BAVARIAN NORDIC

A Real Options Valuation of Bavarian Nordic's smallpox vaccine IMVAMUNE

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Executive Summary

The purpose of this thesis has been to investigate the value of IMVAMUNE, a vaccine under development. To answer this, a sub research question was composed to investigate how real options theory could be applied to do the valuation. A working hypothesis was developed, stating that I expected the value of IMVAMUNE to constitute more than 30% of the total company value. Bavarian Nordic has a contract with the National Institute of Health to develop IMVAMUNE as a safer smallpox vaccine than the current alternatives. The company is due to deliver 20 million doses of the vaccine starting in 2010. During 2010, the company will initiate the phase III IMVAMUNE clinical trials, which are expected to be concluded in 2014.

A decision tree was created to identify which real options Bavarian Nordic would face in the future. This shows that Bavarian Nordic has an option to invest and an option to abandon in 2010, as well as an option to invest and an option to abandon in 2014 if the 2010 decision is to invest, otherwise known as a sequential compound option. The 2010 option concerns the decision to invest in phase III studies or abandon IMVAMUNE, whereas the 2014 option concerns the decision to apply for a license with the FDA or abandon the project.

The expected future cash flows and the WACC has been estimated and shows that the present value of future cash flows is 2.616 million DKK. Using the present value estimate, the binomial lattice for the IMVAMUNE project was created. Based on this lattice, the option lattice for the 2014 options was calculated. This lattice was then used to valuate the compound option since the value of the 2010 options are dependant on the value of the 2014 options.

A sensitivity analysis showed that the project value was most sensitive to changes in the WACC, the exchange rate and the market size. The total value of the project was estimated at 786 million DKK or 50% of the market value of the company, which, at the valuation date, was 1.583 million DKK, thereby validating the hypothesis that IMVAMUNE constitutes the main part of the value of Bavarian Nordic.

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Preface

In 1982, smallpox was declared eradicated after having scourged earth for more than three millennia. After the virus had been declared eradicated, production of the smallpox vaccines was abandoned. However, in the late 1990s, focus shifted to the risk of not having enough vaccines in storage to immunize the population in case the virus is weaponized and used for biological warfare or terrorism.

Since the current vaccines have a low safety profile in healthy people and is lethal for immune compromised individuals, a few biotech companies started investing in research to develop a safer vaccine against smallpox. The vaccines currently on the market are using a technology that was developed in the 1930s. A new vaccine should also be suitable for immune compromised individuals. In 2002 and 2005, the US passed legislation to support the development of pharmaceuticals within bio defense, authorizing the National Institute of Health to provide financial support to companies developing pharmaceuticals against biological pathogens.

However, it usually takes around 15 years from the time a new drug is discovered until it reaches the shelves, that is, if it isn't abandoned during the preclinical or clinical trials. Out of 10.000 ideas for new drugs, only one will end up as an approved pharmaceutical (Novo Nordisk From Idea to Patient). The political focus on smallpox preparedness may have shifted by the time the new and safer smallpox vaccine has been developed and is ready for use, thus the future market size is highly uncertain.

So what is the value of investing millions of dollars in researching a vaccine against a disease that for the past 32 years has not had a natural outbreak? This thesis will investigate what the value of Bavarian Nordic's smallpox vaccine IMVAMUNE is by applying real options theory to the project.

I Title

A real options valuation of Bavarian Nordic's smallpox vaccine IMVAMUNE

I.i Research questions

What is the value of Bavarian Nordic's Smallpox vaccine IMVAMUNE?

- How can real options theory be applied to value IMVAMUNE?

Working hypothesis

- The value of IMVAMUNE will constitute the main part of the value of Bavarian Nordic, since IMVAMUNE is the only project in the pipeline about to enter stage III clinical trials, and the only revenue generating project in the pipeline. I expect the value of IMVAMUNE to constitute more than 30% of the value of the company.

To determine the value of the project IMVAMUNE, this thesis will apply real options analysis. The estimates for the real options analysis will be based on an analysis of qualitative data describing the company and the market attractiveness. The quantitative estimates will then be used for the actual valuation. A sensitivity analysis will be performed to investigate how sensitive the valuation is to changes in various estimates, and the valuation will then be used to explore the validity of the working hypothesis.

I.ii Structure

The overall structure of the thesis is outlined below.

Part One: Strategic Analysis
Part Two: Identifying the real options
Part Three: Estimation of variables
Part Four: Valuation and sensitivity analysis

In part one, the reader will get an introduction to the company and the project IMVAMUNE followed by an analysis of the external factors that impact the value of the project, such as competitors, market size and politics. The qualitative analysis will form the basis of the assumptions necessary to estimate the different variables needed in the real options analysis.

In part two, I will identify the real options associated with the project IMVAMUNE and build a decision tree.

The third part of this thesis goes through my assumptions for the estimations of the future revenue, costs and the estimates of other variables, such as future exchange rates and the WACC. The estimates will be based on the findings in part one, as well as by analyzing quantitative data, e.g. financial reports and share prices.

Part four is where the actual valuation will be done, based on the data from part one and part three. The result of the valuation will be analyzed with regard to how sensitive the data is to changes in the estimated variables. Finally, I will use the estimated value of IMVAMUNE to determine how valid my working hypothesis is. I will compare the estimated value of the project with the market capitalization of Bavarian Nordic and determine the proportion that the estimated value constitutes of the company's value.

The thesis will end with a conclusion and an epilogue.

I.iii Delimitation

This thesis will use a real options approach to valuation and will not be a comparison or discussion of the different approaches that may be applied when valuing a project. Although this project will first estimate the present value of future cash flows using DCF, the thesis will not include an extensive discussion about why DCF alone is inappropriate to value R&D projects.

The focus of this thesis is on valuation of Bavarian Nordic's main product today, IMVAMUNE. It is currently the most promising product of Bavarian Nordic's. It is the only product already generating revenue streams as the only product in the pipeline. Since the value of the product increases proportionately with the stage of its production within the clinical trials, it is assumed that the value of IMVAMUNE will also constitute the main part of the value of the company. Thus, this thesis will not include valuations of any of the other projects in Bavarian Nordic's pipeline.

The data included in this thesis is publicly available data. Data published after 31st October 2009 will not be included in this thesis.

I.iv Methodology

In this section, I will briefly go through the major parts of the methodology used in this paper, however, the methodology for the individual estimates are described when going through each variable, since this will make more sense.

In the first part of this paper, I will do a strategic analysis of the company's internal strengths and weaknesses by using Porter's value chain framework. I will combine this analysis with an analysis of the external environment where I will analyze the competitors and the buyers in order to determine the market attractiveness. In addition, I will do a threat assessment and finally an assessment of the market size. The results of the strategic analysis will be summarized in a SWOT diagram, since this gives a good overview of the results obtained. The data obtained through this analysis will form the basis of the assumptions necessary to do the financial estimates in part three.

In the second part of this thesis, the real options analysis will be performed based on the approach described by Copeland and Antikarov (2003) in their book Real Options – a practitioner's guide. They have set up a four step approach to calculate the value of a real option.

1. Compute base case present value without flexibility using DCF valuation model
2. Model the uncertainty using event trees
3. Identify and incorporate managerial flexibilities creating a decision tree
4. Conduct Real Options Analysis

When valuing real options one can use the replicating portfolio approach, however this approach requires an asset or combination of assets that produce cash flows perfectly correlated with the projects cash flows.

Finding a replicating portfolio for a research project is not easy and as such, Copeland and Antikarov suggests that one makes the MAD[1] assumption, which states that the present value of the project without flexibility is the best unbiased estimate of the market value of the project if it was a traded asset (Copeland & Antikarov, 2003). However, the replicating portfolio approach also requires that one makes a new replicating portfolio for each node

[1] Marketed Asset Disclaimer

of the binomial tree. When working with multi-period binomial trees, this methodology is cumbersome. Instead, Mun (2006) recommends calculating the risk neutral probabilities.

The risk neutral probabilities require that you calculate the up and down movement to calculate the binomial lattice, as well as an estimate of the standard deviation of the return on the underlying asset. In addition, the time to expiration and the number of up/down steps the asset can take from today until expiration are needed. This method also requires the MAD assumption since I will be using the present value of the project to create the binomial tree.

The MAD assumption makes no stronger assumptions than those used to estimate NPV in the first place. Therefore, if the NPV without flexibility can be estimated, then we can use the MAD assumption as the basis for valuing real options. The MAD assumption also ensures that the comparables are truly comparable, because what could be better correlated with the projects projected future cash flows than the project itself.

To calculate the risk neutral probabilities for the valuation uses the calculated up and down values and the risk free rate. I will go into more details on how the risk neutral probabilities are calculated in part four of this paper. The advantage of this approach is that the risk neutral probabilities do not change with each node in the option three, which makes this approach applicable when valuing options with more steps.

I.v Data

The data for this thesis have been gathered mainly on the internet, using the library's databases as well as a variety of homepages.

One of the main sources for data has been Bavarian Nordic's homepage. Since it is the company's homepage, the data is naturally somewhat biased. I have taken this into consideration when using the data from Bavarian Nordic and made my own estimates of the future prospects combining the data from Bavarian Nordic with other sources, as well as looking on actual history to verify if Bavarian Nordic's own estimates appear realistic.

DataStream has been used to gather information about the risk free rate and returns on the stock market. DataStream is considered to be an unbiased data source. Oanda.com has

been used to collect the spot rate for USD as per the valuation date 30th October 2009[2]. Oanda.com has an online FX trading portal and supplies historical data about the exchange rate. There are different choices for the exchange rate one would like to see. In this thesis, the interbank rate has been used for simplicity.

Wikipedia.org has been used to check facts. Wikipedia is a web based encyclopedia where the users are adding the information as well as correcting other people's entries. The accuracy of the Wikipedia model is still being tested and no final conclusion has been reached. Thus, one should always double-check data from Wikipedia with other sources to ensure that these are accurate.

Data from the Food and Drug Administration, Center for Disease Control and World Health Organization are considered to be reliable and fairly unbiased.

I.vi Definitions and abbreviations

- BLA: Biologic License Application
  The application that should be filed with the FDA to get a license to sell a drug on the American market
- CDC: Center for Disease Control
- EUA: Emergency Use Authorization
  An authorization to use an unlicensed vaccine or drug in case of a declared emergency
- FDA: The US Food and Drug Administration
- IMVAMUNE: Bavarian Nordic's MVA based smallpox vaccine
- MAD: Marketed Asset Disclaimer
  Assumption stating that the present value of a project is an unbiased estimate of the true market value, had the project been a marketed asset
- MVA: Modified Vaccinia Ankara
  The vaccine vector Bavarian Nordic has worked on to develop the patented MVA-BN technology
- NIH: National Institute of Health
  US governmental institution that Bavarian Nordic has the RFP contracts with
- RFP: Request for Proposal
  The contracts Bavarian Nordic has signed with the NIH, RFP 1, 2 and 3

[2] The valuation date is the last trading day in October, as the 31st was a Saturday

- ROA: Real Options Analysis
- SNS: The Strategic National Stockpile
  A US warehouse containing enough vaccines and medical supplies to supply at least two major american cities in case of an emergency
- Vaccinia: A cowpox virus that can be used to immunize humans against smallpox
- Variola Major: The deadliest form of the smallpox virus with a mortality rate of 30%
- Variola Minor: The mildest form of the smallpox virus with a mortality rate of 2%
- WHO: World Health Organization

Part One: Strategic Analysis

1.1 Smallpox

The Variola Virus, more commonly known as smallpox, plagued the world for more than three millennia and killed around 30% of those infected. Out of those who were lucky enough to survive the disease, around 80% had deep scarring from the pocks, most commonly on the face. Blindness was another common complication for the survivors of smallpox.

In the early 1950s, an estimated 50 million cases of smallpox occurred every year around the globe. The WHO[3] launched an intensive program to eradicate smallpox in 1967 and after an intensive vaccination effort and the use of containment policy[4], the disease was declared eradicated in 1979. The last natural outbreak of smallpox occurred in 1977 in Africa. Since then, the only known case of smallpox was caused by a laboratory accident in the UK where a small outbreak occurred and killed one person.

When smallpox had been declared eradicated, countries and labs were asked to destroy or send samples of Variola Major, the most lethal form of the smallpox virus, to one of two secure facilities in the US or Russia. However, no official record existed of which labs or countries had samples of the Variola Major virus. After the collapse of the Soviet Union, the WHO became aware that there where samples of the virus that the Russian lab could not account for. This, along with the ever increasing threat of terrorism, in this case bio terrorism, caused several countries to stock up on smallpox vaccines to protect the population in case of bio terrorism. At the same time, a smallpox outbreak will be difficult to diagnose, as most doctors today have never seen an actual smallpox case. This means that it will most likely take up to 2-3 weeks to diagnose the first patient. In that time, several others would have been infected, and they in turn would have infected others.

Prior to the end of the vaccination programs it was estimated that one person infected with smallpox would infect five others. Today, the estimate is that one infected person will infect ten others. This increase is due to the fact that people are no longer being immunized by vaccination or by having survived the disease which makes the general

[3] World Health Organization
[4] Containment policy: Creating a so called vaccination ring around the infected patients by vaccinating the family members and people the patients had been in contact after the onset of symptoms and isolating the patients and their immediate family.

population more susceptible to the disease (WHO). If one person infected ten others, then after 12 weeks there could be 1.000.000 infected if the disease is allowed to run unchecked. 300.000 of the infected people would die and 560.000 would be severely pockmarked.

The high death toll and the relative ease with which the disease can spread is one of the reasons that the virus is considered to be a threat in the hands of terrorists. To protect the population against a deliberate dissemination of the smallpox virus by terrorists, many countries have started stocking up on smallpox vaccines.

The obvious solution to the threat of a smallpox attack is immunization of the general population; this would effectively remove the incentive to initiate a biological attack with the smallpox virus. However, the vaccination has adverse events and the risk of such side effects is sufficiently high, therefore the vaccination is not recommended if there is no or little real risk of exposure. The list of possible adverse events to the smallpox vaccination is long; amongst the more serious are myocardial infarctions and encephalitis. At the same time, the vaccines that are currently on the market should not be administered to pregnant women, persons with eczema, transplant patients or immune deficiencies e.g. HIV and cancer patients.

In 1798, Edvard Jenner demonstrated that if a person was exposed to cowpox, Vaccinia Virus, this person would become immune to the variola virus. The first vaccinations took place by scraping pulp out of the pocks of an infected cow, punctuating the skin of the person to be vaccinated and inserting the virus. Vaccines produced by harvesting the Vaccinia virus from diseased animals are called 1st generation vaccines. 2nd generation vaccines are produced in cell cultures and 3rd generation vaccines are vaccines where the Vaccinia Virus is unable to replicate itself in human cells.

The 1st and 2nd generation vaccines are associated with severe side effects, such as eczema, rashes, lesions and encephalitis, the two latter often cause the patient to die and to become severely brain damaged or disabled. The vaccine can also be transferred from one person to another. Since the US military started vaccinating healthy young adults that were going to war, the 2nd generation vaccines have come under suspicion of causing heart attacks. It has been estimated that 1 in 1.000.000 of healthy adults will die as a result of complications due to the vaccination.

Third-generation vaccines are currently being developed by Bavarian Nordic, and CJ Corporation; while Siga Technologies is developing a therapeutic drug against smallpox to prevent the decease's transmission from cell to cell. The third-generation vaccines are assumed to have fewer adverse events than the vaccines currently in use. CJ Corporation just finished phase 1 trials and Bavarian Nordic is due to start phase 3 clinical trials. Acambis also had a candidate for a third generation smallpox vaccine, but abandoned the clinical trials when the RFP-III contract was awarded to Bavarian Nordic.

The vaccinations are based on the vaccinia virus, also known as cowpox, which is similar to smallpox and provides immunity against smallpox for a period of time. The WHO recommends that people that are at risk of contracting smallpox be vaccinated every year, today, those would be people working with the variola virus in the labs. Since the vaccine is based on the vaccinia virus, a less contagious and much milder form of the pox viruses than the variola variants, it is not a requirement to be vaccinated if you are handling the vaccinia virus, only if you are handling the variola virus.

1.2 Bavarian Nordic

In 1994 Bavarian Nordic was founded by a team of German and Danish researchers to do research in gene therapy, cell therapy and vaccines (Bavarian Nordic, 2005). The company went public in 1998 and is registered on the Copenhagen Stock Exchange. Bavarian Nordic is classified as a biotech company, however, with the smallpox vaccine IMVAMUNE, they may be initiating the transition into a pharmaceutical company. A biotech company is a research intensive company without any pharmaceuticals that have been approved for sales, thus it generally only generates revenue through research grants. The main funding for activities is through investors. A pharmaceutical company, on the other hand, already has products that are licensed and thus are generating revenues to fund the company's R&D activities.

