nationalmssociety.org](http://www.nationalmssociety.org)  
[www.nbcnews.com](http://www.nbcnews.com)  
[www.ncbi.nlm.nih.gov/pubmed/](http://www.ncbi.nlm.nih.gov/pubmed/)  
[www.pwc.com](http://www.pwc.com)  
[www.reuters.com](http://www.reuters.com)  
[www.roche.com](http://www.roche.com)  
[www.seer.cancer.gov](http://www.seer.cancer.gov)

[www.who.int](http://www.who.int)

[www.worldbank.org](http://www.worldbank.org)

[www.yahoofinance.com](http://www.yahoofinance.com)

**Databases:**

Danmarks Statistik

Ebscohost

Emis Professional

Medwatch

National Library of Medicine/National Institute of Health

Thomson One Banker

World Bank

## Appendix

Products in development(Source: Genmab Annual Report 2016, pp 18):

## Products in Development

Product	Disease Indications	Development Phase
<b>Daratumumab</b> Target: CD38, Partner: Janssen	Multiple myeloma (MM) Non-Hodgkin's lymphoma (NHL) Natural Killer/T-Cell lymphoma (NKTCL), Nasal Type Solid tumors	Pre-clinical I II III
<b>Olotumumab</b> Target: CD20, Indications: Cancer, Partner: Novartis	Chronic lymphocytic leukemia (CLL) Follicular lymphoma (FL)	Announced Announced
<b>Olotumumab (OMB157)</b> Target: CD20, Indications: AL, Partner: Novartis	Relapsing multiple sclerosis (RMS) (SubQ)	
<b>Tisotumab vedotin</b> Target: Tf	Solid Cancers	
<b>HuMax-AXL-ADC</b> Target: AXL	Solid Cancers	
<b>Teprotumumab (RV001)</b> Target: IGF-1R, Partner: River Vision	Graves' ophthalmopathy*	
<b>AMG 714</b> Target: IL-15, Partner: Cellimmune (publicized from Amgen)	Cellar Disease	
<b>ADCT-301 (HuMaxTAC-ADC)</b> Target: CD25, Partner: ADCT	Lymphoma Acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL)	
<b>JNJ-61186372</b> Targets: EGFR, cMET, Partner: Janssen	Non-small cell lung cancer (NSCLC)	
<b>JNJ-63709178</b> Targets: CD3, CD123, Partner: Janssen	Acute Myeloid Leukemia (AML)	Clinical Hold
<b>&gt; 20 Active Pre-clinical programs incl., HexaBody-D85/D85, DuoBody-CD3xCD20</b>	Proprietary programs: HuMab, HuMab-ADC, DuoBody, DuoBody-ADC & HexaBody Partnered programs: HuMab, DuoBody & HexaBody	

\*Study completed, but listed on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) as Active, not recruiting

BTD = Breakthrough Therapy Designation

## Income Statement Genmab

DKK '000				
Income Statement-Genmab Group	2013	2014	2015	2016
Revenue	663,570	850,385	1,133,041	1,816,122
Research and development expenses	- 527,576	- 505,679	- 487,656	- 660,876
General and administrative expenses	- 66,741	- 79,529	- 91,224	- 102,413
Operating expenses	- 594,317	- 585,208	- 578,880	- 763,289
Other Income			176,218	
Operating Result	69,253	265,177	730,379	1,052,833
Financial Income	30,446	57,921	56,706	86,609
Financial expenses	- 34,297	- 25,752	- 29,558	- 9,225
<b>Net result before tax</b>	<b>65,402</b>	<b>297,346</b>	<b>757,527</b>	<b>1,130,217</b>
Corporate tax	4,753	3,950	5,986	56,858
<b>Net Result</b>	<b>70,155</b>	<b>301,296</b>	<b>763,513</b>	<b>1,187,075</b>

