The Business Model of Biotech SMEs:

How do biotech SMEs cope with the industry’s challenges?

Authors: Fransisca Kappfjell Herbst
Julian Tölle

Supervisor: Peter Hultén

Student
Umeå School of Business and Economics
Spring semester 2016
Master thesis, two-year, 30 hp
Abstract

The purpose of this study was to investigate how biotech SMEs structure their business model to deal with the industry’s challenges. The first step was to lay a theoretical foundation of the business model and clarify ambiguities surrounding the business model concept. This lead to the Business Model Canvas, which was used as tool of analysis for this thesis. Semi-structured interviews were then conducted with companies, experts and cluster managers, following the nine building blocks of the Business Model Canvas.

The results showed that two typologies of business models could be seen, which we divided in pharmaceutical biotech SMEs and non-pharmaceutical biotech SMEs. Both business models face challenges of research and development process, but to different degrees. Pharmaceutical biotech SMEs deal with long, costly and risky research process, which results in a research-centered business model. During the research period, these companies don’t generate revenues through sales. Non-pharmaceutical biotech SMEs on the other hand, face less harsh research and development processes, which allows them to market their products faster and generate revenue from sales. This results in a more customer-centric business model than the pharmaceutical biotech SMEs.

Keywords: Business Model, Business Model Canvas, Biotech, Pharmaceutical SME
We like to thank our supervisor Peter Hultén for his great support throughout this thesis. We also want to thank our colleagues for their feedback.
5 Empirical Results

5.1 Case Companies
- 5.1.1 Pharmaceutical Company 1
- 5.1.2 Pharmaceutical Company 2
- 5.1.3 Non-Pharmaceutical Company 1
- 5.1.4 Non-Pharmaceutical Company 2

5.2 Company Results
- 5.2.1 Key activities
- 5.2.2 Key Resources
- 5.2.3 Value Proposition
- 5.2.4 Key Partnerships
- 5.2.5 Customer Segments
- 5.2.6 Channels
- 5.2.7 Customer Relationship
- 5.2.8 Revenue Streams
- 5.2.9 Cost Structure

5.3 Experts
- 5.3.1 Industry Consultant
- 5.3.2 Intellectual Property Advisor
- 5.3.3 Venture Capital Agent
- 5.3.4 Contract Research Manager

5.4 Expert Results
- 5.4.1 Key Activities
- 5.4.2 Key Resources
- 5.4.3 Value Proposition
- 5.4.4 Key Partnerships
- 5.4.5 Customer Segmentation
- 5.4.6 Channels
- 5.4.7 Customer Relationship
- 5.4.8 Revenue Streams
- 5.4.9 Cost Structure

5.5 Cluster Manager
- 5.5.1 Marine Cluster Manager
- 5.5.2 Agriculture Cluster Manager

5.6 Results Cluster Manager
- 5.6.1 Key Activities
- 5.6.2 Key Resources
- 5.6.3 Value Proposition
- 5.6.4 Key Partnerships
- 5.6.5 Customer Segment
- 5.6.6 Channels
- 5.6.7 Customer Relationship
- 5.6.8 Revenue Streams
- 5.6.9 Cost Structure

5.7 Emerging Themes
- 5.7.1 Pharmaceutical Biotech - Challenges
- 5.7.2 Non-Pharmaceutical Biotech - Challenges
- 5.7.3 Strategic Themes
- 5.7.4 Cultural & Political Factors

6 Analysis and Discussion

6.1 Comparison of Pharma and Non-Pharma

6.2 Overview of the Business Models
6.3 The Pharma Business Model ................................................................. 105
6.4 The Non-Pharmaceutical Business Model ........................................... 108
6.5 Discussion of Emerging Themes ......................................................... 110

7 Conclusion .............................................................................................. 112
  7.1 Research Findings ............................................................................... 112
  7.2 Theoretical Contribution ................................................................. 116
  7.3 Managerial Implications .................................................................... 116
  7.4 Future Research .................................................................................. 117
  7.5 Limitations ......................................................................................... 118

Reference List ............................................................................................ 121

Appendix 1: Interview Guide

Table 1: The drug development process (FDAc) ........................................ 3
Table 2: Clinical trials (FDAc) .................................................................. 3
Table 3: Characteristics of the 5 business model types (Nosella, 2006, p. 208) .... 7
Table 4: Building blocks and example questions ....................................... 36
Table 5: Non-pharma and pharma characteristics per building block .......... 104

Figure 1: The converge of European biotechnology business models (Fisk
en & Rutherford, 2002, p. 194) ................................................................. 6
Figure 2: The business models’ position in the discovery-to-market process (Adapted
from Nosella, 2006, p. 208) ................................................................. 8
Figure 3: The Business Model Concept Hierarchy (Osterwalder et al., 2005, p. 5) .. 22
Figure 4: Value Creation & Capture (Baden-Fuller & Haefliger, 2013, p. 420) .... 24
Figure 5: The Business Model Canvas (Osterwalder & Pigneur, 2010, p. 44) ....... 27
Figure 6: Overview interviews .................................................................. 42
Figure 7: The pharma business model ..................................................... 105
Figure 8: The non-pharma business model ............................................. 108
Figure 9: The business models’ position in the discovery-to-market process (Adapted
from Nosella, 2006, p. 208) ................................................................. 113
Figure 10: R&D length and product number ........................................... 115
1 Introduction

The chapter of introduction will give the reader information about the authors’ choice of subject and explain the biotechnological industry today. The specific challenges faced by biotech companies are introduced, and so is also the concept of the business model. We then move on to establish the research problem, which is the starting point for this research project. Further, we state the research purpose and delimitations.

1.1 Choice of Subject

The subject of this thesis are the business models of biotech SMEs and how their business models relate to the challenges of their industry. We discovered the topic through an article written by Gary Pisano, an author and professor at Harvard Business School. In the article, he claims most biotechnology firms are not profitable due to falsely applied business models (Pisano, 2006, pp. 114). Since our field of study is business development, including business models, we have a genuine interest to investigate this strong statement. Further investigation showed that up to date, business model research is barely applied in the biotech industry. Specifically, we look into the underlying challenges that the biotech firms are facing and how their business models are structured today. In essence, the business model describes the logic behind how firms manage their value creation and value capture to achieve profitability. By identifying how and why the biotech firms manage their business models today, we hope the thesis can be of both theoretical and practical use for the researchers and practitioners concerned with building a sustainable business model for the future.

1.2 Problem Background

Humanity has made biotechnological alternations for thousands of years, e.g. through the domestication of animals and cultivation of crops. Today, biotechnology [biotech] has advanced and its scientific methods are broadly applied in many industries, such as life science, agriculture and industrial biotechnology. Throughout modern history, biotech has contributed to many society-changing innovations, such as new drugs and treatments, alternative fuels and renewable materials. However, small and medium-sized biotech firms [SMEs] are facing challenges of high uncertainty, high costs and long development times. These challenges threaten the firms’ profitability and survival, thereby threatening the realization of potential new and great innovations. The business model is a concept intended for analysis of the logic behind firms’ profitability. Hence, it is an appropriate lens to apply when investigating how firms overcome the challenge today, and ultimately how they can manage their business to overcome them in the future. The following sections describe the characteristics of the biotech industry, the role of biotech SMEs, and the challenges which they are facing. Then follows an introduction to the business model concept and motivation for why it is a useful lens in context of biotech SMEs.

1.2.1 Definitions and Characteristics of Biotech

Biotechnology [biotech] is any alteration or creation of biological systems and living organisms, using various technologies (UN, 1992, p. 3). OECD (2015, p. 1) defines it as
“the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services”. Modern biotech is interdisciplinary by nature and additionally utilizes non-biological methods like computer science, engineering and robotics. Plein (1991, p. 474) describes it as modifying life forms through recombinant DNA techniques, cell fusion and bioprocessing techniques, to achieve commercial and research goals.

There exist a wide range of biological products. Due to the technological nature of these products, their invention and commercial realization depends on what can be scientifically complex, lengthy and costly R&D projects. This pose an intriguing challenge for the companies developing the products, because it can imply a substantial time delay between when the investment is put into the project and when the company finally capitalizes on its investment. From an entrepreneurial business perspective, it is interesting to understand how the biotech companies manage to overcome such challenges. In this respect it is especially interesting to investigate companies that are developing pharmaceutical drugs. Because these are so highly regulated, pharmaceutical drugs are classified into one of the types of biological product which requires the longest, most expensive and most uncertain R&D projects before it can be commercialized.

A drug is defined a substance which is “intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease”, and which is “(other than food) intended to affect the structure or any function of the body” (FDAb). Because drugs have effects that are internal to the body, there are high demands and strict regulations for the development process. These regulations are world-wide, and organizes the drug development process into distinct chronological phases, in which the product must pass the trials in one phase before it can begin the next (FDA). Table 1 shows a general overview of the drug development process and the three stages of discovery and development, preclinical and clinical research:

<table>
<thead>
<tr>
<th>Stage 1: Discovery and Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researchers discover a new compound and start testing it for beneficial attributes. At this early stage, thousands of compounds can be potential new drugs, but only few are suitable after the first testing. The few suitable are further tested to gain more information.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 2: Preclinical Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>In preclinical research the goal is to find possible harmful effects in vitro and in vivo, meaning toxicological studies in tubes or living organisms like animals. At this point researchers implement good laboratory practices [GLPs], which are quality standards for the research.</td>
</tr>
</tbody>
</table>
Stage 3: Clinical Research

The clinical research, also called the clinical trials, test the potential drugs in humans. The clinical part of the development process is organized in four phases.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Test for the safety of the drug in healthy patients, taking up to several months.</td>
</tr>
<tr>
<td>II</td>
<td>Test for proof of concept (efficacy) in humans suffering from the condition the drug is aiming to treat. Divided in part A and B, taking up to 2 years.</td>
</tr>
<tr>
<td>III</td>
<td>Test for statistical significance and gain market approval. Number of patients is increased, and ranges from 300 up to 3000 volunteers who suffer from the relevant disease. Can take from 1 up to 4 years.</td>
</tr>
<tr>
<td>IV</td>
<td>Monitoring of the drug on the market, using several thousand volunteers suffering from a certain disease.</td>
</tr>
</tbody>
</table>

On average, drug development processes last for 10-20 years (Pisano, 2006, p. 117). This has significant financial implications. There are no revenues generated during the development, and therefore the developing firms rely on great amounts of funding. In 2015, biotech investments were estimated to 10.1$ billion, which is the second highest after software development (PWC, 2016, p. 2). The average, single drug is estimated to cost 900 million USD (Kola & Landis, 2004, p. 711). DiMasi & Grabowski (2007, p. 469) estimate the average out-of-pocket costs in the preclinical phase to be 198 million USD and the clinical phase 361 million USD. However, including development times and discount rates, the number rises to 615 million USD for pre-clinic and 626 million USD for clinical tests. Table 2 shows the several phases within the clinical trials and each objective. Especially phase III, where hundreds or thousands of volunteers are monitored, indicates why these huge investments are required. In both phases, preclinical and clinical, financial burdens are immense even before the actual commercialization of the product.

Drug development is also characterized by high uncertainty. The overall success rate (attrition rate) for drug approval in Europe and the US is 11 percent, meaning that only 1 out of 10 drugs survive the journey from the first clinical testing to the market (Hay et al., 2014, p. 41; Kola & Landis, 2004, p. 711). In certain areas the attrition rates are even lower. In therapeutic areas of oncology (cancer treatment) and central nervous system, the rate is between 5 and 8 percent (Kola & Landis, 2004, p. 712). In general, the attrition rate is 70 percent from phase I to II, 33 percent from II to III, and from there only 25-30 percent make it to the market (FDA).

### 1.2.2 The Role of Biotech SMEs

Despite the challenges, biotech is growing. According to EY (2015, p. 28), public European biotech companies increased their net income by 199 percent up to 3,255$
million in 2014, compared to the previous year. Mostly the large corporations, such as the big pharmaceutical companies [big pharma], are the ones experiencing this growth. Small and medium-sized enterprises [SMEs] are important actors in the process of realizing the innovation, because they function as the bridge between the large corporations who commercialize the products on the one hand, and the academia who first discover the technology or substance on the other. However, very few SMEs and startups actually generate profits (Sandström et al., 2011, p. 24). In Sweden the R&D investments in biotech were 411$ million in 2013, while small R&D companies received only 18% of these expenditures (OECD, 2015, p. 1). More than half of Sweden’s biotech SMEs were not profitable over the course of 1997 to 2009 (Sandström et al., 2011, p. 33).

When looking further into their bridging role between discovery and realization, the SMEs’ struggles are worrying. Due to the multidisciplinary nature of biotech, the large corporations tend to enter alliances with the SMEs (Cavalla, 2003, p. 268). Under need for a complex and broad knowledge base, one company simply cannot have all the necessary qualifications on its own. Making alliances is then a solution facilitated by advancing IT, because it allows cooperation with other parties also on a global scale, and because the exchanged goods in a partnership are mostly of intellectual nature (Cavalla, 2003, p. 268).

Often these alliances manifest in the form of SMEs laying the groundwork for innovative new products, which the large corporations either acquire or license in later stages of the R&D process (Pisano, 2006, p. 117). The large corporations then do the commercialization and final realization. The basic research or discovery is, on the other hand, made by universities and research institutions, before flowing into SMEs through licensing or sales of intellectual property [IP], or as university spin-offs (Cavalla, 2003, p. 267; Fernald et al. 2015, p. 971). Biotech SMEs, be they established or startups, bridge the gap between academia and large corporations (Sabatier et al., 2010, p. 432). In other words, they are essential actors in the process of bringing potential innovations from discovery to realization.

According to Cavalla (2003, pp. 270-271) this interdependence between the different actors in the industry is increasing. Biotech SMEs require cash and technical validation, while big pharma is dependent on new innovations (Jones & Clifford, 2005, p. 807). Previously, the big pharma tended to perform more of the R&D process themselves. However, in the period from 2000 to 2009 the FDA approval rate was on an all-time low (Kaitin & DiMasi, 2011, p. 183). The industry was failing at producing enough new products, which resulted in a paradigm shift for the big pharma (Cavalla, 2003, p. 270). Now, more than ever, the big pharma outsources their R&D activities to other actors. And, judging by the approval rates, this strategy seems to be working. Compared to earlier years, the FDA approval rates for 2015 was doubled (FDA, 2016).

To summarize, the big pharma and other large corporations in the biotech industry are experiencing growth, and they rely on other actors, such as the SMEs, to perform many of the activities in their value chain. But why are the SMEs struggling? According to Pisano (2006, p. 115), a reason for their profitability issues may be due to the industry borrowing its business model, referred by him as the industry’s ‘anatomy’, from other industries. He argues that even if the business models are proven successful for other industries, such as software and computer development, it does not necessarily apply to the specific challenges and needs faced by biotech companies today. For instance, he
highlights that the limited understanding of the biological system makes the research process uncertain. Trial and error is often required, and outcomes are unpredictable. Hence, he claims that where the R&D process of software can be broken down to incremental steps, the R&D of biotech cannot.

1.3 Theoretical Background

This chapter will introduce the business model concept and how it has been applied in a context of biotech so far. The knowledge gap is introduced, as well as the research problem and the research question evolving from it.

1.3.1 The Business Model Concept

The term ‘business model’ appeared already in the academic article of Bellman et al. in 1957, followed by yet another academic article by Jones in 1960 (Osterwalder et al., 2005, p. 4). However, it did not achieve any significant attention until the late 1990s. According to Osterwalder et al. (2005, p. 4) and Zott et al. (2011, p. 4), this wave of research on business models was due to the millennium’s new technological developments. Internet generated new opportunities for doing business, and the business model rapidly became a popular tool for the researchers who were analyzing these new phenomena and changes. Today’s biotech industry and its innovations offer, like the introduction of internet technologies, new ways of creating businesses. We see that both industries are highly dynamic and just as the business model became a popular tool to understand new business in e-commerce, we think it could be applied in the context of biotech and help to understand newly formed biotech businesses.

The business model has its origins in e-business and information technologies, but is by no means exclusive to these sectors. The concept is now applied for businesses in all industries and sectors of the global economy. Despite its popularity and broad application, the consensus to a common definition is lacking (Osterwalder et al., 2005, p. 4; Shafer et al., 2005, p. 200; Zott et al., 2011, p. 1019-1020). Researchers do, however, seem to agree on some basic features of the concept. In essence, it is a model with the means of describing and analyzing the logic behind how firms create and capture value (Zott et al., 2011, p. 1020), or in other words, it describes the logic behind how they generate profits.

From section 1.2.1 and 1.2.2, we see that many biotech SMEs struggle with profitability under circumstances of high costs and high uncertainty related to the financial and innovative outcomes of their lengthy R&D processes. Exactly because the business model facilitates analysis of the value creation and value capture behind firms’ profitability, it could be appropriate to investigate biotech’s challenges through this lens. This has been done to firms in numerous industries, and as presented in the following section, it has also been done to biotech.

Theoretically though, the business model is still a work in progress. There are shortcomings not only in the definition of the concept, but also in the operationalization. There exist many competing frameworks for the business model which include different dimensions in the analysis. For other studies, yet again, the dimensions of the business models are not clearly, or more ambiguously, defined. For instance, the “Business Model Canvas” is a framework by Osterwalder & Pigneur (2010) which operationalize the business model in nine dimensions, while the framework proposed by Baden-Fuller &
Haefliger (2013) consists of only four. There are numerous other business model frameworks, such as Chesbrough & Rosenbloom (2002), Hedman & Kalling (2003), Shafer et al. (2005), Morris et al. (2005), Halme et al. (2007), Demil & Lecocq (2010), Mason & Spring (2011), Tsvetkova & Gustafsson (2012) and Frankenberger et al. (2013). Indeed, there are similarities between the frameworks, yet the differences still remain. A challenge is thus to compare the results of studies where the business model has been applied, because they so often use different definitions and dimensions for the analysis.

1.3.2 Biotech Business Models

The idea of applying the business model concept to biotech is not new. Among others, this has been done by Fisken & Rutherford (2002), who classify biotech companies into four generic business models: the FIPCO model, the product model, the platform model and the hybrid model. Of these, the FIPCO model is the initial model of the industry, used by the first successful biotech companies Genentech and Amgen (Fisken & Rutherford, 2002, p. 192). In this model, the biotech company has control over all operations in the entire value chain (Fisken & Rutherford, 2002, p. 192), meaning both discovery, basic research, product development and commercialization. However, Fisken & Rutherford argues this is a business model of the past, because the companies coming after Genentech and Amgen could not financially sustain it (Fisken & Rutherford, 2002, p. 192). At the time of Fisken & Rutherford’s study, biotech companies had moved away from the FIPCO model and gone toward using the platform, product and hybrid models. This threefold classification distinguishes between product companies, who do product development, platform companies, who provide technology or tools for the product development, and hybrid companies, who do both (Fisken & Rutherford, 2002, pp. 192-194).

As illustrated in Figure 1, the models perform differently on various aspects of their operations. Differences such as these are useful for the industry to know. For instance, the purpose of Fisken & Rutherford’s study was to examine how the business models relate to investment trends in the public and private equity markets (Fisken & Rutherford, 2002, p. 191). They found that 72 percent of the private funding was given to companies
with hybrid models (Fisken & Rutherford, 2002, p. 197), thus implying a strategic benefit of choosing this particular model. The companies included in the study were, however, large corporations with hundreds or thousands of employees. It is therefore uncertain how, or if at all, this business model classification would apply to the SMEs. Considering the dynamic nature and fast-paced development of the biotech industry it can also be questionable how relevant a study from 14 years ago is today.

The study by Mangematin et al. (2003) is only slightly more recent than Fisken & Rutherford, but does give specific attention to the biotech SMEs. Through a survey of 60 biotech SMEs in France, they identified two main types of business models. The first was “SMEs that run small projects and target market niches” (Mangematin, 2003, p. 624) and the second was “[r]esearch intensive SMEs that target broader markets” (Mangematin, 2003, p. 625). The main difference between these models is the ability to cover the running costs of the firm (Mangematin, 2003, p. 626). Because the first business model runs smaller and shorter-term R&D projects, its activities cover the running costs of the firm. In contrast, the second business model conduct larger, longer-term R&D projects and therefore rely on external capital to cover the costs (Mangematin, 2003, p. 626).

The later studies of Nosella et al. (2005), Bigliardi et al. (2005) and Nosella et al. (2006) were part of the same research project. Through quantitative and qualitative methods, they investigated the business models of startup ventures in the Italian biotech industry. Similar to Mangematin et al. (2003), the firms in the Italian studies were of smaller sizes. E.g. the four case companies in Nosella et al. (2006, p. 210) were in the range between 12 and 107 employees. The result was a classification of 5 distinct business models (Table 3). The classification was mainly based on which activities were included in the model and where those activities were positioned in the innovative process, which goes from discovery of the technology through to production and introduction of the product to the market (Figure 2).

<table>
<thead>
<tr>
<th>Business Model</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>New biotechnology firms</td>
<td>Specialized in basic and applied research. Dedicated to the beginning stages of the innovative process.</td>
</tr>
<tr>
<td>Industrial development of products and production for other firms</td>
<td>Specialized in the use of biotechnological processes. Act as supplier to other firms’ R&amp;D projects.</td>
</tr>
<tr>
<td>Integrated firms</td>
<td>Carry out all the activities needed to research, produce and commercialize.</td>
</tr>
<tr>
<td>Manufacturing companies</td>
<td>Buy the results of research carried out by other firms. Dedicated to the final stages of the innovative process.</td>
</tr>
<tr>
<td>Service companies</td>
<td>Providing innovative analysis and research services to other companies.</td>
</tr>
</tbody>
</table>

*Table 3: Characteristics of the 5 business model types (Nosella, 2006, p. 208)*
Interestingly, there are some similarities in the classifications proposed by Fisken & Rutherford (2002), Mangematin (2002) and Nosella et al. (2006). They all attempted to identify the ‘typical’ business model of biotech. In some aspects they are different, such as when it comes to the number of business model types and the size of the companies they include. A similarity is how they use the key activities of the firm and its position in the innovative process to distinguish between models. Both Fisken & Rutherford (2002) and Nosella et al. (2006) distinguish between 1) firms doing all the activities in the value chain/innovative process, 2) firms providing supportive technology or services to the process and 3) firms whose main (and only) activity is product development. Mangematin et al. (2003) is different because they use the length and complexity (thereby cost) of the firms’ research processes. However, this is also related to the key activities (i.e. the research processes) of the biotech firms.

In contrast to the studies mentioned above, Sabatier et al. (2012) explored business models which are different from the dominant logic of biotech. By investigating companies that have chosen other ways of value capture and value creation than what is the “general scheme” in the industry, their purpose was to identify the triggers for industry evolution (Sabatier et al., 2012, p. 949). In this regard, they found four types of business models which were contradicting the dominant logic: 1) software as a service, 2) platform technology, 3) bundling, and 4) collaborative discovery. Surprisingly, they concluded that the industry’s evolution is not lead by the introduction of new technologies, but rather the introduction of new business models (Sabatier et al. (2012, p. 958). While the other studies show some similarities in how the business models are classified, the study of Sabatier et al. (2012) show examples of how heterogeneous the biotech industry is. Biotech firms are not developing homogeneous products, thus neither should the firms have homogeneous business models. Sabatier et al. (2012) use the firms in their study to show how this heterogeneity, and by that meaning the use of new and different business models, is what drives the evolution of the industry forward.

---

**Figure 2:** The business models’ position in the discovery-to-market process (Adapted from Nosella, 2006, p. 208).
1.3.3 Knowledge Gap

Biotech is a novel industry. It has a set of unique challenges (e.g. research orientation), and therefore is interesting to investigate through the business model lens. A few studies have already made empirical efforts to identify biotech business model classifications, but these studies are very limited in number. Neither have they established consensus to what the classifications or business model ‘types’ are, nor are they including the same dimensions in the analysis of the business models. They also set different criteria for who is included in the study. Thus there exist a knowledge gap not only in the limited amount of empirical evidence, but also in the comparability between the existing results. This is likely due to the business model being a relatively young research concept. Numerous definitions and dimensions have been proposed and taken to use, but there is a lacking consensus to any single definition or framework. The past instances where the business model has been applied to biotech therefore predates the latest developments of the concept.

1.4 Research Problem

The biotech industry is receiving great amounts of investment and the large corporations operate profitably, but many biotech SMEs are struggling and they seem particularly vulnerable to the industry’s challenges. According to Sabatier et al. (2010, p. 432), the SMEs are the “bridge” between the upstream of technology and innovations coming from universities and academia on the one side, and the downstream commercialization of the ‘industry giants’, such as the big pharma, on the other. Hence, to facilitate further innovation, we should take the struggles of biotech SMEs seriously.

Pisano (2006, p. 115) suggest the failures are due to dysfunctional business models. In this thesis we therefore set forth to investigate the business models of biotech SMEs. Because Sabatier et al. (2012, p. 958) suggest business model innovation is what drives the biotech industry’s evolution forward, the intended contribution of this thesis is to facilitate further business model innovation for the SMEs. We propose that in order to effectively implement changes in the business model, one must first understand its underlying logic for value creation and value capture. We acknowledge that Pisano’s article was written in 2006, which could raise concerns how valid his claims are today, especially since the biotech industry develops at a very fast pace. This article was more of a starting point on how we began to investigate this topic. As such it is not the concern of this thesis to investigate the claims he made back in 2006. However, there is a knowledge gap concerning the classification and characteristics of the biotech SMEs’ business models. We therefore focus our study on mapping the business models of the SMEs, thereby investigating how the characteristics relate to the challenges of the industry.

1.5. Research Question

“How do biotech SMEs structure their business model to cope with the challenges of the industry?”
1.6 Purpose

The purpose of the thesis is to map the business models of biotech SMEs and understand how the business models are related to the challenges of the industry. By analyzing biotech SMEs through the lens of the business model concept, we gain insight to the underlying logic for their value creation and value capture.

The first step of describing the business model of biotech companies can set a foundation for future researchers to innovate current business models, so that the SMEs can achieve profitability and effectively overcome the challenges of the industry. The intended contribution to the scientific community is to use the business model concept as a tool of analysis, and create a typology for biotech SMEs.

It is visible in the problem background that we have taken special interest in the biotech companies developing pharmaceutical drugs. As stated, this interest is due to the drugs being “extreme cases” of biological products in terms of length, cost and risk of R&D. Therefore, it is the initial purpose of this thesis to investigate how in particular these SMEs structure their business models to overcome the abovementioned challenges.

Biotech is however applied also for development of other types of products, and there exist a wide range of biological products besides drugs. Loosely defining them as ‘non-pharmaceutical’ products, many of these other products operate under substantially less regulations, or no product-related regulations at all. Although the characteristic of being high-tech products should imply a certain need for R&D to develop and commercialize also the non-pharmaceutical products, it could be assumed that less strict regulations for these products leads to shorter, less costly and less risky R&D processes than for the pharmaceutical products, which again could lead to pharmaceutical and non-pharmaceutical companies having different business models. To better understand whether and how the challenges affect the business models of biotech companies, we therefore include also non-pharmaceutical SMEs in the study. An important assumption underpinning this choice, is that we believe what makes the business models different, can be factors determining why the business models are the way they are.

1.7 Delimitations

Establishing a typology of biotech SMEs can be difficult, especially in the area of non-pharmaceutical biotech. Non-pharmaceutical biotech includes a variety of products, ranging from biological products in diagnostics, to purely physical products like hospital equipment. Therefore, the established business model for non-pharmaceutical SMEs in this thesis is likely not to be fully representative. One important variable here is the required development time of the product, which determines if the non-pharmaceutical SME has more emphasize on the research or market side of the business model.

In addition, we look at the current state of the companies. Start-ups in the biotech industry might take different shapes during different points in time, which ultimately could lead to different business models during the growth process. We tried to minimize this by interviewing the experts and cluster managers, asking for a broader picture on how the biotech companies are usually shaped.
The informed reader might wonder why we excluded business model innovation. In our opinion, the first step is to establish a description of biotech companies that currently are found on the market. The next step then could be to apply business model innovation. We think that both steps would have been too extensive for this thesis. Especially considering that we did not have any background knowledge about the biotech industry.
2 Methodology

This chapter presents the methodology of the thesis. In accordance with Saunders et al. (2012, p. 4) we understand methodology as “the theory of how research should be undertaken”, and when using the term method, we refer to the “techniques and procedures used to obtain and analyze data”. Put simply, methodology defines the direction for the thesis and makes the overarching choices, while the methods are the specific ‘tools’ used to perform them (Hatch & Yanow, 2008, p. 24). The methodology affects which practical methods can be applied for data collection and analysis (Hatch & Yanow, 2008, p. 24). Methodology also affect the logic behind theoretical reasoning, and therefore it is presented before the theoretical framework. The practical method is later presented in chapter 4, preceding the presentation of empirical results.