1.2.1 Pipeline

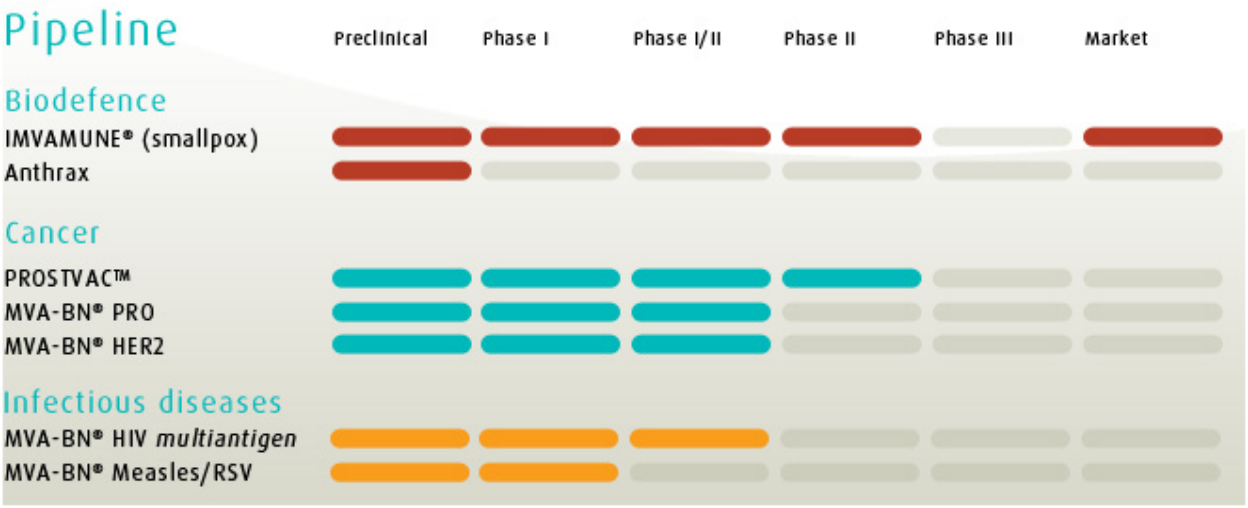

Figure 1: Bavarian Nordic Pipeline

The company currently has two bio defense products in clinical trials: one is a vaccine against the infectious smallpox virus and the other is a vaccine against the anthrax bacteria as can be seen from figure 1. The smallpox vaccine, IMVAMUNE, is due to initiate Phase III clinical trials in late 2010. The development of the Phase III studies has already been agreed with the US FDA[5]. Once all the protocols are in place, the Phase III studies will begin. The Anthrax vaccine is undergoing Phase I clinical trials but if the vaccine proves effective Bavarian Nordic is considering combining it with IMVAMUNE thereby creating one vaccine to protect against two of the major biological threats (CDC, 2009). Both Anthrax and smallpox have been classified as high priority agents that pose a threat to national security by the US.

The cancer research is carried out in the US subsidiary and includes two vaccines to prevent prostate cancer and one to prevent breast cancer. The prostate cancer vaccine PROSTVAC has recently finished phase II clinical trials, whereas the two other candidates are undergoing a simultaneous phase I and phase II clinical trial.

Within infectious diseases, Bavarian has two vaccine candidates; one for measles/RSV that is in phase I clinical trials, and the other is a vaccine against HIV in simultaneous phase I and II clinical trials.

[5] Food and Drug Administration

1.2.2 Strategy

Today the main focus areas in Bavarian Nordic are bio defense, cancer and infectious deceases, but the current business is based on bio defense, which is a sector that has been developed in the biotechnology industry as a response to the threat of bio terrorism, which was significantly magnified by the Anthrax attacks in the United States in 2001/2002 after 9/11.

1.3 IMVAMUNE

The research program for IMVAMUNE was initiated by Bavarian Nordic in 1998, and in November 2008, the company successfully completed the Phase II clinical trials for IMVAMUNE; an extensive Phase III study will be initiated in 2010 once the conditions for the Emergency Use Authorization (EUA) have been fulfilled[6]. Bavarian Nordic and the FDA have already agreed on how the phase III studies are to be done.

To make the reader familiar with the process from discovery to market, the next section will go through the path to get a drug approved for sale.

1.3.1Pre clinical and Clinical Trials[7]

There is a process to follow to get a new drug approved by the FDA in the US. This process is similar to what needs to be done to get a new drug approved in the EU, although an FDA approval does not necessarily mean that the drug will be approved for the EU market and vice versa. This section will give a brief overview of the US process to get a drug approved for the US market. It will be assumed that if the FDA approves IMVAMUNE as a new drug, it will also be approved in the EU.

From the time a new drug is discovered until it is ready for the market, it has to go through several tests of safety and efficacy.

The first stage is the pre-clinical trials, where the drug is tested for safety in animals, among others, it is tested if the drug impacts reproduction or causes cancer. The data collected during the pre clinical trials are used to estimate a safe starting dose of the drug for clinical trials in humans.

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[6] An EUA is an approval from the FDA to use a vaccine under development in case of an emergency, even though the vaccine has not yet been approved for the US market.
[7] This section is based on the following sources: (Survivorship A-Z) & (Wikipedia Clinical Trial)

If the drug clears the pre clinical trials, it will go into phase I, clinical trials. The primary purpose of this phase is to evaluate the safety of the drug in humans and estimate the range of the dose. It also seeks to determine the possible side effects. Approximately 70% of the drugs move on to phase II clinical trials.

The purpose of phase II is to determine the efficacy of the drug and to further evaluate the safety of the drug. If the drug is efficient, it moves on to phase III. Only about 33% of drugs move on to phase III.

In phase III, the safety and efficacy is confirmed and the most effective dose level is determined. If the drug clears phase III trials, the pharmaceutical company can make a Biologic License Application, BLA, with the FDA. Only 25-30% of the drugs in phase III clinical trials will proceed to the market.

Phase	No of humans in testing	Moving to next stage
Pre clinical	N/A	N/A
Phase 1	10-80	70%
Phase 2	100-300	33%
Phase 3	500-5000	25-30%
Phase 4	Tested in market	N/A

Table 1: Percentage of successful clinical trials

In phase I and II, the company is testing the drug on a limited number of people normally between 10 and 300, whereas phase III studies tend to include a larger group from 500 to several thousands.

Once the drug has been approved by the FDA, it proceeds into phase IV of the clinical trials. In phase IV, data are collected to determine if there are any additional side effects, as well as side effects connected with long term use. These data are collected from the doctors and hospitals after the drug has been marketed.

1.3.2 IMVAMUNE contracts

In 2003, Bavarian Nordic received the RFP-1 contract from the US National Institute of Health. Under this contract, the company received 29 million USD for developmental support of IMVAMUNE and in 2004 the company was awarded the RFP-2 contract with further funding for the clinical trials. The RFP-2 contract was also designed to test the

robustness of the manufacturing process and required the delivery of 500.000 doses of IMVAMUNE. In addition, an extension was granted to further test the product on people with atopic dermatitis. The total value of the RFP-2 and the extension is 115 MUSD.

In 2004, the FDA granted IMVAMUNE "Fast Track[8]" status which gives it priority status when being reviewed by the FDA. This is supposed to ensure that the drugs reach the market faster than under normal procedure. On average, it takes approximately 15 years from a manufacturer first approaches the FDA with an idea for a new drug until its final approval for marketing (FDA, 2009).

The RFP-3 contract, which Bavarian was awarded in June 2007 by the U.S. Department of Health and Human Services (HHS), is an order for 20 million doses of IMVAMUNE at a price of 500 MUSD. The base contract supports additional research and development of the product to fulfill the requirements for the potential use of IMVAMUNE during an emergency, as well as funding to register IMVAMUNE as a safe and effective vaccine in healthy people with the US Food and Drug Administration (FDA). This contract also includes an option to order 60 million additional doses and funding for additional clinical studies to extend the FDA license to include people infected with HIV at a price of 1,1 billion USD.

The contract contains performance-based payments, an advance payment of USD 50 million, as well as milestone advance payments. The advance payment of USD 50 million is a prepayment for the delivery of a part of the 20 million vaccines. The performance based payments and milestone are conditioned by progress in the clinical studies. The advance payment is subject to a repayment obligation if Bavarian Nordic does not meet the contractual obligations; it will be recognized pro-rata in the income statement when delivery of the vaccines begins. Thus, if the project is abandoned or Bavarian Nordic is unable to deliver the 20 million doses of IMVAMUNE, then the company must repay 50 million USD.

Bavarian Nordic delivered Phase II study data to the FDA in November 2008. These data will be the basis for whether Bavarian Nordic receives the Emergency Use Authorization

[8] Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious diseases and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier.

(EUA) from the FDA that is needed to start shipping the 20 million doses of IMVAMUNE and bill the remainder of the contract sum, 375 MUSD. Prior to receiving the EUA, however, the FDA has performed a Good Manufacturing Practice inspection, GMP, in May 2009 of Bavarian Nordic's facilities where a number of observations requiring corrective actions were noted (Bavarian Nordic Q2, 2009). Bavarian Nordic has initiated the corrective actions but these and the final GMP review have pushed the delivery schedule. Bavarian Nordic plans to hand in the data for the corrective actions taken in early December 2009 and then expects to receive the EUA and to finally begin delivery in December 2009 (Bavarian Nordic Q2, 2009). This thesis will assume that delivery starts in 2010. No deliveries made in December 2009 will have a cash flow impact before 2010. In addition, when dealing with a large governmental institution like the FDA, Bavarian Nordics assumption about receiving the EUA within the same month as they deliver the requested data appears to be quite unrealistic.

IMVAMUNE® cannot be fully commercialized until the vaccine has been licensed upon completion of the Phase III studies, after which, the company may choose to apply for a BLA (Biologic License Application), which the US FDA has to approve before a drug can enter the US market.

In the US RFP-3 contract, the price can be calculated to be 25 USD, whereas the price per dose in the option is 18,33 USD. Since both contracts also include funding for further clinical studies, it will, for the purpose of this paper, be assumed that the price per dose of IMVAMUNE will be set at app. 15 USD per dose for future contracts. Two doses are required to be completely immunized, thus the cost of the vaccination is USD 30. This assumption is also supported by Carnegie, who has set the expected future price per dose at 16 USD (Carnegie, 2006).

Bavarian Nordic is currently a biotech company, however the contract to deliver 20 million doses of IMVAMUNE to the US are gradually moving the company into being a pharmaceutical company. The US has an option to purchase an additional 60 million doses of IMVAMUNE but this option is unlikely to be exercised unless BAVARIAN NORDIC proves that they can deliver the first 20 million doses in a timely manner. Furthermore it seems unlikely that the US will exercise the option before IMVAMUNE has been approved by the FDA and registered for healthy individuals. With the phase III trials due to initiate in 2010, with duration of 1-4 years, it seems probable that the option will be

exercised no earlier than 2013 if at all. The exercise of the option also depends on the threat assessment and likelihood of a biological attack in the upcoming years. If the world bears witness to a successful attack within the next few years, the probability of the option being exercised would without a doubt increase significantly. However, if the next few years do not bring any biological attacks the probability of exercise should decrease, all other things being equal.

In addition to the RFP-III contract, Bavarian Nordic has also contracted with the Canadian government to provide 20.000 doses of IMVAMUNE with an option to purchase an additional 180.000 doses. If we assume, as stated above, that the price per dose is 15USD, then the value of the base contract is 300.000 USD and the value of the option is 2.700.000 USD (Bavarian Nordic Canada, 2008).

In September 2009, Bavarian Nordic received a small contract for the delivery of an undisclosed number of doses of IMVAMUNE with an unnamed EU country. The order is not large enough to change the expectations to 2009. As Bavarian's first contract for IMVAMUNE with an EU country, the company finds that it is an indication of the fact that there is a demand for stocks of safer smallpox vaccines in case of an emergency (Bavarian Nordic EU, 2009) within the EU. This order has been delivered during Q3 2009.

Bavarian Nordic estimated in the Prospectus Rights Issue 2007 that IMVAMUNE would receive EUA in 2008 and obtain registration in 2010 (Bavarian Nordic, 2007), which would have meant that the delivery of the 20 million doses of IMVAMUNE had been initiated in 2008. In the 2008 Annual report, the company is awaiting the approval of the Phase II data from the FDA and with that the EUA, which will trigger the production and shipping of the first 20 million doses. In the annual report for 2008, this is planned from 2009-2012 since Bavarian Nordic is still waiting for the EUA. The production and shipping is now more likely to be carried out in 2010-2013 (Bavarian Nordic Q2, 2009). This delay has caused Bavarian Nordic to amend the expectations to the 2009 revenue and results since the original estimates for 2009 included revenue from the delivery of the first two million doses of IMVAMUNE.

Bavarian Nordic expects that IMVAMUNE is registered with the FDA in 2013 and, after registration is completed, that future sales will be able to fund the other research and development activities in the company (Bavarian Nordic, 2007).

In my opinion, it is far more likely that the phase III studies will be completed in 2014, whereafter Bavarian Nordic will need to apply for a BLA. It will then take app. six months from the FDA receives the BLA until IMVAMUNE will either be licensed or rejected.

1.4 Value Chain Analysis

In this section I will analyze the internal processes, by applying Michael Porter's Value Chain framework. By using this framework, the paper will give the reader an overview of the internal strengths and weaknesses related to the IMVAMUNE project that may impact the valuation. As can be seen from figure 2 below, the framework focus is on analyzing the support activities and the primary activities.

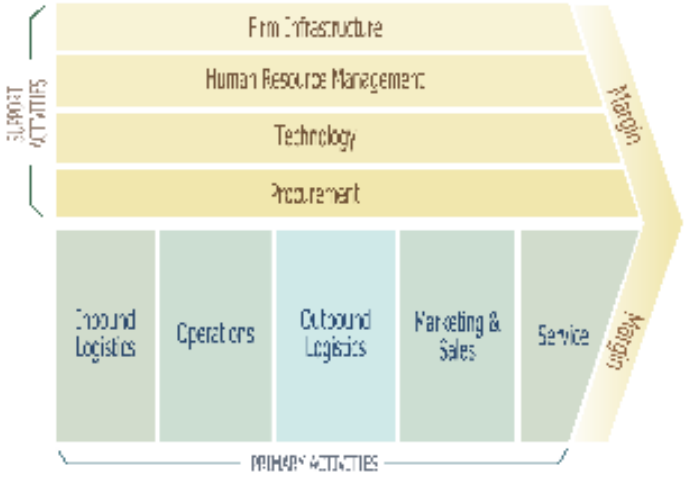

Figure 2: Porter's Value Chain

1.4.1 Support Activities

Although the support activities are built up around the company as a whole and not just the project, they have a vital influence on the project. It is thus important to analyze how the support activities are build up to evaluate what will benefit the project and what will be a disadvantage to the project.

1.4.1.1 Firm Infrastructure

In this section I will describe and analyze the board of directors and the management, the legal capabilities and the financial management, since these three parts will have a crucial influence on the final value of the project.

Board of Directors: The CoB is Asger Aamund, who is one of the founders of Bavarian Nordic and has been the CoB since 1994. Asger Aamund has extensive experience within the pharmaceutical industry where he worked as the CEO of Ferrosan for seven years, as

well as participated on boards for biotech companies. Besides being a well known business-man, he is not afraid of participating in the political debate. There is a great deal of focus on him as a person in the public debate. As the CoB, this attention also includes Bavarian Nordic, which thereby benefits from the media attention.

The other board members are Erling Johansen, Flemming Pedersen, Claus Bræstrup and Gerard van Odijk. Gerards van Odijk is the CEO of Teva Pharmaceutical Europe B.V. He has previously worked in GlaxoSmithKline, which is one of the largest manufacturers of vaccines in the world. Claus Bræstrup has an extensive background within pharmaceuticals as the former president and CEO of H. Lundbeck. With a career path through Novo Nordisk and Schering, as well as a medical degree, he has the necessary expertise to participate and add value to the board. Flemming Pedersen has a background in Neurosearch and Maersk Medical and Erling Johansen has a background from BASF health and Nutrition, Ferrosan and Dano-Chemo.

It can be concluded that the board members all have relevant experience within the pharmaceutical or biotech industry and are capable of adding value to the business decisions that need to be made. Their backgrounds make them able to understand the medical aspects of the IMVAMUNE project. A disadvantage is that they all come from a similar industry and thus have similar backgrounds, which could be a disadvantage since the board members may have too similar ways of thinking and approaching obstacles.

Executives: The CEO Anders Hedegaard was appointed in August 2007 with the purpose of transitioning Bavarian Nordic from a biotech company into a pharmaceutical company. He has extensive experience with pharmaceutical companies like ALK-Abelló, Foss and Novo Nordisk. With the exception of Paul Chaplin and Morten Max Rasmussen the remainders of the executive group are fairly new to the company with less than two years in the company. But generally, the executives have a broad background including economics and legal capabilities.

The broad range of experience within the executives is an advantage for Bavarian Nordic, as they will be able to consider multiple sides of the projects and take different aspects into consideration.