## Balance sheet Genmab:

Balance Sheet '000	2013	2014	2015	2016
<b>Assets</b>				
Intangible Assets	2,541	62,530	192,642	181,895
Property, Plant and Equipment	22,662	25,684	28,812	32,194
Equity Interest in subsidiaries	-	-	-	
Receivables	6,163	6,428	6,863	1,473
Deferred Tax Assets	7,178	5,685	6,342	125,035
<b>Total Non-current assets</b>	<b>38,544</b>	<b>100,327</b>	<b>234,659</b>	<b>340,597</b>
Receivables	136,004	105,839	174,660	975,674
Marketable Securities	1,388,844	2,301,428	2,619,243	3,614,942
Cash and cash-equivalents	168,135	359,087	873,986	307,023
<b>Total Current Assets</b>	<b>1,692,983</b>	<b>2,766,354</b>	<b>3,667,889</b>	<b>4,897,639</b>
<b>Total Assets</b>	<b>1,731,527</b>	<b>2,866,681</b>	<b>3,902,548</b>	<b>5,238,236</b>
<b>Shareholders Equity and Liabilities</b>				
Share Capital	51,756	56,967	59,531	60,350
Share premium	5,887,957	6,920,226	7,560,991	7,769,577
Other Reserves	77,180	84,101	94,476	102,883
Accumulated Deficit	-5,357,370	-5,028,355	-4,228,278	-3,106,114
<b>Total Shareholders Equity</b>	<b>659,523</b>	<b>2,032,939</b>	<b>3,486,720</b>	<b>4,826,696</b>
Provisions	1,433	1,433	1,433	-
Lease Liability	356	118	-	-
Other payables	162,713	176,223	-	-
<b>Total Non-current Liabilities</b>	<b>164,502</b>	<b>177,774</b>	<b>1,433</b>	<b>-</b>
Provisions	861	-	-	1,433
Lease Liabilities	2,129	237	118	-
Deferred Income	817,492	550,243	282,708	228,150
Other Payables	87,020	105,488	131,569	120,345
Corporate tax payables	-	-	-	61,612
<b>Total Current Liabilities</b>	<b>907,502</b>	<b>655,968</b>	<b>414,395</b>	<b>411,540</b>
<b>Total Liabilities</b>	<b>1,072,004</b>	<b>833,742</b>	<b>415,828</b>	<b>411,540</b>
<b>Total Shareholders Equity and Liabilities</b>	<b>1,731,527</b>	<b>2,866,681</b>	<b>3,902,548</b>	<b>5,238,236</b>



## Analytical Income Statement Genmab:

Tax rate	0.25	0.245	0.235	0.22
<b>Analytical Income Statement-Genmab Group</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
<b>DKK ' 000</b>				
<b>Revenue</b>	<b>663,570</b>	<b>850,385</b>	<b>1,133,041</b>	<b>1,816,122</b>
Research And Development Expenses	- 516,501	- 493,736	- 456,083	- 620,279
General and administrative Expenses	- 66,152	- 79,141	- 90,974	- 102,254
<b>Operating Expenses</b>	<b>- 582,653</b>	<b>- 572,877</b>	<b>- 547,057</b>	<b>- 722,533</b>
<b>EBITDA</b>	<b>80,917</b>	<b>277,508</b>	<b>585,984</b>	<b>1,093,589</b>
Depreciation, Amortisation and Impairment	11,664	12,331	31,823	40,756
<b>EBIT</b>	<b>69,253</b>	<b>265,177</b>	<b>554,161</b>	<b>1,052,833</b>
Corporate Tax on Result	- 16,351	- 72,850	- 178,019	- 248,648
Tax Shield, net financial Expenses	- 963	7,881	47,791	17,024
<b>Nopat</b>	<b>51,940</b>	<b>200,209</b>	<b>423,933</b>	<b>821,210</b>
Other Income			176,218	
Financial Income	30,446	57,921	56,706	86,609
Financial Expenses	- 34,297	- 25,752	- 29,558	- 9,225
Tax On net Financial Expenses	963	- 7,881	- 47,791	- 17,024
<b>Net Financial Income/(expenses)</b>	<b>- 2,888</b>	<b>24,288</b>	<b>155,575</b>	<b>60,360</b>
<b>Group Profit After Tax</b>	<b>49,052</b>	<b>224,496</b>	<b>579,508</b>	<b>881,569</b>