2.1 Research Philosophy

Research philosophy relates to “the development of knowledge and the nature of that knowledge in relation to research” (Saunders et al., 2012, p. 680). Our philosophical assumptions ultimately influence how we choose to conduct our research (Lincoln & Guba, 2013, p. 37; Long et al., 2000, p. 191; Saunders et al., 2012, p. 128). Therefore, before we present the methodology of this thesis, it is beneficial for the reader to understand the philosophical assumptions behind our choices. In the following we discuss ontology and epistemology, two sets of philosophical assumptions which are separate, yet closely related to each other (Long et al., 2000, p. 190). Then follows a section discussing which implications the ontological and epistemological assumptions have for the methodology of this thesis.

2.1.1 Ontology

Social ontology is a branch of philosophy concerned with the nature of reality (Bryman & Bell, 2015, p. 32; Hudson & Ozanne, 1988, p. 509; Long et al., 2000, p. 190; Saunders et al., 2009, p. 666). The central question is whether social reality is external to social actors, or if it is a social construct made up by their perceptions and actions (Bryman & Bell, 2015, p. 32; Long et al., 2000, p. 190). The answer to this question is subject to an ongoing debate between objectivism and subjectivism. Objectivism holds the assumption of reality as external to the individual, while subjectivism views reality as a social construct (Long et al., 2000, p. 190). Such a discussion may seem trivial at first, but does have implications for how research is undertaken. The ontological assumption influences the research purpose, and thus ultimately which methods are deemed as appropriate.

The external assumption of objectivism implies a single reality. In this reality, the events occur in specific way or pattern, regardless of who is participating or observing it. In other words, objectivism believes it is possible to find a single truth. The research ideal is therefore much like in natural sciences, to adopt value-free (objective) methods in order to arrive at factual and generalizable results. In opposition to objectivism, subjectivism views reality as socially constructed, and because reality is socially constructed, there are multiple realities (Long et al., 2000, p. 191). There are different realities for each individual, none of which are more or less true than others. Hence, according to subjectivism, the ‘single truth’ of objectivism is neither possible nor desirable. The
research ideal is rather to explore contextual data and gain an understanding of the individual phenomenon or event.

So far, objectivism and subjectivism are presented as mutually exclusive alternatives. A more nuanced view is to see them as the extreme ends of a continuum (Long et al., 2000, p. 190; Saunders et al., 2012, p. 129). Seeing ontology as a continuum, implies the possibility of viewing reality somewhere in between that of the purely subjective and the purely objective. This makes sense in the perspective of business models, which is the reality studied in this thesis. The subjectivist assumption holds true in the sense that business models are created by its social actors, and that the different managers, employees and partners taking part in it may experience it differently. On the other hand, there is also some truth in the objectivist assumption. Norms, regulations and shared beliefs are likely to create patterns of behavior, which on a collective level might lead to a group of firms adopting the same or very similar business models. Taken together, our view of the social reality indeed is a mix between objectivism and subjectivism.

2.1.2 Epistemology

Epistemology is yet another branch of philosophy. Saunders et al. (2009, p. 670) refer to it as “the nature of knowledge and what constitutes acceptable knowledge in a field of study”. Long et al. (2000, p. 190) describe it as “the basis of knowledge and in what manner it can be transmitted to others”. Epistemology is closely related to ontology, because different assumptions of reality lead to different views of what is acceptable knowledge (Long et al., 2000, p. 190). Therefore, the polarized debate between objectivism and subjectivism is present also in epistemology. On the one side there is positivism, an epistemology associated with the objectivist ontology. On the other is interpretivism, which is associated with the subjectivist ontology.

Bryman & Bell (2015, p. 26) say a central issue in this debate is whether social sciences can adopt the same research principles as natural sciences. Positivism is of the opinion that it can. Again, this is due to the objectivist ontology. Positivism has the ontological view that reality is objective, and can have an independent existence from the conscious minds of its social actors. This leads to the epistemological view that what is acceptable knowledge within the natural sciences also should be what is acceptable for the social. In other words, to focus on observable data and law-like ‘facts’ (Bryman & Bell, 2015, p. 28; Saunders et al., 2012, p. 140). Social positivists therefore adopt the same, or similar, principles and ideals as those associated with the natural sciences. The researcher should strive to remain value-free and objective towards the subject that is being studied (Saunders et al., 2012, p. 140).

This objectivity is however criticized by the interpretivist philosophy. Neither does it see value in finding single truths or making law-like generalizations like it is done in the natural sciences, nor does it think this is possible. This is again related to the subjectivist ontology. Of the multiple realities which exist per each of social actors, none are more true or false than others. Therefore, interpretivism has the epistemological view that only by understanding the subjective, context-specific meanings behind the social phenomena one can truly understand the social reality. Unlike positivism, interpretivism believe it is impossible to remain value-free throughout the research process, because through the necessary interaction in the research process, the researcher inevitably becomes part of what is being studied (Saunders et al., 2012, p. 140).
Same as they are built on different assumptions, positivism and interpretivism also come with different norms for what they see as appropriate research approaches and methods. Typically, positivism is associated with a deductive approach and quantitative methods, while interpretivism is associated with an inductive approach and qualitative methods (Saunders et al., 2009 p. 119). Both Bryman & Bell (2015, p. 25) and Saunders et al. (2012, pp. 135; 140) point out that these are not absolute rules. But despite certain exceptions, there is still a set of expectations linked to each the interpretivist and positivist epistemologies, which many researchers try to follow.

Pragmatism is in this regard a third epistemological alternative. It has the practical principle that philosophical presumptions, such as those belonging to interpretivism and positivism, should not dictate which methods are applied by the researcher. Rather, pragmatists believe that the research approach and practical methods should be decided based on the specific nature of the research problem at hand (Saunders et al., 2012, p. 678). Therefore, according to the pragmatist position, one could apply both an inductive and a deductive approach in a single thesis, and mix the use of qualitative and quantitative methods.

Upon reflection, we find it difficult to agree solely with the assumptions of positivism or interpretivism. Ontologically, we see the social world as created by its social actors. However, we also see that certain law-like tendencies such as norms, regulations and shared beliefs do create patterns of behavior, which on a collective level exist independently of single individuals. Epistemologically, we consequently believe there is not one nature of knowledge, as might be assumed in the debate between subjective interpretivism and objective positivism. What is acceptable knowledge, be it subjective or objective, is rather decided by what is the purpose of the study. In consequence, our pragmatist position influences us to choose research approach and research methods based on what is appropriate for the kind of knowledge we need in order to fulfill the purpose of our study, and not merely on what is conventionally seen as appropriate for either positivism or interpretivism. These choices are discussed in the following sections of this chapter and later in the chapter for practical methodology.

2.2 Research Approach

Research approach refers to “the logic of theoretical reasoning” (Saunders et al., 2012, p. 143). Traditionally, induction and deduction have been the two main approaches within the social sciences (Bryman & Bell, 2015, p. 27). The logic behind deduction is to test existing theory by gathering empirical evidence (Bryman & Bell, 2015, p. 23; Saunders et al., 2012, p. 669). In this approach the researcher starts by investigating existing theory. The researcher then collects data to test whether the prior theories are false or true. Induction follows a reversed logic. In this approach the logic is to build new theory based on empirical evidence (Bryman & Bell, 2015, p. 23; Saunders et al., 2012, p. 669). Hence, where deduction moves from theory to data, induction moves from data to theory.

In the case of our thesis, we followed a mix of both. Our research started by studying existing theory, from which we identified the so-called ‘Business Model Canvas’ as an appropriate business model framework to organize and guide the data collection and analysis. At this point in the process, the approach was deductive. Simultaneously though, we remained open to the possibility that there may be certain aspects of the biotech
business models that we have overlooked or that not yet are covered by the existing theory. From the analysis and outwards, the thesis therefore included an inductive approach. While analyzing the data, we gained insights which enabled us to identify which other studies and perspectives could shed further light to the topic. The approach we used of mixing induction and deduction is called abduction, which according to Bryman & Bell (2015, p. 27) is associated with pragmatism.

2.3 Research Design

The research design is the general plan of how to structure a study in order to answer its research question (Saunders et al., 2009, p. 136). Here, we present how we have chosen to design our thesis in terms of strategy and time horizon. We also discuss how these aspects relate to the thesis’ purpose, because as we have highlighted in the previous sections, we let the research question and purpose guide our methodological choices. The practical specifics of how we have implemented this plan is later presented in chapter 4.

2.3.1 Research Purpose

Saunders et al. (2009, p. 139) present that there are three main classifications of research purpose; explanatory, exploratory and descriptive, each consisting of different objectives. First, the descriptive studies have an objective of portraying “an accurate profile of persons, events or situations” (Robson, 2002, p. 59 cited in Saunders et al., 2009, p. 140). Second, explanatory studies have the objective of “studying a situation or a problem in order to explain the relationships between the variables” (Saunders et al., 2009, p. 140). Third, exploratory studies are applied when the precise nature of the research problems are less certain (Saunders et al., 2009, p. 139).

Saunders et al. (2009, p. 139) argue that a research project may have a purpose belonging to more than one of these classifications at the same time, which we see is the case for the purpose of this particular thesis. We presented in the introduction that the research question of this thesis is “How do Biotech SMEs structure their business model to cope with the challenges of the industry?”. Finding the answer(s) to this question necessitates to first identify what the firm’s business models in fact are, which means to be doing descriptive research. Further, we would also be gathering descriptive data on the challenges of the industry, and the specific challenges of the firm. Having established these ‘facts’, we are then able to investigate the causal relationships between the challenges and the business models, which would be the explanatory part of the study.

Lastly, the exploratory nature manifests due to our prior limited insights to the firms and the industry at large, and due to limitations in available literature about the topic. As evident in the theoretical framework, there exist ‘general’ frameworks for business models, which is possible to apply universally to all industries and types of firms. Even though we have our starting points in such general models, we still have the end goal to find the business model typical for biotech SMEs. Not knowing fully what the SMEs needs and challenges are before having started the empirical investigations, has the unfortunate implication of not knowing whether we are asking all the right questions. Therefore, we do indeed see advantages of adopting the exploratory principles allowing for flexibility and adaptability to change (Saunders et al., 2009, p. 140), which moreover is why we argued for an abductive approach in the previous section.
2.3.2 Research Strategy

In regards to research strategy, there are six main alternatives according to Saunders et al. (2009, p. 141): experiment, survey, case study, action research, grounded theory, ethnography and archival research. Yin (2009, p. 8) give a somewhat different classification of strategies, consisting of experiment, survey, archival analysis, history and case study. Of all these alternatives mentioned here, we have chosen to design this thesis as a case study. Yin (2009, p. 18) provide a twofold definition of the case study strategy:

1. The case study is an empirical inquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident.
2. The case study inquiry copes with the technically distinctive situation in which there will be many more variables of interest than data points, and as one result relies on multiple sources of evidence, with data needing to converge in a triangulating fashion, and as another result benefits from the prior development of theoretical propositions to guide data collection and analysis.

The first part of Yin’s definition indicates for which kind of research purpose the case study is appropriate. Yin (2009, p. 6) refer to a hierarchical view in research where case studies are seen as appropriate only for exploratory studies, surveys and histories only appropriate for the descriptive, and experiments only for the explanatory. Yin (2009, pp. 6-8) oppose this view and further argues that case studies are appropriate for exploratory, explanatory and descriptive purposes alike. Rather than choosing strategy based on purpose classifications, Yin (2009, p. 8) suggest basing the evaluation on 1) the research question, 2) the required control of behavioral events, and 3) whether there is a focus on contemporary events.

In regards to research question, case studies are especially appropriate for questions asking why and how (Yin, 2009, pp. 8-9), and the question for this thesis is formulated as how the biotech SMEs structure their business model to cope with the industry’s challenges. Further we have stated in section 2.3.1 that we seek to answer this question by going through two steps: first descriptively mapping the business model, and second seek explanation for why the business model is structured the way it is. One of the major assumptions motivating this thesis, is that we believe the structure of the business model is largely dependent on the context of the industry. Hence it is essential when attempting to fulfill this purpose of investigating the connection between business model and industry challenges that we choose a strategy facilitating a holistic perspective. As previously established, the general purpose of this thesis is to investigate the business model of biotech SMEs in light of their industry’s challenges. Thus seeing the industry as the context for the phenomenon we are investigating, this motivates choosing the case study strategy because it is specifically designed for such a context-dependent purpose.

Also experiments and histories could be appropriate for how and why questions (Yin, 2009, p. 9), however experiments require a control over behavioral events (Yin, 2009, pp. 8; 11) which would be neither possible nor provide any value for this thesis. History, on the other hand, is designed specifically for those studies dealing with the “dead past” where there are no respondents still alive to provide primary data (Yin, 2009, p. 11). In
this thesis we need not rely on the methods associated with the history strategy, because we are dealing with contemporary events.

The survey and archival analysis are designed to “describe the incidence or prevalence of a phenomenon or when it is to be predictive about certain outcomes” (Yin, 2009, p. 9). In fact, we see benefits of both the survey strategy and archival analysis strategy in relation to the chosen topic for this thesis. The survey strategy could be applied for the purpose of mapping the business model characteristics of biotech SMEs across a wider population, and the archival analysis could be applied to investigate the business models’ impact on occurred and reported financial results. We could have chosen either as an alternative to the case study strategy, or we would have included one of them in combination with the case study strategy. However, we have discarded either option for multiple reasons.

The first reason is because we have a limited period of time to conduct this thesis. It would become too much data for us to collect and analyze if we were to combine two strategies. We could for instance use the case study strategy as an initial inquiry to explore the topic and identify possible causal relationships, after which we could apply the survey strategy to test the relationships and seek generalizable results. If we included the archival analysis strategy, we could go into the firms’ financial data to see whether there is a connection between different types of identified business models and their financial performance. But we believe that such a combination of strategies, if wanting it to be fruitful, would necessitate completing one strategy before initiating another. There is a gap in the identification of biotech business models, hence there are limited grounds to test, and the case study would need to be performed first. Considering the length of time needed to collect and analyze the case study data (which is discussed more closely in chapter 4), we simply would not have time left to conduct the second strategy.

Arguments for not choosing the survey strategy or archival analysis study instead of the case study strategy are closely linked to those at the end of the preceding paragraph. Surveys generally consist of static questions and pre-fixed optional answers which would need to be developed by the researchers before the data collection and be based on pre-existing knowledge. As knowledge about biotech business models is limited, it is a risk the survey could be asking the wrong questions or not be including the right or sufficient alternatives. Neither the survey strategy nor the archival analysis strategy would facilitate contextual understanding (which we believe is necessitated by the purpose of this study and the knowledge gap it is addressing) to the same extent as the case study.

Therefore, all things considered, we have chosen the case study strategy. It suits the purpose of this thesis well, because it is especially designed (more so than others) for research questions related to investigating social phenomena in light of their context. Case studies offer the possibility to include the real-world context to observe temporary phenomena in a holistic approach (Eisenhardt & Graebner, 2007, p. 25; Yin, 2009, p. 4). The subject of business model research appears to be highly dependent on context, considering for instance the financing of biotech SMEs, which highly relies on external sources. The cases and the implicit phenomena are also contemporary. Since the companies are evolving, different challenges and solutions occur at different times. For this characteristic, case studies are suitable (Yin, 2009, p. 8).

More specifically, we have chosen to conduct a comparative case study. The comparative character of the case study displays the intent to find common characteristics among
different cases (Dion, 2002, p. 95). This cross-case analysis supports an analysis of one particular phenomenon across different settings (Darke et al., p. 277), which for example in our case could be how biotech SMEs face financial challenges throughout R&D processes. We here define “one case” to be the equal of one company. Since there is one business model per each company, it makes sense to compare the business models of different biotech SMEs to see if and why there are similarities and/or differences. The cases (i.e. companies) chosen for to include in the study are more closely discussed in chapter 4.

2.3.3 Primary Data Collection

As stated initially, the data collection is subject to discussion in the chapter for practical method. However, it can be beneficial for the reader already at this point to understand the nature and purpose of the data that is collected and used for analysis in this study. We have chosen to follow a case study strategy because of its ability to study a phenomenon in light of its context. For the same reason we believe qualitative data is the most suitable to be used as primary data.

Contrary to quantitative data, qualitative data is non-numerical or non-quantified (Saunders et al., 2009, p. 598). As mentioned in relation to the discussion of research philosophies, qualitative data is often associated with interpretivism, because qualitative data is ‘soft’ contextual data which facilitates deeper meaning and understanding of the phenomenon that is being investigated. As stated by Saunders et al. (2009, p. 324) qualitative data is likely to be used when it is necessary “to understand the reasons for the decisions that your research participants have taken, or to understand the reasons for their attitudes and opinions”. In our case, it is implied by the thesis purpose that we need to understand the reasons for why the business models are structured the way they are. Business models are the results of managers’ decisions, hence it is necessary for us to get insights to their thoughts and motivations for why the business models are the way they are. Furthermore, business models (as will be elaborated in the chapter for theoretical framework) are complex structures which could be difficult to fully grasp by using only numerical/quantified data.

As we discussed in the previous section, it could have been beneficial to include also a survey strategy or archival analysis strategy, both of which could have included quantitative data. This study would then have been a so-called “mixed-method” study, utilizing the advantages of both methods (Saunders et al., 2009, p. 152), but as we pointed out, we see that we lack the time to go through with it. Specifically, we have chosen to conduct the qualitative data collection through interviews. The rich amount of data resulting from each interview means there is a limit to how many interviews we have capacity to conduct. It should therefore be noted that a drawback of not including a quantitative method in the study is that the limited number of cases makes statistical generalizability of the results impossible (Saunders et al., 2009, p. 327). In accordance with our pragmatist position, however, we still deem the circumstances of the study to speak in favor of the qualitative method and to gather qualitative data, as this is what we believe most feasibly and effectively address the specified knowledge gap considering the time and resources we have at hand.
2.4 Preconceptions

In this section we present an overview of the assumptions and knowledge which we had previously to starting this thesis project. Why we believe it is valuable for the reader to understand our preconceptions is presented in 2.4.1. In sections 2.4.2. and 2.4.3 we present those preconceptions which we believe are the most relevant, and why.

2.4.1 Axiology

Earlier in this chapter we discussed our ontology and epistemology. Yet another branch of research philosophy is axiology. According to Saunders et al. (2009, p. 116), axiology is the study of judgements about value. Saunders et al. (2009, pp. 116-117) further explains that axiology is of importance to social research, because the researcher’s own values affect decisions and judgements made at all stages of the research project. E.g. the researcher’s values affect not only the choice of subject and methods, but also the analysis and interpretation of results. Bryman & Bell (2015, p. 40) support this notion by exemplifying several points in the research process where the researcher’s own values may have influence: “choice of research area; formulation of research question; choice of method; formulation of research design and data collection techniques; implementation of data collection; analysis of data; conclusions”.

How exactly the researcher’s own values and preunderstandings influence, and in which way, is a discussion related to ontology and epistemology. Interpretivists generally believe that it is impossible for researchers to conduct value-free research. That meaning it is impossible for the researchers to remain completely objective, while on the other hand positivism contradicts this belief, and assumes that objectivism is possible and an ideal to strive for (Saunders et al., 2012, p. 140). In alignment with our epistemological view of pragmatism, we do not view this question of objectivity and subjectivity as black or white. We believe that under certain circumstances, following the methods similar to that of the natural sciences, it should be possible to remain to great extent objective when interpreting and analyzing the results. This has to do with the nature of data; analyzing quantitative data by using standardized statistical methods, leaves little room for misinterpretation and bias. For this thesis, however, we have chosen a qualitative method. Both data collection and analysis is therefore highly subjective. In order for the data to have any meaning, it is necessary for us to continuously relate and compare it to the knowledge which we have personally and collectively acquired, both before and during the research process.

Due to the significance of our preconceptions, we present our academic and theoretical backgrounds in the following section, then followed by our preconceptions of biotechnology and the biotech industry. These preconceptions are first and foremost of relevance to our choice of research area, the content of the data collection, analysis and conclusion. Our values related to research and research methods have already been discussed in depth in previous sections.

2.4.2 Academic and Theoretical Backgrounds

Participants in this research project are Julian Tölle and Fransisca Kappfjell Herbst. As previously stated, we are both graduates in the two-year master program of Business
Development and Internationalization [BDI] at Umeå University. In total, the program consists of 120 ECTs. Of these, the courses directly related to our specialization in BDI amounts to 30 ECTs. The theoretical focus of the BDI courses was strategic issues such as growth, innovation, entrepreneurship and internationalization. Before starting the two-year program, Herbst completed a bachelor’s degree of Business and Administration in her native country Norway. Tölle completed a bachelor’s degree of Business and Psychology in his native country Germany.

When choosing a research topic, we were obligated to choose something defined within the business model is one of the central concepts in the BDI program at Umeå University. We encountered and studied the concept in several courses. Some of the courses were specific for the program, and some were elective business courses in entrepreneurship and product development.

It can be noted that some confusion stemmed from these different courses, because they treated the concept of business models somewhat differently. In one of the courses, the business model was presented in terms of the Business Model Canvas [BMC], a framework for analyzing how firms on the one side creates value through production of goods and services, and on the other side captures value through revenue streams. In other courses the concept was presented as a set of archetypes. E.g. ‘the business model of McDonalds’ or ‘the business model of Starbucks’, each representatives of a certain way of doing business. The McDonalds business model was used to exemplify franchising, while the Starbucks business model exemplified a specific way of designing the customers’ experience of service and efficiency.

As is discussed in the chapter for the theoretical framework, none of these different applications of the concept is wrong per se. However, the different usages did lead to our confusion as to what ‘a business model’ really is. Hence, a great effort was made in the beginning of this thesis project to counter the confusion, an effort which hopefully shows in our discussion of business model definitions and frameworks. Another note can be made concerning the final choice of using the BMC as our main theoretical framework. Among the several frameworks made by business model scholars so far, the BMC was the one most frequently and most thoroughly presented by the teaching professors in our program. This provided extra credibility to the BMC, and the extra credibility might have contributed to why we deemed it to be the most suitable and best developed framework. This is something the reader can bear in mind when we discuss the business model concept in the theoretical framework, although we did try keeping an open mind and evaluate the alternative frameworks objectively.

2.4.3 Preconceptions of Biotechnology and the Biotech Industry

Before beginning this thesis project, neither of us had experience (neither professionally nor academically) with biotechnology or from the biotech industry. Our knowledge about the technology and how the biotech firms ‘do business’ was at a minimum.

The idea of researching the biotech business model was initially sparked by a general interest in high-technology business models in combination with Umeå’s relative high concentration of entrepreneurial biotech firms. The opportunity of easier access to these firms, combined with what we perceived as a knowledge gap in the research and literature, eventually lead us to pursue the idea. Additionally, whether the project would
be feasible and whether it would give a positive contribution, was investigated through off-the-record discussions with the local biotech incubator. Upon conducting the first interviews, we got a clearer image of how the industry works, and which questions were the most relevant to ask. The insights provided by these informants also helped steer the information search and development of the theoretical framework in more accurate and relevant directions.

For the sake of efficiency, it would have been favorable to possess these insights at an earlier stage. It would definitely have sped up the research process and left more time available for data collection and to further enhance the quality of the thesis. On the other hand, our limited preconceptions of biotech also limited our bias toward the topic. We went into the project with open minds, leaving no question unasked in meetings with actors of the industry. Being inexperienced with the industry also helped open doors to informants, since biotech firms tend not wanting to share ‘million dollar ideas’ with potentially competing peers. In this perspective, it was beneficial being mere business students when gathering information from biotech informants (and, as we discuss in section 4.2.2, we also tried to ensure a relationship of trust between the informants and ourselves by avoiding details of the technology.)
3 Theoretical Framework

The theoretical framework presented in the following will begin with the question of why business models appear to have different definitions. Resulting from our literature review, we will first present an explanation for the ambiguity in business model definitions and then proceed to introduce three different business model concepts, each increasing in its complexity. The purpose is to demonstrate how business models are based in its core on value creation and capture, and how newer concepts build their complexity on this foundation. The final concept, the business model canvas, will be the tool of analysis for this thesis’ research.

3.1 The Business Model Concept

Our literature review shows that there are two main explanations for why there is still ambiguity in the definition of business model. According to Zott et al. (2011, pp. 1020; 1023), this confusion stems from the concept being used for different purposes, in different management perspectives of e-business, strategy and innovation management. In each of these perspectives, the business model has a different emphasis and is applied differently. Osterwalder et al. (2005, pp. 5-6) give a different explanation for the business model ambiguity. According to them, the confusion stems from the concept being applied at different levels of analysis. As illustrated in Figure 1, they present the business model concept as a hierarchy consisting of three different levels of analysis: 1) conceptual, 2) taxonomies, and 3) instances.

![Figure 3: The Business Model Concept Hierarchy (Osterwalder et al., 2005, p. 5)](image)

At the highest conceptual level (1), researchers are concerned with definitions and meta-models. I.e. what a business model in fact is, and which elements the business model is consisting of. Business model research within the second level is concerned with
taxonomy of types (2), meaning the classification of business models that resemble each other. These business models types are further broken down into smaller elements in the sub-(meta)-models, where the objective is to identify their differences and common characteristics. Lastly, at the instance level (3), business models are being used to describe and analyze real-world business models.

Zott et al.’s (2011) literature review analyzed 103 relevant articles in depth. As mentioned previously, the business model has been used as a tool of analysis in the context of three phenomena: e-business and information technology, strategic issues and performance and lastly in innovation and technology management (Zott et al., 2011, p. 1023).

The field of e-business in terms of value includes, for instance value streams, customer value and value proposition. Financial structures include revenue streams and cost structures, while network can include all relevant exchange partners of the focal firm. The business model represents the bigger picture, including all the mentioned elements (Zott et al., 2011, pp.1028). In the field of strategic issues, business model is used as a tool to analyze value creation in the network and the correlation of performance and business model. In the context of strategy, scholars have also emphasized the activities in the focal firm and how this could lead to a competitive advantage. Researchers in that field also distinguished between business model and other concepts. The business model is not a linear mechanism of value creation, it rather describes a complex picture of interconnected players and activities. Activities can be boundary spanning and help to achieve a competitive advantage (Zott et al., 2011, pp. 1031). In the field of innovation, Zott et al. (2011, p. 1034) describe the main characteristics of business model as a mechanism to connect innovation with customer needs. Teece (2010, pp.172) is one of the researchers focusing on business model and innovation, and has according to Zott et al. (2011, p.1034) a predominant definition in that area. Teece (2010, p. 173) sees the business model as important logic that shows how a company creates and captures value, as well as the financial structure in it. Zott et al. (2011, p. 1034) summarizes the view on business models in the management field of innovation as functionalist perspective, as a complementary part to technology. The business model mainly focuses on financial structure, value proposition and value capture.

Zott et al. (2011, p. 1021) suggest that, independent from context, business models have four characteristics in common. Business model is used as a tool of analysis and has a holistic approach to the focal firm. Value creation and capture are dominant, while in e-business and strategic view, also the network is described as part of the business model.

Osterwalder et al. (2005) and Zott et al. (2011) provide different explanations for the confusion concerning business models. However, we see it as two variables or dimensions: the management perspectives and levels of analysis. This assumption is backed up by Baden-Fuller & Morgan (2010, p. 168) by explaining the business model’s role as a model that can be applied differently depending on both the level of analysis, and from which management perspective, or which specific context, the study is conducted. For our research and to avoid ambiguities in the business model applied by us, we want to emphasize our exact position on these two dimensions.

In the concept hierarchy of Osterwalder (2005, p. 5-6), we start at the instance-level by investigating real-world companies. Upon exploring their business models, we move up
to the level of taxonomy of types. At this level of analysis, we intend to conceptualize the
‘Biotech SME business model’, based on the common characteristics found at the
instance level. The management perspective will evolve around new technologies, which
can be seen as the perspective of innovation management according to Zott et al. (2011,
p. 1021).

3.2 Different Business Models

In this section different business models are presented to show their similarities and how
they might differ in complexity. First, the introduction of the business model by Baden-
Fuller & Haefliger (2013), Chesbrough & Rosenbloom (2002) and finally the business
model canvas by Osterwalder & Pigneur (2010) are introduced. Baden-Fuller & Haefliger
(2013) have a simplistic business model, focused on value creation and capture. The
complexity increases with Chesbrough & Rosenbloom (2002), adding cost structures.
Finally, the business model canvas by Osterwalder & Pigneur (2010) offers more detailed
and operationalize building blocks, which will be used for the research of the thesis.
Presenting the theory in this way, might assist in understanding the development of the
business model concept and how it is applied for this thesis.