Legal Capabilities: As a biotech company, the main assets for the project are the human resources and the patents protecting the technology. However, merely having a patent does

not ensure that it is enforced; that requires constant monitoring and legal action if anyone breaches the patents or the registered trademarks. This requires solid legal skills to deal with and this is why the legal capabilities may influence the value of IMVAMUNE.

Bavarian Nordic place a great deal of emphasis on the protection of patents and trademarks and has a large portfolio of patents registered. Bavarian Nordic has shown that it is able to protect the patents through the lawsuit against Acambis for patent infringement and Oxford Biomedica (Bavarian Nordic, 2008). It is considered to be a strength of the company that it has focus on protecting the immaterial assets and is willing to take the expense of a lawsuit in order to protect against infringement.

Financial Management: Since Bavarian Nordic is a biotech company, it is no surprise that it has been unable to cover the cash needs of the company through internally generated cash flows, and the company has thus, on several occasions, issued new stocks to have the sufficient liquidity to stay in business. However, the company expects to be able to generate sufficient cash flows from the IMVAMUNE project to start generating enough cash to cover the firm's other R&D projects. When looking at the financial expectations for 2009, the net free liquidity is expected to be 175 million DKK (Bavarian Nordic Q2, 2009). The net cash outflows in the past two years have been app. 400 million DKK (Bavarian Nordic, 2008) thus, a new stock emission is needed to cover the operating costs during 2010 if the pattern continues and at the same time it will be necessary to cut costs for everything but the absolutely necessary projects until there is free liquidity to initiate these projects again. Due to the very high production costs for IMVAMUNE at present, it is unfortunately not enough to start delivering and receiving payment for the deliveries of IMVAMUNE to keep the net free liquidity positive. This means that Bavarian Nordic will have to issue new stock, preferably in the first quarter of 2010, to avoid running out of cash.

Based on the above, I consider the financial strength of Bavarian Nordic to be very low and the low free net liquidity is an issue for the IMVAMUNE project, which is the most cash demanding project in their pipeline, as the company is to buy raw materials for the production of the 20 million doses of IMVAMUNE the company is due to deliver. Thus, if no additional cash is raised, there is a significant risk that Bavarian Nordic will be unable to deliver the vaccines to the US government.

1.4.1.2 Human Resource Management

One of the most important assets for Bavarian Nordic and IMVAMUNE are the employees since they carry a lot of tacit knowledge about the product and processes. It is thus necessary to be able to retain employees, but at the same time attract new bright employees.

Bavarian Nordic offers their employees flexible working hours, competitive salary packages, retirement and insurance plans. In addition, there is a focus on training and education and the possibility of international work assignments, they also offer an employee cafeteria (Bavarian Nordic Working).

However, this is pretty much a standard package and not something that sets Bavarian Nordic apart from their competitors. However, the company has in the past been very good at retaining their employees, which indicates that the employees are happy to be with the company

1.4.1.3 Technology

Bavarian Nordic's key technology is based on MVA (Modified Vaccinia Ankara), which "*is a highly attenuated strain of vaccinia virus that was developed towards the end of the campaign for the eradication of smallpox by Professor Anton Mayr in Germany. Produced by hundreds of passages of vaccinia virus in chicken cells, MVA has lost about 10% of the vaccinia genome and with it the ability to replicate efficiently in primate cells* (Wikipedia MVA)." Without the ability to replicate in primate (human) cells the safety profile of MVA based vaccines is considerably higher than in vaccines using virus that can multiply and spread out in the body after vaccination. Vaccines based on the MVA technology are appropriate for use in immune compromised individuals such as people with HIV, eczema etc. The MVA technology can be used as a vector for other types of viruses to safely immunize against a variety of diseases.

Bavarian Nordic's patented MVA based technology is called MVA-BN® and was patented in the period 2001-2005. With patents that last for 20 years from the filling, IMVAMUNE has 10-15 years left to exploit the patent before low price competitors enter the market.

IMVAMUNE was patented in the US in 2004 and is currently patented in 25 countries including Europe, Japan, Australia and Canada. The brand IMVAMUNE is trade mark protected in app. 80 countries worldwide (Bavarian Nordic, 2005).

The technology and patent portfolio of IMVAMUNE is considered to be one of the greatest competitive advantages for the company.

The procurement part of the support functions are covered under the primary activities in the Inbound Logistics sections.

1.4.2 Primary Activities

1.4.2.1 Inbound Logistics

For the production of IMVAMUNE Bavarian Nordic requires raw materials and sterile disposable materials. Most of the materials needed to produce IMVAMUNE are generic within the pharmaceutical industry, however part of the materials used are custom made for Bavarian Nordic, e.g. all the sterile disposable materials (Bavarian Nordic, 2007).

The most important raw material in the production of IMVAMUNE is the SPF[9] eggs. As opposed to the other materials needed for the production, the SPF eggs cannot be stored for long periods of time. Therefore, if the supplier was to experience infections or contaminated batches, this would have a great impact on the production and delivery of IMVAMUNE (Bavarian Nordic, 2007). Bavarian Nordic has attempted to guard against such factors, by using more than one supplier in order to reduce the dependence on the individual suppliers.

According to Bavarian Nordic's rights issue from 2007 they have at least two suppliers lined up for delivery of the materials needed for the production of IMVAMUNE. Therefore, the risk related to the suppliers of materials defaulting is considered to be relatively low.

The inbound logistics are neither a strength nor a weakness for IMVAMUNE. As long as Bavarian Nordic keeps a focus on reducing the dependence of individual suppliers, the risk of delays due to delivery default from a supplier is limited.

[9] Specific Pathogen Free eggs

1.4.2.2 Operations

Bavarian Nordic bought a manufacturing facility in Kvistgaard, Denmark, to be able to supply the necessary doses of IMVAMUNE under the RFP 2 and RFP 3 contracts. Novo Nordisk Engineering was given the contract to construct the new production facility and to date, it is the only production facility that is built, solely to produce MVA based vaccines. With some modifications, the plant can also produce traditional vaccines (pharmaceutical-technology.com). The plant and production process was approved for production in 2007 and has recently had a GMP[10] review by the FDA, where some improvement requirements were made. Bavarian Nordic is working on implementing these changes (Bavarian Nordic Q2, 2009).

The plant can produce 40 million doses a year. This can be expanded to 120 million doses a year by hiring additional production resources. Although the plant was build with the production of IMVAMUNE in mind it can be used for all current and future recombinant vaccines based on the MVA-BN technology (Bavarian Nordic, 2007).

The plant in Denmark produces the vaccine bulk but the filling and packaging is completed by Impstoffwerk Dessau-Tornau GmbH (IDT) in Germany. Bavarian Nordic and IDT has a framework agreement that governs the filling and packaging; they only need to negotiate the price, quantity, time to delivery and place of delivery from time to time (Bavarian Nordic, 2007).

Bavarian Nordic is inexperienced when it comes to producing vaccines and currently the plant is not producing at max capacity. Because of the inexperience and the low volumes produced, the production costs are very high. In 2008, production costs were app. 95% of revenue (Bavarian Nordic, 2008), whereas GlaxoSmithKline and Novo Nordisk, two experienced pharmaceuticals, only have app. 25% of revenues as production cost (Novo Nordisk A/S, 2008; GlaxoSmithKline, 2008).

The cooperation with IDT is also important since delays in IDT and limited production capability may impact the timely delivery of IMVAMUNE, as well as increase the production costs.

[10] Good Manufacturing Practice

It can be concluded that due to the fact that Bavarian Nordic is capable of producing the required vaccine, their own plant is a strength in the long run. However, in the short run, it is a weakness that they have so little experience with production, which increases the production price per unit. At the same time, the dependence on IDT is a risk that could impact the delivery schedule of IMVAMUNE.

1.4.2.3 Outbound Logistics

The outbound logistics may have a vital importance for the success of the IMVAMUNE project, especially since the production and filling are carried out in two different locations, Denmark and Germany. IMVAMUNE is a fluid vaccine that needs to be transported and stored in a refrigerator. If the cooling element was to malfunction during the transportation between the manufacturing plant and the filling plant, an entire batch might be destroyed. The transportation task is outsourced to an unnamed security company (Bavarian Nordic, 2007).

The final delivery form is agreed with the individual client. Often, the client arranges the final delivery themselves, by e.g. sending a transport carrier to pick up the vaccines. This is the general approach used by the US and it is expected that other large orders will be delivered in the same way. Since the clients are spread out all over the world, it is a clear advantage for the IMVAMUNE project that the client takes on the final transportation of the vaccines, since Bavarian Nordic saves the money and the trouble of creating and managing their own distribution network.

The outsourcing of the delivery from the Danish plant to the German filling and packaging plant is an advantage, keeping the size of Bavarian Nordic in mind, since managing the logistics of this part can be challenging for a small company.

It appears that the distribution network is optimal for the IMVAMUNE project. However, it could be recommended that Bavarian Nordic continually evaluates their distribution network. Once the vaccine is licensed for use, they may expect orders from many places all over the world, which they need to be prepared for.

1.4.2.4 Marketing, Sales & Service

The company has built a marketing and sales division in connection with the award of the RFP 3 contract. The people that are recruited into the marketing and sales division had many years experience in dealing with public authorities.

In 2006, a service office was opened in Washington D.C., USA to cooperate with and ease the communication with the US authorities. This office will play a key part when it is time to issue the Biologic License Application to the FDA (Bavarian Nordic, 2006). In addition to the US office, another office was opened in Singapore with the purpose of strengthening the sales work for IMVAMUNE in the Asian region.

It is a strength of the project that a marketing and sales division has been built prior to registration of IMVAMUNE. The continued sales and marketing effort prepares the market for the upcoming vaccine and may assist in getting further pre-registration orders for the vaccine. In this way, the IMVAMUNE brand should be very strong once the product is a registered vaccine. It is also an advantage that the focus has been on recruiting people who are experienced in dealing with public authorities since the company has limited experience and the employees are learning as they go along.

1.5 Market Attractiveness

This section introduces the reader to the external environment around the project. I will initially give an overview of the competition within the smallpox area and then analyze the influence of the suppliers and the buyers.

1.5.1 Competitors

Acambis was considered the only competitor to Bavarian Nordic for years, since it was also developing an MVA-based smallpox vaccine. Acambis dropped these studies when they were excluded from the RFP-III contract, which was awarded exclusively to Bavarian Nordic. This gives Bavarian Nordic a strong position on the 3rd generation smallpox vaccine market. However, Bavarian Nordic is not the only player in the smallpox market.

The South Korean company CJ corporation initiated phase I studies of a 3rd generation smallpox vaccine in 2008. This study is estimated to be completed in December 2010 and no results regarding the safety or effectiveness of this vaccine have yet been delivered to the FDA (ClinicalTrials.org a Service of the US National Insitutes of Health, 2008). Nonetheless, it is a company that Bavarian Nordic needs to keep an eye on, with regards to how its smallpox vaccine is progressing and what data the clinical trials show.

Although, there are only two vaccines under development, the company SIGA Technologies is currently investigating a drug called ST-246®. The drug has shown positive results in laboratory tests so far and can be used for prophylaxis and preventing

the disease in non-vaccinated individuals; therapeutics, treating those with smallpox symptoms or non symptomatic individuals that have been exposed to smallpox. Finally, the drug can be used in combination with smallpox vaccines to prevent disease and reduce vaccine related complications (Siga). The drug is currently undergoing Phase I clinical trials. It is not known at present whether this drug would be useful in immune compromised individuals, but SIGA Technologies drug ST-246® must be considered to be a potential competitor to IMVAMUNE with the possibility to sell vaccines for the national stockpiles around the globe. ST-246 is developed in a tablet form for oral ingestion, whereas Bavarian Nordic's vaccine requires two injections from a doctor. At the same time, IMVAMUNE is not suited for treating symptoms, although it can alleviate symptoms in infected individuals if administered within a week of infection. However, as ST-246® is only in Phase I clinical trials, it is a potential future competitor.

Biotechnology is a research intensive industry and it requires a large supply of cash to start a biotech company. The cash should be used to fund the company's operations for many years until it has a project that can either be sold to a pharmaceutical company, or until it has a project that can be produced by the company itself. In the current financial markets, it may be difficult to raise the required funds in the stock market for a biotech company. Another entry barrier is the investment that a company would need to make in building a laboratory. In addition, it can be considered a barrier to entry that Bavarian Nordic has a lucrative contract for developing a smallpox vaccine with the US government. Taking into account that it takes up to 15 years from the initiation of a smallpox vaccine/drug until it can be marketed, it seems unlikely that a new entrant would be able to obtain government funding for their research in the early stages, that is unless IMVAMUNE fails.

The threat of new entrants within smallpox vaccines/drugs are not very high, and since there are currently only two other competitors within the smallpox niche and both their projects are in phase 1, Bavarian Nordic should be able to monopolize the smallpox vaccine market with a safe vaccine for a minimum of 6 years or if both CJ Corporation and SIGA's projects fail to reach the market, until the IMVAMUNE patents expire between 2021 and 2025.

1.5.2 Buyers

The market for IMVAMUNE mainly consists of sovereign states and could also include larger supranational organizations such as the WHO. Bavarian Nordic has signed contracts

with the US, the Canadian Government and an EU country to supply IMVAMUNE to the national stockpile or military.

The US has a great deal of power with regards to the IMVAMUNE project, since the NIH is funding part of the clinical trials. If the NIH withdrew their funding, Bavarian Nordic would be forced to turn to the stock markets for funding of future activities. The NIH is, through the funding of IMVAMUNE, also entitled to make certain demands as to the production facilities and the testing required.

Dealing with states and supranational organizations can be a cumbersome procedure due to the additional documentation required. The advantage of the IMVAMUNE project is that they are gathering experience in dealing with these types of institutions while developing the vaccine, and at the same time they are getting partly funded while gathering this experience.

Both the company and the project are very much depending on the buyers, both in the short run and in the long run. Since the buyers are governments or supranational organizations, they are likely to experience price pressure since the vaccines will most likely be ordered in large batches, once it is licensed.

1.5.3 Bioterrorism – threat assessment

"The most important under-addressed threat relating to terrorism, and one which acutely requires new thinking on the part of the international community, is that of terrorists using a biological weapon." (United Nations, 2006, s. 11)

The main line of discourse about the likelihood of a biological attack with massive casualties suggests that it is possible for terrorists to obtain biological weapons and that there is a high risk that they will use these weapons against civilians. The post 9/11 attacks in the US with Anthrax increased the already existing anxiety about the possibility of a devastating biological attack. This line of discourse gains acceptance by being supported by some of the world's most prominent people as illustrated with the quote from Kofi Annan. The US President, George W. Bush, also accepted the threat as being likely and high, and responded by implementing the Project BioShield act in 2004. "The purpose of Project BioShield is to accelerate the research, development, purchase, and availability of effective medical countermeasures against biological, chemical, radiological, and nuclear agent (U.S. Department of Health & Human Services)."

Although the majority of the discourse has suggested that a biological attack is an imminent threat, there has also been a minor discourse trying to calm the debate. This line of discourse claims that a biological attack by terrorists are currently unlikely since the terrorists would need access to advanced labs and highly educated people to develop the biological agents and to weaponize these. To get access to this, the terrorists would most likely need the support and backing of a sovereign state, which is considered unlikely to occur at present. One of the participants in this discourse is Milton Leitenberg[11] who states that: "*Bioterrorism may or may not develop into a serious concern in the future, but it is* not *one of the most pressing problems that we have on the planet today*" (Leitenberg, The problem of biological weapons, 2004).

Type	Example	Casualties	Frequency
Natural	Outbreak of contagious disease	From a few hundred to many millions	Regularly (>10 per year)
Accident	Leakage during transport or production	Few, but potentially several thousands	Frequently (≈1 per year)
Crime	Contamination of food with regards to extortion	Very few	Rare (≈0,2 per year)
Terrorism	Contamination of air or food in urban areas	Few hundred, but potentially many thousands	Very rare (≈0,1 per year)
War	Attack on the public	Thousands - millions	Very rare (≈0,05 per year)

Table 2: Dansk Center for Biosikring og Beredskab - threat assessment

The threat assessment in table 2 was issued by Dansk Venter for Biosikring og Beredskab.

Throughout modern history, biological warfare has rarely been used. In the 1930s and 1940s, Japan released plague bacteria over China, and as for bioterrorism, the only recorded deaths from bioterrorism in the US were caused by the post 9-11 anthrax attacks. Biological weapons have been used infrequently due to difficulty in obtaining and processing the pathogens, uncertainty that they will affect an intended target and in some cases moral inhibitions.