## Analytical Balance Sheet:

DKK '000				
Analytical Balance Sheet	2013	2014	2015	2016
<b>Invested Capital</b>				
<b>Non-current Assets</b>				
Intangible Assets	2,541	62,530	192,642	181,895
Property, Plant and Equipment	22,662	25,684	28,812	32,194
Equity Interest in subsidiaries	-	-	-	-
Receivables	6,163	6,428	6,863	1,473
Deferred Tax Assets	7,178	5,685	6,342	125,035
<b>Total Non Current Assets</b>	<b>38,544</b>	<b>100,327</b>	<b>234,659</b>	<b>340,597</b>
<b>Current Assets</b>				
Receivables	136,004	105,839	174,660	975,674
<b>Total Current Assets</b>	<b>136,004</b>	<b>105,839</b>	<b>174,660</b>	<b>975,674</b>
<b>Non Interest Bearing Debt</b>				
Provisions	1,433	1,433	1,433	-
Other payables	162,713	176,223	-	-
Provisions	861	-	-	1433
Deferred Income	817,492	550,243	282,708	228,150
Other Payables	87,020	105,488	131,569	120,345
Corporate tax payables	-	-	-	61,612
<b>Total Non Interest Bearing Debt</b>	<b>1,069,519</b>	<b>833,387</b>	<b>415,710</b>	<b>411,540</b>
<b>Invested Capital(Net operating assets)</b>	<b>-894,971</b>	<b>-627,221</b>	<b>-6,391</b>	<b>904,731</b>
<b>Total Equity</b>	<b>659,523</b>	<b>2,032,939</b>	<b>3,486,720</b>	<b>4,826,696</b>
<b>Net Interest Bearing Debt</b>				
Lease Liabilities	356	118	-	-
Lease Liability	2,129	237	118	-
<b>Interest Bearing Debt</b>	<b>2,485</b>	<b>355</b>	<b>118</b>	<b>0</b>
Cash and cash-equivalents	168,135	359,087	873,986	307,023
Marketable Securities	1,388,844	2,301,428	2,619,243	3,614,942
<b>Interest bearing Assets</b>	<b>1,556,979</b>	<b>2,660,515</b>	<b>3,493,229</b>	<b>3,921,965</b>
Net Interest Bearing debt	-1,554,494	-2,660,160	-3,493,111	-3,921,965
<b>Invested Capital</b>	<b>-894,971</b>	<b>-627,221</b>	<b>-6,391</b>	<b>904,731</b>

### Beta Regression MSCI World:

RESUMEOUTPUT								
<i>Regressionsstatistik</i>								
Multipel F	0.421255							
R-kvadreret	0.177456							
Justeret R	0.163025							
Standardfejl	0.119397							
Observationer	59							
ANOVA								
	<i>fg</i>	<i>SK</i>	<i>MK</i>	<i>F</i>	<i>signifikans F</i>			
Regression	1	0.175304	0.175304	12.29717	0.000892			
Residual	57	0.812572	0.014256					
I alt	58	0.987876						
	<i>Koefficient</i>	<i>standardfejl</i>	<i>t-stat</i>	<i>P-værdi</i>	<i>Nedre 95%</i>	<i>Øvre 95%</i>	<i>Nedre 95.0%</i>	<i>Øvre 95.0%</i>
Skæring	0.04559	0.016441	2.772965	0.007493	0.012668	0.078512	0.012668	0.078512
X-variabel	1.884814	0.537484	3.506732	0.000892	0.80852	2.961108	0.80852	2.961108

### Beta Regression MSCI Europe:

RESUMEOUTPUT								
<i>Regressionsstatistik</i>								
Multipel F	0.064136							
R-kvadreret	0.004113							
Justeret R	-0.01367							
Standardfejl	0.131873							
Observationer	58							
ANOVA								
	<i>fg</i>	<i>SK</i>	<i>MK</i>	<i>F</i>	<i>signifikans F</i>			
Regression	1	0.004022	0.004022	0.231304	0.632432			
Residual	56	0.973867	0.01739					
I alt	57	0.977889						
	<i>Koefficient</i>	<i>standardfejl</i>	<i>t-stat</i>	<i>P-værdi</i>	<i>Nedre 95%</i>	<i>Øvre 95%</i>	<i>Nedre 95.0%</i>	<i>Øvre 95.0%</i>
Skæring	0.066292	0.017322	3.827164	0.000329	0.031593	0.100992	0.031593	0.100992
X-variabel	-0.19718	0.40998	-0.48094	0.632432	-1.01846	0.624112	-1.01846	0.624112