3.2.1 Baden-Fuller & Haefliger

The framework by Baden-Fuller & Haefliger (2013) offers a simplistic approach by
highlighting what most business model definitions have in common: value creation and
value capture. They further narrow it down to their definition of the business model as “a
system that involves the problem of identifying who is (or are) the customer(s), engaging
with their needs, delivering satisfaction, and monetizing the value” (Baden-Fuller &
enables us to break down the business model into four observable categories. As reflected
in their definition, these categories are 1) customer identification 2) customer
engagement, 3) value delivery, and 4) monetization (see figure 4).

![Figure 4: Value Creation & Capture (Baden-Fuller & Haefliger, 2013, p. 420).](image)

Identifying the customer is according to Baden-Fuller & Haefliger (2013, p. 420) the first
step in the value creation process. A distinction between the user and the actual payer for
the service or product has to be made. It is possible, especially with the rise of the Internet,
that users are not the ones paying for services. As a user of Google, you utilize their search
engine, but advertisers are the ones who finance the service. This differentiation can also be found in ‘Freemium’ models, adopted by many internet companies, where basic services can be used for free, but additional ones are charged, for instance for businesses (Teece, 2010, p. 179). In regards to the biotech industry, it is for instance the user of a drug not necessarily the one purchasing it. In this case the hospitals are the customers, and the patients are the users. This shows, that there can be customer-user groups, which have to be differentiated in order to identify their need, which the next step of customer engagement.

Customer engagement focuses on identifying customer needs, as well as the user’s needs, if there was a distinction made in the identification of customers. This approach can be done in two ways; a project based approach, where individual customers-users are engaged, or in a scaled up approach, where bigger groups of customer-users are in the focus (Baden-Fuller & Haefliger, 2013, p.421). The difference can be seen, for example in consulting services versus car manufacturers. Consultants offer specific services for very specific needs, fitted to their customer-user, while car manufacturers try to engage a much broader group. Both approaches demand different resources and skills in the company (Baden-Fuller & Haefliger, 2013, p.421).

After identifying the customer and their needs, the question is how value is delivered, often described as the value chain. Facing multiple customer-user groups can also lead to multiple value chains (Baden-Fuller & Haefliger, 2013, p.421). The value chain can be described as “a system of interdependent activities” which is performed to pass a product to a buyer (Porter & Millar, 1985, p. 150).

Lastly monetization, which not only involves pricing, but also timing and effectiveness. Depending on the business model, money can be collected before, during or after the sale (Baden-Fuller & Haefliger, 2013, p.421).

Similarities can be seen in other frameworks by Chesbrough & Rosenbloom (2002), as well as Teece (2010). In its core, they have the value creation and capture in common but mention additional elements. Chesbrough & Rosenbloom (2002, p. 543) see the firm’s position in a value network as another important point, as well as sustaining a competitive advantage, which Teece (2010, p. 173) also added as a factor for a successful business model.

### 3.2.2 Chesbrough & Rosenbloom

Chesbrough & Rosenbloom (2002) looked in their study into the business models of spin-off companies coming from the Xerox technology company. Their concept of the business model mainly focuses on innovative technologies and is well cited by other researchers. Their main description of the business model involves value proposition, identification of market segment, defining structure of the value chain and estimating cost structure and profit potential (Chesbrough & Rosenbloom, 2002, pp. 533). In addition, the value network and the competitive strategy are also important factors.

Value proposition and identification of market segment can be seen similar to Baden-Fuller & Haefliger’s (2013) concepts of customer identification and engagement, as well as a concept of a value chain. However, Baden-Fuller & Haefliger (2013) speak more on monetization, but do not clearly involve cost structures. Chesbrough & Rosenbloom
describe the cost structure and potential profits based on costs and revenues resulting from the value proposition and value chain structure. Another factor that is additional in Chesbrough & Rosenbloom’s (2002, p. 543) model is the value network, including suppliers and customers, as well as possible complementary alliances. Also describing a competitive strategy, on how the focal firm can maintain an advantage over rivals.

However, Chesbrough & Rosenbloom (2002, p. 536) make a distinction between their business model concept and business strategy. According to them, the business model focuses on the value creation and the structure around it to deliver value. Strategy on the other hand focuses on value capturing and the sustaining of it. Secondly, the business model focuses on the internal financial value creation, as opposed to creating value for the shareholder. The business model as a structure of value creation and capture tries to maintain itself in financial terms, while the financial side of shareholders might not be included. Lastly, a major difference lies in the assumption of knowledge. The business model acknowledges limitation of knowledge and possible biases through previous success. Strategy assumes that knowledge is available but has to be very carefully analyzed and responsible actions can be taken. Chesbrough & Rosenbloom (2002, pp. 535) see early stage technologies and their commercialization at risk, especially if they are spin-offs from bigger companies and it is tried to apply previous successful business model to completely new products.

The authors conclude that innovation has to deliver value to the customer (Chesbrough & Rosenbloom, 2002, pp. 549). Especially research-driven innovation and possible spin-offs that lacked a clear commercialization in first place, can inherit the potential for a technology push and therefore new products. Valuable for this thesis is their perspective on the business model as a mediator between technology and economic domains. The business model offers the possibility to put a technology into a configured model where it can be commercialized. This inherits a heuristic approach and sometimes different business models might be applicable. Start-ups can face a lot of uncertainty and a business model can be sort of a prototype strategy on how to deliver value, where a business strategy would take more information carefully into consideration.

### 3.3 The Business Model Canvas

The well cited business model canvas shows many similarities to the models we have discussed so far and offers a practical guideline to map a business model. This business model will be described in the following, as well as an argumentation for why it appears to be suitable for this research project.

Osterwalder & Pigneur (2010, p. 14) define the business model as how a company creates, delivers and captures value. Similar to Baden-Fuller & Haefliger (2013), Osterwalder & Pigneur (2010, p. 15) call for a shared language in the business model to progress through description and discussion. Their business model perspective is built on the foundation of value creation and capture, like all other models introduced before, but offers further nine practical building blocks. This allows to operationalize each part of the business model into feasible observations. The advantage over Baden-Fuller & Haefliger (2013) business model is the more detailed and inclusive definition of each business model part. Osterwalder & Pigneur’s (2010, pp. 16) is built around the nine ‘building blocks’, as it can be seen in figure 5.
Each building block contains the definition by Osterwalder & Pigneur (2010) and we tried to supplement these with additional articles. Osterwalder & Pigneur (2010) partly utilize concepts in their building blocks that are already applied in the research of biotech companies. In adding this information, we already try to put the business model canvas in the context of biotech SMEs.

### 3.3.1 Customer Segments

The goal is to identify the group of customers, as a crucial point to build the business model around it (Osterwalder & Pigneur, 2010, p. 20; Tsai et al. 2015, p. 65). As mentioned by Tsai et al. (2015, p. 65), companies increasingly see their customer as the most important asset to operate profitably. In recent literature the term of customer relationship management (CRM) occurs, including all interactions with customers, under which customer segmentation is an essential aspect (Kim et al., 2003, p.5). Since consumers on the market have different needs, the market can be divided in segments, where customers have similar attributes (Kotler et al. 2011, p. 57). This, as Kotler et al. (2011, p. 57) call it; market segmentation, is required to specify the companies’ actions toward a distinct group of customers. Osterwalder & Pigneur, (2010, p. 20) add that each segment requires a distinct offer, will be reached through different channels, and call for different types of customer relationships. The segments might offer different profits and each segment could require other pricing models. A company can further serve a multiple set segments, if the business offers products & services for customer with different needs, behaviors and other attributes (Osterwalder & Pigneur, 2010, p. 20).

Osterwalder & Pigneur (2010, p. 20) mention several examples of different segments. Companies can address customers on a continuum of mass market versus niche markets, where customers share broadly similar needs or smaller segments with specific requirements. A business model could also serve diversified segments, meaning completely different customers with unrelated needs. The business’ ability to serve diversified segments relates to their resources. Osterwalder & Pigneur (2010, p. 21)
mention the example of Amazon, who had a well-developed IT infrastructure for their retail business and was able to introduce cloud computing services. This allowed to use existing infrastructure and diversify their customer segments. Another possible segment is multi-sided platforms or multi-sided markets. Free newspaper for example, have to serve the reader’s need but finance themselves through companies’ advertisements (Osterwalder & Pigneur, 2010, p. 21).

Biotech SMEs usually target big pharmaceutical companies or bigger R&D companies as customers (Renko et al, 2005, p. 252). Biotech’s market is described as a global marketplace (Tolstoy & Agndal, 2010, p. 24), which can result in a larger group of possible customers. Non-pharmaceutical companies might respond to a bigger amount of customers than pharmaceutical biotech SMEs. The latter develop a single product up to 20 years and then sell it one time to a big pharmaceutical company. Although this process might differ from non-pharmaceutical SMEs, the principle of identifying customer needs might remain similar. If pharmaceutical biotech SMEs want to sell to big pharma, they need to know the certain needs of this company, even though their number is much smaller and selling process is different to other industries. This assumption is based on the article “Partnering with Big Pharma – What Academics Need to Know” (Lipton & Nordsted (2016, p. 512) where needs by the big pharma are described.

3.3.2 Value Proposition

The value proposition is a “set of benefits or values” to serve the customer needs (Kotler et al., 2011, p. 15). This also includes a propositions that makes the customer choose the focal company’s products over competitors (Osterwalder & Pigneur, 2010, p. 22). This value proposition can be a mix of quantitative features, such as price, speed of service, or qualitative nature, like design or customer experience. Osterwalder & Pigneur (2010, p. 23) further give an example for possible value propositions, such as newness, better performance or more options of customization than competitors offer.

Since products from biotech often have to surpass approval by governmental institutions, they have to offer some kind of improvement compared to existing products. A new chemical entity (NCE) for instance has to offer better effects or less aversive effects than the ones on the market. Therefore, a value proposition is already implied in the application process for new drugs.

In terms of competition, Biotech SMEs are especially exposed due to the very global industry, which is described by Pitt et al. (2006, p. 600) as a hypercompetitive market environment. The way to gain a competitive advantage are intellectual property rights [IP] (Mets et al., 2007, p. 20). On the same hand, developing new products can become legally complex, if patents by competitors restrain companies’ freedom in the market (Mets et al., 2007, p. 20). A new developed product or parts of it might infringe existing patents.

3.3.3 Channels

Channels include the communication, distribution and sales the company has with its customer in order to deliver the value. These contact points also allow to give the customer an experience, including after sales services (Osterwalder & Pigneur, 2010, pp. 26). The channels offer following functions:
1. Raise awareness.
2. Explain value proposition.
3. Allow customer purchase.
4. Deliver value.
5. Provide post-purchase support.

The channels can address the customer directly or indirectly utilizing intermediaries (Kotler et al. 2011, p. 335). For example, a salesforce owned by the company can directly contact the customer, while selling a product through partner stores would be indirect.

Using intermediaries can increase efficiency, due to the partners possibly better experience, network, specialization or scale of operation (Kotler, 2011, p. 334). On the other hand, using intermediaries also implies a certain loss of control and lower margins (Osterwalder & Pigneur, 2010, pp. 27; Kotler, 2011, p. 334). Owning the channel gives greater control and possibly higher margins, but requires the company to plan and operate more (Osterwalder & Pigneur, 2010, pp. 27). To decide which channel to use, it is crucial to put the customer’s needs at the center and understand how they can be served in the best economically way, possibly utilizing a mix of both channels (Osterwalder & Pigneur, 2010, pp. 27). According to Tolstoy & Agndal (2010, p. 35), face to face interaction is common in Biotech to get access to possible customers.

3.3.4 Customer Relationship

This building block, also described as customer relationship management (CRM), plays an important role in marketing and deals with the previous mentioned issues of acquisition, growth and retention of customers (Kotler et al., 2011, p. 19). CRM has gained more importance to companies over the last years (Su-Yeon et al., 2006, p. 101). In a broad sense it describes managing interactions with customers (Kim et al., 2003, p.5). According to Kim et al. (2003, p. 6) this implies a paradigm shift from product centric company perspective to a customer centric perspective. They define CRM as “managerial efforts to manage business interactions with customers by combining business processes and technologies that seek to understand a company’s customer.” (Kim et al. 2003 p.6)

According to Kotler et al. (2011, p.20) crucial parts to build a lasting customer relationship is the customer-perceived value and customer satisfaction. The customer-perceived value describes how the customer sees the focal firm’s products compared to competitor’s products. Depending on the product and market, a customer might be able to choose from a variety of products. Offering a distinct customer-perceived value can help a company stand out. Kotler et al. (2011, p. 20) further mention customer satisfaction as another crucial factor in CRM. This factor links the customer-perceived value with the actual experience of the product. If the product does not hold up to the perceived value, the customer could be dissatisfied.

CRM activities can range widely, from a personal relationship to computer based and automated relation, which has an overall impact on the customer experience with the company as well as implications for costs (Osterwalder & Pigneur, 2010, p. 28). It is also possible to utilize communities where customers can help each other solving problems.
or co-creation, where customers can create value for the company (Osterwalder & Pigneur, 2010, p. 29). Threadless for example, a clothing retailer, uses solely designs created by their community.

Another emerging theme is database marketing, including behavioral patterns of buyers (Marcus, 1998, p. 494; Tsai et al. 2015, p. 65). More present information technology allows companies to analyze their consumers buying behavior and optimize it. As a result, current customers can be segmented in a more sophisticated way to understand customer needs in a better way.

3.3.5 Revenue Streams

While the core of the business model is built around the customer, revenue streams show how financial capital comes into the business. A key factor is pricing and how transactions are designed. Possible are for example one-time purchases, subscription fees, licensing or renting (Osterwalder & Pigneur, 2010, pp. 30). Pricing mechanisms can be fixed or dynamic, for example products can be sold based on a fixed list price, or sold based on a dynamic negotiation, which can have major impacts on revenue streams (Osterwalder & Pigneur, 2010, p. 33).

The high risk environment of Biotech companies, due to uncertain research processes, and required high investments create a special situation for revenue streams. Biotech SMEs who are involved in long R&D processes do not have sales during the period of their development process. Companies have to try to generate multiple revenue streams which can be in form of early licensing deals (Jones & Clifford, 2005, p. 807) and milestone payments through research collaborations (Cavalla, 2003, p. 270). Milestone payments can be for finishing steps in the research process.

3.3.6 Key Resources

The key resources are what is required to maintain the activities around the customer, including creation of value proposition, channels and relationships to customer. These resources can be of different nature, depending on the business’ requirements. This means they can be physical, financial, intellectual or in form of human capital (Osterwalder & Pigneur, 2010, pp. 34).

Key resources for Biotech SMEs is qualified personnel. Start-ups naturally deal with scarce resources, which results for Biotech SMEs in personnel that has to take responsibility for different tasks at the same time. Building relationships with VCs, doing marketing research and the business development are responsibilities to take besides doing research (Renko et al., 2005, p. 264).

3.3.7 Key Activities:

Key activities, according to Osterwalder & Pigneur (2010, pp. 36), describe the action that must be undertaken in order to keep the business model working. The activities are required to utilize the key resources to serve the customer. They can be characterized in production, problem solving and platform or network activities. Production activities try to improve a product or service. Problem solving refers to solving an individual
customer’s problem. Platform and Network activities are important to business models that are a platform itself, for instance eBay.

The building block of key activities as defined by Osterwalder & Pigneur (2010, pp. 36) is not in this form thematized by other articles. However, the key activities for the research heavy biotech SMEs is the R&D process and “persuade capital investors” (Mangematin et al. 2003, p. 621) to be able to survive expensive development processes.

3.3.8 Key Partnerships:

These describe the network surrounding the focal firm. Three partnerships can be distinguished: optimization and economy of scale, reduction of risk and uncertainty and acquisition of particular resources and activities. The first refers to the most basic partnership and help to reallocate resources and activities in a useful way. This can happen for instance through outsourcing. Reduction of risk can be achieved through strategic alliances, sometimes with your competitors to reduce risk in a competitive environment. The acquisition of particular resources is a method to gain additional resources that are not owned by the focal firm. This can happen through licensing, as mobile phone manufacturers do it with operating-systems for instance (Osterwalder & Pigneur, 2010, pp. 38).

Considering the resource scarcity small biotech companies can face in terms of financial or human capital, they should try to utilize their network, consisting of “opinion leaders, universities and industry associations” in the best way to get market intelligence (Renko et al., 2005, p. 264). According to Renko et al. (2005, p. 264) Biotech companies are dependent on their network’s support to commercialize their product. Jonas & Clifford (2005, p. 807) agree on that, calling collaborations and partnerships “key success factors” in overcoming he industry’s challenges. Where in bigger companies the role of gaining market intelligence is usually covered by person in a marketing position, smaller Biotech firms can generate these market insights by interacting with their network (Renko et al., 2005, p. 264).

3.3.9 Cost Structure

The cost structure is an important factor of the business model and can vary depending on the actual business. Different models will have other fixed and variable costs than others, depending on if a low cost product is pursued or higher cost premium products and services. It is obviously important to take costs into consideration in order to shape a profitable business model (Osterwalder & Pigneur, 2010, pp. 40).

As seen in the introductory chapters, R&D costs during the clinical phases are immense and will probably be the highest cost factors for Biotech SMEs. In addition, Mets et al. (2007, p.19) mention the cost of IP protection. Patents are a financial burden for the company, especially startups, wherefore the authors recommend different ways of protecting IP, through trade secrets for example, to lower the patents costs if the introduction on the market is still far away.
3.4.1 Choice of Business Model Framework

Mapping the biotech business can be helpful to create a sound business model and give direction to create and capture an innovation’s value. Osterwalder & Pigneur’s (2010) Business Model Canvas is built on value capture and creation, as most other business models are. At its core, the Business Model Canvas wants to map out “how a company intends to make money.” (Osterwalder & Pigneur, 2010, p.15). As explained in 1.2.2, we see that especially biotech SMEs struggle to achieve profitability. Showing different business models in chapter 3 and how they increased in complexity, intends to demonstrate why we choose the business model canvas over other possible business models.

We want to give an example for why the increased complexity of the Business Model Canvas appeared to be more suitable: Baden-Fuller & Haefliger (2013, p. 421) last point of monetization mainly involves pricing, as well as timing and effectiveness of invoicing. These are especially for pharmaceutical companies not immediately relevant, since the commercialization of the product can happen decades after discovery of a new component. More necessary, would be to look at the cost structure, which is not as clearly defined in Baden-Fuller & Heafli- ger’s (2013) business model, as it is in the Business Model Canvas (Osterwalder & Pigneur, 2010).

Chesbrough & Rosenbloom’s (2010) business model shares many characteristics with the Business Model Canvas, such as cost- and revenue structures, possible alliances and customer segmentation to name a few. However, there are a few dimensions we think Chesbrough & Rosenbloom’s business model is lacking, most importantly the key activities and resources, which can be found in the Business Model Canvas. For instance, the building block of key activities, which can be summarized as the most important actions to maintain the company (Osterwalder & Pigneur, 2010, pp. 36). In Baden-Fuller & Heafli- ger’s and Chesbrough & Rosenbloom’s business model this dimension is not as clearly defined as it is in the Business Model Canvas. However, they see customer identification as one of the first and important steps in building a business (Baden-Fuller & Heafli- ger, 2013, p. 420; Chesbrough & Rosenbloom, 2002, pp. 533). Looking at pharmaceutical SMEs, identifying customers is an important first step, but most activities will revolve around the research, which can take up decades. Therefore, having this additional building block of key activities, allows to better describe the reality of pharmaceutical businesses. If we had used the other business models, this information could have been excluded or it would have been at least up to our interpretation on how to include them.

We therefore think it is of advantage to use the Business Model Canvas with more dimensions, as it reduces the amount of interpretation done by the researchers, as well as its comparability with future research utilizing the Business Model Canvas. Having clearly defined building blocks, which are easily operationalized for this thesis’ semi-structured interviews, which will be discussed in more detail in the next chapter. We therefore think that the Business Model Canvas, in our eyes a superior business model compared to the others presented previously, is a relevant tool of analysis in this context.
4 Practical Method

This chapter presents the practical method for this thesis, i.e. data collection and analysis. The chapter also includes a discussion of how we have addressed ethical considerations and quality criteria. The methodology underpinning these choices was presented in chapter 2.

In general, research is characterized by a systematic data collection and interpretation to achieve a research goal. This also implies explaining the used methods, the relevance of the results and what limitations might apply (Saunders et al., 2006, p.5). Saunders et al. (2006, p.6) argue that business research has twofold goals. One is to ensure the advance in scientific knowledge, and the other is to address real-life challenges of business organizations. Accordingly, the goal of this thesis is to add knowledge to the scientific view of biotech SMEs business models and hopefully create some insights for practitioners on how to deal with the industry’s challenges. To achieve this goal, we conduct semi-structured interviews in a comparative case study. The study has a mixed deductive and inductive research approach, where qualitative data is explored and applied to existing theory. The practical methodology follows the “Seven stages of an interview inquiry” by Flick (2007, pp. 35). The seven stages are:

1. Thematizing
2. Designing
3. Interviewing
4. Transcribing
5. Analyzing
6. Verifying
7. Reporting

4.1 Thematizing

The first step consists of asking basic questions on why, what and how of the interview (Flick, 2007, pp. 37). The why refers to the purpose of the study, already described in the sections 1.6 and 2.3.1. In short, the aim is to understand how biotech SMEs cope with their industries challenges, especially considering that many SME are struggling to be profitable. The what question is about clarification of the study’s theme and a theoretical conceptualization of the phenomenon (Flick, 2007, p.39). The investigation in this thesis follows the theoretical framework of the business model canvas. This has the implication that our results will be analyzed based on the concept of business model canvas. The “how” of the study refers to the procedures and techniques used for the interviews (Flick 2007, p. 41). At this stage the purpose is to get familiar with different techniques and deciding which to apply. This leads to the next step: Designing the interview.

4.2 Designing

Carefully planning and designing the interviews lays the foundation for the analysis and reporting of results afterwards (Flick, 2007, p. 50). This study conducts semi-structured interviews with a total of 10 informants. As established in the methodology chapter, the
thesis follows a qualitative case study strategy, and more specifically we have chosen to compare multiple cases. The practical details of how we carry out this strategy are explained in the following sub-sections.

4.2.1 Qualitative Data Collection Method

According to Saunders et al. (2009, p. 318) there are three main methods for qualitative collection of primary data through interviews: unstructured, semi-structured and structured interviews. The distinction between them is largely found in the degree to which interview questions are pre-determinately standardized.

The unstructured interview has no pre-determined questions and allows for a free and fully flexible conversation with the informant concerning the topic and research question at hand (Saunders et al., 2009, p. 602). This holds the advantage that the informant can speak freely and contribute additional insights to what the researcher on beforehand may have expected to gain. Furthermore, the questions and conversation can vary greatly between each interview conducted in the study. This is in contrast to the structured interview, during which all informants receive the same pre-determined questions, the questions following a pre-set order (Saunders et al., 2009, p. 601). The structured interview holds the advantage that it facilitates comparability between data from the respondents and also it ensures that the respondents cover the insights which the researcher believe is needed to answer the research question.

As implied by its name, the semi-structured interview allows to develop a set of questions prior to the interview, yet it opens up for more flexibility than the structured interview since it allows the researcher “to vary the order in which questions are asked and to ask new questions in the context of the research situation” (Saunders et al., 2009, p. 601). As such it is a method which takes advantage and lowers the disadvantages of both the structured and the unstructured method, and is the method we have chosen for this thesis. Structured interviews seemed not to be appropriate due to the explorative character and predetermined questions might not allow to learn about new relevant parts of the business model. Unstructured interviews on the other hand would support the explorative character, but since the research is based on the business model framework, it might be difficult to relate the data to the certain parts of the framework. The semi structured interviews follow a list of themes or questions but the answers can be open (Saunders et al., 2006, p. 312). This allows us to establish questions based on the business model canvas, but also keep an explorative character.

There are, however, potential disadvantages with using interviews that can be noted. The person interviewed might by itself not be able to give the necessary details to establish deeper knowledge, simply because the person interviewed possibly does not know. As Eisenhardt & Graebner (2007, p.28) suggest, that the interviewed might be image-conscious and in retrospective try to make sense of their actions. March & Sutton (1997, p.699) also mention, that interview data could be influenced by a retrospective bias, in which participants reconstruct the past in a narrative, fitting with their current beliefs. This could give an unclear picture of the real cause and effect structure of the business model and possibly threaten the research’s validity.
4.2.2 Sample

This thesis is a comparative case study. As stated in the methodology chapter, we define one case to equal one company. In total the thesis includes four cases for which the purpose of the empirical investigation is to map and identify their respective business models and then compare the business models to each other. The main selection criteria we have set for these companies are 1) that the core product of their business is a biological product and 2) that the companies can be defined as SMEs. The first criterion is further nuanced by the intention to investigate potential differences and similarities between the business models of pharmaceutical and non-pharmaceutical SMEs, which lead to two of the companies selected for the study being pharmaceutical SMEs, and the other two being non-pharmaceutical. Meaning that the pharmaceutical SMEs are developing drugs that must go through the strictly regulated clinical phases before they can be commercialized, while the products of the non-pharmaceutical SMEs must not. The second criterion is fulfilled for all companies since none of the four companies have more than 20 employees.

As suggested by theory, the business model goes further than the borders of the focal firm (Zott et al., 2011, p. 1021). Therefore, we also include other informants from outside the SMEs – those who take part in their value chain, or otherwise share insight to different aspects of their operations. Four of these informants are industry experts, and include a venture capital agent, a consultant, an intellectual property advisor and a contract research manager. As partners who provide the SMEs with funding, support, managerial advice, and supply services for their development processes, they are well acquainted with the reality of biotech SMEs. They also provide insight to aspects of the business models where the SMEs themselves may be biased. For the same reasons we included two cluster managers of biotech clusters. These provide a higher-level perspective, because they work with facilitating growth and innovation for biotech in a regional network context.

Even if we include other informants, the level of analysis is still centered on the focal firm, i.e. the biotech SMEs. The thesis focuses on the business model of the companies, while we interviewed participants of the industry to validate and gain additional insights from different perspectives, which will also be discussed in the point of triangulation, section 4.6 Verifying / Truth Criteria. In total we have conducted 10 interviews. One for each of the four external experts and the two cluster managers, and one for each of the four SMEs. For the SMEs it was a criterion that the representative from the company we spoke with had insights as to why the business model is structured the way it is, and therefore we asked to interview the decision makers of the company. For three of the companies we interviewed the Chief Executive Officer, and for one we interviewed the Chief Marketing Officer, because the company suggested this person to be the one best able to answer the questions.

It was not easy to gain access to the companies. We first contacted the consultant through personal contacts, which lead to a connection to Pharma 2. In the following weeks, we contacted companies and experts by calling and emails. After interviews we asked if the informant could recommend others to interview, which lead to more contacts. As our knowledge about the industry’s actors and mechanisms gradually grew by each interview, it also became easier to identify potential informants.
However, it was a challenge that many of the potential informants we contacted did not respond or wish to participate in the study. For the industry experts and cluster managers nearly all we contacted responded positively to the request, but a far greater number of the potential company informants we contacted were negative. A possible explanation for this could be the necessity to hold the details surrounding patent-pending products that are potentially worth millions as secret as possible, thus it is reasonable to assuming they might be fearing of corporate espionage. We were aware of this issue before we started the recruiting process and ensured each potential informant that we would not ask for details about their products per se, but rather the value creation and value capture processes surrounding it. We also promised to ensure anonymity and offered to sign non-disclosure agreements. But despite our efforts, it is understandable that some companies might still have been sceptic.

### 4.2.3 Interview guide

The interview guide prepared for the semi structured interview contains the nine building blocks of the business model canvas. For each block we created simple questions and every building block is followed by a question regarding the challenges the informant may have faced. In the following table we give example questions and relate it to a building block and the theoretical foundation.

<table>
<thead>
<tr>
<th>Building Block</th>
<th>Example Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Customer Segmentation</td>
<td>When and how did you identify the customers/users for your product/service?</td>
</tr>
<tr>
<td>2. Value Proposition</td>
<td>When and how did you discover that the technology could be useful for a specific type of customer or user?</td>
</tr>
<tr>
<td>3. Channels</td>
<td>How do you communicate with your customers? (Including sales &amp; distribution)</td>
</tr>
<tr>
<td>4. Customer Relationship</td>
<td>Does your company currently have customers? How do you describe your interactions with (potential) customers and users?</td>
</tr>
<tr>
<td>5. Revenue Streams</td>
<td>Does your company sell a product currently? What is the major income source of your company?</td>
</tr>
<tr>
<td>6. Key Resources</td>
<td>What are the most important resources to support key activities?</td>
</tr>
<tr>
<td>7. Key Activities</td>
<td>What are the most important activities for the company to be profitable?</td>
</tr>
<tr>
<td>8. Key Partnerships</td>
<td>Is the company cooperating with other organizations?</td>
</tr>
<tr>
<td>9. Cost Structure</td>
<td>What are the biggest cost factors?</td>
</tr>
</tbody>
</table>

*Table 4: Building blocks and example questions.*
One will note looking at the questionnaire that we changed the order of the building blocks. Our intention was to ask about finance related questions at the end of the interview, since it might be a more delicate issue to talk about and we wanted to establish a trustful situation first.