When it comes to the threat assessment and likelihood of a biological terrorist attack, opinions are widely dispersed. The post 9/11 biological Anthrax attacks caused five

[11] Milton Leitenberg is a Senior Research Scholar at the Center for International and Security Studies at Maryland, University of Maryland. Leitenberg's research work is concentrated in three disparate areas of study: biological weapons; actual wars and conflicts of the past two decades, and the issue of international intervention in these. With specific reference to Biological Weapons, Leitenberg's academic training was in Biology and Chemistry and his first paper dealing with biological weapons was published in 1967

fatalities. The low number of casualties was due to the method of distribution, through the mail. Even though the number of casualties was low the fear of more attacks was significant and magnified by the fact that they occurred so short a time after 9/11, and that the Anthrax was professionally prepared. The fear is that terrorists will be able to spread a bacteria, virus or poison through the air with a biological weapon causing massive fatalities.

Although a biological terrorist attack is unlikely according to scholars, there is still a market for preventing such an attack. This market is driven by the fear of the devastating consequences of not being prepared.

1.5.4 Market Size

In 1998, the WHO estimated, based on a survey, that the world stock of smallpox vaccines was 90 million doses. Since then, several of the developed countries have increased their supplies of smallpox vaccines to be prepared in case of bio terror. In 2005, it was estimated that the number of doses was up to 720 million, which would be enough to vaccinate app. 10% of the world's population. This estimate was made for an exercise called Atlantic Storm[12] with "…the best available open-source material…" (Liebert, 2005). As can be seen from table 3 below, the estimates from 2005 also showed that only nine countries had enough smallpox vaccines in stock to immunize the entire population. For the purpose of this exercise, it was also estimated that the max production of smallpox vaccines would total 40 million per month, even in a state of emergency. The exercise concluded that the international community should work together to build up the necessary medical resources needed in case of an international crisis.

[12] *Atlantic Storm* was a tabletop exercise simulating a series of bioterrorism attacks on the transatlantic community. The exercise occurred on January 14, 2005, in Washington, DC, and was organized and convened by the Center for Biosecurity of UPMC, the Center for Transatlantic Relations of Johns Hopkins University, and the Transatlantic Biosecurity Network. The exercise scenario was that the smallpox virus had been released in several major cities throughout Europe and north America simultaneously.

National stocks of first and second- generation smallpox vaccines (start of 2005)

Country	No. Of doses (million)	% of the population covered
USA	300	100
Germany	100	100
United Kingdom	80	100
France	60	100
The Netherlands	20	100
Czech Republic	10	100
Israel	7	100
Denmark	6	100
Singapore	4	100
South Africa	30	70
Malaysia	15	65
Austria	3	40
Switzerland	3	40
Japan	31	25
South Korea	10	20
Canada	6	20
Greece	2	20
Spain	6	15
Ireland	<1	15
Norway	<1	15
Italy	5	10
Belgium	1	10
Hungary	1	10
Sweden	1	10
Iran	2	5
Australia	<1	5
Poland	<1	5
India	6	1
Croatia	<1	1
Slovakia	<1	1
Turkey	<1	1
WHO	2,5	NA
Total	**Approx. 720**	**10**

Source: Biosecurity and Bioterrorism: Biodefence Strategy, Practice and Science, Volume 3, number 3, 2005

Table 3: Total stocks of smallpox vaccines

In the US, the CDC has a Strategic National Stockpile (SNS) of medicine, vaccines etc. in case of a public health emergency. This stockpile has been expanded since the signing of the Project Bioshield Act in July 2004 to include drugs to treat and prevent illnesses related to a terrorist attack. The SNS contains enough medicine and drugs to supply two major cities with drugs for all the inhabitants at the same time.

The Project Bioshield Act also includes funding to buy for up to USD 6 billion of "next-generation" countermeasures against biological agents that can be used for terrorism,

thereby encouraging researchers to develop products that have stayed the same for decades, such as the smallpox vaccine.

1.6 SWOT

The strategic analysis is summarized in the below SWOT diagram, to provide the reader with a quick overview of the main points of part one.

Strengths

- Strategic focus on bio defense
- Patent portfolio and defense of this
- Unique technology
- Management and board has extensive experience within biotech and pharmaceuticals
- Marketing and Sales has experience with dealing with governmental institutions
- Marketing and Sales departement build up prior to registration may help develop the market
- Possibility of combining IMVAMUNE with other bio defense vaccines
- RFP 3 contract awarded 100% to Bavarian Nordic – gives strong market position

Weaknesses

- Liquidity
- Biotech company in transition to phamaceutical company
- High production costs
- EUA not yet granted due to GMP inspection changes requested. These changes are expected to be implemented in December 2009.
- Custom made supplies may delay the production process if the supplier defaults
- Production facility build solely for MVA production – modifications required to produce non-MVA based vaccines
- IDT delays may impact Bavarian Nordic

Opportunities

- Project Bioshield – possibility of funding for further development of IMVAMUNE
- Market size and market share– possibility of getting a large market share prior to patents expiring
- Possibility to gain valuable experience in dealing with governments under the RFP contracts
- The threat of new entrants on the smallpox market is considered to be relatively low, thus there is an opportunity to gain monopoly profits for a while

Threats

- Emerging competitors
- Low probability that an attack may happen – could influence/shift the focus of politicians to more imminent threats
- Large clients, governments and supranational institutions
  – Often cumbersome to work with
  – Price pressure
  – NIH is able to make certain requirements that may reduce Bavarian Nordics independence as a company, as the NIH is funding large parts of the research for IMVAMUNE

Part Two: Decision tree

In this section, I will identify the future events that will have an impact on the value of IMVAMUNE. These will be illustrated in an event tree and analyzed to determine where the management has to make a decision about whether to continue with the project. The decision tree will create an overview of the real options connected to the IMAVMUNE project. Finally, I will identify the type of real option and summarize the theory relating to valuing this type of option.

In this section I will analyze the different future events that will impact the value of IMVAMUNE. I have illustrated the possible events in the figure below.

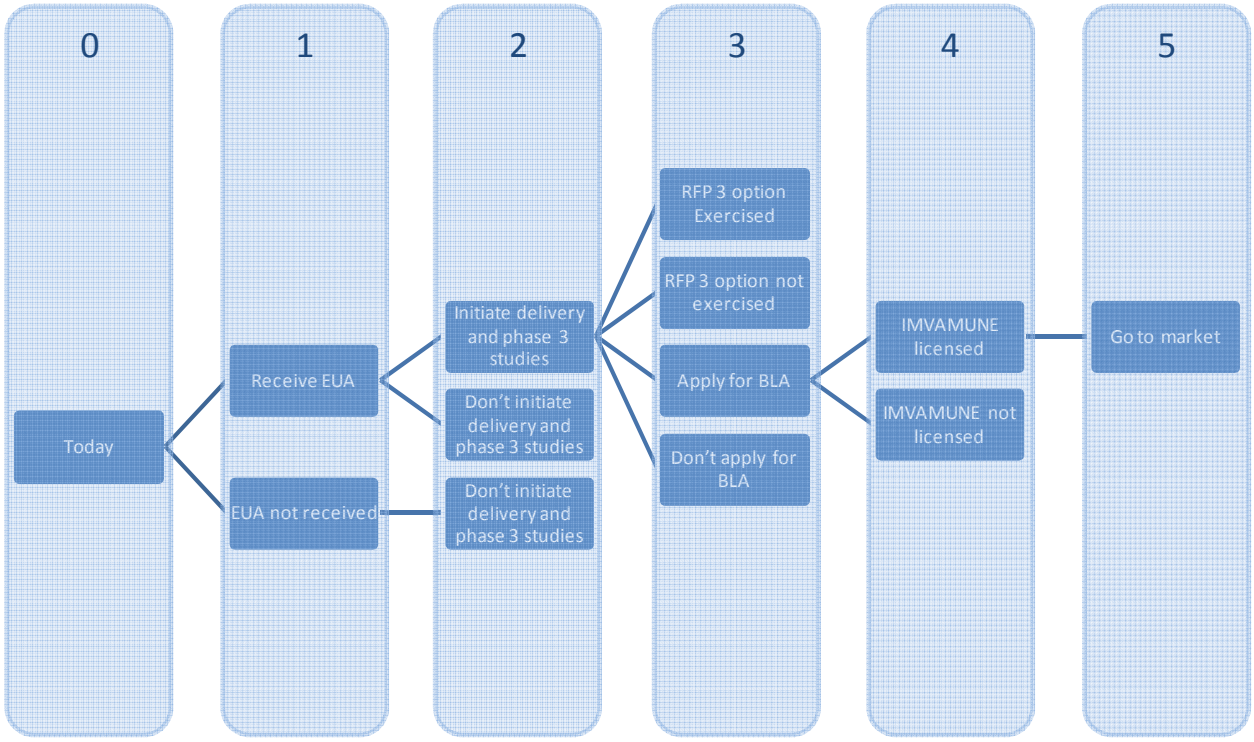

Figure 3: Event Tree

The first column zero, illustrates the valuation date and the events that will occur after this date. When we go from column zero to column one, we see that Bavarian Nordic is awaiting an Emergency Use Authorization from the FDA. If they do not receive the EUA, they will be unable to initiate the delivery of the 20 million doses of IMVAMUNE. Furthermore, since Bavarian Nordic are dependant upon the cash flows that will be generated by these deliveries to support the phase III studies, it is likely that IMVAMUNE will be abandoned if the EUA is not received.

Based on the information gathered in the strategic analysis, it appears unlikely that the FDA will not issue the EUA, since they have already approved the phase II study data and have discussed how the phase three studies are to be done. It also appears that all that is standing in the way of receiving the EUA are some minor technical upgrades to the production facility. Bavarian Nordic can influence the process up to when the decision is made, but they will not have any influence on the final decision on whether or not the EUA will be issued for IMVAMUNE.

If the EUA is received, moving from column one to two, then Bavarian Nordic will have to choose if they want to comply with the RFP 3 and initiate delivery of the 20 million doses and initiate the phase III studies. The phase III studies are planned to be initiated in late 2010, and, as such, will be limited how much longer the phase III studies can be postponed, due to the conditions of the RFP 3 contract. It is considered highly unlikely that Bavarian Nordic will not initiate delivery of the 20 million vaccines, since they have already built a stock of vaccines, which is to be the first shipment of the vaccines. Unless the present value of the expected future cash flows is negative, it is also likely that the phase III studies will be initiated.

The next event likely to take place in column three is that the option for the delivery of 60 mio doses to the NIH is exercised or abandoned. This is, again, a decision that Bavarian Nordic has no influence on. The NIH's decision to exercise the option or not, will most likely be influenced by several factors:

- Bavarian Nordics ability to make deliveries according to schedule
- The indicative results from the phase 2 studies
- The preliminary results of the phase 3 studies
- Change in threat assessment
- Availability of required funds

If the option is not exercised this will naturally have an impact on the expected future cash flows, but the option exercise will not be conditional for applying for a BLA to get IMVAMUNE licensed. This is a decision Bavarian Nordic will have to make, based on the available data after the completion of the phase III studies.

Moving to column four, we see that the event following the BLA application is that either IMVAMUNE gets licensed or it doesn't get licensed. Again, this is a decision not made by

the management , although it is possible to attempt to influence the final decision through lobbyism.

Finally, in Colum five, the event following receiving a license is to go to market. This is a decision Bavarian Nordic will make. However, it seems unlikely that Bavarian Nordic will choose not to go to market once the product is registered and licensed with the FDA. At this point in time, the very large negative cash flows connected with the research and development of the vaccine will be finished and production experience should have been gained to ensure that net cash flows from sales and production are positive.

In figure 4 below, I have created the decision tree by highlighting the decisions that Bavarian Nordic's management will have to make upon receival of an EUA. The below decision tree is based on the assumption that IMVAMUNE will get an Emergency Use Authorization.

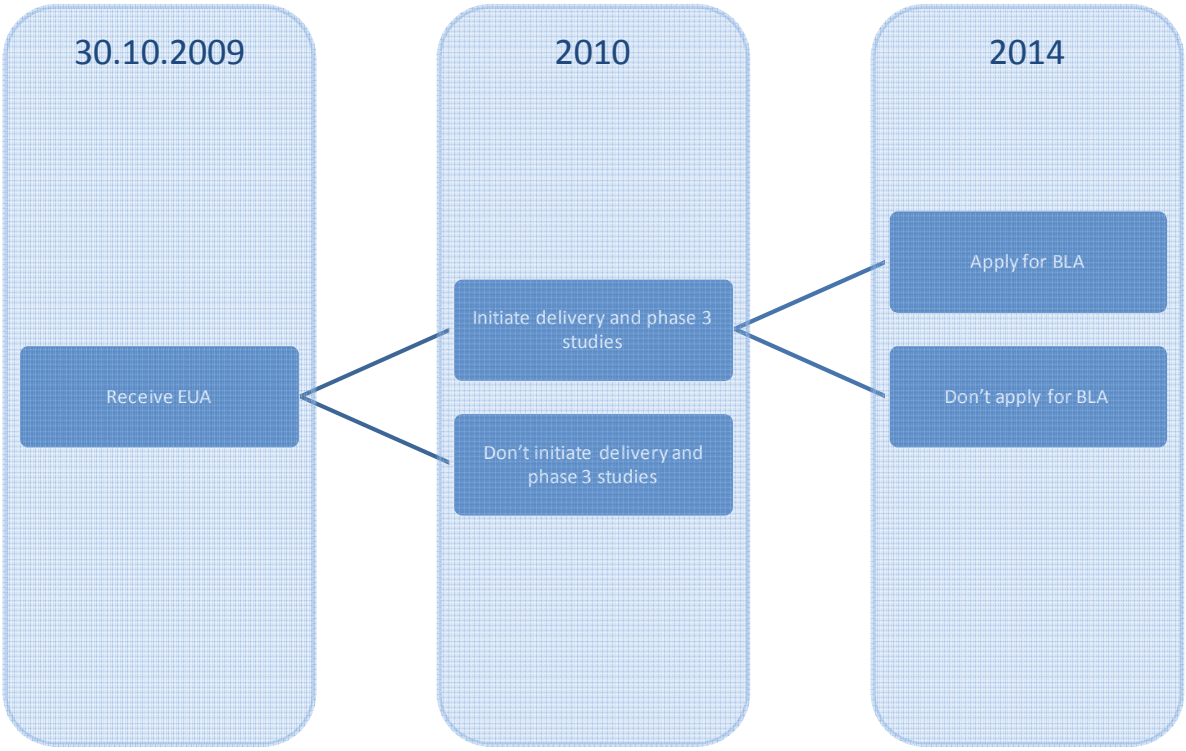

Figure 4: Decision Tree

The decision tree illustrates that at each node, Bavarian Nordic has an option to expand and an option to abandon the project. The type of real option this thesis is dealing with is a compound option.

With compound options, the value of one option depends on the value of another option. According to Mun (2006) there are two types of compound options; the simultaneous compound option and the sequential compound option. The simultaneous compound option is when the two options are both occurring at the same time, whereas the sequential compound is when one option occurs before the other, but the exercise of the latter option is dependent on the exercise of the first option. Thus if a project has multiple phases, and the latter phases depends on the success of previous phases, then we are dealing with a sequential compound option, as is the case with IMVAMUNE.

The following estimates are required to calculate the value of a compound option:

- The present value of future cash flows
- The up and down factors for the lattice of the underlying asset
- The risk neutral probabilities for the option lattices

To calculate a sequential compound option, one must first estimate the present value of the future cash flows and create a lattice for the underlying asset. Using this lattice, the value of the latter option is calculated in a new lattice, and the lattice for the latter option is then used to estimate the value of the sequential compound option. "*The analysis requires the calculation of the longer term option first and then the shorter term option because the value of a compound option is based on another option*" (Mun, 2006, s. 184-185).

2.1 Summary

The purpose of this part was to create a decision tree and identify the type of real option to be valued.

First, an event tree was created to give an overview of the future events that may impact the value of the project, then it was determined at which nodes the management of Bavarian Nordic would be able to make decisions as to what should happen next, and, based on this, the decision tree was created. This showed that Bavarian Nordic has an option to invest and an option to abandon in 2010. Depending on the decision made in 2010, Bavarian Nordic will also have an option to invest and an option to abandon in 2014.

Since the latter option is dependent on the success of the former option, the option type was identified as a sequential compound option. It was identified that three estimates were

necessary to valuate the sequential compound option, the present value of future cash flows, the up and down factors and the risk neutral probabilities. It was then explained that to calculate the value, one should first calculate the value of the latter option based on the lattice of the underlying asset, and then use the lattice of the latter option to calculate the value of the compound option.

Since we first need the present value of future cash flows to calculate the binomial lattice for the underlying asset, this will be done in part three and in part four of the up and down factors, as well as the estimate of the risk neutral probabilities.

Part Three: Estimating the variables

In part two, the decision tree was constructed to give an overview of the options available to Bavarian Nordics management. Before the real options valuation can be performed in part four of this thesis, a number of estimates are necessary. In the following sections, I will go through each of these estimates, analyzing on how they have been estimated, what the assumptions behind them are and the pros and cons of using these estimates. All the estimations done in this part are essential in their own way to the valuation that will be done in part four.