### Forecast of Value drivers:

	2013	2014	2015	2016	AVG	E2017	E2018	E2019	E2020	E2021	E2022	E2023
R&D as % of Revenue	-78%	-58%	-40%	-34%	-53%	-0.34	-0.3	-0.3	-0.3	-0.3	-0.3	-0.3
G&A as % of revenue	-10%	-9%	-8%	-6%	-8%	-0.05	-0.05	-0.05	-0.05	-0.05	-0.05	-0.05
Depreciation & Amortisation as % of Revenue	2%	1%	3%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Tax rate					-22%	-22%	-22%	-22%	-22%	-22%	-22%	-22%
Intangible and Tangible as % of Revenue	5%	11%	20%	12%	12%	12%	12%	12%	12%	12%	12%	12%
NWC as % of Revenue	22%	13%	16%	61%	28%	55%	50%	45%	40%	35%	28%	28%

### Milestone Forecast '000'

Milestone Forecast	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Milestone payments	110,833	385,603	705,688	1,187,244	1,780,866	2,493,212	3,241,176	3,889,411	4,278,352	4,492,270	4,716,884
Growth %		248%	83%	68%	50%	40%	30%	20%	10%	5%	5%

### Other Income Forecast '000:

Other Income Forecast	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Other income	552,737	464,782	427,353	171,392	123,482	95,139	78,058	67,947	62,543	59,416	58,227
Growth %		-16%	-8%	-60%	-28%	-23%	-18%	-13%	-8%	-5%	-2%

### Revenue Forecast '000:

Revenue Forecast	2017	2018	2019	2020	2021	2022	2023
Revenue	3,030,748	4,841,151	7,235,817	9,220,930	10,788,342	11,752,066	12,300,374
Growth %	67%	60%	49%	27%	17%	9%	5%

## DCF-Valuation:

DCF Valuation	E2017	E2018	E2019	E2020	E2022	E2023	E2024
'000	1	2	3	4	5	6	7
FCFE	678,880	1,405,569	2,429,102	3,856,012	5,020,272	6,138,688	5,818,831
r(.e)	9%	9%	9%	9%	9%	9%	9%
Discount Factor	0.920047842	0.846488032	0.778809488	0.716541989	0.659252911	0.606544219	0.5580497
PV of FCFE	624,602	1,189,798	1,891,808	2,762,995	3,309,629	3,723,386	
PV Value of FCFE in forecasting horizon	13,502,217						
PV of value in Terminal period	51,224,646		r(.e)	1.80%			
Estimated market value of equity before NIBD	64,726,862		growth	8.7%			
NIBD	- 3,921,965						
<b>Market value of Equity after NIBD</b>	<b>68,648,827</b>						
No of shares	60,350,056						
<b>Share value</b>	<b>1137.51058</b>						

## RI-Valuation:

RI-valuation	E2017	E2018	E2019	E2020	E2022	E2023	E2024
'000	1	2	3	4	5	6	7
<b>Nopat</b>	<b>1,393,210</b>	<b>2,376,482</b>	<b>3,552,004</b>	<b>4,526,479</b>	<b>5,295,909</b>	<b>5,768,994</b>	<b>6,038,154</b>
Invested Capital	904,731	2,030,601	3,001,514	4,124,416	4,794,883	5,070,521	4,700,826
r(.e)	9%	9%	9%	9%	9%	9%	9%
Cost of Capital	78,621	176,459	260,832	358,412	416,675	440,628	408,502
RI	1,314,589	2,200,023	3,291,173	4,168,068	4,879,234	5,328,366	5,629,652
Discount Factor	0.920047842	0.846488032	0.778809488	0.716541989	0.659252911	0.606544219	0.5580497
PV RI	1,209,485	1,862,293	2,563,196	2,986,596	3,216,649	3,231,889	
Invested capital beginning	904,731						
PV of RI in forecasting horizon	15,070,108		R(.e)	1.8%			
PV of RI in Terminal Period	48,747,326		growth	8.7%			
Market value of Equity before NIBD	64,722,166						
NIBD	-3921965						
<b>Market value of Equity after NIBD</b>	<b>68,644,131</b>						
No of shares	60350056						
<b>Share value</b>	<b>1137.432758</b>						