4.3 The interview Situation

Presenting how the interviews were conducted and which techniques were used is part of the methodology and might assist the reader to understand how the results were created. The first step in conducting the interview is to set the stage and generate a relationship with the informant (Flick, 2007, p. 55). In the beginning of the interviews we give brief explanations of the thesis’ topic, the purpose of the interview, information on audio recording and emphasize that the informants stay anonymous and can make use of the non-disclosure agreement. The results of the interviews are sent to the informant in a summarized form pre publishing, in order to ensure nothing gets published they do not agree on. The first questions of the semi-structured interview will evolve around the informant’s personal experience in the biotech industry to gain momentum and create a relaxed atmosphere. During the interview one person will be the main speaker, while the other takes additional notes and might intervene with additional questions or comments. The interview is ended by a debriefing, where the informant can add any further comments regarding the content of the interview, as well as further suggestions regarding the interview itself (Flick, 2007, p. 56). Only one of the informants wished to make use of the non-disclosure agreement. Throughout the thesis the anonymized informants received a code word. Upon request we can provide anonymized transcripts or parts of the audio records.

4.4 Transcribing

Transcribing the interviews can be a difficult task, since the transfer from oral speech to written texts implies an interpretative element (Flick, 2007, p. 92). Neglecting this issue, “the interview research’s road to hell becomes paved with transcripts” (Flick, 2007, p. 92). The first step of transcription for this thesis will be the audio recording of the interviews. The next step of transferring the oral to a written text is a first step of structuring and analyzing the material. The transcription can vary in detail, including pauses in speech and other linguistic characteristics of the interviewed. This word by word, or verbatim, transcription style might allow to gain information ‘between the lines’ (Flick, 2007, p. 95) but appears to be too detailed for the interviews conducted in this thesis. Therefore, the transcription in this thesis will only be verbatim to a certain degree in order to capture the informants’ words as correct as possible, but elements like “uhms” or “ehm” are excluded.

An important aspect of transcribing is its validity. Since the process of transcription is a transfer from oral language to a written text it includes interpretation. The transcript decontextualizes the previous interview, like maps are abstractions of the actual countryside; emphasizing different characteristics depending on the intended use (Flick, 2007, p. 98). To support the validity of the research’s transcripts, we send the summarized transcription back to the interviewed for approval. Sending the whole transcription seems impractical and unnecessary, as it spans over 20-25 pages and not all information is used in the results section. An additional challenge in transcribing was that one interview was
conducted in German and two in Norwegian. Being aware that the translation from German or Norwegian to English might cause translation and interpretation errors, we conducted the translation carefully to maintain their meanings across translations. Therefore, the informants received the English summary so they could validate if our translation captured what they intended to say.

4.5 Analyzing

Semi structured interviews lead to qualitative data, which in its nature is not quantifiable like numeric results. The analysis has to identify the meaning in the data to develop a theoretical contribution (Saunders et al. 2006, p. 470). This challenging process can be supported by fitting the data to an existing framework for the business model to generate a point of direction (Saunders et al. 2006, p. 488). Qualitative data is contextual and thus the interpretation demands a lot from the receiver. It can be challenging and in worst case lead to wrong conclusions. However, it supports the purpose to explore and gain insight on how biotech SMEs face the industry’s challenges.

The thesis has an exploratory approach where we might find additional elements for the business model framework (Saunders et al., 2006, p.139). This approach is also useful to gain insight of the actual phenomenon and asses it from a different perspective, which suits our research, where we want to investigate biotech SMEs from a business model perspective (Saunders et al. 2006, p. 133).

The issue of analysis has to be addressed before conducting the interview and could already be included in the interview process itself (Flick, 2007, p. 102). Flick (2007, pp. 103) describes different modes of analysis and their different implications. As there are several modes of analysis and not a ‘one fits all’ method, we looked at two major modes of analysis: One mode focusing on the language and one focusing on meaning.

The mode of analysis focusing on language implies much attention to the speech and how information is presented through words (Flick, 2007, pp. 110). This could imply for a linguistic analysis if and how the interviewed person uses for instance “an active or a passive voice”, “personal and impersonal pronouns” or in which tempus the language is (Flick, 2007, p. 110). Several methods in the mode of linguistic analysis became popular recently in qualitative social science research, including for example analysis of the narrative or discourse. The purpose is gain more insights or verify the transcribed statements, when more details of the language are added (Flick, 2007, pp. 109).

The mode for analysis focusing on the meaning seemed to be more relevant for this thesis’ research. Three different approaches are explained by Flick (2007, p. 104). Meaning coding, meaning condensation and meaning interpretation. Meaning coding involves attaching keywords to segments of the texts. It also allows to quantify texts by breaking down text’s meanings in different categories. Meaning condensation implies translating paragraphs in short statements. This can help to summarize longer interviews and focusing on the most relevant issues (Flick, 2007, pp. 106). Meaning interpretation goes beyond the mere structuring of the transcription and includes already an interpretation about the content and what might lay behind it (Flick, 2007, p. 108).

For this thesis we chose first a mode of analysis focusing on the meaning. We do not see a language analysis as necessary, as our semi-structured interview has straightforward
themes and a deeper analysis of the language might not give more necessary insights. For
the analysis of the transcript, we utilize the method of meaning condensation, resulting in
summarized statements from the transcription. A point of direction for this analysis will
be the nine building blocks of the business model canvas. Having nine building blocks or
themes, allows to categorize the statements of the transcription and support a structured
analysis and reporting, as well as its comparability to other interviewed companies.

This approach is also similar to the thematic network analysis by Attride-Stirling (2001,
pp. 388). It is a method to break up the text to organize it, using a theme hierarchy starting
at the smallest, the basic theme, then organizing theme and lastly global theme. Our global
theme is the business model and the organizing themes are the nine building blocks. The
basic themes consist of the actual textual data.

Throughout the interviews we recognized emerging themes coming up that might be of
interest to draw a bigger picture. These reoccurred during interviews and didn’t fit directly
into the business model canvas. We used the approach of thematic network analysis, to
establish three themes of culture, communication and strategic issues, which were further
broken down in in smaller themes.

4.6 Verifying / Truth Criteria

A major concern of interview studies is their “reliability, validity and generalization”
(Flick, 2007, p.128).

Reliability refers to the consistency of results during the interviews (Flick, 2007, p. 122).
An easy example would be a tool to measure length. If this tool has a high reliability,
other researchers could at different points of time reproduce the same results. Using
the interview as a tool of measurement, a high reliability would mean that other researchers
at different points of time would receive the same answers or results (Flick 2007, p. 122).
Other problems arise with the transcription and analysis. As mentioned in point 4
Transcription, transcribing inherits interpretations, which might differ with different
researchers doing the transcription. Similar differences can arise in the process of analysis
(Flick, 2007, p. 122). In order to increase the reliability we use a semi structured interview
with nine main themes derived from the business model canvas. Carefully preparing the
interview guide will not only support the reliability of the interviews, but also the
transcription and analysis.

Validity refers to the truth of a statement (Flick, 2007, p. 122). Achieving the one and
absolute truth is obviously difficult to achieve. Nevertheless, the quality of the statements
or findings from the interviews can be improved. This process of validation includes
examining competing and falsifiable results to achieve a relative credibility (Flick, 2007,
p. 123). This process has to be done by the researcher continuously throughout the
research process. Flick (2007, p. 123) mentions three major tasks: “checking, questioning
and theorizing”. Checking refers to the continuous attempt to falsify the knowledge
propositions of the research process. Questioning asks for a constant alignment of the
researchers’ work with the purpose of the study. Does the research ask the right questions
for what it wants to investigate? Lastly theorizing concerns the conceptualization of the
phenomena. The question here is whether our concept of the business model is valid. We
try to achieve the first two points by being constantly in a critical discourse with our own
work, which led to many improvements of our thesis throughout the process, especially
due to discussion in our team, as well as in the work in progress seminars. For the validation of the business model concept we conducted an extensive literature review, which led us to believe that the business model canvas is a sound tool of analysis. Another important aspect to improve the validity of our findings is the process of triangulation, described by Saunders et al. (2006, p. 139), Woodside (2010, p.9) and March & Sutton. (1997, p. 699). The aim is to collect different data within a research project to improve its validity. We try to achieve this triangulation by involving 6 participants from the Biotech industry, for example a VC, OCRs or industry consultant. By validating our results with experts of the industry, we hope to improve the quality of the research’s results.

Generalization is another major concern in the analysis in the thesis’ research project. Referred to this thesis’ project it means whether or not the results are representative to other biotech SMEs, due to a limited number of interviews. Flick (2007, p. 126) gives two questions on the topic of generalization: Why and how generalize? The call for generalization of created knowledge implies the assumption, that there is one truth applicable to other situations in different points of time and place (Flick, 2007, p.126). We see this underlying assumption critical, especially in the highly contextualized issue of business models. Therefore, generalization might not be the first priority, but rather a possible transfer of produced knowledge to similar situations (Flick, 2007, pp. 126). We do not intend to find an absolute truth, but by presenting our results and how they were generated, the reader might be able to transfer this knowledge to other situations in different contexts. This leads to the idea of analytical generalization. The basic idea is, since the thesis results can’t be universally valid for all other companies, at least the thesis can offer reasoned statements on how other companies might benefit from the produced knowledge. It is important to present the results and its context in a clear and reasoned manner to allow the reader to decide, whether or not the results might be applicable to its own company (Flick, 2007, p. 127). This lead to the last step of reporting the results.

4.7 Reporting

Before presenting the results, it is important for the reader to know about the design and method used, which led to the findings (Flick, 2007, p. 130). This is represented in this thesis in the parts of methodology. It is further relevant to give sufficient information about the context of the interview, especially if quotes of the interview are used to present statements (Flick, 2007, p. 132). As the results are presented in summarized statements according to the meaning condensation mentioned previously, giving the reader information about the context can help to increase its readability. Quotes were added where they appeared to give the reader more insights and possibly make the results more interesting to read. Other methods, like presenting the interviews word by word or in a narrative way, appeared to be inappropriate due to its length and inconvenience for the reader.

4.8 Ethical Considerations

How have ethical considerations been addressed in this thesis? As argued by Bryman & Bell (2015, p. 135) it is unacceptable to conduct research that is likely to harm the participants. When conducting scientific experiments (such as those performed when the testing the efficacy of a potential new drug) the risk of physical harm is an obvious aspect
to consider. This thesis does not include any such experiments or physical interaction, so physical harm was never a likely outcome. However, harm may come in many forms. Saunders et al. (2013, p. 231) exemplify that harm may also come in the form of “embarrassment, stress, discomfort, pain or conflict”.

Besides ourselves, the ‘participants’ in our study were the interview informants. Naturally, it was our objective during the interviews that we gain as much information from them as possible, but we were conscious of the harmful effect it could have for them if we include the wrong kind of information in the published thesis. We were also aware of the possibility that the informants sometimes can be unfortunate and reveal more than they really want to. In the case of the companies this could for instance be technological information they want to keep hidden from their competitors, or for the experts it could be confidential information about their clients.

We sought to limit the risk of disclosing sensitive information through three steps. First, we carefully designed the interview guide such that it only included questions relevant to the research question and the topic at hand. For instance, there was no need for personal information besides their professional background, nor needed we knowing the details of the technology behind their products. Third, we made the focus of the interviews explicit to the informants prior to the interviews. By discussing what kind of knowledge we were after, and which knowledge we were not, the informants had the opportunity to reflect on what they should and should not say. As a result, when we offered to sign confidentiality agreements, most informants felt comfortable enough to recline. Third, we censored the data by avoiding as many identifiable attributes as possible, so that if we included something the informants did not want us to include, it would be difficult to trace it back to them. Fourth, we sent the informants a copy of the parts we wrote about them in the thesis. Thus they had the opportunity to inform us if there was anything they wanted to exclude.
5 Empirical Results

This chapter presents the empirical data from the interviews. Figure 6 shows how we grouped the interviews. First, the companies are introduced and followed by their perspective on the nine building blocks from the business model canvas. After presenting the companies’ results, the experts are introduced and what their perspective on the nine building blocks is. Lastly, the results of the cluster managers’ interviews are presented. In this order, we show first the results on firm level, then what experts think is common for the industry and in the last chapter of the results, what cluster manager think is the bigger picture. This different levels of interview partners is supposed to support a holistic approach, which is inherited in the business model (Zott et al., 2011, p. 1021). The focus is on the companies’ business model and the expert and cluster interviews serve as supplementing information to verify and build a picture of companies’ business model.

It might appear that data for a certain building block is mentioned in other building blocks as well. For instance, efficient timing in key activities is important due to increasing patent costs. The patent cost, which is a factor in the cost structure block, is still necessary to mention in the key activity to explain the context for the reader.

The last section named “Emerging Themes” consist of information that did not fit into any of the nine building blocks per se, but which recurred in most of the interviews and seem to influence the business model in its entirety. This section describes the challenges we identified, as well as political and cultural themes, that in our view effect the business model and are valuable contextual information to understand the biotech business models.
5.1 Case Companies

In the following, we present the case companies and the informants for each company. There are four companies and each are defined as one case. All four companies are SMEs whose operations are centered around biotechnological products. There is a distinction between pharmaceutical and non-pharmaceutical SMEs, meaning that two of the companies develop medical products (pharmaceutical), while the other two do not. This was also explained in the chapter for practical method.

5.1.1 Pharmaceutical Company 1

<table>
<thead>
<tr>
<th>Duration:</th>
<th>0:48h</th>
<th>Place:</th>
<th>Scandinavia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting:</td>
<td>Skype</td>
<td>Reference Code:</td>
<td>Pharma 1</td>
</tr>
</tbody>
</table>

The first of the two pharmaceutical companies is given the code name ‘Pharma 1’. The company was founded about 10 years ago by a university professor. While teaching and researching medicine, the professor discovered a compound which could be used to treat hormone related diseases. At first, the professor established one company, but eventually as more uses for the compound was discovered, the company was split into three, of which Pharma 1 was the latest to be founded.

The fact that Pharma 1 was formally founded ten years ago, does however not mean that the idea for this specific product originated ten years ago. As told by the current CEO of Pharma 1 (which is another person than the founding professor), the initial development and basic research started long before:

“I think actually [the professor] started some 20 years ago or something like that, but the company [Pharma 1] is only 10 years old.”

(The CEO of Pharma 1)

Pharma 1 has only one product, and this product is meant to target only one specific hormone disease. The product has not been introduced to the market yet. Before it can be introduced to the market, it must be approved through all three phases of the clinical trials. At the time when the interview for this thesis was conducted, the product had recently finished its phase 2a trials. As such, the company has spent 10 years reaching only halfway through the clinical trials. However, it is likely they will not need to spend 10 additional years before the product will be approved for the market, according to the CEO:

“If you have the funds and know what to do, then we basically say in pharma that it takes about 13 to 14 years from you get an idea chemically [until you can sell the product on the market]. You start to experiment first in animals. After six to seven years you are so far that you can move into men, and that takes an additional six to seven years. So we are actually quite late stage. If you look at a 13-14-year development, we have about four years left to go, so we are a little less than three quarters away. We are halfway through clinical development and we have all pre-clinical development behind us.”

(The CEO of Pharma 1)
The professor who founded Pharma 1 has kept as a part of the company’s ownership, and is still involved with the clinical development of the product. However, the professor is not the person in charge of managing the company on a daily basis. The company has employed a chief executive officer (CEO) and a chief operational officer (COO) to be responsible for management. The COO is responsible for running the clinical activities, while the CEO takes care of all other management- and administrative tasks. Among such tasks as the CEO is concerned with, is raising money for the product’s subsequent phases of the clinical trials.

In addition, there are five other employees involved with different areas of Pharma 1’s operations. Since the product has not yet been approved for sales on the market, the operational activities are focused solely on the process of product development. The other five employees are specialists on different areas of knowledge that are needed for the trials, such as clinical regulations and production.

The case informant for Pharma 1 is the CEO, who was hired into the company about one year ago. Same as the founding professor, also the CEO has a formal education in medicine. The CEO was first working as a surgeon in the 80s and 90s, before moving on to working the next 20 years in several large pharmaceutical companies in Scandinavia and the US. In the more recent years before becoming CEO of Pharma 1, the CEO co-founded and managed three other pharmaceutical companies.

5.1.2 Pharmaceutical Company 2

<table>
<thead>
<tr>
<th>Duration: 0:40h</th>
<th>Place: Scandinavia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting: Personal</td>
<td>Reference Code: Pharma 2</td>
</tr>
</tbody>
</table>

The second pharmaceutical company is given the code name ‘Pharma 2’. This company shares some similarities with Pharma 1. The first similarity being that also Pharma 2 has its operations solely focused on the clinical development of a pharmaceutical product. The company has registered a patent for a compound, and this compound has properties which can be used to treat a specific disease. And similar to Pharma 1, also Pharma 2 has come a good way into the clinical trials. At the time when the interviews for this thesis was conducted, Pharma 1 had secured funding and was preparing for phase 2a:

“We have done the phase 1 clinical studies. We’re finished. In these studies, you test for safety. We have done that, and we have secured funding for performing the phase 2a.”

(The CEO of Pharma 2)

Another similarity shared with Pharma 1, is that the discovery of Pharma 2’s compound was made at the University. However, in the case of Pharma 2, several researchers were involved in the discovery and founding of the company. And, unlike Pharma 1, these researchers chose to stay and remain in control of the company’s key management roles.

The case informant for Pharma 2 is the CEO. This person was one of the co-founders of the company. The CEO is known as one of world’s leading scientists in this person’s field of study. The CEO has been working with pharmaceutical research ever since the beginning of this person’s professional career. During this time, the CEO has also been
involved with multiple biotech startups, both in Scandinavia and the US. Like the other co-founders of Pharma 2, the CEO still is employed by the university, working 20% of as a professor at the university and 80% as CEO of Pharma 2.

The exact time for discovery of the compound and founding of the company was not presented explicitly during the interview with the CEO, but it was told that the company has been working to develop a treatment for the disease for about 12 years. While the CEO spent 20 years of researching another field of study, another of the co-founders continued researching the disease which the company now is developing a treatment for. When this co-founder had made progress, the company switched its focus from another area to this current one:

“We did this [other field of research] for 20 years. In the meantime, [the co-founder] continued with the [disease]. And then when we were done with the early work and development, I felt that I wanted to go back to [the co-founder’s field of research]. Then I started doing an academic switch of the company, which I think is 12 years ago.”

(The CEO of Pharma 2)

5.1.3 Non-Pharmaceutical Company 1

<table>
<thead>
<tr>
<th>Duration: 1:04h</th>
<th>Place: Scandinavia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting: Skype</td>
<td>Reference Code: Non-pharma 1</td>
</tr>
</tbody>
</table>

The first of the non-pharmaceutical companies is given the code name ‘Non-Pharma 1’. The greatest difference between Non-Pharma 1 and the two pharmaceutical companies in this study, is that the Non-Pharma 1’s products are not meant for use in the body of animals or men. The company is a supplier of compounds that are meant for use in diagnostic tests. It has a marine profile, as the compounds have their origin in marine plants and fish. Also, another difference from the pharmaceutical companies, is that Non-Pharma 1 develops and sells multiple products. The company is not concerned with basic discovery of the compounds, but licenses patents from external actors. The company then does a relatively short product development process, lasting normally no longer than one year, before it introduces the new product to the market.

The case informant for Non-Pharma 1 is its Chief Marketing Officer [CMO]. This person has a formal education within biotechnology as well as an MBA and a second PHD, and was working as a researcher at a university before joining Non-Pharma 1. The CMO has now been with the company for 12 years, ever since before it was formally founded:

“I started here in 2004. The [diagnostic products] was a department in a larger company, which mainly worked on [pharmaceutical development of a product]. The [diagnostic products] were just a small, cash-providing part of it.”

(The CMO of Non-Pharma 1)

The department was small, and had only 1 customer. Besides the CMO, there were only 3 other persons working in the same department. The rest of the company was concerned with pharmaceutical development, much like that of Pharma 1 and Pharma 2. Eventually,
the number of customers increased, and it was decided to move the departments operations into a separate company.

“My role was to do everything that was not science. It meant finding customers, defining a market plan, preparing the shipments, sending things, making this [diagnostic test] business visible in the World. And, for some reason, I found some new customers. We were able to grow the business, and [about 8 years ago] it was decided to split this department into a new business.”

(The CMO of Non-Pharma 1)

After the founding of the new company, the number of customers continued to increase. Along with the customers, also the number of employees, equipment and products grew. Thereby also the costs increased. This has taken its toll on the company’s finances, but it seems the expansion of the company’s operations has been a successful one:

“[The last 5 years] we have been about 15 people in the company. At the same time, we also built out with more products, and also invested in production technology. So the last 5 years or so, we haven’t been on the plus side economically. [...] but we are sort of okay now. Our part of the company is going to be cash positive next year. So, from now on, we are just going in the right direction.”

(The CMO of Non-Pharma 1)

### 5.1.4 Non-Pharmaceutical Company 2

<table>
<thead>
<tr>
<th>Duration: 1:03h</th>
<th>Place: Scandinavia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting: Skype</td>
<td>Reference Code: Non-Pharma 2</td>
</tr>
</tbody>
</table>

The second non-pharmaceutical company is given the code name ‘Non-Pharma 2’. This company has an agricultural profile, as it has developed and is selling a product targeting agricultural genetics companies. Non-Pharma 2’s product could be described as a sort of ‘added feature’, which enhances the performance and quality of the genetic companies’ existing products. The genetic companies then sell their enhanced products on to farmers, who are the product’s end customers.

The company was founded about 8 years ago. Similar to Pharma 1 and Pharma 2, Non-Pharma 2 has only one product. The first research and development was made by Non-Pharma 2’s parent company. Like Non-Pharma 2’s customers, the parent company is a genetics company. It started development of a product intended for its own use. Today, the parent company buys the product from its subsidiary, Non-Pharma 2. Non-Pharma 2 introduced its product to the market about 5 years ago, and is now selling the product to multiple genetic firms (not just its parent company) on an international basis.

“There was research going on in the mother company. [Non-Pharma 2] is owned by [the parent company], mainly, and [the parent company] is selling genetics. The research which is the basis for the [Non-Pharma 2] technology, it started in [the parent company] in 2001. So there were research activities in [the parent company] which lead us to realizing that this technology is to interesting that it
has international potential. And then we started [Non-Pharma 2] in 2008, with intention to start international commercialization.”

(The CEO of Non-Pharma 2)

Non-Pharma 2’s case informant is their CEO, who has an educational background in business and administration. Before becoming the CEO of Non-Pharma 2, the informant worked in a broad range of industries before being hired as the CEO of Non-Pharma 2. The CEO entered the management position right around the time when the product was first introduced to the market, about 5 years ago. This was a couple of years after Non-Pharma 2 became a separate organization from its parent company.

Like Non-Pharma 1, Non-Pharma 2 is a business in growth. Since the CEO entered the company about 5 years ago, the number of employees has increased from 3 to 20. The income from customers has so far not exceeded the costs of the R&D and increased marketing efforts, but the CEO says there is a positive outlook for the company’s future:

“It’s making a loss and has been eating the equity we got in 2011, but we’re not far from reaching a breakeven. If we get 1 or 2 more customers the company will be making surplus”.

(The CEO of Non-Pharma 2)

The CEO tells of good prospects and high goals for the company’s future. Currently, Non-Pharma 1 is the only company on the market who delivers this kind of product, and the technology is protected by patent. The company runs an aggressive marketing campaign to make it happen.

“There are quite big hopes that we will succeed internationally. We have set the goal that we will build the World’s strongest brand in this industry. Then I hope and believe that we will earn a lot of money.

(The CEO of Non-Pharma 2)

5.2 Company Results

The following section presents the results for each of the nine building blocks. Each building block is shortly described as a reminder for the reader, detailed descriptions are found in the theoretical part of the thesis. As mentioned in the chapter of research design, the following presentation of results intends to describe the business model and the challenges the companies face.

5.2.1 Key activities

In essence, key activities are the actions that keep the company alive (Osterwalder & Pigneur, 2010, pp. 36). Science is at the core of any biotech firm, so naturally, research and development [R&D] is the common most important activity for all the four case companies. Essentially, the biotech companies are selling high-technology products. Research is required both for the biomaterial (or its properties) to be discovered, and to turn the discovery into a product which can be sold on the market. Without the R&D, there would be no biotech product, and there would be no biotech company. But even if R&D is a common activity among all the four case companies, there are differences
between them both in which form the R&D takes place, and in how much time the company spends on it, relative to other activities.

For the pharmaceutical companies, R&D takes up near all the time and resources of the firm. Because of the strict regulations to medicinal products, Pharma 1 and Pharma 2 must complete the clinical trials before their products can be sold on the market. Though both companies have come about a decade into the clinical development process, they still are years away from completing the trials. Hence, there is little point in spending too much time on marketing activities and sales, so long as there is yet no product to be sold. Rather, the pharmaceutical companies focus most of their time on the R&D involved in the clinical trials. The CEO of Pharma 2 explains that a lot of this work comes with the strict regulations set for the clinical trials, and that the demands increase as you move from one stage of clinical development to the next. He mentioned the examples of GLP and GMP:

“You have to do GPL [Good Laboratory Practice] when you do tox [toxicological] studies in animals. In our case we’ve been running in dogs and rats. You make a 28-day tox study. Then the compound has to be produced on the GLP. But when you go into man, then it’s GMP [Good Manufacturing Process], which is 10 times stricter. You have to control for everything. Basically, the water has to be controlled for everything, everything has to be, you take notes of everything. I mean, if something goes wrong, you have to go back and see everything. You won’t get approval unless you control GMP. It’s a much stricter form of GLP.”

(The CEO of Pharma 2)

Mostly, the pharmaceutical companies are concerned with R&D and clinical trials. However, there are a few activities worth mentioning that are ‘non-clinical’, yet crucial in order to keep the companies alive. According to the CEO of Pharma 2, the most important thing to begin with is to patent the possible product. Without the intellectual property protection in form of a patent, the company has no product to sell and is ultimately without value.

“The only thing that counts in this business is patents. Really the only value you have in a biotech company is patents, and the rest has no value. The company is actually useless. The company structure is useless, it’s all in the patent.”

(The CEO of Pharma 2)

The patent is crucial, because it secures the potential future value of the product. The CEO of Pharma 2 further explains that one should be careful not to make any mistakes during the patent process. One such mistake could be to make the patent too narrow. E.g. by not registering the patent in enough countries, or not covering the entirety of the discovered compound.

“We work in these small molecules. What you really want is a patent that covers the molecule. If you get a patent on a molecule, the structure of the molecule, you can use it for any disease. That we have done, and we have it granted in the EU, US and China and a lot of other countries. It will be a World-wide patent.”

(The CEO of Pharma 2)
By registering the molecule on a World-wide basis, Pharma 2 has ensured the value of their patent. First, because even if their current product development process (e.g. clinical trials) should at any point fail, meaning the molecule cannot be used the way it first was intended, the molecule could still be utilized in a different way. Second, they have ensured a high value of the product, if and when it is ready to be introduced to the market, because it will be protected against competition for a certain period of time.

Pharma 1 and Pharma 2 have no revenues from sales, hence they depend on external funding in order to cover their costs. Ensuring a high value of the patent, increases the chances for the pharmaceutical SMEs’ survival, because it makes the product more attractive for large pharmaceutical companies to buy once the clinical development is finished. This prospect again makes the SME more attractive to invest in.

“When you start off and you have an idea, and you make it to your father-in-law (or God knows who that have any money), or so-called business angels can support you for some years. [...] When you get into later stage, you almost inevitably have to revolve into capital. [...] We have private investors that have invested in [Pharma 1]. Basically, they want to get a return on their investment, and they would like to do a so-called exit. There is a limit for how many years they want to be in a company. When we have finished the phase 2b study [in about 2 years], we intend to probably sell the company or the assets.”