I will start by estimating the present value of the expected future cash flows, since the present value is equal to the value of the underlying asset without options, thus the present value is used to model the binomial lattice which the option values are calculated on. Within this section, the WACC is estimated, as well as the price and quantity.

Secondly, I estimate the exercise prices of the options to invest. These are equal to the present value of the expected future investments. And finally, the exercise price of the abandonment option is estimated.

3.1 Present Value of future cash flows

To determine the value of the underlying asset, I will estimate the present value of future cash flows excluding the investments to be made in latter stages. To calculate the present value of the project, I will need to estimate the WACC and the future cash flows.

3.1.1 WACC

To calculate the value of the IMVAMUNE project without flexibility, the Weighted Average Cost of Capital (WACC) for Bavarian Nordic has been selected as the discount rate and estimated to 8,97%. This section will first go through why I have chosen to use the WACC as the appropriate discount rate, as well as the upsides and downsides of using the WACC, and end with how the WACC has been calculated.

According to Brealy & Myers (2003), the opportunity cost of capital is the appropriate discount rate for valuing projects, whereas the WACC is only appropriate for projects that have the same risk as the firms existing business, as well as the same capital structure. The opportunity cost of capital is equal to the expected rate of return offered by equivalent investment alternatives with similar risk in the capital market. According to Copeland and Antikarov (2003), the WACC is appropriate for discounting project cash flows because if

you have a positive present value when using the WACC, then the return is sufficient to pay both sources of capital – debt and equity, and any residual value goes directly to the shareholders.

One of the assumptions behind the WACC is that the capital structure of the firm remains constant over time and that the business risk remains the same. Although these are strong assumptions, I have nevertheless decided to use the WACC as the appropriate discount rate for the project, since IMVAMUNE is by far the largest project in Bavarian Nordics Pipeline, as well as the only project currently generating revenue. It is thus assumed that the risk of the IMVAMUNE project and the risk of Bavarian Nordic are equivalent, as the risk of the company will be highly correlated with the risk of the project. The capital structure of the project and company is the same.

Below you can find the WACC formula and the definitions of the different parts of the formula.

$$WACC = R_E*E/V+(1+T)*R_D*D/V$$

Equation 1: WACC

R_E = the expected return on equity
R_D = the expected return on debt
V = Market value of company
E = Market value of Equity
D = Market value of debt
T = Corporate tax rate

3.1.1.1 Return on Equity

The first part of the WACC equation concerns the expected return on equity. To estimate the expected return on equity, I have used the CAPM which states that:

$$R_E=\beta*(R_M-R_F)$$

Equation 2: CAPM

R_E= the expected return on Equity
β=the covariance with the market portfolio

R_M= the expected return on the market portfolio
R_F=the risk free interest rate

Thus to estimate the expected return on equity for Bavarian Nordic, the beta, the expected return on the market portfolio and the risk free rate should be estimated. It is assumed that all these estimates remain constant over time.

Beta

The beta is the estimate of the company's stock return covariance with the market portfolio's return. If the beta is 1, then it can be said that the stock tends to follow the market, whereas a beta of 0 means that there is no correlation with the market and a high beta above 1 indicates that the asset magnifies the market movement, e.g. if the market decreases with one, the asset would decrease more than the market. Beta is also known as a measure of market risk or non-diversifiable risk, as opposed to the standard deviations of a stocks return that are known as diversifiable risk.

Since we cannot predict what the future beta of a stock is going to be, we tend to use historical data as an indicator of what the future beta is going to be. When doing the regression to measure past beta, a minimum of 60 data points should be used. However, going very far back in time will not increase the accuracy of the beta estimate since beta may fluctuate over time as the company changes (Koller, Goedhart, & Wessels, 2005). McKinsey recommends calculating the beta on monthly data to avoid systematic biases. A stock that is rarely traded will have many returns equal to zero, not because the stock's value is constant but because it hasn't traded.

The beta estimated in this beta has been estimated on 60 months of monthly returns since Bavarian Nordic's Stock is not the most liquid of stocks. This should smooth out any systematic bias in the beta. When regressing the return of Bavarian Nordic on the MSCI Index return for Denmark, the R^2 is only 36% and the standard error of the beta estimate is 0,24. This indicates that the true beta does not necessarily equal the estimated beta of 1,36.

To further analyze on the beta estimate, I mapped the monthly rolling beta for the past year and compared this to the monthly rolling betas of Neurosearch, Genmab and the Dow Jones indices for biotech and pharmaceuticals. The pharmaceuticals index was included as Bavarian Nordic is supposedly transforming from a biotech company into a

pharmaceutical, and the graphic comparison will show if Bavarian Nordic's estimated beta is close to the pharmaceutical betas.

As can be seen from the graph below, Bavarian Nordic's and NeuroSearch's beta are showing the same trend; an increase in market risk during the past year. In comparison, Genmab is showing a reduced market risk in the past year, as is the Dow Jones index for Danish Biotech companies. It should be clear from the graph that Bavarian Nordic's beta should be within the range of the biotech companies, since the pharmaceutical industry is showing a notably lower beta than the biotech industry.

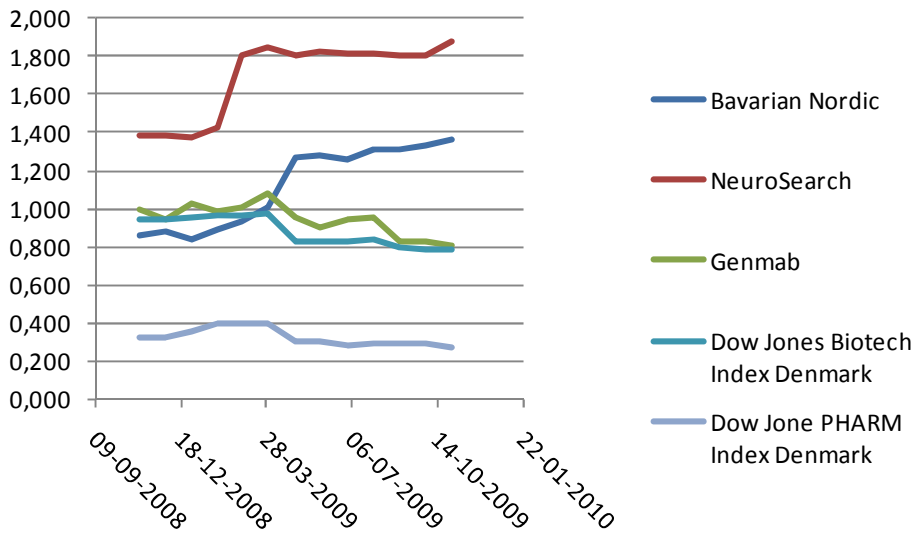

Figure 5: Rolling Beta comparison

The rolling betas in the graph above are calculated without looking at the debt/equity ratios of the individual firms, and to be directly comparable, one should use the unlevered beta. However, unlevering the industry beta would be difficult to achieve. Instead, I have looked into the annual reports for NeuroSearch and Genmab, and both companies are in essence 100% equity financed. Their current assets exceed the mortgage and liabilities, just as is the case with Bavarian Nordic. I will go into more details about how this has been estimated later in section 3.1.1.2 debt. Since the biotech sector generally cannot borrow money for the primary activities, as these are risky and normally won't generate positive cash flows for many years if at all, it will be assumed that the biotech industry is generally all equity financed and the beta's can thus be compared.

Since estimating beta is an imprecise exercise, it is recommended to use the industry beta, since companies in the same industry face similar operating risks, they should have similar

operating betas, and thus the unlevered average beta for an industry should be the best estimate of the future beta for a company (Koller, Goedhart, & Wessels, 2005). When regressing the return for Dow Jones index for Danish Biotech companies against the MSCI Denmark index return beta is estimated at 0,79 with an R^2 of 32% and a standard error of 0,15.

When comparing the historic industry beta to the historic beta for Bavarian, it becomes obvious that a shift happened in the data, causing the company beta to be higher than the industry average. It appears that the covariance with the market is increasing in the later observations. Since this is not the case for the industry as a whole, it will be assumed that the company beta is the best estimate of the future beta for Bavarian Nordic, and as such, is 1,36. It is furthermore assumed that beta will remain constant over time.

Expected return on the market portfolio

This thesis will use the MSCI Denmark Index as the market portfolio used to calculate the various estimates. This is not the optimal approach according to Koller, Goedhart and Wessels (2005) as most countries are heavily weighted in a few industries. If this is the case, it is not the market risk that is being estimated, but the company's sensitivity to a particular industry. Although this is a valid argument, it is also the case that the macro economic factors impacting a Danish company do not equal the macro economic factors impacting a Greek or an African company, and as such, using the MSCI World or MSCI Europe index would not be appropriate. Also, the Danish stock market is quite well diversified across sectors, even though the larger companies, such as Novo Nordisk, A.P. Møller – Maersk, Vestas and Carlsberg do impact the index when they move upward or downward. However, as these are representatives from different industries, this should not bias the MSCI Denmark towards one industry.

The expected return on the market portfolio has been estimated by calculating the average monthly return from October 2003 until October 2009. The expected monthly return is 0,62% and the annualized expected return is 7,42%.

Expected Risk Free interest rate

To estimate the return on equity via the CAPM, it is necessary to estimate the expected risk free interest rate. This has been done by calculating the average 10 year interest rate on Danish government bonds since the year 2000. The expected risk free interest rate is 4,34%.

The reason that the 10 year government bonds have been chosen is that these match the duration of the cash flows better than the short-term bonds. Using the yield to maturity from a short-term bond fails to recognize that a bondholder must reinvest when the short-term bond matures, and as such the opportunity cost of investment for projects with a longer duration is misestimated (Koller, Goedhart, & Wessels, 2005).

Estimated return on equity

With all the estimates in place, it is now possible to estimate the return on equity. In the below table I have summarized the results of the CAPM, and as can be seen, the calculated expected return on equity is 6,8%

CAPM Cost of Equity	
Expected Return Market	7,42%
Risk-Free Rate	4,34%
Industry beta	0,80
Re, the cost of equity	**6,80%**

Table 4: CAPM

With the expected return on equity estimated, we turn to the remaining parts of the WACC equation, the market value of equity, the expected return on debt and the market value of debt. The market value of the equity is easily calculated as the number of shares times the share price. The market capitalization as of 30.10.2009 was as can be seen from the below table DKK 1.582.652.520.

Number of share	7.815.568
Price 30-10-2009	202,5
Market value 30-10-2009	**1.582.652.520**

Table 5: Market Capitalization

3.1.1.2 Debt

The second part of the WACC equation is the debt ratio and the interest on debt, and to find this I have been looking into the financial statement of Bavarian Nordic. Since Bavarian Nordic has not issued any corporate bonds on which the market value of the debt can be calculated, this paper will assume that the book value of debt is the best estimate of the market value of the firm's debt.

According to Madura (2006), the size of the firm can induce creditors to give preferential behavior for large debt issues, while large issues also reduce flotation cost. The effect being that the cost of capital is reduced. However, this is not the case for Bavarian Nordic

who, apart from being a relatively small company, also operates within the biotechnology industry where debt is hard to come by, given that the firms rarely generate revenue that can be used to repay debt. The same reasoning can be applied to Madura's second argument for how operating internationally can reduce a firms cost of capital, where he states that the firm has access to international capital markets, and as such, can raise funds where the cost of these are lower.

Debt 2008	134.771.000
Less cash and cash equivalents 2008	559.160.000
Less investment securities 2008	226.160.000
Net debt (DKK)	**-650.549.000**

Table 6: Overview of net debt

The debt in 2008 has been calculated as the long term debt plus the part of the long term debt due for repayment in 2009 since these types of debt are financing debt as opposed to operating debt e.g. accounts payable and prepayments. Debt relating to the activities (vendor credit, prepayments etc.) has not been included in the above calculation of debt. However, even if the total liabilities are subtracted from the current assets, the net debt liabilities are negative and the net interest is 23 MDKK. Thus it can be concluded that the company is in effect 100% equity financed.

2008	**DKK thousands**
Credit Institutions long term	52.659
Credit Institutions short term	82.112
Prepayment from Customer	276.640
Accounts Payable	57.553
Payables to subsidiaries	50.236
Other debts	192.949
Total Liabilities	**712.149**
Cash and Cash Equivalents	559.160
Securities	226.160
Total current Assets	**785.320**

Table 7: Total current assets exceeds total liabilities

Furthermore, the net interest is a positive value, meaning that the company is in effect more earning money on the current assets than it is paying for its liabilities. This is normally only possible if the assets exceed the liabilities as interest rates on debt are normally higher than interest rates on cash and other assets.

Interest Income	39.964
Interest Expenses	-16.747
Net Interest	**23.217**

Table 8: Overview of net interest

As noted when estimating beta, it is not surprising that Bavarian Nordic is 100% equity financed as biotech companies' primary activities are research and development, and it is highly uncertain when and if any of these R&D activities will pay off, which is why the companies cannot finance their operations with debt. They can borrow against fixed assets such as property, which is what Bavarian Nordic has done, but financing for the primary activities must come from issuing equity, receiving grants or similar. Since a biotech company rarely generates revenue, these types of companies tend to have large amounts in cash, and trade able securities to ensure an efficient financing of activities. When equity is issued, it is based on the firm's expectations of how much cash they will need to fund R&D for a period of many years.

Since Bavarian Nordic is 100% equity financed, there is also no tax shield on debt, thus the WACC is equal to the expected return on equity of 6,8%.

Market value	1.582.652.520
Cost of Equity	6,80%
Equity (%)	100,00%
Debt (%)	0,00%
WACC	**6,80%**

Table 9: WACC

3.1.2 Future Cash Flows

Now that the WACC has been estimated, it is time to look into estimating the future cash flows and what impacts these. In this section I will go through the exchange rate risk, as well as how and why the future exchange rates have been estimated. Next, I will look into the inflation level to forecast the future inflation. I will end with an analysis of how the future revenues and cost have been estimated.

3.1.2.1 Currency Exposure

When calculating the expected future revenues and costs of IMVAMUNE, it is important to recognize the currency exposure the cash flows will be subjected to, as fluctuations in the exchange rate can have a significant impact on expected cash flows.

There are several ways to forecast future exchange rates. It can be done using technical forecasting where historic exchange rates are used to predict future values, however, technical forecasting focuses on the near future and should only be used for very short-term periods such as one day because patterns in exchange rate movements are more systematic over such periods. Since patterns are less reliable for forecasting long-term movements over a quarter, a year or more from now, technical forecasts are less useful for forecasting exchange rates in the distant future (Madura, 2006).

Another way to forecast future exchange rates is called fundamental forecasting. This involves using historical and current values of changes in: the difference in inflation between the two countries, the interest rate differential, the difference between the home and foreign income level, government control, and expectations of future exchange rates (Madura, 2006). This forecasting technique applies regression analysis to estimate the regression coefficients on historical data. Once these are estimated, the coefficients can be applied to the forecast. Fundamental forecasting requires a large time series database to warrant any confidence in the relationships detected by such a model and the coefficients estimated will not necessarily remain constant over time.

Finally, there is the market based forecasting which is usually based on either the spot rate or the forward rate. The spot rate may be used as a forecast for the near future since the spot rate represents the market's expectations of the near future spot rate, e.g. if investors are expecting the pound to appreciate against the dollar in the near future, they will buy pounds and sell dollars forcing the pounds value up immediately (Madura, 2006).

The forward rate on the other hand should move towards the markets general expectations of the future spot rate, e.g. if investors expect the spot rate of pounds to be $1.54 and the prevailing 30 day forward rate is $1,50 they would buy pounds 30 days forward at $1,5 and then sell them when received (in 30 days) at the spot rate existing then, thereby pushing the forward rate to increase until the speculative demand stops. The forward rate is easily accessible and therefore serves as a convenient forecast (Madura, 2006). Like the other methods for forecasting exchange rates, the forward is typically more accurate when forecasting exchange rates for short-term horizons than for long-term horizons.

Although the future cash flows relating to IMVAMUNE will mainly be in USD, EUR and DKK, it has, for simplicity, been assumed that all future cash flows are in USD. This

thesis will calculate the forward rates for the USD based on the 10 year risk free rate estimated for the date of the valuation, 30-10-2009.

As can be seen from the chart below, the USD DKK exchange rate has been volatile during the last ten years, from a high of almost 9 DKK per USD in 2001 to a low of 4,7 DKK per USD in 2008.

Figure 6: USDDKK exchange rate

This thesis will assume that all future cash flows are in USD. Using the calculated forward rates for USD, the cash flows will be transformed into DKK.