(The CEO of Pharma 1)

Both Pharma 1 and Pharma 2 intend to sell the ownership of their products to large pharmaceutical companies before phase 3 of the clinical process. As explained by the CEO of Pharma 2, this is necessary because of the massive increase of costs that follows with the next stages of the clinical trials. We asked the CEO of Pharma 1 if it could be possible for an SME to make it alone and take the product all the way to the market:

“In drug development, there is no way. Biotech [SMEs] can take it through phase 2a. In our case we will use 60 patients. But phase 2b, that’s a thousand patients. I mean, the costs are enormous. And then you have phase 3, which is astronomic. There is no way. You need to have big pharma.”

(The CEO of Pharma 2)

Because the SMEs cannot make it to phase 3 themselves, they depend on large pharmaceutical companies buying or licensing its assets (i.e. the patent) to gain any value from their current and past R&D activities for themselves. Because of this necessity, Pharma 1 proactively began seeking out potential buyers about 1 year ago.

“You know, you cannot the day when you have finished the study, start calling companies that have never heard your name before and say “Would you like to buy the company?”. It’s a long process, so I already initiated it [about 1 year ago]. I was in [the US] and talked to almost 20 companies, to present what we have and to get their feedback as to the development plan and the market. A number of these are very interested in what we are doing, and could potentially be the ones that we either make a cooperation with already at this stage, or that we license it out with when we are finished with this study that we are working on now, or actually sell the entire company to.”

(The CEO of Pharma 1)
It was stated earlier that the pharmaceutical companies do not spend much time on marketing and sales. This is true for the earliest stages of clinical development, especially in the pre-clinical trials. But as shown by the previous quote by the CEO of Pharma 1, efforts spent on finding buyers (i.e. large pharmaceutical companies) increases as the clinical trials moves forward. It also seems like these efforts do not start until after a certain point. According to the CEO of Pharma 2, there is little use in spending time and resources on finding buyers before the company has enough proof of the product’s potential value.

“There is a dialogue. You talk to them [the large pharmaceutical companies] early on, but the real interest starts when you can show efficacy in man. You have to go to the human [i.e. to test the product on humans] to get the real value out of it, you have to do clinical trials. It’s very rare that they in-license something that hasn’t been in man.”

(The CEO of Pharma 2)

Because the pharmaceutical companies have not yet finished their clinical trials, they are not allowed to sell their products on the market. And, because their objective is to sell off their patents to large pharmaceutical companies before the trials are completed, it is likely they never will need to be concerned with marketing strategy or employ sales personnel. This is something the large pharmaceutical companies will take care of in the future, given that the product ultimately gets approved through all phases of the clinical trials. The activities performed by the pharmaceutical companies can be summarized into three main categories: 1) R&D and clinical development, 2) secure funding from private investors, and 3) partnering up with a large pharmaceutical company, and/or finding a large pharmaceutical company to buy off the company’s intellectual property.

Unlike the pharmaceutical companies, Non-Pharma 1 and Non-Pharma 2 have completed their initial product development. Both companies have chosen to keep ownership of their products. Rather than selling off the companies once the R&D finished, they are now doing the manufacturing-, marketing- and sales- activities themselves. When asked which activities are the most important for the company to stay alive, the CMO of Non-Pharma 1 emphasized interaction with customers as the most important.

“Customers. You need them. One thing is that you need them for selling stuff to them, but you also need them to get feedback on what’s needed in the market. What products do they need? How do they want them? How do they want them packaged? Everything of this information is important for business – answers you get from customers. So, I would say, getting the customers is the most important thing a business can do. At any stage. How you do that, that’s a different story. Getting a customer is the most important thing, you should do that even before you start producing anything.”

(The CMO of Non-Pharma 1)
the local university, from which Non-Pharma 1 licenses the right to use the compounds in their products. Feedback from customers decides which of the discoveries they take forward into product development.

“We do everything, except the bio-discovery. We have a tight contact with the University. They do a lot of bio-discovery. They find these [compounds], describe a little about what they do, and guess what they could be useful for. When they have an idea, we get a license, then start going asking customers if it is worthwhile pursuing. If we find out it is worthwhile, we start process development.”

(The CMO of Non-Pharma 1)

Besides interacting with customers and keeping tight contact with the university, Non-Pharma 1 does their own manufacturing, has its own R&D department and has employed its own personnel for marketing and sales. In this respect the non-pharmaceutical companies are similar, because also Non-Pharma 2 has a R&D department and does its own manufacturing, marketing and sales. Another similarity is that although Non-Pharma 2 has not yet introduced additional products to the market, also this company is investing in R&D in order to expand their product portfolio in the future.

“We are doing research and development on our own. We have our own R&D department with 10 researchers, who are doing research full-time; further developing the technology, documenting [its effects] and transferring [its properties to be used in new products]. Today the technology is used in [a specific animal]. The idea is that in the future it's also going to be used on other species.”

(The CEO of Non-Pharma 2)

From the parent company began the initial R&D, it took 10 years before Non-Pharma 2’s product was introduced to the market. For the same reason, Non-Pharma 2 can expect to spend substantially longer time doing R&D before it finishes any additional products than Non-Pharma 1, which spends only a maximum of 1 year per each of their product development projects. The CEO explains that Non-Pharma 2’s longer development time is due to the nature of genetics, and the time it takes to test the product’s effect in animals.

“What is special for us, is that we are dealing with slow technology. When we need to prove that our technology works, we don’t get the proof until after [the animal] gets pregnant and after we know if the offspring is healthy without any deformities or anything like that. So it can take a year from we start an experiment until we get an answer, because the animal is pregnant for [a certain amount of months]. So there long processed for us to prove that the technology works.”

(The CMO of Non-Pharma 1)

To summarize the key activities, research and development are the common most essential activity performed by all four of the biotech SMEs. For the pharmaceutical companies, R&D takes up near all of the firms resources and time. Because these firms rely entirely on funding to cover their costs, and because they after a certain point cannot expect to continue the clinical developments on their own, it is also important that they spend time on securing funding from private investors and attract the interest of large pharmaceutical companies. The non-pharmaceutical companies have on the other hand already commercialized their initial product development, and are selling their products on the market. Non-Pharma 1 and Non-Pharma 2 therefore have high focus on attracting
and interacting with customers, in addition to performing their R&D activities. They also do their own manufacturing.

5.2.2 Key Resources

Key resources are the means to carry out the key activities (Osterwalder & Pigneur, 2010, pp. 36). When asked what is the key resource of the company, the CEO of Pharma 2 emphasized intellectual and financial capital as their two most essential resources. As already shown in section 5.2.1, the CEO of Pharma 2 especially emphasized the patent (which in terms of being intellectual property, is one form of intellectual capital) as the fundamental resource of the company:

“The only thing that counts in this business is patents. Really the only value you have in a biotech company is patents, and the rest has no value. The company is actually useless. The company structure is useless, it’s all in the patent.”

(The CEO of Pharma 2)

Though the other case informants did not state the importance of patents as explicitly as the CEO of Pharma 2, they too have patents at the core of their business models. Like Pharma 2, Pharma 1 has a patented compound which is the basis of the pharmaceutical treatment that the company is developing. Non-Pharma 1 licenses patents from the university environment, and these patents are the basis for the products which they ultimately sell to be used in diagnostic tests. Non-Pharma 2 has developed a new technology to optimize the genetic companies existing products, for which they have a patent that protects the company from threats of competition.

Other forms of intellectual capital are important too. When asked what is the key resource of Pharma 1, the CEO immediately answered “experience”. To start a company and work in this industry, experience and education in biology is important. Gathering experience from working in different departments or positions in the pharmaceutical industry can be a valuable resource. As a consequence of experience might another important resource develop: a network. Networks the CEO of Pharma 1 described as important, because they simplify the access to other resources. For instance, contacts that might have knowledge about certain types of production or new personnel.

“Experience. When you come out of University, you are actually quite narrow. When I was a young physician, [my company] had a fantastic program where we were sent to the different departments and you got some experience from the neighboring areas. [My co-worker] has a similar career. We have spent a lifetime in this area, and that means we have seen most of the things before. I wouldn’t say we know how to solve necessarily each and every thing, but we have seen a lot of things before, and we have a huge network we can call and ask: “Do you know anybody who has worked with this before?”. In your network you will very quickly be able to find someone that somebody else recommends you to. I think that’s what it’s about”

(The CEO of Pharma 1)

Also for Non-Pharma 1 intellectual capital is given to be the key resource. More specifically, The CMO describes three types of intellectual capital to be important: 1) knowledge about the customers, 2) knowledge about the product, and 3) knowledge about
how to do business. Together, these play an important role in near all of Non-Pharma 1’s operations. As was exemplified in section 5.2.1, the customer knowledge plays a significant role in Non-Pharma 1’s process of finding new products to develop. The CMO further adds that the customer knowledge does not come easily:

“Customers should be your best friends, because it’s so important that you keep the same customers over several years. It takes years to get to know them, to make sure that you’re talking with the same words. But also for the companies to know us, to be able to trust that we deliver what they expect us to deliver.”

(The CMO of Non-Pharma 1)

And naturally, when developing the product, Non-Pharma 1’s researchers must have sufficient knowledge about the chemistry behind the biotechnology. Perhaps a bit surprisingly, the same knowledge which is required to develop the products, is also required to sell them. To explain exactly the importance of intellectual capital, the CMO of Non-Pharma 2 tells us that without a PHD in biotechnology, their sales personnel is not able to communicate with the company’s customers. For the same reason, the CMO decided to do a PHD after having started in her position in Non-Pharma 1:

“I started out as a civil engineer in biotechnology. Then, after I started here, I also took a PHD in a completely different field in plant physiology, because I needed the 3 extra letters on my business card. And that’s not even a joke. In the global World you need to have a PHD to be able to communicate with molecular biologists, because everyone has a PHD. Otherwise, you are not working in this business, because it’s just too complicated.”

(The CMO of Non-Pharma 1)

The CMO continues, and tells us that she also did an MBA, because she felt it was necessary in order to do her job well:

“Since I was working in marketing and sales, I also needed an MBA. So when I was finished with my PHD, I took the MBA. As I use to say: That’s the least you need in this business. Because it’s small companies, you need to cover a lot of roads. Lots of people I know have huge amount of education. I think it’s important to tell that it’s a lot knowledge needed to start a business, and also to build a business. I started in an established company, but it’s the same challenges as in a new startup company, because the field [i.e. biotechnology] is developing so fast, and companies are small.”

(The CMO of Non-Pharma 1)

In addition to its patent, intellectual capital is a crucial resource also for Non-Pharma 2. Similar to Non-Pharma 1, Non-Pharma 2 utilizes business knowledge, product knowledge and customer knowledge in the company’s operations. Especially the importance of product knowledge (i.e. knowledge within biotechnology) comes to show in how many of the company’s employees are working in the R&D department. As many as 10 out 20 employees are working full-time with doing research:

“When I started [about 5 years ago] we were 3 employees, now we are 20. [...] We have our own R&D department with 10 researchers, who are doing research full time. [...]”

(The CEO of Non-Pharma 2)
In contrast to Non-Pharma 1, the CEO of Non-Pharma 2 do not see PhD not as required for sales and marketing positions. All of Non-Pharma 2’s marketing and sales employees have educational backgrounds within business and marketing, and none have biotech-oriented degrees. The Non-Pharma 2 informant highlighted however that it is important for their sales personnel to “learn the industry”. We mentioned how another company in our study had said it was necessary to have a PHD in order to do sales, and asked the CEO if their sales people are educated in biotechnology:

“No, it’s marketing. Here it’s not like that. I also doubt it’s like that everywhere else, but it’s a tradition. It depends a bit on who’s the target segment, of course. But for us, who’s selling to the genetics companies, it’s about communicating. I mean, everyone’s got to learn the industry. If you come here with a master’s degree in marketing, you must learn what’s the situation for a milk farmer.”

(The CEO of Non-Pharma 2)

All informants emphasized intellectual capital as the key resources for their companies, under which intellectual property (patents) and human capital (i.e. different kinds of knowledge and experience) can be classified. But what about monetary and physical resources?

Pharma 2, Non-Pharma 1 and Non-Pharma 2 have all invested in physical resources. Pharma 2 has its own laboratory, and in the same building you also find their offices. Also Non-Pharma 1 and Non-Pharma 2 have their own laboratories and offices. In addition, they have invested in manufacturing equipment so that they can do their own production. A difference between the non-pharmaceutical companies is that Non-Pharma 2’s manufacturing facilities are permanently located in one place, while Non-Pharma 2 performs manufacturing at the various locations of their customers. Both emphasize that intellectual capital is their most important resource, however they acknowledge that their physical resources are not without significance.

In the case of Non-Pharma 2, the CEO reflects that the company would be able to scale its productions and grow even further than today’s potential, if the company manages to develop a solution where the employees do not need to be present at the customer’s location during manufacturing:

“We don’t have our own production facilities. It’s produced at the customer. [...] They call us and kind of order a production. Then we send a team out to the customer. However, it is a goal for us to develop a product where we deliver a chemistry set. Meaning that we deliver it, and then the customers can produce the [Non-Pharma 2 product] themselves by using their own employees. It’s only then you really can scale up the production from a couple of hundred thousand units to several million. So that’s some of the research we’re doing now, to simplify the production of the [Non-Pharma 2 product] so that it can be scaled up to larger volumes.”

(The CEO of Non-Pharma 2)

Non-Pharma 1, on the other hand, takes its manufacturing capacity into consideration when deciding which customers to target, and when deciding which products to develop. Because their production capacity is limited, the company does not want to take on products and orders which would require producing large volumes. Hence, there are some
groups of customers which the company deliberately avoids, because these would require greater volumes than Non-Pharma 2 can produce.

“We try as soon as possible to find out: “How much do you need of this?”, because that affects how we have to produce it. Sometimes you can produce in a bench-size scale. You can have from one liter to hundred liters, or thousand liters. For industrial [compounds] it’s several thousand liters. We are not going into that market, because we don’t want to build a factory that size. Now we have a one-room factory for everything we make, because we keep to the small stuff, or what can be made in high enough concentrations to keep it small. Just the rent of housing would be extreme.”

(The CMO of Non-Pharma 1)

In terms of physical resources, Pharma 1 does things a bit differently from the other companies, because it has a higher focus on cutting costs and keeping a lean business model. The CEO explains that this is a trend in the industry; companies outsourcing great parts of the activities which previously were performed by the company’s employers, and cutting costs that are of less importance to the company’s key activities, such as grand offices, and even lab facilities:

“Even the big companies outsource many things. I mean, in our case, we even outsource production. Basically, we outsource everything! [The COO] and I are sitting in a very small office, in the same office. We each have our own little desks, and that’s basically it. That’s the company. If you look around the building, I think there are 25 companies in the building, it’s very small. But of course, some biotech companies would have their own animal facilities, or at least a lab where they can do some primitive studies, but most work with outsourcing.”

(The CEO of Pharma 1)

The CEO of Pharma 1 further explains that this trend has something to do with the financial crisis, in combination with the high risk of failing the clinical trials. We asked if Pharma 1’s lean business model is typical for the industry at large:

“After the financial crisis this is more the model. When I started in biotech, [my company] had a really nice, super modern building with facilities, and you wouldn’t dream about it. Really nice. But you know, investors won’t pay for that anymore. They simply don’t have to pay for it. And since some of the companies are sold, or they go under, we basically don’t want to have to lease anything for more than 3 months, so that we can basically pack it up and be out of there over-night if it doesn’t work out. There’s a lot of insecurity.”

(The CEO of Pharma 1)

As for monetary resources, it was stated by the CEO of Pharma 2 that in relation to key activities, the company cannot do anything without first securing the funding, because the costs of R&D and clinical development are so high. In the case of the pharmaceutical companies, their costs are covered through funding provided by private investors. Also the non-pharmaceutical companies rely on funding to a great extent, because they have invested (and continue to invest) R&D projects. In their case, both Non-Pharma 1 and Non-Pharma 2 have received funding from their parent companies. (More about funding in section 5.2.8).
In summary, all the case companies emphasized intellectual capital as their key resource. Which exact form of intellectual capital was seen as the most important one varied somewhat between the companies, but knowledge and experience (be it protected in a patent or embedded in the minds of employees) were in any case the common most essential resources in enabling the firms to perform their key activities. Physical resources, such as equipment and facilities, seem to be of greater importance to the non-pharmaceutical firms, because their access to physical resources affects not only the volumes they are able to produce, but thereby also which customers they can target and which products they aim to develop. In comparison, the pharmaceutical companies have invested in less physical resources, but one more so than the other. Perhaps unsurprisingly, monetary resources are of high importance to all companies. The sources of the monetary resources, and how they are spent, is discussed more in depth under other building blocks.

5.2.3 Value Proposition

The value proposition is a statement of how the company seeks to fulfill the customers’ needs. In short this is about what value the company offers so that the customer chooses this specific product over its competitors (Osterwalder & Pigneur, 2010, p. 21).

Finding or developing a value proposition is a lengthy process, according to the CEO of Pharma 2. It usually starts with a discovery that appears to have beneficial characteristics at the university. This is followed by a critical evaluation. The first step is to show that it not too toxic, which is the point where most potential products fails. If the product shows useful attributes and is not toxic, it can be compared to the clinical need, which is the market.

The product has to be in some way an improvement to the existing drugs on the market, otherwise it will not receive any approval, according to the CEO of Pharma 1. A new drug can be better than existing one in two ways: either it is more effective or it has less aversive effects in the patient. It is also important to consider the usability of a new drug.

“You know, I love science, and I think it’s very exciting, but the problem is that you get so carried away with your own science and what your molecule may be able to do in a given model, that you sort of blinded run towards the market. Nowadays, maybe not 30 years ago, but nowadays, if you go to the market with something that’s good – maybe as good as the on the market that is already there, the pricing authorities will say “We don’t really need another Mercedes, we already have one.” So you really, very, very, very early on have to look at what you’ve got, and look if there’s a fit with a descent market need or clinical-medical need.”

(The CEO of Pharma 1)

From the Pharma 2 perspective, requirements by the big pharma are clear, as well as the licensing activities. This means it is clear for the biotech company, what kind of product is valuable to the big pharma.

Non-Pharma 1 follows also a critical evaluation, but including differences, since their product is not pharmaceutical. If an enzyme looks interesting, it has to be analyzed if it
also can be produced and shipped properly, since customers are found worldwide and shipping living material requires certain conditions.

Where Pharma 1 and 2 would look at the market of patients, Non-Pharma 1 is shipping the product to the customers who want to test the product, which results in more information about the customer needs that can be used to define the value proposition. Non-Pharma 2 developed their product themselves and tested it, which took more time as their product has to be shown throughout animal life cycles. It is a unique product worldwide and offers therefore a unique value proposition to its customers.

5.2.4 Key Partnerships

Key partnerships describe the network surrounding the focal firm that have a positive impact on the company (Osterwalder & Pigneur, 2010, pp. 38).

In the industry of biotech, companies heavily outsource. From contract research organizations to contract manufacturing organization, legal and business consulting, biotech companies can be very lean. This is the case for Pharma 1, which only has 2 of its employees working full time in the company. The others are considered by the CEO as employees, but in practice one could also see them as consultants, because they only participate in those occasions when the company is in need of their respective fields of expertise. The rest of the time they are working with other companies.

“We are 7 in total, but it’s very rare that all of us are together in the same meetings. So it’s usually [the COO] and me, and one or two persons on a specific topic. Like, for instance, how do we tackle the American FDA? We don’t need the consultants on production to sit in on that meeting, that would just be a waste of money.”

(The CEO of Pharma 1)

Pharma 1 outsource most of its activities and keeps a flexible work-force in order to save costs and keep a lean organization. They also outsource certain activities because this is something the pharmaceutical regulations require. The CEOs of Pharma 1 and Pharma 2 explain that the CROs [Contract Research Organizations] are necessary partners for the clinical trials. According to Pharma 2’s perspective, hospitals play an important role for the clinical tests, since these tests require certified institutions and is done by specialized companies, which know the strict requirements. Physicians were not involved significantly, except to find out in the beginning about clinical needs. There are no collaborations with other biotech SMEs like themselves, since developing their product requires decades of experience in a narrow area, which means that collaboration with others is limited due to lack of expertise by others.

“You use an outside company to do that. We’re not allowed to do the clinical studies ourselves. The clinic has to be certified. It’s extremely strictly regulated when you go into man. So you need to have very specialized companies to deal with it.”

(The CEO of Pharma 2)
"We have consulting on all kind of input from there [the CRO] about the laws and process about the regulatory authorities, about the legal... When we do this clinical study that we are raising money for at the moment, basically we will ask 3 different CROs how they would do it, how many patients, where they would do it, and what it would cost. Then we compare those and go back and discuss with them, and then we agree on something."

(The CEO of Pharma 1)

Another important partner is the university, since they discover new drugs which can be transferred to a possible product. Pharma 1 & 2 both keep a close relationship with their respective universities. Pharma 1 & 2 are still involved with the university through their staff, which is partly employed at the university. For instance, both the CEO of Pharma 1 and the CEO of Pharma 2 are still involved with the university through their respective universities.

"The University is enormously important. You can take Pharma 1 as an example, because it comes directly out of a university. I mean, it’s a spin-off of an idea or a research project that [the founding professor] conducted. So in essence, it’s everything, also in other companies. The idea in modern biotech is that universities and biotech companies should work closely together. And that’s actually a lot of fun. I probably have lunch in the student cafeteria two or three times a day, two or three times a week. It’s pretty common nowadays that students, professors and lecturers see each other regularly."

(The CEO of Pharma 1)

Non-Pharma 1 also keeps a close relationship with the university. They have a collaboration with the university’s technology transfer office, which gives them a right of first refusal. The right of first refusal means that in exchange for a certain fee, the firm is granted a right to consider if they want to license any new patents before they are offered to anyone else.

"When the University scientists find something, they have to think if it can become a product. They have to write a paper telling what it is and what they think it can be used for. If the University is patenting it, a company can go in as a partner and license it. You can get an exclusive license, and that’s what we do. Because of the close collaboration, we are paying a sum of money to have a first right of refusal."

(The CMO of Non-Pharma 1)

Non-Pharma 1 could in theory license from other institutions or companies, but all of their products has their origins from this agreement with their partner university. The CMO of Non-Pharma 1 believes there is a possibility that they will cooperate with other universities or companies in the future.

"We could. We are now going into a project with several players, and it could be that something is discovered by some of the others in the project. That would be either another company or another university. So far most of our compounds are sourced from [the local university] just because we are in the same building as them, and because they’re working in the same field as us."

(The CMO of Non-Pharma 1)
Besides the university, Non-Pharma 1 also cooperate with a research institute that supports developing the production process for Non-Pharma 2. For instance, the researchers can help to optimize the production of a new biomaterial.

“We have a collaboration with a research institute that’s developing production technologies. They are important to us, because they can tell a lot of general things for how to produce quicker, because they have a huge project on that. They help us make more compounds in less space, or making it a little differently. Whatever we need, we can discuss the problems regarding processes with them.”

(The CMO of Non-Pharma 1)

Unlike Non-Pharma 1, Non-Pharma 2’s core product was made by the company’s own R&D department, but they do report to have research collaborations with external parties.

“We are cooperation quite closely with an independent research organization. Buy a lot of research resources from that organization.”

(The CEO of Non-Pharma 2)

5.2.5 Customer Segments

Customer segmentation describes the possible customer groups of a company (Osterwalder & Pigneur, 2010, p. 21). For the biotech SMEs in this study, it is not necessarily intuitive who the customers are. From the interviews, we see that the biotech SME’s customers can be classified as to whether they are 1) the paying customers that are directly interacting with the biotech SME, or 2) the customer and/or end user of the product.

For Non-Pharma 1 and Non-Pharma 2, their direct customers are what can be described as ‘distribution companies’. The distribution companies of Non-Pharma 1 and Non-Pharma 2 share the characteristic that they buy the products from the biotech SMEs, then integrate them into their self-manufactured products, or combine them with products bought from other suppliers.

The direct customers of Non-Pharma 1 are more specifically named ‘re-agent companies’. The re-agent company is the actor in the value chain which gathers the different components of diagnostic tests from multiple sources, and then creates the complete ‘kit’ so that it becomes ready for final use.

“We mostly sell to the re-agent company. They take it into their test lab, combine it with other compounds, and make a kit. A kit is a sort of a test. It contains everything you need to find out for instance the sequence of DNA. There will be a lot of tubes. One of them will come from us. The other will come from other companies, or from this re-agent company, because they make some of the components themselves.”

(The CMO of Non-Pharma 1)

Non-Pharma 1 knows a great deal about who the end customers of the re-agents’ products are, but the CMO states that they do not have a complete overview of exactly all who might possibly be buying diagnostic tests where their compounds are included.
The direct customers of Non-Pharma 2 are genetics companies. As described in the initial presentation of Non-Pharma 2, the genetics companies license the right to integrate Non-Pharma 2’s technology into their own products. Afterwards, the finished products are sold on to farmers, who again are the end customers of the product.

“We sell our technology to genetics companies out there in the World. Currently in Europe, but we are on our way to the US. [...] Europe is characterized by very many national genetics companies, while in the US there are multi-national companies that covers the US and largely the rest of the World.”

(The CEO of Non-Pharma 2)

Non-Pharma 2 chooses its customers carefully, and only allows them to distribute their product if they believe the genetics companies are able meet their sales expectations. The overall number of actors is limited and Non-Pharma 2 described that identifying possible customers is fairly easy. In addition, they seek out to the end users, the farmers, to get feedback on their product.

“We have some direct customers, foreign genetics companies, and those are 5-6 companies. Our greatest customer is our owner [the parent company], which is responsible for selling on the global market. They distribute all over the World. So we don’t have a large number of customers, but it’s not a goal either. The goal is to get a customer the right customers, who can take us further. [...] When we go out into a new market, we are looking for the most interesting genetics company. In the US or in Germany where there are many companies competing, we are not necessarily interested in getting in touch with the market leader, but the company who wants to become the market leader. We look for the company that has a strong culture for sales, that has experience from innovation in some kind of form, that has opened new markets, or found new ways, new business models, or that has ambition to use [the Non-Pharma 2 product] as a strategic tool. The results should be good sales.”

(The CEO of Non-Pharma 2)

The end customers of Pharma 1 and Pharma 2’s products, once they are commercialized, will be physicians. But because Pharma 1 and Pharma 2 intend to sell their assets to big pharma companies long before their products enter the market, they rather see and treat big pharma as their customers.

“It’s two different kind of companies. When you are in biotech, the pharma companies are your customers, because basically, we are more in a business-to-business setting. There are very few biotech companies that form their own sales force and cover the patients around the World. But, whether we are alone, or we are in a partnership with a pharma company, or a pharma company that has bought us, the end customer of course are physicians. If the physicians don’t like the product, or don’t understand it, it has no future.”

(The CEO of Pharma 1)

However, the CEO of Pharma 1 emphasizes that it important to also consider the input given by physicians, and that this is especially important early on in the process. If the product is sold to a big pharma, the end customer is still the physician, who have to understand the product and be willing to use it on their patients. The CEO of Pharma 1 explains that especially later in the clinical trials, the pharmaceutical companies do not
spend too much time with the physicians, because by this point there are only very limited opportunities to make any changes.

“The real customers in pharma and biotech are of course physicians, so those we see at congresses when we present our data and we draw from there the questions that they ask. But you know, in our example we’re so far down the track, there’s a limit to what we can change. But there can of course be improvement that is very relevant.”

(The CEO of Pharma 1)

The CEO of Pharma 2 explains that another reason why they do not spend too much time with the physicians, is because the physicians do not have the knowledge that is needed to successfully develop the products. The CEO explains that the physicians must be present during the clinical trials, but otherwise they have little influence on the scientific development. We asked the CEO of Pharma 2 if they involve physicians previous to beginning clinical trials:

“No. Not at all. In the clinical trials you need to have physicians. Of course, because we’re dealing with patients. But I mean, physicians, their knowledge is restricted. Which it should be. They don’t know about mechanisms. Normally I would say you have to spend 10-20 years in the research field to really understand what we’re talking about.”

(The CEO of Pharma 2)

5.2.6 Channels

Channels describe the communication, sales and distribution of the company in relation with its customers (Osterwalder & Pigneur, 2010, p. 22).

As shown in previous sections, the major difference between the non-pharmaceutical SMEs and the pharmaceutical SMEs, is that the non-pharmaceutical SMEs has ongoing and repeated sales, while the pharmaceutical SMEs are developing a product over a long time and then sells all the assets once, including the intellectual property behind the product.

Pharma 1 and Pharma 2 have personal contact with possible customers; the big pharma and physicians. In practice they reach out and discuss if their products might be interesting or not. This happens prior to completing the phase 2 to already get to know possible customers. Pharma 1 and Pharma 2 have to communicate with the customer, the big pharma, beforehand, but the selling and distribution of the patent are different from selling the non-pharmaceutical SMEs’ products. The patent can be sold and distributed simultaneously and the process of transferring the patent is clear on beforehand, according to the CEO of Pharma 2.

“I mean, it’s very straightforward. It’s no problem. You have very straight out-or in-licensing activities from the big pharma. We know the requirement. That’s no secret. You have a patent, you have data and you give them World-wide rights and all indications. That’s it. Once you sell these, they own it. And it’s just the pricing. It’s standardized. No problem, unless you get to the point where they’re unwilling to pay.”

(The CEO of Pharma 2)
The CEO of Pharma 1 explains that they generally do not make a lot of efforts to communicate and gather information about their potential customers, at least not relative to their efforts spent on R&D. However, when they do make such efforts, they tend to do it by attending conferences and talking to people in their networks.

“Very, very little [marketing]. Basically, we do what I told you; we go to congresses. Primarily in the US, but also in Europe; talk to people in our network, present to companies and have their feedback, that’s basically it. We don’t do large marketing research. We have actually done a market research study, but that’s quite unusual for biotech. They don’t usually spend a lot of money on that.”

(The CEO of Pharma 1)

Non-Pharma 1 and Non-Pharma 2 also have direct and personal communication. Most of the time, Non-Pharma 1 & Non-Pharma 2’s marketing is business-to-business, although Non-Pharma 1 also has an online web shop to be visible to researchers that want to try their products for research purposes.

“[…] And then we do of course the marketing, but that’s direct marketing, because we are focusing on the business-to-business market. But we are also doing some outreach… We do have a web shop, for instance. That’s because we want scientists doing basic research also being able to find our products, because they can maybe do something they were not able to do before. Then it’s important for them to be able to get that product without buying a combined kit, for instance; if they are doing something completely new. So we sell [the compounds], as is, from the website also.”

(The CMO of Non-Pharma 1)

Considering distribution, Non-Pharma 1 & 2’s products have to be shipped under certain conditions. Living material requires certain conditions, for instance temperature. Because their customers are global and located in sometimes far-way countries, their products have to be transported on dry ice. Shipping biological products under controlled conditions can therefore be costly, which also is partly due to the cost of insurance for the products.

“[…] Transport is hugely expensive. Just getting it to the main airport [in Non-Pharma 1’s country] costs a lot. Also, insurances, because it’s living material we’re selling. It has to be sent on dry ice. […]”

(The CMO of Non-Pharma 1)

As previously mentioned, Non-Pharma 2’s distribution differs from Non-Pharma 1, because Non-Pharma 2 do not ship the finished product, but send a production team to recreate their product at the customer’s facility. According to the CEO of Non-Pharma 2, this is something the company is currently working to change. By in the future sending pre-made ‘kits’ which their customers can use to themselves producing the product without Non-Pharma 2’s production team being present, they can produce larger volumes. As long as they have not developed such kits, they cannot allow their customers to produce the products on their own, because Non-Pharma 2 wants to keep the ‘recipe’ a secret.
“They don’t have access to it. They call us and kind of order a production [...], then we send a team out to the customer [...]. Even if it’s patented, it’s important for us to keep as much as possible secret.”

(The CEO of Non-Pharma 2)

In terms of communication, both Non-Pharma 1 and Non-Pharma 2 use ads, contact defined market segments and travel in person to conferences and exhibitions. In this regard, Non-Pharma 2 has more control over the communication between the genetics companies who are their direct customers, and the farmers who then again buys the products from the genetics companies. Non-Pharma 2 has their right to influence their customer’s marketing written in the contracts.

“It’s marketing on several levels. The first is that we do traditional marketing through ads and exhibitions and so forth. The second is that we systematically target defined segments, like veterinaries among others. We cooperate closely with the companies that we have contracts with. They are obligated to use the logo in all market communication that is related to our product, so we have tight control of all marketing they are doing. We must on beforehand approve all the marketing material where [the Non-Pharma 2 product] is mentioned.”

(The CEO of Non-Pharma 2)

In addition, Non-Pharma 2 stated that word of mouth is an important aspect in their marketing efforts. Also, the research done by the company’s employees in its R&D department is important.

“This is a relatively conservative industry [the genetics industry]. There have been relatively few big innovations the last 30-40 years. The basic technology has remained relatively similar. So it arouses a lot of attention when a completely new technology enters the playing field. Most or all of our customers have heard about [Non-Pharma 2] before we initiate contact. Therefore, we get contacts on the CEO-level and meet the senior management of the companies and present the technology and the product to them. [...] To a great extent, the entire industry is participating in the same conferences – international conferences where the rumor spreads. And of course, we have our own research as well. They [the researchers] are also at the conferences, speaking and presenting news. Our researchers are benchmarking in the research community; people with PHDs in veterinary science, molecular biology, biopolymers, and so forth. So they are out there writing articles as a part of our marketing.”

(The CEO of Non-Pharma 2)

5.2.7 Customer Relationship

The company can create a customer relationship to affect the customer's experience. This can for instance vary from a very personal level to a computer based interaction (Osterwalder & Pigneur, 2010, p. 28).

In terms of customer relationship, Pharma 1 recommended to early on get in touch with possible customers, big pharma and physicians. This helps to be known on the market and getting direct feedback, which is mostly the way market research is done. In general, they try to achieve a close relationship with these possible customers. Pharma 2 as well keeps a dialogue with the big pharma to learn about their requirements to a product.
“Another reason why I contacted the [big pharma companies] is that they ARE the market right now. They are out there every day, their webs are out with the physicians, and I wanted that feedback. Not from a market research study, but an actual company that say “Well, your data is super interesting, but we think this is a difficult market”, or “It’s not as large as you present to us and think it is”. That sort of input I think is important to get early on.”

(The CEO of Pharma 1)

It is Non-Pharma 1’s priority to create a strong customer relationship. On conferences or visits to customers Non-Pharma 1 tries to get as much information as possible to improve their products. They try to establish long term relationships and want to learn about current customer needs as well as future ones. Future needs appear to be an important factor, since the industry is moving constantly. They describe their customers as their “best friends” and want to be on a very personal level. Anecdotally the CMO of Non-Pharma mentioned how they at a few occasions have corrected the customers’ orders, because they knew what the customers needed.

“It’s sort of personal contacts. Not private, but personal. It’s people. We always have to remember; It’s people we’re talking to. They have their needs and interests. What they need in most countries is to get their salary. To do that, they need to do a good job and look good to their bosses, so we need to help them do a good job. Sometimes that means that we need to tell them that what they put in the order, can’t actually be what they need. Because since we know them well, we know what they are, what they need. Even if they write something wrong. So that’s the connection we’re talking about; being able to understand what they need. That’s how you build trust. Sometimes they change something in the business, and it’s actually correct. But they appreciate us asking.”

(The CMO of Non-Pharma 1)

Non-Pharma 2 also works in a close collaboration with its customers. Besides recreating their product instead of shipping it at the costumer’s facility, they also collaborate on marketing efforts to promote their brand. Contracts last 1-3 years and are linked to the customer’s ability to meet their sales goals.

“[…] That [the marketing] is something we regulate in the contract; how it’s supposed to happen. We have yearly meetings where we follow up on our customers. They are obligated to report their sales once a month, and they are obligated to deliver a marketing plan before November every year, where they describe how they will market [the Non-Pharma 2 product] and increase sales. Then we go in and support that marketing. For example, when a company in Austria want to run an ad-campaign for [the Non-Pharma 2 product, we typically cover half of that cost. So it’s a close relationship with our customers where we work to motivate them to market the product and increase the impact in the market.”

(The CEO of Non-Pharma 2)
5.2.8 Revenue Streams

Revenue streams describes the financial capital the company can generate (Osterwalder & Pigneur, 2010, p. 30).

Major difference between the non-pharmaceutical companies and the pharmaceutical companies, is that the pharmaceutical companies do not have sales. The major revenue comes in place when the patent can be sold successfully after years of development and its price is based on negotiation.

In terms of revenue streams, pharmaceutical SMEs can evolve at a very early stage from first financial sources represented by business angels or on small scale capital provided by friends and family, according to the CEO of Pharma 1. At one point during process, as the costs associated with the clinical trials substantially increase, Venture Capitalists (VCs) become necessary to achieve sufficient funding for the research.

“When you start off and you have an idea, and you make it to your father-in-law (or God knows who that have any money), or so-called business angels can support you for some years. When it’s very low money, it can very often be friends and family, as we call it. When you get into later stage, you almost inevitably have to revolve into capital, which has the drawback that they are of course greedy financial people that don’t always allow the freedom during development that we who come from the medical side and development side like to have, but I don’t see another way to finance companies [...]”

(The CEO of Pharma 1)

Partnering with a VC can however have the drawback of cutting the researchers’ freedom in the development process. VC’s interest to maximize return on investments might be in conflict with researchers’ goals to produce significant results in the research process. For instance: in the clinical trials are a certain number of patients required to achieve statistical significance. Keeping the number of patient low is cheaper, but puts statistical significance at risk. If this is not clearly communicated, investments can be wasted.

Some start-ups can be financed through umbrella companies that are stock listed. In other words; to go public and finance the SME’s operations on the stock market. Though a bit hesitant, the CEO of Pharma 1 reflected that this could be a valid alternative for some companies, but that the volatility of stock prices can disturb the research process, which can take over a decade.

“[…] I don’t see another way to finance companies [than by funding from private investors], except of course to go public. They allow a small company to grow on the market, but again, it’s not very certain. Very little things can make the stock go up dramatically, and very small things can make it drop like a stone in water, so many of us hesitate to do that.”

(The CEO of Pharma 1)

The CEO of Pharma 2, on the other hand, does not like the idea of pharmaceutical SMEs going public. The informant commented on public offerings in biotech, that it would be unsuitable for pharma products at the research stage, due to the high uncertainty of outcome and little understanding by investors. From the informant’s experience, the
market has no way of knowing or judging a pharmaceutical product’s value and potential for success. For non-pharmaceutical products, as stated by Pharma 2, the situation differs, since their function can be more predictable than pharmaceutical products.

“You should avoid that. I think it’s almost criminal. Because it’s impossible to judge. If we go to the market, how is anyone going to be able to judge our product? Really, what you do, is fooling old ladies into investing. Even if you work with a similar company yourself, you can’t really judge it. I think it’s just a scam. It’s just based on ignorance. People don’t understand what they’re buying.”

(The CEO of Pharma 2)

Pharma 1 mentioned that raising funds can be difficult, except if a company has a very unique product. The CEO of Pharma 2 explain that similar to how stock-buyers’ understanding of biotech is limited, so can it be for the private investors, such as the VCs and the business Angels. The impression of Pharma 2 is that investment culture in the US is better since they “think bigger” and access to capital appears to be easier.

“[It’s easier to get funding] if you are in the US. It’s very difficult in Europe. I mean, in drug development you know that 99 percent fail. So you have to be one of the few that makes it. You need to have intelligent capital who knows, and that’s really lucky. They don’t know what they invest in. They have no idea what they invest in. Biology is so much more complex than technology. Technology is built on physics, and you can calculate it. Here [in biology] we don’t know. We know so little about our human bodies. It’s almost impossible for the investor to understand.”

(The CEO of Pharma 2)

Non-Pharma 1 and Non-Pharma 2 get large parts of their revenues from sales. As previously mentioned, they are both spin-off companies from larger umbrella corporations. In addition to the income from sales, they have been living off the equity given to them by their parent companies. Neither have reached breakeven yet, hence they are still financing their operations based on this equity. However, they are both close to reaching breakeven in the near future.

“We are in what you call a corporation. It’s two companies with a mother company, which is on the stock exchange market. So it’s the stock market that’s funding the business. They expect a return of money in some years, of course, but it’s the investor’s money we are spending currently, or have been spending.”

(The CEO of Non-Pharma 2)

“It’s making a loss and has been eating on the equity we got in 2011, but we’re not far from reaching breakeven. If we get 1 or 2 more customers the company will be making surplus.”

(The CMO of Non-Pharma 1)

The non-pharmaceutical SMEs have also received funding from national research councils, which fund R&D projects by up to 50% of the R&D projects’ total worth.

“The research council is funding differently every year, because sometimes we have 3 projects, sometimes we have 1. But generally, they are funding up to 50
percent of the research projects. Then it depends; how much of the total business? That depends on how much marketing we are doing, for instance. Most of the business is funded by sales, but good parts of the research is funded by the research council. That’s where we get extra funding.”

(The CEO of Non-Pharma 2)

“We are continuously running different research projects. All of them are partly financed by the national research council, meaning 50-50 so that they pay for half. The other half we pay for ourselves.”

(The CMO of Non-Pharma 1)

In terms of pricing, Non-Pharma 1 has to take several factors into consideration. Like in other industries, production and shipping costs, as well as price of similar products on the market have to be considered. Important for their pricing is also to consider the costs for the development of the next product, such as licenses and developing the production. For Non-Pharma 2, a large part of the price is dictated by previous R&D costs.

“[…] and then we can start calculating more detailed prices, because in the first round we don’t have an idea of that the price range is. We know what the prices are for similar compounds, but these are new compounds. No one else is producing it. In this market, most of the cost is for development and for marketing. Somehow that makes it more difficult. You cannot just put the price of producing one unit as an indicator of what it should cost, because then you wouldn’t have money to develop the next thing.”

(The CMO of Non-Pharma 1)

“The thing with biotechnology, as you may have understood from others, is that there are large costs in R&D while the production costs can be modest. So when we sell [the Non-Pharma 2 product] we take a high price for it, but our [production] costs are relatively small.”

(The CEO of Non-Pharma 2)

Non-Pharma 2 uses licensing fees to generate revenues from their customer’s distribution of the product.

“The genetics company pays for the number of dosages they sell. They report, for instance, on May 15th: “In April we sold 7 000 units”, then we bill them for that. So it’s a kind of licensing model. They pay a license fee per unit.”

(The CEO of Non-Pharma 2)

Within the company is additionally a small amount of private capital by employees. Non-Pharma 2 didn’t want to give away ownership and declined other private investors. We asked the CEO of Non-Pharma 2 if they use external capital:

“No, there’s a small ownership by a company where farmers and employees have invested, but that’s the only external capital besides the parent company, which is the main owner. Otherwise there has been international companies interested in buying into the company, but the parent company has chosen not to sell. They believe the company has an interesting future and want to keep it for themselves, because there’s a great future potential for revenues.”
5.2.9 Cost Structure

The cost structure describes the company’s costs, fixed or variable (Osterwalder & Pigneur, pp.40).

According to Pharma 2, costs are ever increasing throughout the research process. Quality standards like GLP and GMP increase the costs in the earlier process and throughout the clinical tests costs increase enormous. Clinical tests are clearly the biggest costs for pharmaceutical SMEs.

“[…] Biotech [SMEs] can take it [the clinical trials] through phase 2a. In our case, we will use 60 patients. But phase 2b, that’s a thousand patients. The costs are enormous. And then you have phase 3, which is astronomical. […]”

(The CEO of Pharma 2)

As previously mentioned, Pharma 1 is focusing on cutting costs through keeping a lean organization and by outsourcing to other firms and by keeping a staff of consultants, rather than having many full-time employees.

Non-Pharma 1 mentioned that it’s important for the cost structure to early on specific customer needs. Variables on quantity, quality and the place where it has to be shipped to are important to determine cost structure.

The largest cost is for development, according to the CMO of Non-Pharma 1. Other major costs are for licensing the product from the university and marketing. Transport and having stocks of products globally are also cost drivers, since materials need to be transported ice dried. Insurance on the transport also increase costs. Travel costs to conferences or customers worldwide are emphasized as a major cost driver for marketing.

“The highest cost is for development, and for marketing and sales. There is a lot of costs just keeping stocks in the parts of the World where we need them. Transport is hugely expensive. […] It has to be sent on dry ice. These things costs a lot. But marketing is generally driving costs a lot, because you have to travel to conferences all around the World. […] You have to go to several of these. Both the researchers and the marketing people have to go there, because you need to be able to know what’s going on in the field to be able to adjust. But also to meet customers. Then you have to visit customers to quite often to learn what they need and what to develop, how they want things done, making contracts for these… And, since the customers are all over the World, the traveling costs are taking a lot. Marketing and research are the biggest costs. Production is not.”

(The CMO of Non-Pharma 1)

Non-Pharma 2 mentioned that currently their R&D costs are the highest, but with their ambition to market on a global scale, marketing costs are increasing. And, as mentioned in the previous section, the CEO of Non-Pharma 2 stated that the costs of production are small compared to R&D. We asked the CEO of Pharma 1 how the marketing costs looks like, compared to research:
“No, it’s small compared to the research budget. But it’s likely to increase when we get to the US. For example, if we attempt sales there and get so far that we launch in the US, and say that we are building the industry’s strongest brand in the US, then that’s not particularly cheap. It’s a quite costly objective. So in the future we will need to put aside large resources to marketing. But we are prepared for that. And the thing with biotechnology, as you may have understood from others, is that there are large costs in R&D, while the production costs can be modest. So when we sell the [Non-Pharma 2 product] we take a high price for it, but our costs are relatively small.”

(The CEO of Non-Pharma 2)

5.3 Experts

The experts interviewed for this research project had various roles in the environment of biotech companies, which are explained for each in the following section. The experts received the same semi structured interview guide as the companies, to have a thematic point of direction. Since these experts don’t necessarily have their own biotech company, we asked about their impression how the nine building blocks usually look like in companies they have observed.

5.3.1 Industry Consultant

<table>
<thead>
<tr>
<th>Duration: 1:10h</th>
<th>Place: Scandinavia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting: Personal</td>
<td>Reference Code: Consultant</td>
</tr>
</tbody>
</table>

This informant with a background in Mathematics and Physics, has extensive experience in various roles in the Biotech industry. From sales position, product management, international marketing and board memberships, the informant offered interesting insights to the industry. In addition to the many tasks carried out through this person’s career, the informant was also responsible for selling IP rights in the informant’s latest chairman position. In addition to experience in pharma, the informant also worked with projects in the non-pharmaceutical biotechnology sector as well as beverage industry. After decades of experience in the industry, the informant is partially retired and otherwise participates in selected projects as a consultant.

5.3.2 Intellectual Property Advisor

<table>
<thead>
<tr>
<th>Duration: 1:10h</th>
<th>Place: Scandinavia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting: Personal</td>
<td>Reference Code: IP advisor</td>
</tr>
</tbody>
</table>

The IP advisor is employed in a holding company that is the umbrella organization for three incubators, where the informant is involved with all three. One of these incubators specializes in biotech. The IP advisor also does work more generally related to entrepreneurship and innovations, but was suggested as an informant for this thesis especially because of this person’s expertise and past experience with intellectual property rights. The informant has an educational background within law, and worked with trademarks and intellectual property. The informant later co-founded or was
otherwise involved with a number of startup companies within ICT and also had several board member positions.

5.3.3 Venture Capital Agent

<table>
<thead>
<tr>
<th>Duration: 1:03h</th>
<th>Place: Scandinavia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting: Personal</td>
<td>Reference Code: VC</td>
</tr>
</tbody>
</table>

The informant works for a smaller venture capital company, which mainly invests with public funding. This person has a background in molecular biology and worked within the pharma industry for 15-17 years, before starting the position as the VC about six years ago. This interview tried to capture a point of view from an investor side on the biotech business model. Their customers are not exclusively biotech phamas, but the informant is the one person usually working with the pharmaceutical biotechs. They are rooted in the local innovation system, working together with the incubators from which the biotech’s start their journey. They keep a close relationship to the companies they invest in, sometimes sitting in the board. They aim for exits after 3-5 years, but usually their investment stays longer at the companies, in rare cases up to 17 years.

5.3.4 Contract Research Manager

<table>
<thead>
<tr>
<th>Duration: 0:48h</th>
<th>Place: Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting: Skype</td>
<td>Reference Code: CRO</td>
</tr>
</tbody>
</table>

The informant is CEO of a so called contract research organization (CRO) based in northern Germany. The CRO’s task is to offers contract based services to biotech companies. This company supports the planning and conducting of clinical testing. Their goal is to optimize safety and efficacy of the development process in a clinical environment. In addition, they offer scientific consulting for new pharmaceutical projects. The company’s customers vary from small sized to bigger companies, as well as national and international. The informant has a background in biology and worked in the pharmaceutical industry as clinical researcher. After that, the informant was also involved in product management. As the informant mentioned, this allowed him/her to see the side where money is spent, in the clinical tests, and how money is generated, through product management. After this work experience the informant launched the CRO company, which has existed since 1997.

5.4 Expert Results

The results are presented according to the nine building blocks, like the previous section of results for companies.

5.4.1 Key Activities

During the interview with the VC Agent, we asked what are the actions that keep the company alive. Similar to what we had heard from the Pharma 1 and Pharma 2 case
informants, the VC Agents emphasized the importance of developing pharmaceutical product accordingly to the big pharma companies’ expectations.

“Of course it’s very important to develop a product that someone needs; to be very focused on the market need, the customer need for this product. Sometimes it depends on what area it is. If it’s pharma, then you need to focus maybe not on the customer in the end, because you will not be the one selling a drug, but you need to focus on the big pharma companies. Even though you have a very interesting technique or knowledge, maybe there are already 10 effective medications on that indication on the market. No one wants to spend several billion to develop another one. You need to be aware of the market before you spend too much on development.”

(The VC Agent)

Both the Industry Consultant and the VC Agent suggested that the first step to launch a venture is to define the market size, to see if there is a potential. If there is a considerable market size, meaning for pharma development a certain number of patients with that disease, then it is important to map out the goals of the company.

“I think in the first place, you have to define what the market is, and you shall also care about the size of it, of course. How will it be distributed or sold, and what kind of approval do you want? If you want to develop it into a pharmaceutical product, then you know that you have a product which will cost you at least 3 billion dollars. I don’t have the actual figure today, but it’s extremely expensive. The last product [my former big pharma company] developed, we had 25 000 patients. So what you can see, is that if you have a classical drug development, the road there is such that no one will do it by themselves. First of all because you have to have the money, but you also need the various competences, which are very special since you have to make it the way the authorities want you to do it, with the toxicology and whatever else you have to do. So the most important is in my way to see where are at the end is a consumer who will pay for this. And then you have to define: what is my aim? Is it to make a first development where we prove that the theory holds? If this is good enough, interesting enough, then you sell it to the pharmaceutical industry; those that sit with the 3 billion and the competence. That’s the key thing to see, what kind of ship am i going to make, where will I end? ”

(The Industry Consultant)

You need to consider the regulatory framework and how far you want to take the development process before you sell your product to the big pharma. To get your product on the market you need the big pharma, otherwise the costs for the clinical trials are too high. A company might be able to take it to phase 1 or sometimes 2a with the help of investors. In order to sell it successfully you need to show proof of concept, which happens in phase 2a.

For pharmaceutical products a unique selling proposition [USP] is necessary compared to the drugs already on the market, according to the VC Agent. The USP doesn’t have to be a completely new product, it can be a pharmaceutical product, which has either a better effect or less aversive effects. Since development processes are very uncertain, from an investor's perspective it’s a major task of the company to generate as much viable data as
possible. For instance, the VC Agent prefers to see efficacy studies and preliminary tox studies in animals, rather than invest on a product which has been solely tested in tubes.

“The more proof of concept you have, the less risk. A new drug for instance, it can fail what is called phase 3. It’s extremely expensive to perform a phase 3 study, big pharma can do it, but it can still fail, even if they have passed all those tests. That’s why I prefer to see animal data. If you have data only from cells or test tubes, it can be very interesting. But if you can show that it works in an animal model of your disease, at least that’s a very good step forward.”

(The VC Agent)

For non-pharmaceutical products, the VC Agent suggests to early on get in contact with end customers and find out their needs. Information on what they use today and what challenges the physicians might face right now, can be valuable input for a new non-pharmaceutical product. The VC Agent used ‘medtech’ as an example (a type of biotech product targeting the healthcare sector, which is not a drug):

“What they would do is to go out and talk. Let’s say it’s a medtech product that you have, then you go out and talk to some physicians who use that kind of machine in their work and ask them what they are using today. Do they have some kind of problem with it, or how can it be improved? Maybe it’s a cliché, but they say that you should have 2 ears and one mouth. You shouldn’t tell them what you think, should you get their input – because that’s what’s interesting.”

(The VC Agent)

In other industries it is common to have a minimal viable product [MVP] to put a product to a critical marketing test and see how it holds. While this might be possible for non-pharmaceutical products, pharmaceutical products can’t just be tested on the market, because it has to pass clinical phases first. However, according to the IP Advisor, pharmaceutical SMEs can still early on seek contact with possible companies, to early on shape their pre-clinical studies to fit the needs of the companies (e.g. big pharma) that could be interested in the intellectual property at a later stage.

“You can’t [put the product on the market] in that case. It’s really not possible. You need to have certain clearances first. What can be interesting, is that before you do the pre-clinical testing, you already discuss it with a company, because they might be interested in certain things. So you can set up the study in a way that prospers a license deal. You can prosper from by pretty early on be asking: “what would you like to see”, then form the study in a way that sort of matches this. You should then bear in mind that maybe it doesn’t match some of the other alternatives. So I say: “pick two, and try to structure the study so that you at least have two [companies] competing”. But it also depends on the application; where to use it. So it’s not feasible every time, but that’s what I generally would recommend.”

(The IP Advisor)

The IP advisor further adds that these tests are crucial for pharmaceutical SMEs not only in terms of approval, but also to have the possibility to find other areas of application if the drug development process fails.
“Even if you’re in phase 1 or phase 2, it can be that someone goes back to your pre-clinical study and says: “we would like to see this instead”. There are so many avenues open. So you pick one, and then you try it. Okay, so perhaps it didn’t work, then you go back and try another avenue. Maybe you can gain revenues early on by using it or providing it to others in earlier phases. So maybe, if it’s a solution that has a method or something, someone else can use it for something completely different. Trying to find early revenues is of course good.”

(The IP Advisor)

Other areas of application could be in non-pharmaceutical or veterinarian areas, where regulations are lower. Finding applications additional to medical use is beneficial not only if the clinical trials fail, but also to find a way of generating revenues while you’re running the clinical trials.

“You know, they can still use it for medicine, but another application could finance all the phases up to the pharmaceutical sort of solution or result. A way that they sometimes employ this is using it in a veterinary field. Because then you can create revenues, which finance the human application later on. Whatever it is, there are options. But you need to be a bit creative.”

(The IP Advisor)

Another important aspect is to have the correct timing for when to patent.

“To be a speaking partner, if you talk about big pharma and those kind of guys, you need to have a patent at the core of the business, because then they can exploit it during the time that they can exploit it. I wouldn’t call it a problem, but the challenge is the time it takes to perform all those steps [in the patent filing process]. They are not harmonized in different parts of the World, so there is a lot of paperwork that goes into it. And then, you know, 10-15 years is not unusual [for clinical development]. If you have applied very early for a patent, you lose out.”

(The IP Advisor)

The vast amount of regulatory work for applications, directed at funding or governmental departments, is time consuming. While discussing key activities, the IP Advisor emphasizes how time consuming bureaucracy like applications and reporting is for the SMEs.

“There’s a great competition for on all financing, so even if you have a great idea, you might not get financing to do it. It’s a time issue, because when they are applying for financing, they are applying in competition with others. It takes a long time to write those [applications] in a good manner, and they need to be out there and talk about this. What they really want to do is experiment, but then they have to do all the administration around it, and then they have to do the reporting. All of those things take time. It takes time from what they really want to do; experiment.”

Time is also an issue why the VC Agent recommends to have at least one person focusing solely on the company, and that is not involved with the research per se. This appears to be an issue, since most life science startups come from the university and are run by scientists or professors still employed by the university. In the informant’s experience
that is a factor why startups fail, because there is not a person completely focusing on the firm, but rather stay mostly employed at the university and consequently not focusing their time enough on the company.

“They [university researchers] will definitely not get the same salary in this small startup, as compared to their professor salary. They cannot get that kind of salary, because it will drain all the money from the company very quickly, so I think it’s a natural risk. Some academics, at least in my experience, are less prone to take that risk, to leave their well-paid jobs and do this. [...] Sometimes it’s good that the professor stays at the university, because it can be good for the company to have a tie to research and to the university. But there should always be someone in the company who is running the company. It’s a lot of work to run a company, and that is maybe not really understood by everyone; how much work that is, and how much responsibility that is.”

(The VC Agent)

The expert working in the contract research organization stated that the first step is to find an investor. If the company receives funding, it is crucial to manage the research and the funds efficiently.

“So the most important thing is obviously to find an investor. And they need someone by their side from the clinical research, so they get help to keep the research in time. Because the people with new ideas in this area usually don’t know what kind of processes they are facing. They are very scientifically oriented, but not economically. At the point when they receive money, they need someone by their side to manage these funds effectively. That’s a point where most fail. It’s a management process.”