To calculate the forward rates, the risk free interest rate of the two countries and the spot exchange rate are needed.

$$\text{Forward Premium} = ((1+i_{\text{home}})/(1+i_{\text{foreign}}))-1$$

$$\text{Forward Rate} = (\text{Spot} * (1+\text{forward premium}))^{t}$$

Equation 3: Forward rates

The annual risk free rate on 10 year government bonds on the valuation date in Denmark was 4,069% and in the US it was 4,074% giving a forward premium of -0,004% or an expectation that the US dollar will depreciate further against the Danish Kroner over the

next ten years. With a spot rate of 5,03570 DKK per USD on the valuation date, this gives a 1 year forward rate of 5,03550, which represents a discount to the current spot.

Optimally speaking, the 1 year forward rate should be calculated on the one year risk free interest rate, the two year forward rate on the 2 year forward, etc. This thesis has instead used only the 10 year interest rate under the assumption that the difference from year one to year 21 will level out over time. The approach used in this thesis can cause the near-term cash flows to be undervalued and the long-term cash flows to be slightly overvalued, since the present value takes the time value of money into consideration. This will have a larger impact in the short-term cash flows, thereby giving a conservative estimate of the near-term cash flows. If the forward premium had been positive and an appreciation of the US dollar against the kroner had been expected, the effect would have been to overvalue the near-term revenue and undervalue the long-term revenue. This effect would then have caused a very optimistic PV calculation, since the time value of money states that a dollar today is worth more than a dollar tomorrow, and thus places higher value on near-term cash-flows, causing the overvalued cash flows to have a larger impact on the PV calculation.

The calculations of the forward rate can be viewed in Appendix 6: "Forward" on the attached cd-rom. The next section will estimate the future inflation.

3.1.2.2 Inflation

Since the expected future interest rate already includes inflation expectations, it is necessary to build inflation into the cash flows to make these comparable.

The Danish inflation rate has been calculated as an average of the yearly inflation from 1980 until 2008 and during these 28 years the Danish inflation has on average been 3,5%[13] (Danmarks Statistik, 2009). It should be noted that this is biased upwards by the very high inflation in the beginning of the 1980s. The average inflation since 1990 has only been 2%. However, there can be no guarantee that the inflation will not spike upwards in the future, thus this thesis will apply the long term average inflation of 3,5%.

With the future exchange rate and the expected inflation estimated, it is time to look at how the price per dose has been estimated.

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[13] Appendix 7: "R&D"

3.1.2.3 Price

The RFP contracts with the US government has established an indicative estimate of the price per dose of IMVAMUNE, however, both the RFP-3 and the RFP-3 Option contain funding for the research and development of IMVAMUNE, which drives up prices. The base RFP-3 contract yields a price of USD 25 per dose, whereas the option part yields a price per dose of USD 17.

This paper's base case scenario will assume that the future price will be USD 15 per dose. The rationale behind the USD 15 per dose is that the future clients will not directly be paying for the development of IMVAMUNE. This is also in line with the estimates made by Carnegie in a company analysis from 2006, although Carnegie assumed a price of 16 USD per dose.

For comparison, an ordinary flu vaccine costs USD 10 per dose, but only requires one shot to be effective, whereas the first vaccine developed for and delivered to the BioShield Program was rPA Anthrax this vaccine requires three doses to be effective and each dose costs app. USD 12, giving a total treatment cost of USD 36, as can be seen from the below table (Carnegie, 2006).

IMVAMUNE Prices, USD

Projects	*Est. Dose price*	*No doses*	*Treatment costs*
Anthrax rPA vaccine	12	3	36
2nd generation smallpox vaccines	2	1	2
Flu vaccine costs	10	1	10
IMVAMUNE base case	15	2	30

Source: Carnegie

Table 10: Price Comparison

Although a 2nd generation vaccine only costs USD 2, there are additional costs associated with these vaccines as patients need to be pre-screened and then followed up to monitor side effects and to check if the vaccine works. This cost is estimated at USD 200 per treatment for 1st and 2nd generation vaccines (Carnegie, 2006). With IMVAMUNE's high safety profile and the vaccines inability to replicate itself in humans, it becomes a cost efficient alternative when looking at the total cost perspective.

Even though the average price per dose of IMVAMUNE under the RFP-3 base contract is 25 USD, the expected future cash flows are the 375 million USD that will be invoiced pro

rata when delivery of the 20 million doses is initiated. Thus, the price used for the future estimate of revenues are 375 million divided by 20 million which yields a price of 19 USD per dose.

To take into consideration the insecurity about the price estimate, the simulation has calculated revenue based on a price of 10, 15 and 20 USD per dose.

The next section will cover the estimated quantities Bavarian Nordic will be able to sell of IMVAMUNE per year. This is the final step before the expected revenue can be calculated.

3.1.2.4 Quantity

As mentioned in part one, the global stockpiles of 1st and 2nd generation smallpox vaccines in 2005 was 720 million vaccines. This is assumed to be the total potential market size for smallpox vaccines. In this section, I will estimate how large a quantity Bavarian Nordic will be able to sell each year after the BLA is received. Thus the quantity estimates start in 2015. Until 2015, the source of revenue is assumed to be only the RFP 3 contract and the option.

A market size of 720 million vaccines is equal to 1.440 million doses of IMVAMUNE since the new vaccine requires two doses to inoculate an individual. It is unlikely that all of these vaccines will be replaced with IMVAMUNE. I assume that Bavarian Nordic will be able to capture the part of the market relating to the first responders. This is app. 5% of the population. In addition, I expect that the company will be able to capture the immune compromised part of the market, which is app. 20% of the total market equal to 101 and 444 million doses, calculated as the percentages of the amount of people in the countries that already have smallpox vaccines.

IMVAMUNE has a shelf life of five years (Bavarian Nordic, 2008), thus it would be necessary to replace the stock of IMVAMUNE after five years, creating a stable demand. For the purpose of this thesis, the max quantity is assumed to be distributed equally over a five year period and then replaced over the next five, etc. The maximum demand over a five year period should thus be 545 million doses or 109 million doses per year. To consider the insecurity about future quantity, the simulation has estimated quantity with 100%, 75%, 50%, 25% and 0% of the estimated maximum market share. The calculation can be viewed in appendix 14 and 16 on the CD.

3.1.2.5 Costs

To estimate the future net cash flows from the IMVAMUNE project, I have used indicative data from stock analysis done by Carnegie and Jeffries International Ltd. who both estimate the profit margin of Bavarian Nordic's IMVAMUNE project to be between 25% and 35%. This appears to fit well when looking at gross margin of GlaxoSmithKline and Novo Nordisk who have gross profit margins of 65-70%. However, this gross profit margin does not include the administrative costs associated with production.

At the same time, it should be noted that Bavarian Nordic is lacking the production experience that Novo Nordisk and GlaxoSmithKline have already built up. To include this lack of experience in the profit estimate, this thesis will assume that the profit margin for IMVAMUNE will be between 25% and 35%, and the net cash flows have been simulated with 25%, 30% and 35% profit margin.

The probability of success with the EUA receiving the option of 60 million doses and completing phase III has been used to risk adjust the projected cash flows, as can be seen in appendix 14. I have assumed that the probability of receiving the EUA is 75%, whereas the probability of receiving the option is only 25%, and, as we saw in part one section 1.3.1 app., 30% of the drugs that enter stage III receive a license to sell the drug on the market.

The net cash flows from production can now be estimated, and the expected net cash flows and the present value of these can be viewed in the table below. Cash flows have been estimated for a period of 15 years from 2010 ending in 2024. The reason that 2024 has been chosen as the cutoff date is that this is the year that the IMVAMUNE patents expire. Once the patents expire, low cost competitors will enter the market which will cut into the profits.

Year	Cash flow	PV
2010	185.684.003	171.089.284
2011	141.617.721	120.230.386
2012	141.612.051	110.775.871
2013	201.789.093	145.442.379
2014	201.781.014	134.005.277
2015	394.596.915	241.459.116
2016	406.533.094	229.210.309
2017	418.886.620	217.612.105
2018	431.672.081	206.627.843
2019	444.904.578	196.223.075
2020	458.599.738	186.365.417
2021	472.773.736	177.024.422
2022	487.443.311	168.171.454
2023	502.625.788	159.779.571
2024	518.339.096	151.823.420
Total PV		**2.615.839.930**

Table 11: PV of future cash flows

As can be seen in the above table, the expected present value of the cash flows from production is projected to be 2.616 million DKK.

The next step is to estimate the future investments necessary to complete the project and abandon the option's value.

3.2 Future investments – Exercise price of options to expand

The investments needed to complete the IMVAMUNE R&D program are an investment in the phase 3 study, and an investment in preparing the BLA to get IMVAMUNE licensed. For IMVAMUNE, there are two phase III studies, one in healthy subjects and one in immune compromised subjects. Likewise, there will be two BLAs.

The average R&D cost for a phase III study in Rotavirus vaccines is app. 210 million USD in 2009 prices (Light, Andrus, & Warburton, 2009). It will be assumed that the cost of completing a phase III study in smallpox vaccines is equal to this number. Since the two phase three studies are expected to be initiated in 2010 and 2011, the expected investments have been adjusted for inflation, and the forward rate for USD has been applied. This gives the below estimates for future investments. The present value of the future investments has been calculated using the WACC, as it is the present value of the future investment that is the exercise price of the call option. The combined phase 3 investments to be made are a little more than 2 billion DKK.

	2010	2011
Investment DKK	1.094.465.572	1.132.726.513
PV of investment	**1.024.734.028**	**992.986.106**

Table 12: PV of future R&D investment

The combined expected R&D costs for phase III is 2 billion DKK. This will be distributed over app. 4 years, until the studies are completed, or app. 500 million DKK per year. However, to keep it simple, it will be assumed that the 2 billion will be the 2010 exercise price of the call option to initiate phase III.

The next investment to be made is the one for the preparation of the BLA to get IMVAMUNE licensed. I have been unable to find any sources that define the investment needed to submit a BLA, and I have thus made assumptions as to the size of the BLA investment necessary.

Prior to the submission, a lot of time and effort is needed to complete the required documentation and gather the necessary information for the BLA. It will also be necessary to hire one or more external consultants with experience in the submission of BLA, to ensure that all required material are included in the submission. It will take three to four months to complete the BLA documentation, and it is my assumption that this will cost between 50 and 75 million USD.

Just as with the phase 3 investment, there will be two of these investments. Thus, the total expected investment for the BLA is 510 million DKK in present value. The calculations of the expected R&D costs can be viewed in appendix 7: "R&D".

3.3 Manufacturing plant – Exercise price of Abandonment option

In 2005, Bavarian Nordic's production facilities in Kvistgaard, Denmark were ready for use. The primary purpose for building the plant was to be able to produce large quantities of IMVAMUNE vaccines, which were required by the RFP III contract.

The factory can be used to produce other MVA based vaccines. Non-MVA based vaccines can also be produced at the plant, but this will require changes to the settings of the plant and possibly extra machinery.

The plant is considered to be a part of the value of IMVAMUNE because it was built for the production of IMVAMUNE. The plant is able to produce 40 mill doses of IMVAMUNE per year. Through small investments in staff, this can be increased to 180

mill doses per year (Bavarian Nordic Production, 2005). The RFP III contract is for 20 million doses of IMVAMUNE delivered in four batches from 2009-2012. Failure to deliver the vaccines will result in the repayment of the advance payment of 50 MUSD that Bavarian received from the US government in 2007, thus it is essential that the plant fulfill the contractual requirements.

3.3.1 Abandon IMVAMUNE

If Bavarian Nordic chooses to close down (abandon) the IMVAMUNE project, they will be required to repay 50 million USD or app. 250 million DKK. With the expected net free liquidity, by the end of 2009 on 175 million DKK, it would, without an additional emission of shares, be necessary to sell the manufacturing facility to cover the repayment commitment.

The value of the production facility is assumed to be equal to the public valuation of the property and buildings, which were valued at 83 million DKK in 2008 (Skat.dk, 2008), by the Danish Tax authorities. It is assumed that the public valuation will increase at the rate of inflation, whereas the repayment commitment will be influenced by the exchange rate. However, no interest or inflation will be applied to the amount. The future value of the repayment obligation will be calculated applying the previously estimated forward rates. To reach the present value, the figures have been discounted using the WACC.

Using these assumptions, we get a present value of the property in 2010 of 82 million DKK. A present value of the repayment obligation is -232 million DKK, which gives a 2010 put exercise price of -150 million DKK. To exercise the abandonment option in 2010, Bavarian Nordic would have to pay 150 million DKK in cash.

3.4 Summary

This part has gone through how the different estimates needed for the present value calculation of future cash flows have been calculated, as well as the estimates for the exercise price of the options to invest and the options to abandon.

First, the WACC was estimated by calculating the expected return on equity, the risk free rate and the value of debt was estimated. The final estimate for the WACC ended up at 8,53%, which is equal to the return on equity as Bavarian Nordic is essentially 100% equity financed, which was shown in section 3.1.1.2 Debt.

To estimate the future revenue, the price, the exchange rate, expected inflation and quantity had to be estimated. The future revenue was then calculated by assuming three different prices and five different market shares by assuming a maximum market size equal to the 5% of the population who are first responders and the 20% of the population who are immune compromised. The expected inflation was calculated by taking the average inflation rate in Denmark since 1980, and the forward rate for USDDKK was estimated.

It was estimated that Bavarian Nordic would most likely have a profit margin between 25 and 35%, which is significantly lower than already established pharmaceuticals. However, this takes into account that Bavarian Nordic has not established a large scale production yet, and to date the production costs have so far been almost equal to the revenue. Thus, an average profit margin of 30% over the next 15 years appears plausible.

The present value of the expected future cash flows for the base case scenario ended up at 2.616 million DKK.

Next, the exercise price of the two options to invest was estimated. The future value was calculated by applying the inflation estimate, and then the amount was discounted with the WACC to find the present value of the future investment. In 2010, the exercise price was estimated to 2.000 million DKK, and in 2014 the exercise price was estimated to 508 million DKK.

Finally, the part was concluded with estimates of the exercise price of the abandonment option. The exercise price of the abandonment option was composed of the present value of the repayment obligation and the present value of the manufacturing facility in Denmark.

Part Four: Valuation

In this part, the actual valuation will be done. I will go through how the value of the underlying asset has been calculated. Then, I will explain how the value of the options has been calculated. The next section will include a sensitivity analysis to show how changes in the assumptions impact the result of the valuation. Finally, I will be analyzing how valid my working hypothesis is.

Since the present value of the future cash flows were estimated in part three, we will jump directly into calculating the up and down factors to create the lattice of the underlying asset.

4.1 Estimating the up and down movements

The expected value of future cash flows for the IMVAMUNE project has been calculated in a binomial tree. The size of the up and down movements has been determined using the following formulas (Elton, Gruber, Brown, & Goetzmann, 2007):

$$u = e^{+\sigma\sqrt{t/n}}$$

$$d = e^{-\sigma\sqrt{t/n}}$$

Equation 4: Up and down equations to calculate the binomial tree of the underlying asset

u = The size of the up movement
d = The size of the down movement
e = The exponential function
σ = The annual standard deviation of the log of returns on the stocks of Bavarian Nordic
t = The time to expiration
n = The number of up/down movements in t

This is used to simulate a stochastic case where uncertainty exists and should be built into the model. It follows an exponential Brownian motion, which has a deterministic and a stochastic part. The exponential function and the time are the deterministic factors of the equation, and the standard deviation is the stochastic part. To make the lattice recombining, we assume a proportionate move both ways, which is why the down movement is calculated as the reciprocal of the up movement (Mun, 2006).

Standard Deviation

Optimally speaking, it should have been the standard deviations of the IMVAMUNE project that was used, as Bavarian Nordics stock price is also influenced by the other activities in the firm. In line with the working hypothesis that IMVAMUNE is the main project in the pipeline constituting a significant part of the overall company value, this thesis will assume that the standard deviations of the IMVAMUNE project is equal to the standard deviations of the company's stock.

The standard deviation of the stock has been estimated on the log of monthly returns from October 2003 and up until October 30th 2009. This gives a total of 73 observations. The monthly standard deviations where estimated to be 13,42%, which was annualized by taking the square root of observations per year, 12, and multiplying with the daily standard deviations. This gives an estimate of the yearly standard deviation at 46,48%[14].

Time to expiration

The time to expiration is calculated as the time to expiration of the last real option. This is done as a compound option. This is calculated backwards, such that the value of the last real option is dependent on the value of the underlying asset, whereas the value of the option preceding the last option is dependent on the binomial tree calculated for the last option. You will be able to read more about this in part four.

The time to expiration in years is five years, from 30.10.2009 to 30.10.2014.

Time steps

The number of up and down movements within those five years could be said to be five times the number of days in a year, since the value of IMVAMUNE can be affected from day to day. However, to simplify the calculations, it has been assumed that there will only be one up/down movement per year until expiration, or a total of five up/down movements from now to expiration. It should be noted that using a higher "n" will bring the value of the binomial options pricing model closer to the value that may be estimated using Black-Scholes (Elton, Gruber, Brown, & Goetzmann, 2007).

[14] Appendix 10

Substituting these data into the equation to calculate the size of the yearly up and down movements, we get an up movement of 1,59 and a down movement of 0,63[15].