(The CRO)

The development process requires harsh quality standards and it is necessary to map out clear and measurable goals during that lengthy and complex process, which in most cases the goal is to get proof of concept in the 2a clinical phase. If there is no clear structure, in the CRO’s experience the project is likely to fail, since unnecessary lengthy development processes deplete financial resources.

“Another point is that they need clear goal for where they want to go. Do they want to develop the product on their own, or do they want to bring it to the clinical phase and get proof of concept, so that they can sell it? It’s good to have a clear and measurable goal. Otherwise, they drown. Many processes seem to be interesting, and they take their time – meaning they get distracted – but after a while they run out of money, with which they also have to pay their salaries. So it’s surely a management process, but it’s important that they set an early goal for what they really want. Only few are doing that.”

(The CRO)

In addition, if quality standards are not met early on, the product can become worthless. For instance: A product can be produced by an altered microorganism. In order to get the same product out of the microorganism again, it’s crucial that researchers describe how they created the microorganism in first place. If it’s uncertain how the microorganism was created in first place, its ability to reproduce a desired product is not reliable. Since
its most companies’ desire to sell the product to the big pharma, meeting quality standards and offering valid statistical evidence is key.

“You can have an expensive proof of concept, everything ready, and you spent a lot of money, but then the big pharma says: “Sounds good, but you didn’t follow the standards!”’. One example: Many biotech companies work with microorganisms. These are supposed to produce something, which supposedly is put into a drug. They [the researchers] do many different things and know the microorganism, but what they don’t do is to early on describe where it comes from. They need to describe very detailed how they got this microorganism. Otherwise, you can’t reproduce the same product, because it’s not organized. These are things they usually don’t have in mind. They need to make everything clear in a standardized way. This is driven by the security of the patients.”

(The CRO)

5.4.2 Key Resources

Key resource is the patent, according to the VC Agent. Without a patent biotech inventions are difficult to commercialize.

“[…] you need to make sure that you’re aware of the intellectual property situation around this. For instance, if you spend a lot of money on to develop something, and then anyone can copy it when it’s out on the market, that’s not a good thing.”

(The VC Agent)

On the human resource side, it’s important to have what the informant called “champion”. A dedicated person, who focuses most of his/her work on the company, preferably holding shares in it so that he/she is fully dedicated to the commercialization process. Otherwise the company might fail if challenges arise and the owners exit immediately.

“There need to be something that we call a ‘champion’. Biotech companies, life science companies in general, they usually come from the university in some respect. And sometimes the researcher is not the person who will run the company. Often it will be like that. If the researcher is not that person, there need to a person that will be focusing on the company and make the company successful. […] Another important thing is that there should be incentive for the people who work in the company. For instance, if the one who is the CEO doesn’t have any ownership of the company, that’s not good in our experience. Because, usually, these are very early companies. They may get some money, and everything is fine and moves as it should. Then maybe somethings goes wrong; they are delayed with development or something, and they don’t have any more money. If you have someone who is only employed, they will probably leave the company and go to another company. But if you have significant ownership in the company, you probably stay and manage these problems.”

(The VC Agent)

According to the VC Agent, it is also preferable to be surrounded by a good network, where different actors of the industry are easy to reach, such as physicians, investors and bigger pharmaceuticals. Material resources, such as laboratories are not a big challenge.
Capital and competence are the crucial resources. We asked the VC Agent what kind of resources the SMEs have when they come to the investors:

“Usually they have too few human resources. They need expertise. This city is maybe bigger than some other cities, but it’s not a huge place, and we don’t have the big pharma companies here. I have colleagues in other cities, and we try to help them [the companies] with our network, to find for instance if there’s a need for a CEO in a company here, or something else. So that’s also important. Financial resources are maybe always lacking. Physical resources; I don’t think that’s something [important]. Capital and competence, that’s the two most important.”

(The VC Agent)

According to the Industry Consultant, a valuable network can help with a market potential evaluation of the product, as well as with information on the regulatory standards that have to be met by a new product.

“I think it is really, really important to get access to a network; a network which has all the knowledge you need in order to make a good marketing evaluation. A good evaluation of what the authorities would require of you.”

(The Industry Consultant)

Crucial part is sufficient funding for the companies, especially with the increase of costs for holding a patent. To bring the product to the market, a big pharmaceutical company is required to deal with the enormous costs of the clinical tests.

“The first year you don’t pay much for patents. But if you want to run this product for, let’s say 5 years, before you sell it, what will happen in year 3, is that then the patent will be, for a small company, really huge. So then you can end up with struggling just funding the patent to keeping the rights.”

(The Industry Consultant)

Talking about key resources, pharmaceutical SMEs need the big pharma companies to develop the product. It is impossible to bring a regular drug to the market without big pharma, since the costs are enormous.

“Way more than 50 percent wants to sell it. I would say 70-80 percent want to develop it quickly and sell it, since if it’s a product that requires a long development process, you’re not able to do it by yourself. It’s better to sell the first two or three, and then it might be possible to develop it on your own. But first you need a money maker, which feeds your company, otherwise it doesn’t work.”

(The CRO)

To get to the point where you can sell the product to a pharma company, meaning usually getting a proof of concept in the 2a phase, the company requires financial and human capital. It requires a person that is able to manage the funds in an efficient way to navigate through the quality standards of drug development. The informant therefore recommends an experienced partner, who is familiar with the quality management and other requirements during the development processes. Having this expertise allows to do the research in an effective and ultimately economic way, which is strongly tied to the goal orientation in the point of key activities.
“On one hand, you need intellectual resources, because obviously it’s good to have money, but you need someone who can handle it. I would say guys like me have a vision; I always have an idea of what to do with the money and have a lot of fun, but if I don’t have the right managers by my side, we are done after three years. You need someone with the intellectual resources, who is an expert in that field, who knows how it works. You also need someone for human resources, meaning someone who knows how to manage a company. Usually the youngsters don’t know that, and they lose time with having conflicts. I don’t like hiring consultants, because it costs a lot of money. They are a bit like ticks on the investors; they suck a lot of money out of them, and when it’s gone they fall off like ticks. What I mean, is you really need someone from the industry. They are usually a bit older and have the experience of how things work. Someone who could be the CEO for 1-2 years to lead the company to the next milestone. It makes sense, but it really has to be an expert. Someone who knows about quality management and dares to take care of it.”

(The CRO)

5.4.3 Value Proposition

According to the VC Agent’s perspective, a company requires a competitive advantage which can come in the form of a patent and which delays the time point at which the product may be copied. Having an advantage is related to knowledge about the market. As previously mentioned in the key activities, knowing about existing products, their effects and aversive effects, is important to position the company’s own new product.

As previously mentioned, the IP advisor emphasized that it can be beneficial for the companies to consider alternative applications of the biomaterial, such as to apply it in a non-pharmaceutical setting where the regulations are lower, because this may give the opportunity to generate revenues at an earlier stage. There is no rule saying a biomaterial cannot be used for drug development if it has first been used in a non-pharmaceutical setting, hence the non-pharmaceutical application can be a way to finance the costs of the drug development.

As it is discussed by the Industry Consultant, the non-pharmaceutical application can even be a lucrative alternative which the firms may choose over the drug development path. The Industry Consultant exemplified this by referring to a real-life case where a firm had attempted to launch its compound as a veterinary drug instead of a human because of the lower regulations and greater likelihood of realizing revenues.

“Actually, this kind of [non-pharmaceutical] product I’m talking about, theoretically it would have been no hinder to develop it into a pharmaceutical drug. Once you can prove that you have a clinical effect, you can claim that it is a pharmaceutical product. You can get it approved as a pharmaceutical product. However, people tend to not go this way, because it is an enormous development work, there are enormous costs making it into a drug. Therefore, you can instead go for functional food, go for medtech approval, or make it as a food supplement.”

(The Industry Consultant)
The Industry Consultant suggested to have a careful look at the market and how many people might suffer from a certain disease. This data is about the number of patients is easy accessible. This is followed by an evaluation, on whether market size can be profitable. The data about competitors and in which state they are and what drug they develop is also accessible. Therefore, having a clear picture of the market and competitors is not the biggest challenge in pharma development.

“You can find out exactly how many patients there are, and then you try to define what are their needs. Then you can see; does this research idea address a significant or severe need for a patient? It’s in a way very, very easy. Because there is such a long time from you go into phase 1 until you have an approval, you find the data; you know exactly how many substances there are in phase 1, 2 or 3 on its way to the market. And you can also see what class of product is it. It’s like in antibiotics; you can see if it’s a ‘me-too’ or if it’s a smaller modification of existing products. Is it a change of route in administration or is it an entirely new chemical entity or biological product? You have to keep an eye on that all the time. It’s relatively easy to access that information.”

(The Industry Consultant)

It might get problematic if scientist solely follow the “noble cause”, as the informant put it, and do not consider commercial aspects. Even if the researchers develop a promising drug, if there is no commercial potential for the big pharma, it won’t get to the market, since the development costs for clinical tests can’t be carried without the big pharma. Owning a patent is again crucial factor for commercialization of a possible new drug. No big pharma will invest millions, if the product is not intellectually protected.

“I think if we go back, culturally, if we look at the university; It was much more in the past that you should not go for money. You should go for the more noble cause; to develop something for people, and you should not be the one who is a greedy. And that’s why you don’t have a commercial thinking. It comes more and more. When I was a rep, I had friends who didn’t even say hello to me because I was working for ‘the Capital’. I think culturally, you can still find people who are not commercially driven. And in a way it’s no problem if you want a product to be successful and you want the benefits of it to come to the people. But then marketing is the way you have to go, and then you also need to patent it. If no one patents it, no one will do the development. No one pays a billion dollars in order to lose it soon as you are on the market.”

(The Industry Consultant)

The potential product usually starts at the university as part of a research project. At that point no one can estimate its actual value to the patient. The researchers have to be driven by a vision and with more research on the product show its usability. Then it is possible to see whether it is an entirely new product or more efficient than existing ones. It is also valuable if it has same effects than already existing ones but with less adverse effects. Otherwise it is a so called “Me too” product, which differs not from existing ones and will probably not be commercialized.

“I would say the first step happens at the university. The biotech startup knows there is a disease, for example cancer, and has a product which was probably part of a doctoral research. It looks like a good idea and they have to find out if it’s an advance in oncology. So, first you have a product and a vague idea. At that point
it’s impossible to know the value. You need a vision, that’s very important, because that gives you energy to follow up the product. If you can convince others of your vision, you get to know people who put thoughts into it about the market. They know if it’s an interesting product and if there are already interactions with other things, such as drug systems. This means they build a strategy for how a product could look and how to test it. For that, you need knowledge about the market and if there are already competitors, and how their products behave. You have to know, that’s the golden rule if you want to put a product on the market. If you don’t find that it doesn’t already exist at all or that you have a USP others don’t have, the departments of approval will call it a “me-too” substance. Me-toos can only do in generic areas, meaning you buy a patent together with one or two other substances that work well, but me-toos which don’t offer any improvements to previous substances are difficult. You need an advantage, either more effective or less aversive effects.”

5.4.4 Key Partnerships

All informants said that the incubator plays a vital role and helps to develop a business plan and strategy.

“I would say that one thing that is very important, is the incubator. All investments that we did here last year, they came from the incubator. They are really important to us, because they set the standard for how these companies work, and they help them with making trustworthy plans, and work for their activities, and financing, and everything.”

(The VC Agent)

The Industry Consultant added that the whole innovation system available supports to verify ideas, evaluate markets and offer general support.

“I think they should, if I were a research worker here at the university, I would absolutely try to get in touch with this organization, the incubator, because there is money available to get for making market analysis and to verify your idea. So the whole incubator system is really important for the researcher.”

(The Industry Consultant)

Utilizing this early on can help to get access to resources, such as offices, labs and support in applying for funding. The CRO told us about an incubator in this person’s own region.

“They take care of very young companies, and they receive coaching and consulting. I wouldn’t call it exactly coaching, but they receive early support. They can use laboratories, offices and are also with colleagues and have close contact with them. In the next step they can use more spaces, and if it works out and they receive funding, they could also build their own building. You have all opportunities there.”

(The Industry Consultant)

Usually the biotech companies have a strong tie to the research at the university, since usually at least parts of the team are still employed at the university and parts of the research might be funded through the university, according to the VC Agent.
“Many of these companies have at least one researcher that is still at the university, and it’s very rare that they say: “okay, I’m going to do this company and quite my job at the university”. That’s very rare, so usually they have a connection to the university. So there is academic research going on at the same time, dealing with the stuff that is going on in the company. That gives more knowledge. Maybe it’s not focused entirely on the need of the company, but it gives more knowledge that they can use. Usually the academic research is funded by the university.”

(The VC Agent)

On partnerships, the VC Agent further added that collaboration between companies happens rarely between similar pharmaceutical biotech companies, but that it can happen sometimes.

“Sometimes. For instance, at the incubator, if there is one company that has certain knowledge on how to do some kind of experiments, and there is another company that needs like that, they usually help each other out. Well, they pay for the service from the other company. Maybe not all the time, but sometimes it happens. We try to encourage also small companies that have some kind of fit together to talk to each other. We never force them, but we tell them that maybe it will be beneficial for them to talk to each other.”

(The VC Agent)

When it comes to negotiations to sell the patent to a bigger pharma, usually legal support is required, since agreements are long and complex.

“I would say that usually some kind of third party is involved, because it’s difficult to get this kind of agreement from the big pharma companies, and you don’t really understand what you’re signing. So I think most of the time there is some kind of help. I would assume that most get some kind of legal advice, but also some consultant that help with the negotiations, that help with that process also.”

(The VC Agent)

5.4.5 Customer Segmentation

For the pharmaceutical SMEs, the key customer is seen by all informants as the big pharma. The VC Agent explains that the needs of the patients, the end users, are considerably important as well, but in the end it doesn’t matter how well the drug fits the need of patients, if it does not get commercialized by the big pharma.

“Of course, they have to see the end user in the end. But the most important thing is that it doesn’t matter how happy the patients are with the product, if the big pharma won’t buy it from us, because then it will never reach them.”

(The VC Agent)

According to the IP advisor, some researchers differ from the mindset that the big pharma is the main customer. Some researchers want to serve the greater good and creator knowledge, rather than being motivated by a commercial perspective. We asked the IP advisor if researchers see big pharma as their customers from the very beginning:
“It depends on the researcher. Some see that. You know, universities have the obligation to provide knowledge to the general public. That’s their mission. So they [the researchers] want to publish it [the research]. They usually want to contribute to a better World. Some of them [the researchers] don’t want to publish it just because they don’t want to commercialize it. Because they feel that that’s a restriction. They don’t want to make money on it.”

(The IP Advisor)

Also the CRO sees the big pharma companies as the ‘real’ customers, however this informant also states that the physicians should not be forgotten:

“The big pharma. The end user is the patient. Physicians just choose the products they use. Paying does the insurance companies of the patients, not the physicians. But that’s none of your concern at first. First you have to develop your product and distribute it. That can only the big pharma do. Therefore, the focus is clearly on the pharma. It’s definitely useful to talk to physicians, who are the experts with certain indications, because you won’t find that medical background in the pharma. You need someone with scientific medical expertise, and usually you find them at the university clinics. Without a physician you’re getting nowhere.”

(The CRO)

Also the Industry Consultant said that the physicians are an important customer group for pharmaceutical products. Physicians are applying the product on the patients, the end users. But the real customer is the big pharma. Only when the product becomes available ‘over the counter’ without prescription, marketing can target patients directly, but that is then in the hands of the big pharma companies.

“In my experience, what we did with [my former big pharma company], and I think they do it today also, is they see the physician as the customer. However, you have a lot of OTC [over the counter] products. You have to look into segments. In the first period of time, the physicians and the specialists are the target for marketing. Once it has been on the market for a long time, and you have safety properly proved, you might then start to sell it over the counter. And then you will see that the marketing will be directed to the consumer, and you can see it on ads. In Europe they spent enormous amounts of money to promote even prescribed products directly to the customer.”

(The Industry Consultant)

5.4.6 Channels

According to the VC’s perspective, it is easy to get in touch with the big pharma. It is based on a mutual interest, where the smaller companies want to sell an innovation and the big pharma is in need of new products. Several events are available, where both parties can meet in person, as well as physicians and other service companies of the industry. We asked the VC Agent if it is difficult to get in touch with the big pharma companies:

“No, not really. I was last week at an event. There you could put up the name of the company and what it does, and then you could send out invitations to the big pharma companies who were there. It’s not difficult to get a meeting, because there is a common interest. Smaller companies want to sell things to them, and
the big pharma; they have a great need to get new, innovative products. So they are equally active to reach out to the small companies. It’s not difficult.”

(The VC Agent)

The CRO told us about a very similar event as the one mentioned by the VC Agent. The CRO did not think that the big pharma companies are difficult to get in touch with, either.

“You have the option 4 weeks prior to the event to book online meetings. You search for cluster physicians, service companies, pharma companies, and so on, and they all offer contact. You can have a meeting every 30 minutes in a box, and maybe there are 200 boxes. It starts around 8:30, so you can go there in the morning and go through the meetings. It’s interesting, because you can find everyone there.”

(The CRO)

5.4.7 Customer Relationship

The VC Agent mentioned that SMEs have a good exchange with big pharma on what the big pharma’s needs or criteria are, at a pre-sale status.

“I would say that the big pharma, they are usually very friendly, and they can give you good advice. They tell you: “I think you should look at this and this, and maybe you should do that, and talk to that person, or try this experiment”. They try to tell you what they would like to see more of for it to be more interesting for them, because usually they want to see more. Maybe sometimes it could be good if they were more frank, to say “this is not for us”. They usually try to be nice and then they give you feedback.”

(The VC Agent)

The IP Advisor mentioned that in the event of selling a patent, the relationship between the parties can still go on. The know-how surrounding the patent can in some cases be difficult to transfer, which can result in post-sale relationship between biotech SMEs and big pharmaceuticals.

“You don’t buy or sell a patent ‘just like that’. There’s a lot of knowledge, know-how and all those kinds of things, which they want and you have, so you need to put in some time in relaying that information.”

(The IP Advisor)

The contact to the big pharma is usually on a personal level, as mentioned previously in the channels; through events and meetings. The CRO emphasized that the contact with the big pharma or the physicians one could have, depends on how far the clinical trials have come.

“I think the contact with the physicians will definitely be first, because a biotech wants to get a first feedback and see how it [the product] could possibly be realized. Big Pharma only becomes interesting if you have proof of concept, but you might have contact also previous to that. You can go to events and talk to these people.”

(The CRO)
5.4.8 Revenue Streams

When companies start coming from the university, they usually apply for governmental money through different public funds. This is stated by both the Industry Consultant, the CRO and the VC Agent. The VC Agent further adds that in some cases, the SME will be able to attract funding from business angels. If the researchers are able to deliver good results, public money can already cover a fair amount of early research, according to the Industry Consultant.

“In the beginning it’s to a large part public money. Some of them, they can attract funding if they have personal connections to some business angel, or sometimes the business angels invest more with their heart than their brain, or if they get a very good connection to a researcher and think it’s really great what they are doing. So sometimes they can supply money early on.”

(The VC Agent)

“Well in the first place, when it comes to sort of basic research at the research institutions, it’s the way it works within universities that they apply for money from the government. If they are good at it, they can do fairly much of the drug development. But after, once they make the step to try to make a product out of this, then there is quite a lot of money in the public innovation system that you can get some money from.

(The Industry Consultant)

“Funding is not really my expertise, since I never really had to take care of it, but I know a few things on the surface. What I know, is that there are of course private investors. The pharma that works with biotech has private capital. And then you can access governmental funds. But that’s usually not enough for the next big step, if they want to do research and go into clinical phase, they need someone else.”

(The CRO)

The VC Agent mentioned that funding for the pharmaceutical companies usually is milestone based, i.e. it lasts for one step at a time, for instance one clinical phase. This was mentioned while the informant explained whether or not the VC agent’s own company has a specific point of time they prefer to sell out of their investment.

“We don’t have any typical phases, because we’re a small player. We don’t have really much money, so we’re dependent on big pharma or larger VC companies coming in with more resources. So basically, we would be happy to sell in most phases. I don’t think we have a typical phase.”

(The VC Agent)

Though many biotech SMEs use government funding in the beginning, this is not enough when the development moves forward. In later stages, the SMEs must attract funding from private investors.

“I think it [from where you get the funding] depends on what stage. In the very early stages you try to get money from these government organizations. But when you scale up, then you need more money because you won’t get the 10-15 million from those. Then you have to either have private owners or you have to go to some private investors.”
In general, funding is usually available (i.e. funding opportunities do exist), but as previously mentioned by the IP Advisor, competition between companies to be granted this funding can be high. The CRO explains that in this person’s region, it can be difficult to obtain funding. The private investors prefer targeting other industries, because the risk is high and development times are long.

“Many people are shy to invest in biotech, because they don’t know if it’s useful, and also it takes long and is expensive. Especially in [the CRO’s country], very few accept that risk. They rather invest in an internet technology, which is faster and after 2 years you already have a product. For biotech it’s especially difficult.”

(The CRO)

Another option is to do medical device products, since regulatory requirements are much less strict than in drug development. This can be a way to generate first revenues to fund further research (Consultant, OCR, IP advisor). As we have seen in a previous section, this was mentioned by the IP Advisor. It was also discussed by the CRO.

“It’s an option and it makes sense, because you can generate fast revenues and with that money you can still develop a drug, if you want. Or as a device, which is also an option. Meaning a medical product, depending on the product, because the approval is based on physical attributes. There is no pharmaceutical effect. That’s also an option, and some products can be used for that. Gels, for example. If you apply them to your skin, they don’t necessarily affect in a pharmaceutical way.”

(The CRO)

Additionally, it might be possible to enter a joint venture. The CRO uses an example of vaccination. A company developing a new way of injecting vaccines could cooperate with a company producing vaccines. This again is highly dependent on the nature of the product.

“There is an option of joint venture. This means there’s a company that already made money and might include the new biotech to supplement their own product. So for example, one company makes a new process to vaccinate, and the other one has a substance for vaccination. If you put that together, it could be successful.”

(The CRO)

### 5.4.9 Cost Structure

The costs for the research process are increasing constantly, especially during clinical tests (VC, OCR). Using quality standards in the early stages like Good Laboratory Practices (GLP) increase the amount of work and costs significantly. When companies enter the clinical tests, costs explode, and can often only be carried until phase 1 or to 2a by investors. After that, big pharma companies have to take over in order to move the product through the other phases, due to the even higher costs in the later stages of clinical testing.
“Really early, you can do experiments in the lab, but when you come to some level you need to do GLP; good laboratory practice experiments for the toxicology of the products. That should be the basis when you hand in an application to give it to humans. It’s very strict how these studies should be performed, so when we come into the GLP tox, the amount of money goes up very much. And also, production of the drug is expensive. For those GLP studies you need very well defined procedures for how you can produce. So that I think is a turning point when you do those studies, and then it gets more expensive for each step after that. Some companies can do at least phase 1, which are small studies with healthy volunteers. You want to see if it’s safe and tolerable. Some companies can do that, or even phase 2a studies, when they try the first studies on sick patients. Usually you try to get the big pharma somewhere around there.”

(The VC Agent)

A major challenge in the cost structure are the highly likely backlashes in the development process, according to the Industry Consultant. Especially start-ups and smaller companies can fail due to backlashes in the research process.

“They [a pharmaceutical SME] did antibiotics and had quite a brilliant idea. They got quite a lot of money, but they went bankrupt, because they took too long time on the human development. What you know for sure, is you will always have backlashes. And if you have a backlash in [a big pharma company], it’s not good – we [the Industry Consultant’s former big pharma company] have withdrawn products from the market, but we survived. If you are in a small company, and you have a backlash, then you are really in a bad position.”

(The Industry Consultant)

The patent application costs can be a financial burden for starting companies. Issuing a patent and increasing renewal fees every year can be costly. In the patent application process, it is not solely the patent application cost to consider, but there are also legal advice and hired support by experts to write the patent which cost a substantial amount of money. The legal fees and such other costs equals the majority of the total patent application costs.

“You have the fee for filing it, which is pretty low. The official fee is very low. And then you have all the attorneys, and the patent counsel, and the engineers, and those kind of things. And then you have to pay something for writing it and putting it together, and you have fees for all the communication, for expanding it [the patent] to other countries. It [the fee for holding the patent] increases over the years.”

(The IP Advisor)

5.5 Cluster manager

The cluster plays an important role in facilitating networking. Clusters can be seen as an intermediator between different actors, such as companies, universities, incubators and investors, to improve local economic development. In addition, cluster managers work on developing the brand of their cluster. More detailed information on activities will be presented in the following results.
5.5.1 Marine Cluster Manager

<table>
<thead>
<tr>
<th>Duration: 00:59h</th>
<th>Place: Scandinavia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting: Phone</td>
<td>Reference Code: Marine CM</td>
</tr>
</tbody>
</table>

The Marine Cluster Manager (CM) is the manager of a biotech cluster that has special focus on products made to be used in the marine sector, or that has a marine origin. Non-Pharma 1 is an example of the latter, and is a member of this specific cluster.

The Marine CM is a Fisheries Science Graduate, who mostly has experience from the public sector in working with development of the marine and fish farming sector. The informant is cluster manager for about 2 years now. This position’s major task is to facilitate networking activities within and outside of the cluster. This includes increase activities between universities, companies and investors. The cluster is also looking into cooperation with other clusters that might offer complimentary skills.

5.5.2 Agriculture Cluster Manager

<table>
<thead>
<tr>
<th>Duration: 1:04h</th>
<th>Place: Scandinavia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting: Skype</td>
<td>Reference Code: Agriculture CM</td>
</tr>
</tbody>
</table>

The Agriculture Cluster Manager (CM) is the manager of a cluster which specializes on products and services that are resulting from or meant for use in the agriculture sector. Membership firms are both those companies developing research-oriented biotech products, and those benefitting from the research, e.g. because they are the research companies’ customers. Non-Pharma 2 is an example of the first, and is one of this cluster’s members. There is a high degree of dependency within the cluster, meaning that many of the companies are suppliers and customers of each other. SMEs in this cluster have an international market.

The informant has a background in marine biology and worked in fish farming and genetic related agriculture. This person recently got the position of the cluster management. Activities besides networking within the cluster, also includes brand management of the cluster to develop international credibility and trust. This cluster also cooperates with other clusters.

5.6 Results Cluster Manager

The output of the interviews with the cluster differed from the ones with the companies. The clusters’ perspective brought in more general impressions or a bigger picture on how the companies act. The results will be presented in the scheme of the nine building blocks as previously, but a fair share of the interviews’ results will be part of the next section of challenges and emerging themes.
5.6.1 Key Activities

The Marine CM described key activities as ‘doing your homework’, building networks and utilizing the resources around you. Companies should try to acquire knowledge from experienced people around them. Even in early processes, decisions should be made carefully and not rushed.

“The human resources are extremely important, and to do a good and thorough groundwork; to have wisdom in the startup phase, where you think carefully before you do the choices, and don’t rush ahead. It’s actually more important than to have a very quick progress. But you depend on it moving forward also, so you can’t wait too long either, so there’s a balance there. But it’s important to get resources with experience. That I would truly say.”

(The Marine CM)

The Agriculture CM did not explicitly discuss what are cluster companies’ key activities, but in connection with other building blocks this informant mentioned several activities, such as R&D, production, marketing and sales. The Agriculture CM emphasized especially the importance of R&D, for which many of the cluster companies spend more than 20 percent of their yearly budgets.

“[…] R&D is a large post. Several of these companies use more than 20 percent of their yearly total budget on research and development.”

(The Agriculture CM)

5.6.2 Key Resources

Key resources, according to the Marine CM, are financial resources and experienced human resources. It can be beneficial to acquire experienced members for the board, who support decision making.

“They survive because they acquire private capital, but for many it’s tough. And the thing is; if you don’t get a good start, you kind of stay poor all the time, because you must choose the less optimal solutions. So it’s very important to get a good start and do thorough groundwork. Do your homework, build a network, use the resources around you, so that you don’t fail from the start. Otherwise, it gets expensive.”

(The Marine CM)

” I believe it’s very important that you also reuse more of the resources so that they [in the cluster] who succeed, could to a greater extent be in each other’s boards. You see some of it now, but there could be even more. To acquire resources, talk formally and informally with those who knows more than yourself, that is very important.”