Underlying asset binomial tree

With the up and down movements estimated, it is now possible to construct the binomial tree for the underlying asset, which is constructed on the present value of future cash flows and the up and down movements.

To calculate the tree you start with the present value of IMVAMUNE, 2.615 million DKK, to reach the up value you multiply this with 1,59, just as you calculate the down value by multiplying the present value with 0,63, as can be seen from figure 7, which shows the intuition behind the lattice.

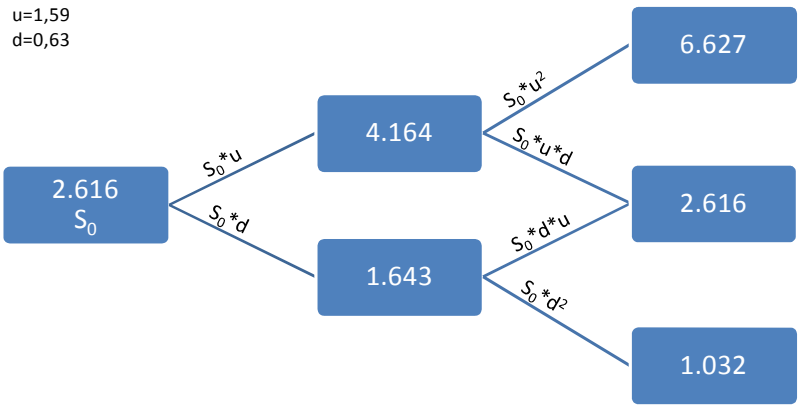

Figure 7: building the lattice of the underlying asset

The complete lattice can be viewed in figure 8 below. Please note that the tree is recombining, and as such the 2011 value of 2.615 million DKK represents the down movement of the 2010 4.164 million DKK, as well as the up movement of the 2010 value 1.643 million DKK.

[15] Appendix 13: ROA

2009	2010	2011	2012	2013	2014
2.615.839.930	4.163.628.800	6.627.242.204	10.548.572.253	16.790.147.871	26.724.855.151
-	1.643.426.652	2.615.839.930	4.163.628.800	6.627.242.204	10.548.572.253
-	-	1.032.498.637	1.643.426.652	2.615.839.930	4.163.628.800
-	-	-	648.677.221	1.032.498.637	1.643.426.652
-	-	-	-	407.537.717	648.677.221
-	-	-	-	-	256.039.500

Figure 8: Underlying Asset Grid

4.2 Call option valuation

With the binomial tree of the underlying asset estimated I can start estimating the value of the real options. There are two call options relating to IMVAMUNE. The first option concerns whether or not to initiate the phase 3 studies, and the second concerns whether or not to apply for a BLA. The second option depends on the success of the first option. To keep it simple, I will first go through how the compund call option has been valued and then add the abandonment or the put later.

This type of option on option is called a sequential compound option. The value of the first option depends on the value of the second option, and the value of the second option depends on the value of the underlying asset (Mun, 2006). As such, it is necessary to first calculate the value of the second option using the binomial tree of the underlying asset, and then calculate the value of the compounded options using the binomial tree of the second option. The reason for this is that the value of a compound option is based on another option (Mun, 2006).

Thus, to estimate the value of the project with flexibility, it is necessary to calculate the binomial three for the second option on the underlying asset grid from section 4.1. Once this is done, we can calculate the value of the compounded options, using the binomial tree of the second option.

To calculate the value of the second option it is necessary to calculate the risk neutral probabilities. Please note that the risk neutral probabilities are nothing more than a mathematical convenience to adjust the cash flows so that they may be discounted at the risk free rate (Copeland & Antikarov, 2003).

As can be seen from the equation below, the risk neutral probabilities are calculated based on the risk free rate and the up and down movements.

$$p_{up} = \frac{e^{Rf*\delta t} - d}{u - d}$$

$$p_{down} = 1 - p_{up}$$

Equation 5: Risk neutral probabilities

p_{up} = Risk neutral probability of up movement

p_{down} = Risk neutral probability of down movement

e = The exponential function

R_F=the risk free interest rate

δt = change in time = t/n

When using the risk neutral probabilities approach, the cash flows are transformed into risk adjusted cash flows and these can then be discounted using the risk free rate. When we put our data into the equation, the risk neutral probabilities become[16]:

p_{up} = 0,43

p_{down} = 0,57

In the last period, I have maximized between the present value from the underlying asset grid, 26.725 minus the expected investment of 508 and zero, to get the value of the option at this state in the last period.

[16] Appendix 13: ROA

Pu = 0,43
Pd = 0,57
Rf = 4,34%
t/n = 1

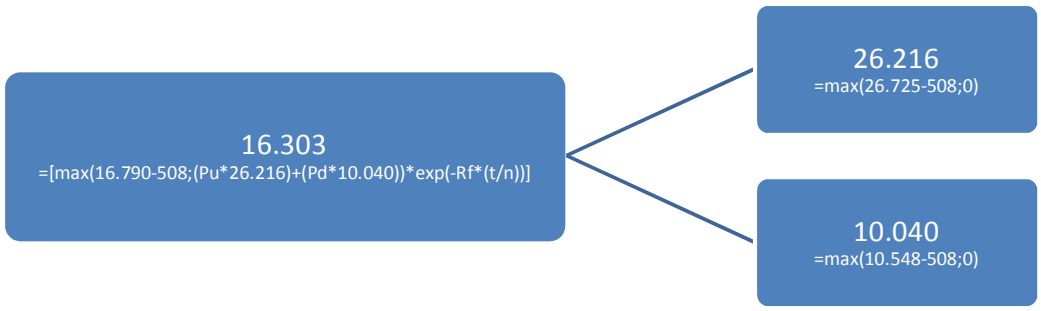

Figure 9: How to calculate the option value using backwards induction

From 2013 and backwards, the maximization is done between the present value of the underlying asset minus investments and keeping the option open. The value for keeping the option open is calculated by multiplying the risk neutral probability for the up movement to the up state value in 2014 on the option grid and then adding the value of the risk neutral probability in the down state multiplied by the value in the down state. The maximized value is then discounted with the risk free rate. This process can be seen in figure 9 above.

2009	2010	2011	2012	2013	2014
2.218.577.650	3.736.188.545	6.180.844.102	10.082.375.485	16.303.274.325	26.216.387.771
	1.238.092.004	2.169.441.828	3.697.432.032	6.140.368.658	10.040.104.873
		626.736.553	1.177.229.884	2.128.966.384	3.655.161.419
			257.180.328	545.625.091	1.134.959.272
				57.982.528	140.209.841
					-

Figure 10: Option BLA tree

Figure 10 is the lattice needed to solve the value of the compound call option, as this lattice will serve as the underlying asset for the first call option. We can now calculate the value of the combined options using the same methodology as was used to calculate the BLA option, although the first option uses the BLA option tree as the underlying asset.

2009	2010
730.349.666	1.766.087.365
	-

Figure 11: Option initiate Phase 3

The option to initiate phase III expires in 2010, which is why the calculation of option value starts here. Since the value of the first option is a function of the value of the second option, which is a function of the underlying asset, the total value of the sequential compound call options are 730 million DKK. I have combined the two option grids below and indicated with color which option the different numbers relate to.

2009	2010	2011	2012	2013	2014
730.349.666	1.766.087.365	6.180.844.102	10.082.375.485	16.303.274.325	26.216.387.771
	-	2.169.441.828	3.697.432.032	6.140.368.658	10.040.104.873
		626.736.553	1.177.229.884	2.128.966.384	3.655.161.419
			257.180.328	545.625.091	1.134.959.272
				57.982.528	140.209.841
					-

Figure 12: Sequential Compound call option value

Recall that the present value of future cash flows were 2.616 million DKK and the present value of future investments were 2.479 million DKK. This, however, gives an NPV without flexibility of 137 million DKK when the value of the sequential compound option. 730 million is added to the net present value of the project and therefore increases to 868 million DKK.

However, the above valuation excluded the value of the abandonment option to sell the factory. The next section will go through how the total project value including the abandonment option has been estimated.

4.3 Project value including abandonment option

To include the value of the option to abandon the project, I have maximized the present value of the cash flows excluding the investments against the exercise price of the put option. Optimally speaking, when the put option exercise price is less negative than the value of the expected cash flows, it would be worth more to Bavarian Nordic to sell the plant and abandon IMVAMUNE.

Max(present value underlying asset – Xc;Xp)

Otherwise, the same methodology is applied when only valuing the compound call options. The option parameters can be viewed in the table below.

	2009	2010	2014
P	2.615.839.930		
Xc		1.970.101.181	508.467.381
T	5	1	5
Rf	4,34%		
σ	46,48%		
N	5	1	5
Xp		-150.052.943	-99.415.190
Up	1,59		
Down	0,63		
P_{up}	0,43		
P_{down}	0,57		

Table 13: Option parameters

The total value of the options including the abandonment options has now decreased to 649 million DKK. This is because the negative outlay of cash connected with the abandonment option is now included in the valuation.

2009	2010	2011	2012	2013	2014
648.722.298	1.766.087.365	6.180.844.102	10.082.375.485	16.303.274.325	26.216.387.771
	-150.052.943	2.169.441.828	3.697.432.032	6.140.368.658	10.040.104.873
		610.732.626	1.177.229.884	2.128.966.384	3.655.161.419
			227.760.827	545.625.091	1.134.959.272
				3.901.614	140.209.841
					-99.415.190

Figure 13: Valuation tree compound options

The put option however, does not impact when the option should be exercised, abandoned or kept open. In 2010, Bavarian Nordic has an option to initiate the phase 3 studies, depending on the market expectations. At that point in time, the company should consider to abandon the project if the market is in the downstate, since the exercise price of the abandonment option at this stage exceeds the present value of the expected cash flows. However, if the market is in the up state, the option should be exercised.

If the phase 3 studies are initiated, there is only one point in time where the project should be abandoned and that is in 2014 if the market is in the lowest possible state. At all other periods in 2014, the option to apply for a BLA should be exercised and at all other points

in time between 2011 and 2013 the option is worth more alive than dead, and should, as such, be kept open.

2009	2010	2011	2012	2013	2014
Keep Open	Exercise	Keep Open	Keep Open	Keep Open	Exercise
	Abandon	Keep Open	Keep Open	Keep Open	Exercise
		Keep Open	Keep Open	Keep Open	Exercise
			Keep Open	Keep Open	Exercise
				Keep Open	Exercise
					Abandon

Figure 14: Exercise Diagram

The total value of the IMVAMUNE project including the option to abandon is 786 million DKK, thus the value of flexibility is worth 649 million DKK for the IMVAMUNE project. The classic NPV calculation for this project is positive at the valuation date. However, this is mainly due to the RFP contracts as these are securing revenue for the project for the next many years until IMVAMUNE is either abandoned or registered as a licensed vaccine.

PV of future investments	-2.478.568.561
PV of future cashflows	2.615.839.930
NPV without flexibility	137.271.369
Value of compund options	648.722.298
NPV with Option	**785.993.667**

Table 14: Project value

4.4 Sensitivity analysis

This section will go through how the value of IMVAMUNE is impacted by changes in the assumptions made to do the valuation. I will start with looking at changes in the forward exchange rate.

Exchange rate

In this thesis, I have estimated that the forward rate is a discount to the spot rate. To investigate how volatile the project valuation is to changes in the exchange rate, I have calculated the value of the project if the USD keeps its current value at spot rate, and also what the impact is if the forward points were positive. The impact of a 10% change in the forward exchange rate has also been estimated.

Exchange Rate	Base Case	USD Spot	Forward Premium	+ 10% change
Project Value	785.993.667	787.420.547	788.847.954	1.219.760.813
Change	0,0%	0,2%	0,4%	55,2%

Table 15: Sensitivity to exchange rate movements

As can be seen from table 15, small changes in the USD forward rate, such as keeping the exchange rate at spot or making the forward points positive rather than negative only have little impact, whereas a 10% change in the forward rate chosen would equal a 50% change in the value of IMVAMUNE up or down. The project value is thus, very sensitive to changes in the exchange rate between DKK and USD.

Market Size

Next, I will investigate the sensitivity to changes in potential market size. Recall that total potential market size was estimated to be 545 million doses distributed over a five year period. A 10% change in the potential market size changes the value of the project by 36%.

Market Size	Base Case	2%	5%	10%
Project Value	785.993.667	858.547.623	927.214.760	1.068.435.853
Change	0%	9%	18%	36%

Table 16: Sensitivity to changes in market size

Even small changes in the market size will impact the value of the project quickly, as can be seen from table 16 above. A 2% change in the market size equals a 9% change in the project value. As such, the project value is very sensitive to changes in the assumptions regarding market size.

Beta

Recall that it was decided to use the company beta rather than the industry beta, since these where so far apart. I thought it would be interesting to see what the value of the project would be assuming that the industry beta is the most accurate estimate.

Beta	Base Case	Industry beta 0,8
Project value	785.993.667	1.287.018.743
Change	0%	64%

Table 17: Sensitivity to beta

The value of beta has a significant impact on the value of the overall project as using the industry beta would have yielded a project value that is 64% higher than the base case scenario.

It is not unexpected that the changes in the beta value will have a significant impact on the project, since the estimate of beta impacts the calculated return on equity, and thereby impacting the WACC as well. As the WACC is used to discount all future cash flows to a present value, even small changes in the WACC may have drastic effects on the value of the project.

Standard Deviations

Standard deviations	Base Case	10%
Project value	785.993.667	836.636.790
Change	0%	6%

Table 18: Sensitivity to standard deviations

Given that the standard deviations are an important factor in calculating the up and down movements of the underlying asset, I have looked at how a change in the standard deviations impacts the value of IMVAMUNE. As can be seen in table 18, a 10% change in the standard deviations only equals a 6% change in the value of the project. As such, a change in the standard deviations will not affect the value of the project significantly.

Abandonment option

I could also have chosen to estimate the market value of the property and buildings, but this would have a marginal effect on the final value of IMVAMUNE. The table below shows that if all other variables are kept constant, the change in total value is +-2,8% if the market price is +-50% of the public valuation. As such, the actual value of the factory will not have a large impact on the overall valuation.

Sensitivity to factory value	Base Case	10%	30%	50%
Project Value	785.993.667	790.490.628	799.403.720	808.316.812
Change	0%	0,6%	1,7%	2,8%

Table 19: Sensitivity to changes in factory value

Since the sensitivty analysis highlights the valuation and the accuracy, this is very much dependant on how realistic the assumptions that were made in part three. These assumptions are built on the information available at the time of valuation and will change when new information is made available.

4.5 Validity of the working hypothesis

Recall that this thesis has been made using a working hypothesis stating that I expect the value of IMVAMUNE to constitute more than 30% of the total value of the company, as the project is the only project in the company's pipeline generating revenues. In addition the project is the one that is closest to completing the clinical trials.

The working hypothesis has been used to build the assumption that was necessary to estimate the standard deviation of the project. It was assumed, based on the working hypothesis, that the standard deviation of the log of the company's stock return would be heavily correlated with the project's standard deviations. To ensure that this assumption has not had undue influence on the final valuation, the sensitivity to the standard deviations were estimated in section 4.4. It could be concluded that although a change in the standard deviations affects the value of the project, it requires a large change in the standard deviations to have a significant impact on the project value. If the true standard deviations are higher, the value of the project will increase, whereas the value of the project will decrease if the standard deviations are lower.

The total value of the base case scenario was 786 million DKK. This constitutes app. 50% of the total value of Bavarian Nordic, and is thus well above my initial hypothesis. Based on this, the working hypothesis is validated.

Project Value	785.993.667
Market Capitalization	1.582.652.520
IMVAMUNE/Market Cap	**50%**

Table 20: Project value as a percentage of market value

Furthermore, the project value would have to decrease by more than 40% to constitute a lower percentage of the company value than stated in the working hypothesis. This could be achieved if the true beta lies above the beta used in this thesis, and if the market size is more than 10% smaller than estimated, or if the future exchange rate decreases by 10%.

It is unlikely that the true beta is much higher than the one used in this thesis, since the industry beta is lower than the company beta. It is more likely that the true beta is lower than the one used in this paper. The market size is very uncertain, e.g. if the politicians become more worried about a more imminent threat such as a pandemic virus (the flue) then the market size might very well contract by more than 10%, however, if another

biological attack, such as the 2001-2002 Anthrax attacks in the US are carried out, then the market size may increase dramatically. While the company has a possibility to influence the market size through lobbyism, this is not an option to hedge against changes in the future exchange rate. However, the company has an option to sell USD forward today to hedge already known cash flows against currency fluctuations. This should limit the currency exposure.

Based on the above, it is my conclusion that my working hypothesis is valid on the valuation date.

4.6 Summary

The purpose of part four was to explain how the value of the compound option was estimated and to find out how large a part of the company value the project value constitutes.

It was explained that to calculate the value of a sequential compound option, one must first calculate the binomial lattice of the latter option using the underlying asset. Then, one must calculate the value of the compounded option using the binomial lattice of the latter option, as the value of the compounded option depends on the value of the latter option rather than on the value of the underlying asset.

The project value was then estimated to be 786 million DKK, which constitutes 50% of the company's value on the valuation date.

A sensitivity analysis was performed to determine which of the estimates may have a significant impact on the project value. It was deduced that the project value was very sensible to changes in the beta, the exchange rate and the market size.

Conclusion

The purpose of this thesis has been to investigate the value of IMVAMUNE, a vaccine under development. To answer this, a sub research question was composed to investigate how real options theory could be applied to do the valuation, and a working hypothesis was developed, stating that I expected the value of IMVAMUNE to constitute more than 30% of the total company value.

To answer the research question, the thesis has been divided into four parts. Part one, the strategic analysis, had the purpose of gathering and analysing the data necessary to build the overview of the future events and decisions that would impact the value of IMVAMUNE. In part two, assumptions were formed for the financial estimates that were developed in part three. Finally, in part four, the actual valuation was done along with a sensitivity analysis and an investigation of the validity of the working hypothesis.

In part one, we found out why the smallpox virus is classified as one the most dangerous biological threats to a sovereign state:

- High mortality rate
- One patient could infect more than 10 others prior to diagnosis
- Difficult to diagnose as most doctors today have never seen an actual smallpox case

We also discovered why it is important to develop a new smallpox vaccine, as the older generation of the vaccine has many severe side effects attached and is unsuitable for usage in immune compromised people.

From the company history, we learned that Bavarian Nordic is on the threshold of developing into a pharmaceutical if IMVAMUNE is successful. It was also revealed that Bavarian Nordic's stratgey supports the IMVAMUNE project, as the company has a strategic focus on the bio defense area.

In 2010, the IMVAMUNE project is due to initiate the phase III studies, and we learned that there is a 30% probability of success for the phase III studies.

In 2003, Bavarian Nordic received the first RFP contract with the NIH, and in 2004, the company was awarded the RFP 2 contract to research the potential of IMVAMUNE. This culminated in 2007 with the award of the RFP 3 contract, which, in addition to funding

research, also included an order for 20 million doses of IMVAMUNE and an option to order an additional 60 million doses. Bavarian Nordic has received an advance payment of 50 million USD as part of the RFP 3, and this is subject to repayment if the contractual obligations are breached.

The thesis then continued by applying Michael Porter's value chain framework to analyze the internal strengths and weaknesses affecting the IMVAMUNE project. It was concluded that the company has a great strength in the rigourous efforts to protect its patent portfolio against infringement. Current patents on IMVAMUNE in the US expire in 2024.

On the other hand, we saw that the financial strength of Bavarian Nordic was very low, and it was pointed out that without additional capital added during 2010, there is a risk that the company might run out of the necesarry cash to fund further research. If Bavarian Nordic runs out of cash, the company may be unable to deliver the agreed amount of IMVAMUNE to the US government.

Bavarian Nordic has built a manufacturing plant with the purpose of producing the ordered doses of IMVAMUNE. Owning the production line is considered to be an advantage for the project, however, the final packaging and filling is outsourced to IDT in Germany, which is a disadvantage as delays in IDT are outside mangaments control and may impact IMVAMUNE negatively.

For the close future, there are no competitors that are as close to reaching the goal of getting a new smallpox vaccine/drug licensed as Bavarian Nordic. However, the company should keep an eye on the development in the projects of the competitors as it may cut into future profits.

It may be a threat to the project that the main buyers are public authorities and supranational institutions, since these are often cumbersome to work with and may apply a great deal of price pressure as they order in large batches.

When looking at the actual threat assessment, it was concluded that the market size for IMVAMUNE will mainly be driven by fear, since the actual probability of a biological terrorist attack is very low. The estimated market size was determined to be 720 million vaccines.

In part two, an event tree and a decision tree were built, and the type of real option to be valued was identified. The event tree was created to give an overview of the future events that may impact the value of the project. Then, it was determined at which nodes the management of Bavarian Nordic would be able to make decisions as to what should happen next. Based on this, the decision tree was created. This showed that Bavarian Nordic has an option to invest and an option to abandon in 2010. Depending on the decision made in 2010, Bavarian Nordic will also have an option to invest and an option to abandon in 2014.

Since the latter option is dependent on the success of the former option, the option type was identified as a sequential compound option. It was identified that three estimates were necessary to valuate the sequential compound option, the present value of future cash flows, the up and down factors and the risk neutral probabilities. It was then explained that to calculate the value, one should first calculate the value of the latter option based on the lattice of the underlying asset, and then use the lattice of the latter option to calculate the value of the compound option.

In part three, the estimates needed for the present value calculation were made. First, the WACC was estimated by calculating the expected return on equity. Then the risk free rate and the value of debt were estimated. The final estimate for the WACC ended up on 8,53%.

To estimate the future revenue, the price, the exchange rate, expected inflation and quantity had to be estimated. The future revenue was then calculated by assuming three different prices and five different market shares by assuming a maximum market size equal to the 5% of the population who are first responders, and the 20% of the population who are immune compromised. The expected inflation was calculated by taking the average inflation rate in Denmark since 1980, and the forward rate for USD/DKK was estimated based on the interest rate differential between 10 year government bonds from the US and Denmark.

It was estimated that Bavarian Nordic would most likely have a profit margin between 25% and 35%, which is significantly lower than already established pharmaceuticals, however this takes into account that Bavarian Nordic has not established a large scale production yet, and to date the production costs have so far been almost equal to the revenue. Thus, an average profit margin of 30% over the next 15 years appears plausible.

The present value of the expected future cash flows for the base case scenario ended up at 2.616 million DKK.

Next, the exercise price of the two options to invest was estimated. The future value was calculated by applying the inflation estimate, and then the amount was discounted with the WACC to find the present value of the future investment. In 2010, the exercise price was estimated to 2.000 million DKK, and in 2014, the exercise price was estimated to 508 million DKK.

Finally, the last part was concluded with estimates of the exercise price of the abandonment option. The exercise price of the abandonment option was composed of the present value of the repayment obligation and the present value of the manufacturing facility in Denmark.

The purpose of part four was to explain how the value of the compound option was estimated and to find out how large a part of the company value the project value constitutes.

It was explained that to calculate the value of a sequential compound option, one must first calculate the binomial lattice of the latter option using the underlying asset. Then, one must calculate the value of the compounded option using the binomial lattice of the latter option, as the value of the compounded option depends on the value of the latter option rather than on the value of the underlying asset.

A sensitivity analysis was performed to determine which of the estimates that may have a significant impact on the project value, and it was deduced that the project value was very sensitive to changes in the beta (WACC), the exchange rate and the market size, whereas the project value was less sensitive to changes in the standard deviations and changes to the actual value of the manufacturing plant. It is not surprising that the valuation is sensitive to changes in the beta, as the beta estimate affects the WACC and the WACC in turn has an impact on the present value of all future cashflows, and this impact increases over time.

The project value was estimated to be 786 million DKK, which constitutes 50% of the company's market capitalization on the valuation date, and the validity of the working hypothesis was confirmed.

Epilogue

It was shown in the sensitivity analysis that the result is influenced by the assumptions made to estimate the present value of the cash flows. There is more than one way to interpret data, and using a different interpretation may result in other assumptions. In the thesis, I have not considered the impact of data published after October 31st 2009, however I will give a brief overview of the information published after this date and comment on what impact this might have on the IMVAMUNE valuation.

The 20.000 doses of IMVAMUNE has been delivered to the Canadian government during 2009 and Bavarian Nordic and Canada are now discussing the possibility of receiving a pre-New Drug Submission (NDS) in 2010 for IMVAMUNE as a safer smallpox vaccine (Bavarian Nordic Q3, 2009). The outcome of these discussions may well be impacted by whether the FDA grants an EUA for IMVAMUNE or not. However, unless the discussions are followed by a much larger order than the option for the 180.000 doses, this is unlikely to affect the value of the project significantly.

Bavarian Nordic has initiated negotiations with the US government about developing a freeze dried version of IMVAMUNE, after having submitted a proposal. In November, Bavarian Nordic was awarded a contract to develop a freeze dried solution of IMVAMUNE. This is an additional business opportunity. A freeze dried formula would increase the shelf life of the vaccine as well as make it easier to ship and store compared to the current liquid-frozen formulation, which requires cold shipping and storage. The freeze dried formulation is, however, still only on the drawing board and needs to go through pre-clinical studies before the value can affect the value of IMVAMUNE.

Bavarian Nordic called for an extraordinary general assembly to be held on 18th December 2009. The topic of this general assembly was to get permission to do an expansion of the share capital and issue another 80 million shares with a nominal value of 1 DKK per share. However, this could not be approved, since less than 50% of the share capital was present. The company has called for an extraordinary general assembly on the 6th of January to get the expansion of the share capital approved. The outcome of this meeting might affect the value of IMVAMUNE negatively. If the expansion of the share capital is not approved, then Bavarian Nordic will have a liquidity issue that may affect the ability to deliver the 20 million doses of IMVAMUNE to the US government. Thus, if they are not able to raise additional capital, there is a risk that the company may close. As it was the general

assembly approved the expansion of the share capital. I would expect the next rights issue to be issued within the first two quarters of 2010, depending on the capital the company is able to raise with this rights issue the risk of defaulting on the delivery is significantly lower.

Switzerland has put in a small order for IMVAMUNE and granted a Special Use Authorization for vaccinating key personnel. In addition, Switzerland has expressed interest in replacing part of their stocks with IMVAMUNE. The order was delivered during 2009, however, it was not large enough to change the expectations to the 2009 result. It is, however, an indication that it is possible to market IMVAMUNE as a vaccine under development to the EU even prior to the clinical trials being completed.

Bavarian Nordic has build up an inventory of IMVAMUNE with a value of DKK 156 million (app. USD 30 million). The vaccines in stock are expected to be sold to existing and future customers, including the initial delivery to the US. According to the Q3 interim report from Bavarian Nordic, they will at most be able to deliver 1,5 million doses of IMVAMUNE to the US if the EUA is granted in December. Thus, it can be assumed that this is the number of vaccines in stock and the cost per dose is app. DKK 104 (USD 20), which is above the average price for the RFP-3 contract. This is to be expected though as mass production has not yet been initiated and experience built up.

Bibliography

Bavarian Nordic. (2006). *Annual Report 2006.* Kvistgaard: Bavarian Nordic.

Bavarian Nordic. (2008). *Annual Report 2008.* Kvistgaard: Bavarian Nordic.

Bavarian Nordic Canada. (2008, December 1). *The Government of Canada procures IMVAMUNE® smallpox vaccine for the country's biological preparedness.* Retrieved June 14, 2009, from http://www.bavarian-nordic.com/investor/announcements/2008-25.aspx

Bavarian Nordic EU. (2009, September 15). *Bavarian Nordic has signed contract with an EU country for the delivery of IMVAMUNE®.* Retrieved October 20, 2009, from http://www.bavarian-nordic.com/investor/announcements/2009-22.aspx

Bavarian Nordic Production. (2005). *Annual Report 2005 - Supplementary Report: Production.* Kvistgaard: Bavarian Nordic.

Bavarian Nordic. (2005). *Prospectus - Rights Issue.* Kvistgaard: Bavarian Nordic.

Bavarian Nordic. (2007). *Prospectus - Rights Issue.* Kvistgaard: Bavarian Nordic.

Bavarian Nordic Q2. (2009, August 28). *Interim Report for the period 1 January to 30 June 2009.* Retrieved October 20, 2009, from http://www.bavarian-nordic.com/investor/announcements/2009-20.aspx

Bavarian Nordic Q3. (2009, November 11). *Bavarian Nordic A/S – Interim report for the period 1 January to 30 September 2009.* Retrieved November 21, 2009, from http://www.bavarian-nordic.com/investor/announcements/2009-25.aspx

Bavarian Nordic Working. (n.d.). *Working at Bavarian Nordic*. Retrieved September 15, 2009, from http://www.bavarian-nordic.com/join-us/working-at-bavarian-nordic.aspx

Benninga, S. (2000). *Financial Modeling - Uses Excel.* Cambridge, Massachusetts: The MIT Press.

Biotechnology Industry Organization. (2008). *Guide to Biotechnology 2008.*

Carnegie. (2006). *Bavarian Nordic - Company report.* Copenhagen: Carnegie.

CDC. (2009, March 9). *Strategic National Stockpile*. Retrieved April 8, 2009, from http://www.bt.cdc.gov/stockpile/

ClinicalTrials.org a Service of the US National Insitutes of Health. (2008, November 20). *Safety and Efficacy of CJ-50300 in Healthy Volunteers*. Retrieved October 20, 2009, from http://clinicaltrials.gov/ct2/show/NCT00607243

Copeland, T., & Antikarov, V. (2003). *Real Options - a practitioner's guide.* Cengage Learning.

Danmarks Statistik. (2009). *Forbrugerprisindeks*. Retrieved August 20, 2009, from http://www.dst.dk/Statistik/nogletal/seneste/Indkomst/Priser/Forbrugerprisindeks.aspx

Department of Health and Human Services. (2005, August 15). *Request for Proposal (RFP) Number DHHS-ORDC-V&B - 05-06.* Retrieved October 10, 2009, from https://www.fbo.gov/download/17a/17a487cf5fda634c355442da210bc4aa/FinalMVARFP.pdf

Elton, E. J., Gruber, M. J., Brown, S. J., & Goetzmann, W. N. (2007). *Modern Portfolio theory and Investment Analysis.* John Wiley & Sons, Inc.

FDA. (2009, April 30). *Fast Track, Accelerated Approval and Priority Review*. Retrieved June 5, 2009, from http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccesstoImportantNewTherapies/ucm128291.htm

Genmab. (2008). *Annual Report 2008.* Genmab.

GlaxoSmithKline. (2008). *Annual report 2008.* GlaxoSmithKline.

Koller, T., Goedhart, M., & Wessels, D. (2005). *Valuation.* John Wiley & Sons, Inc.

Leitenberg, M. (2005). *Assessing the Biological Weapons and Bioterrorism Threat.* U.S. Army War College.

Leitenberg, M. (2004). *The problem of biological weapons.* Stockholm: The Swedish National Defence College .

Liebert, M. A. (2005). Navigating the Storm: Report and Recommendations. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* , 256-268.

Light, D. W., Andrus, J. K., & Warburton, R. N. (2009). Estimated research and development costs of rotavirus vaccines. *Elsevier* , 6627-6633.

Madura, J. (2006). *International Corporate Finance.* Thomson South-Western.

Mun, J. (2006). *Real Options Analysis.* Hoboken, New Jersey: John Wiley & Sons, Inc.

Neurosearch. (2008). *Annual Report 2008.* Neurosearch.

Novo Nordisk A/S. (2008). *Annual Report 2008.* Novo Nordisk.

Novo Nordisk From Idea to Patient. (n.d.). *From Idea to patient*. Retrieved June 25, 2009, from Novo Nordisk R&D: http://www.novonordisk.com/science/from%20idea%20to%20patient/fromideatopatient.asp

Petersen, C. V., & Plenborg, T. (2007). *Regnskabsanalyse for beslutningstagere.* København: Thomson.

pharmaceutical-technology.com. (n.d.). *Industry Projects*. Retrieved August 28, 2009, from http://www.pharmaceutical-technology.com/projects/bavarian_nordic/

Siga. (n.d.). *Anti-Infectives*. Retrieved October 20, 2009, from http://www.siga.com/index.php?ID=9

Skat.dk. (2008). *Ejendomsvurdering 2008*. Retrieved August 22, 2009, from http://www.vurdering.skat.dk/Ejendomsvurdering?&KMNR=217&sideNavn=vliste&EJDNR=220378&POSTNR=&VEJKODE=3052&VEJNAVN=HEJRESKOVVEJ

Survivorship A-Z. (n.d.). *Clinical Trial Phases*. Retrieved April 15, 2009, from http://www.survivorshipatoz.org/sub.php?aid=551#1467

U.S. Department of Health & Human Services. (n.d.). *Project BioShield.* Retrieved August 28, 2009, from http://www.hhs.gov/aspr/barda/bioshield/index.html

United Nations. (2006). *Uniting Against Terrorism.* United Nations.

WHO. (n.d.). *Smallpox*. Retrieved April 8, 2009, from WHO: http://www.who.int/csr/disease/smallpox/en/

Wikipedia Clinical Trial. (n.d.). *Clinical Trial*. Retrieved February 18, 2009, from http://en.wikipedia.org/wiki/Clinical_trial

Wikipedia MVA. (n.d.). *Modified Vaccinia Ankara*. Retrieved February 13, 2009, from http://en.wikipedia.org/wiki/Modified_vaccinia_Ankara

Wikipedia World Population. (n.d.). *World Population.* Retrieved October 20, 2009, from http://en.wikipedia.org/wiki/World_population