(The Marine CM)

In regards to resources, the Marine CM also reflected on that biotech companies are more competing over available resources, such as experienced personnel, than market shares.
“I’m thinking that it’s such a big World, and the companies we have in the cluster, they are to a very limited degree competitors, really. They compete perhaps more over resources – like for instance personnel. The wise heads, if they leave the company for another, then that’s probably more difficult than competing for the same customer.”

(The Marine CM)

In terms of capital, it is favorable to have “competent capital”, meaning investors who are familiar with the industry and can influence the company in a positive way.

“They [of the companies in the cluster] who have opened up [for private investors] in an earlier stage, and got the capital in, and preferably competent capital, they also got competence on how to develop the business. This is about business development, it’s an area of competence we may well strengthen in the cluster. Product development we are good at, but the business development and also the market development and regulations... competence in those areas could have been strengthened. Then I believe the innovation would go faster.”

(The Marine CM)

Human resources require not only knowledge in business but also the biotech industry. The Marine CM described it as beneficial to have a salesperson that also has an PhD in a relevant field for biotech.

“Some companies [in the cluster] are well covered in all areas, but for some, they could have acquired more business competence. But it has to be business competence that also understands the industry. It’s an advanced field of expertise, so I know it has been said that if you want to be a salesperson in biotech, you need to have a PHD in biotechnology. Otherwise, you can’t talk to the others who you’re trying to sell the product to. You can’t just be educated in marketing, you must have knowledge about the product as well. At least it’s a great advantage. It comes down to the product and the industry being a bit more complicated than other industries.”

(The Marine CM)

The Agriculture CM described that most personnel are research orientated, which is required to develop biotechnological products.

“In the [agriculture cluster], when we draw out the SME segment, the small- and medium-sized, who basically are the research intensive companies, then about 40 percent of the employees have a higher education, meaning 4 years or more. I out of 10 have a doctor’s degree. That’s pretty high. That same SME segment is made up of about 750 people. But relatively weak on the commercial side, I would say, compared to other industries. Traditionally, the focus has been on research and development. So there’s a lot to think about when it comes to commercial thinking; marketing and communication.”

(The Agriculture CM)

On the same hand, most companies would benefit from more commercially oriented human resources, such as marketing personnel and sales people.
“I believe the realization is being made in our community. We have several examples of our companies having excellent products, which also have proven experimentally to be of significantly high value compared to competing products, and where the companies by presenting the documentation to potential customers, believe that [the presentation] will be enough to get contracts and sales. Then the experience shows that it works out, in the best case, poorly. So it’s necessary to integrate another commercial way of thinking in organizations. I think that’s something we’re about to learn.”

(The Agriculture CM)

Another key resource to act on the agriculture market, is to have a personal network.

“The agriculture market is transparent, but also partially closed. Being a new actor there can be relatively hard. Closed, in the sense that the channels are mostly based on personal relations. To get inside – just to get a meeting – you’re dependent of having someone who has a personal relation, or that you, well, ‘jam your foot in the door’ somehow. I think it’s astonishingly important to develop the personal relation and to get a long term relationship.”

(The Agriculture CM)

5.6.3 Value Proposition

Some biotech companies in the Marine cluster offer a basic product, for instance fish oil, but deliver it in different versions. This can be in form of capsules, in bottles or with lemon taste. Small alterations of basically the same product can create different value proposition, according to the Marine CM. However, most of the companies in the cluster have only one core product.

“They have oil that they put in capsules. Then they put the oil in capsules, and in that sense they have 2 products. Then they put lemon on one, and then they have 3. But generally, many [companies] have 1 core product.”

(The Marine CM)

The Agriculture CM mentioned a special situation for some of the cluster’s companies, where products often are tested by customers over the course of 3-5 years, to see how genetic products affect the life of the customers’ animals. During this phase the product is closely observed and offered mostly based on royalties. This long testing has the goal to demonstrate the value proposition to the customer.

“The customer himself needs to be given the chance to test the product, and you need to demonstrate the product with the customer. It’s a relatively long process to be accepted by a customer. Only testing the product takes 3 years. So from you have the foot inside the door, until you start earning income, it may actually take 5 years. It’s kind of a special situation. And then I’m talking specifically about genetics, because that’s what’s taking such a long time. Animals are born and tested, and so on, and so on. But in return, when you’re first accepted, there are long agreements, large agreements.”

(The Agriculture CM)
Looking at the competitors is very difficult in this sector, since on an international scale, scientists are in a race to develop new products. The Agriculture CM exemplified this by mentioning one of the newest developments in genetics.

“We see there’s a lot of development work being done in other countries. There was a newsletter saying that in 2020 there will come a new product based on a new technology, where pigs will be immune against the two deadliest diseases for pigs. And it that proves to be feasible, that’s something that will outcompete all the other actors in the market in a short period of time. The company that has developed this product will, at least in the most important markets, be able to push out many of the others. If you have an animal that survives, while the others die, the choice is very simple for the customer.”

(The Agriculture CM)

5.6.4 Key Partnerships

Key partnership for the Marine CM is the university:

“They [the university] play a central role, and they are member of our cluster. It’s not just a partner, it’s actually a member – exactly because it’s so important. In terms of creating a new business environment, the commercialization and research results are important. The university is a very important actor, and they are also very relevant in terms of making education that is adapted to what the future business environment needs.”

(The Marine CM)

The university is of major importance for the R&D process, since most companies don’t have their own laboratories. R&D can be done in cooperation with universities, which however requires clear agreements beforehand, to avoid legal issues in case of ownership of bio discoveries.

“Many of these R&D projects being run by the companies are in cooperation with the university, because they [the companies] don’t have their own R&D departments yet. They are too small for that. So they liaise with the university and rent the resources from them. But then in cooperation with their own resources, so that the rights to the projects are with the companies. The rights are with those who pay. So if they pay the university to contribute to their projects, it’s the company that owns it. There has to be made agreements before, otherwise the rights can be with the university, and then there’s little left for the company.”

(The Marine CM)

Key Partners are according to Agriculture CM the university, where most of the ground work is done in terms of research. Usually companies take over the development of the application of the product, but this is currently changing. More companies invite universities to take part in the research process, even for the actual application of the product. This shift might be due to the fact that universities monitor publications and acquisition of external funding by researchers, which can increase if researcher work on projects with a possible commercial application.

“The companies do very little of the basic research themselves. Generally, the typical divide between companies and universities, is that the university does the
Companies also cooperate with each other in the cluster, but usually on more ‘neutral’ projects. These projects can for instance include the development of database techniques, shared IT or administration.

“We have examples of shared development projects, for instance. And then there’s the development of methods, but to be able to cooperate it has to be more general. For example, there are some research projects on what is called genomic selection, which basically is a method for analysis of DNA and database management, the number crunching afterwards. And that’s the kind of shared projects for genetics companies where they cooperate on the basic method, but when they implement it in their own company, it needs to be adapted. They work together on the basics, then they separate when they use it for themselves. Otherwise, we have companies that have established shared functions, administration and IT, but that’s more because they have offices in the same buildings and because they are companies who naturally can work closely together.”

(The Agriculture CM)

Though the Agriculture CM did not talk too much about it, there also seems to be cooperation with other companies outside the cluster, from other countries in the EU. Participating in such projects has the advantage that they receive good amounts of funding from the EU. Both universities and companies can be partners in these projects.

“There are some of our companies that are partners in specific [EU] programs. Both companies and universities [are participating]. It’s always a cooperation between 2 or 3 partners. It’s a requirement to have at least 3 parties from 3 countries in an EU project.”

(The Agriculture CM)

5.6.5 Customer Segment

The Marine CM described that within the cluster, the companies address suppliers as well as users. For instance, fish oils are delivered to customers directly or to other stores where it is further distributed.

The customer segmentation in agriculture is by definition B2B. The end customers are farmers, and each farmer is formally registered as a business entity. However, this is a special business environment, because most farmers do not consider themselves as
companies. When the companies in the cluster do not sell directly to farmers, they deal a lot with large corporations or distribution companies.

“Per definition it’s business-to-business, but the main customers are farmers. Many of the farmers don’t see themselves as business people. But it’s still business, and many of them have revenues of several millions. But yeah, per definition it’s business-to-business. Internationally [the sales are] exclusively through distribution agreements, regionally or nationally, in many countries. Or direct contracts with large corporations, which is becoming more and more important. I see that the large agriculture- and food producers are organizing. They take all the value for themselves, and some of them are really large corporations.”

(The Marine CM)

5.6.6 Channels

In terms of channels, the non-pharmaceutical companies in the Marine Cluster can act on both B2B and B2C, depending on the product. Some of the cluster companies have for example food supplements that are sold to stores and distributors as well as directly to end customers through web shops. Companies like Non-Pharma 1, which offer a more sophisticated product serves as well other companies and/ or researchers directly.

“They sell online. One can go directly on their [the example company’s] websites and order. They also sell in sports outlets and supermarkets. So there are many companies that are both.”

(The Marine CM)

Agriculture CM described that mostly companies get in touch with possible customers on conferences, private networks and word of mouth. Personal connections seemed to be very important in this industry and entering it without having personal contacts might be difficult.

“There are several channels. Scientific conferences are actually relevant, because there you get to meet researchers from the customers’ companies. So that’s a possible platform; scientist to scientist. Informal references. Showing that you have a customer relationship with actor A to a great extent helps you open the door to actor B. When it comes to large corporations, then there’s not so many of them. In the US, for instance, then we’re talking about the 25 largest companies having nearly half of the market in one sector. So if you first make it with one of them, it spreads. There are only 25 decision makers nearly half of the American market for that sector. Therefore, word of mouth is extremely important.”

(The Agriculture CM)

5.6.7 Customer Relationship

Customer relationships are very personal and last at least 4 years, due to the required time to show effects in animals, in the special area of agriculture.

“In regards to genetics there are rarely made contracts shorten than 4 years, and there’s often 1-year automatic extension, so if you don’t actively terminate, it runs.
But often a minimum period is 4 years. And that’s also the time it takes for the customer to see the effects of the genetics. This is kind of supposed to flow down a pyramid. You begin at the top, and then one generation down, and then one generation down. And the animals, they live and reproduce, so it takes a long time before the product is accepted by the customer.”

(The Agriculture CM)

The Agriculture CM need for trust in the customer relationship. Because it takes a long time for the customer to be sure of the product’s value, it is important that they believe the company is capable of delivering what they are promising to deliver.

“It has a lot to do with trust, because you’re selling a product to a limited extent is physically manageable, right? What you’re selling is a progress. I’m saying that if you buy my product now, your pig will grow 50 grams quicker, and spend 10 kilos less feed before you can slaughter it. And then they need to test it themselves, but at the same time, many of the features they’re selling are not directly possible to measure. It takes several years to document them. So you’re also selling trust. You can’t afford to make mistakes. If you do, it takes an awful long time to get back again.

(The Agriculture CM)

5.6.8 Revenue Streams

Newly founded companies in the Marine Cluster usually acquire public money, while in the next steps, private investors become more necessary.

“What I can say for sure, is that the small companies, the newly established companies, the large part of their income is public funding. So there are many of them that runs the first years with only income form the public sector, plus they get in private capital, because the public funders demand that you also get some private funding, but there are large parts of public funding.”

(The Marine CM)

In general, the rural position of this cluster is dominated by public funding. If companies try to get private investors for their next steps, they have difficulty to find them. The Marine CM mentioned that there exist two perspectives on that: one saying there is a lack of private capital in the rural area, and the other saying companies communicate poorly with investors. New companies in their area are usually public funded, there is little private capital and small markets, therefore public funding is major source.

“I would say it’s a problem. There are few investors [in the region], most are centered around the [biotech] companies in [the capitol city]. They say starting entrepreneurship is easy; to build a business, or that to establish a business is easy; to get capital for that. There’s plenty of public funding, at least in [this region], in the first stage. But then there’s the middle stage, where you are growing larger, and then there are more companies who have difficulties with getting capital. I’m a bit unsure why they are struggling, if it’s because they don’t communicate well enough, or if it’s really a capital draught in that segment. There are different things being said.

(The Marine CM)
In terms of revenue streams, the Marine CM said that some companies try to finance their R&D process with sales, which usually is not sufficient. A company on a low and strict budget can be more expensive in the long run, since other investments, what the informant described as “soft investments” are not done and growth can be slowed down.

“In terms of capital, you might reflect that if there had been more capital, the development phase would go faster, because there’s this saying that it’s expensive to be poor. So if you’re always short, you don’t get to do the most optimal things for innovation. And if you don’t get the investments, not the soft investments either, that stops you from gaining more in perhaps 5 years. We have successful company in the cluster that has been very good at investing in R&D. While others haven’t done that. They [the others] want income from sales, and then it’s supposed to finance the R&D, but then you never really finance R&D sufficiently enough to be able to grow.”

(The Marine CM)

Companies in the Agriculture cluster usually have a conservative funding strategy. Some are stock listed, some even use bank loans, but in general private investors such as VCs and ownership by external companies is seldom. Agriculture CM described this as a cultural issue, where most companies don’t want external owners in their company.

“Today it [the use of capital] is very conservative. In the cluster, we have both cooperatives and regular stock-listed companies. But especially the cooperatives are very conservative in their use of capital. They can go as far as a loan in the bank. There’s no tradition for taking in investors, for instance. It happens probably in spin-offs when it’s a daughter company being established, then at least they consider taking in financial investors. It has something to do with tradition, I think. The cooperatives are very responsible. They are owned by farmers. They don’t want to take risk, and they see taking in other owners in the companies as exposing themselves for risk”

(The Agriculture CM)

This the Agriculture CM believes might have a negative effect on the development rate within the cluster.

“I believe the way capital is being used, or how it’s not being used, is limiting for the development of some of our actors. It’s an explicit objective for the cluster to increase the rate of development. We want to take the good ideas, develop projects and eventually make companies out of the good ideas, meaning spin-offs. But in such a process the unwillingness toward capital is inhibitory, because everything runs slower if you try to finance only by your operations. Then you can do, perhaps, only 1 or 2 projects over 5-year period, or something like that. For us, that attitude can be a challenge.”

(The Agriculture CM)

Other than that, public funding is available, both national and European ones:

“We have a great deal of companies who are good at utilizing those support programs that exist. The most significant are probably the opportunities through the national research council and regional research funds. Also EU projects are running. There are very big research programs being financed by the EU. They
are a bit difficult to get into, but when you’re first in, there’s a lot of money available.”

(The Agriculture CM)

Same as what has been told by other informants, the Agriculture CM estimated that around half of the research processes are publicly funded. The rest of the costs for R&D projects is financed through sales.

“If we really investigate our companies, then I believe we would find almost 50 percent public funding for the R&D activities. And that is all that’s possible. Within the limits that are set, it’s not possible to do anything more. But it means that the companies succeed in turning 1 dollar into 2 dollars in a research and development perspective. For other operations they have the usual income from sales.”

(The Agriculture CM)

The Agriculture CM added that being dependent on sales is one of the reasons why the companies in the cluster are all internationalized. The local national market is too small to generate revenues that can cover the companies’ costs.

“It’s a fact for several of our companies, the national market is too small to cover all their costs and to run their development projects. So that’s the reason why they have internationalized. It’s simply to maintain the activity level of today. They need a larger market.”

(The Agriculture CM)

5.6.9 Cost Structure

In general, the Marine CM described personnel as a cost driver. In R&D extensive companies, main cost is definitely the research.

“Personnel is a high cost, but such as the raw materials is a relatively small expense. But there are many companies having R&D expenses. For those who invest a lot in R&D, the R&D expenses are much higher than the rest of the costs in the company.”

(The Marine CM)

Sales cost appear to increase on average as well, which the Marine CM thought to be due to increased marketing efforts in the cluster.

“If you look at the costs the last few years, compared to 10 years ago, and 5 years ago, you will see that the cluster’s average for sales costs has increased. So perhaps it has increased more than other costs, that I would assume. There is an increased understanding for the need to sell. Many companies have [in the past] been very product oriented. Especially if it comes from the university, then the reasoning is: “my product is so unique, that people will run me down to get ahold of it”. But then you see that’s not the reality. So there’s been given more focus to that [sales] lately.”

(The Marine CM)
When it comes to equipment, the clusters offer the possibility to rent out expensive equipment, so that companies do not have this financial burden. And, as mentioned earlier, many of the companies in the cluster also avoid to invest in R&D resources by renting and sourcing what they need from the University.

The Agriculture CM said that the knowledge intensive companies in the Agriculture cluster spend a big part of their budget on qualified personnel. Also production costs a lot, since wages are high in Scandinavia.

“These are knowledge intensive companies, so it [the highest costs] is people. Personnel is the highest cost – and the greatest resource. At the same time, a lot of personnel is covered by the R&D activities and the public funding for the R&D, because it [the public funding] covers hours, mostly. R&D is a large post. Several of these companies use more than 20 percent of their yearly total budget on research and development. Of course, the production happening in [Scandinavia] costs a lot of money, so there’s a cost of production too.”

(The Agriculture CM)

5.7 Emerging Themes

The interviews showed various challenges which the biotech companies face, some we anticipated as well as additional ones. In addition, informants gave insight to strategic issues and effects of political and cultural implications. In accordance with the holistic research approach the business model and this thesis, these results are presented as well.

5.7.1 Pharmaceutical Biotech - Challenges

First and foremost, for pharmaceutical SMEs, the research process with its implied high risks and high costs is inevitable. Chances of success are very small, and as the CEO of Pharma 2 put it: “This is a gamble”. But on the same hand, researchers know about this challenges before they start. The time it takes to do the research process, preclinical and clinical is known beforehand as well as the risks. The risks in the research process are the unpredictable outcomes of the research process, due to the complexity of biological systems.

“With small companies there is really not much calculating. You have to do it, and then test. You have to do the critical test. If you avoid the critical test, that’s where the problem starts. You have to always test, so that you know if you should kill the product. So I mean, the whole drug development is risky, but it’s part of the business. This is a gamble. You know the risk, and you have to take chances.”

(The CEO of Pharma 2)

As a result, smaller pharmaceutical SMEs experience backlashes in the research process, which are likely to be fatal.

“[…] What you know for sure, is you will always have backlashes. And if you have a backlash in [a big pharma company], it’s not good – we [the Industry Consultant’s former big pharma company] have withdrawn products from the market, but we survived. If you are in a small company, and you have a backlash, then you are really in a bad position.”
“This is a process. Either they [the medical products] have no effect, or they are toxic. It’s very simple. You have to start to show that they do something useful, and the next step is to show that they aren’t toxic. And that’s where most fail. You almost always have some sort of aversive effects. We realized it. I mean, we have had our failures. We had compounds that were toxic. We knew there was no way we should proceed, and we closed down.”

(The CEO of Pharma 2)

In terms of funding, every step requires usually new funding since huge sums are required to finance the research. New funding requires more viable data, so that the investors can see that the product is progressing. Having backlashes in the trials can therefore result in insufficient funding and termination of the product and the company. Since the research and ability to acquire funding are so related, finding an investor who understands the process and product is so important and at the same time challenging. Pharma 2 used the term of intelligent capital to describe this.

“You have to have intelligent capital, who knows, and that [finding such intelligent capital] is really lucky. They don’t know in what they invest in, in biotech. They have no idea in what they invest in. It’s very difficult. You make a promise very early on that you got to the market and there is no way they can judge it, the problems.”

(The CEO of Pharma 2)

Pharma 1 described a case in which investors tried to bargain the amount of money invested for the clinical tests. Not willing to invest the required amount, a clinical study was carried out on a reduced number of patients, which resulted in having no statistical significant outcome. It was still a high investment, but in the end it was useless.

“I once had a story in a previous company, which I took over to turn around. We had a phase 2 study running in 36 patients. I asked my chief medical officer, and I said: “Are you sure 36 patients are enough?”’. He said: “No, it’s not going to be enough, because the statistical power of the study said we should include 48”. And Lord behold, when the study was finished, it showed a trend, but it was just not statistically significant. And then I had to present this to my investors, and the investor said: “What’s this kind of crap? We can’t use that, because it’s only a trend”. So then I said: “Excuse me? But I mean, you were presented with that cost for 48 patients and said you only would give two thirds of it”. It just doesn’t make sense. So they sometimes destroy many [companies] by some unrealistic shrinks.”

(The CEO of Pharma 1)

Even if a company goes successful through the research stages and tries to sell to a big pharma, the chances of success are still low. According to Pharma 2, big pharma screens around 2000 projects annually and realizes only around 3.

“People have a very naive view on this. The only big customer is the pharma, the rest is completely irrelevant, of no interest. And you know, they screen 2000 projects each year and they go further with 3. So that’s a challenge; you have to be one out of 1000. That’s the numbers you have to fight with.”

(The Industry Consultant)
5.7.2 Non-Pharmaceutical Biotech - Challenges

The challenges biotech faces with non-pharmaceutical products are rather different. Where the research process is at the core of the pharmaceutical biotech, non-pharmaceutical biotech can outsource parts of the R&D process, for example to the university. From previous quotes from the CMO of Non-Pharma 1, we see that Non-Pharma 1 outsources its discoveries to the partner university, from which the company then licenses the right to use the compounds in its products. Also the Marine CM and the Agriculture CM mentioned in previous sections that the basic research is often done by the universities. Furthermore, the university often participates in the applied research as well.

The main challenge of the non-pharmaceutical biotech is to keep pace with the rapid changes in the industry. Since the industry acts globally, but is bound by local laws and regulation, countries like the UK and China might be able to develop new products faster and outcompete SMEs in Scandinavia. This puts constant pressure to improve and introduce new products, as told by the Agriculture CM in section 5.6.3.

Companies have to maintain a close relationship to their customer, usually on a personal level, to gain or retain customers (Non-Pharma 1). Customer meetings and international conferences require to be actually present, despite advances in IT. Since most marketing is done on a personal network level (Agriculture CM), companies require certain qualities in their staff, that is knowledgeable in biotech, business and able to network. Acquiring staff with broad knowledge can be especially challenging for startups.

5.7.3 Strategic Themes

As the CMO of Non-Pharma 1 described it, everything in Biotech is a team effort. The industry heavily outsources, because no company can inherit all the interdisciplinary skill required.

“Thinking that you have a compound, you can make a diagnostic test and sell it to the World, that's just too much work for one company. So even the big global companies, they don't do everything themselves. They source in different parts from other companies specializing in for instance one compound, one biological marker, some equipment... everything is sort of a combined effort from different companies.”

(The CMO of Non-Pharma 1)

Structures can be extremely lean as described by Pharma 1, especially in economic downturns. Agreements are project-based and employees are often part-time employed to avoid obligations after the employment ends. As a consequence, biotech companies are constantly interacting with many parties in a very dynamic environment on a global scale.

“I can tell you what happened in the financial crisis. You know, all the industries, it took a while before they sort of negotiated their wages down. In biotech it happened over night. If you had a good position, and your company didn’t change,

(The CEO of Pharma 2)
of course they didn’t decrease your salary. But some companies went under, they couldn’t be financed, and some very experienced people didn’t have a job. Wages were very, very quickly negotiated down to a more realistic level in biotech contrary to many other stable businesses. In a lot of companies, even very profitable companies, they only employ people part-time.”

(The CEO of Pharma 1)

This environment can on the same hand open strategic possibilities for companies. If a product fails first, it is possible in some cases to change the area of its application, as was discussed by several of the informants. The Industry Consultant and the Marine CM both told examples where problems occurred in the pharmaceutical development, which consequently changed the companies’ application of their pharmaceutical products towards non-pharmaceutical products. In these case the products became food additives and gels, instead of medical treatments. Less strict regulations for non-pharmaceutical products can make this switch possible, however it is always highly depended on the product itself and how creative the company gets with its possible applications.

“They [the pharmaceutical SME] made a clinical phase 3 study, then they failed in that phase. It had something to do with the packaging, which they had miscalculated. It was a chemical reaction that happened there, and they did not get good results in the clinical phase 3. They had to withdraw and think, so now they’re not in pharmaceuticals, but in medical device. Now they have a lotion with healing effects. Regulations are a bit easier, and it doesn’t take as much time. Not so cost-demanding.”

(The Marine CM)

“Actually, this kind of [non-pharmaceutical] product I’m talking about, theoretically it would have been no hinder to develop it into a pharmaceutical drug. Once you can prove that you have a clinical effect, you can claim that it is a pharmaceutical product. You can get it approved as a pharmaceutical product. However, people tend to not go this way, because it is an enormous development work, there are enormous costs making it into a drug. Therefore, you can instead go for functional food, go for medtech approval, or make it as a food supplement.”

(The Industry Consultant)

Another strategic issue, which was mentioned by the Marine CM, was in the increase of costs per sales. This let the informant believe that companies increase their marketing efforts and change towards a more customer centric perspective. Also the Agriculture CM had noticed such a shift toward a more customer centric way of thinking in the Agriculture Cluster. This perceived importance of the customer centric perspective was shared with almost all informants. Having a clear look at the market and the need of customers is a central strategic theme, and mentioned by many informants as a key activity.

5.7.4 Cultural & Political Factors

The interviews also showed cultural and political factors that may influence the business models of the companies. Several of the informants, including the VC Agent, discussed that many researches do not always take an economic perspective on their projects.

“It’s a challenge, I think. It’s mental challenge not to be focused on the technical aspects only. Many inventors, they really think it’s a great thing they have, and
often it is. But they need to also ask other people; do you agree this is a fantastic thing?"

(The VC Agent)

The Industry Consultant mentioned that some researchers have an “inside-out” thinking, meaning they believe so much in their product that they do not take a customer-centric perspective. As a consequence, some companies lack relationships with specialists, who could give valuable feedback.

“I’ve seen small companies who really lack a tight and a proper relationship with specialists [i.e. potential customers/users of the product]. They [the researchers in these companies] have another way of thinking. They think that they don’t need the influence of the outside. That’s what I mean with inside-out thinking; you are only considering your own thoughts. But when it comes to marketing, you have to think the other way around.”

(The Industry Consultant)

The IP Advisor explained that some researchers don’t like the idea of starting a company and commercialize their product, because they want to do their researcher for the greater societal good and not follow commercial interests. The IP advisor pointed out that he thinks this is a noble way of thinking, but that it often leads to the research not helping anyone at all, because the commercialization aspect is crucial if you want the knowledge to reach those in need of it.

“I can take an example. We had a product and a method. Everything was out there for treatment of cancer for children. They [the researchers] did not want to make any money, they just wanted to make it good for the kids having cancer. I said: “Why don’t you want to make any money? It doesn’t mean you need to drive a Lamborghini. Think about it, there are areas in the US where you could use the money that you earn to let those kids get it, wouldn’t that be great?”. They didn’t want to make any money, but then they realized: “Okay we can make some money, because then we get a sustainable business model, and can pay any profit to the child cancer foundation”. But one of the parties in the project had created something that was essential to the project, and that person said: “No, I don’t want to make any money. You cannot make any money on this that I have done”. So where did we end up? The product is not out there.”

(The IP Advisor)

The VC Agent and the IP Advisor mentioned that some researchers do not want to give up their safe positions, often at the university, to pursue the risky path of starting a business. Looking at the chances of success, especially for pharmaceutical SMEs, both informants found this understandable. As reflected by the IP Advisor, turning researchers into business people might not even be an effective use of the researchers’ competences. Following a similar line of argument, the VC Agent said it could often be a good solution to bring professional management in as CEO of the biotech companies, rather than the researchers being CEOs themselves.

“Why make an excellent researcher a semi-excellent entrepreneur?”

(The IP Advisor)
They [the researchers] should be very dedicated. They shouldn’t believe that they can do this on the side. That’s a problem we have sometimes. If you are a researcher, you usually have different collaborations on the side [of your main research]. If you think this [the company] can be just another thing you can do on the side, then that will not be very successful.

(The VC Agent)

A reoccurring theme was about the investment climate. Informants described the investment culture in the US as better than in Europe, where investors offer smaller sums and are in general more conservative.

“[It’s easier to get funding] if you are in the US. It's very difficult in Europe.”

(The CEO of Pharma 2)

High taxation and a more egalitarian culture in the Nordics might be a reason to a different mindset on investing, according to the CEO of Pharma 1. We asked the informant why he thinks it is difficult to get funding, and why Scandinavia is more difficult than the US:

“Because in Scandinavia we don’t have much biotech. And the other thing is that we have very different society [from the US] in the extent that we have extremely high taxation and an extremely high ambition to be egalitarian. So Scandinavian politicians talk about how we should have a strong biotech, or a strong IT sector, bla bla bla. Yeah, that’s fine. But you will never as a society now be able to get richer. I mean, I know there’s a few rich people in Scandinavia, but it’s very, very few. Because it’s really not accepted by the societal model that we have. The reverse is true in the US, where there is a culture where they hype people like Elon Musk, who created Tesla and Space X. You know, they don’t even want to talk about that the guy is a multi-billionaire. He is super creative and he brings a lot of money to Silicone Valley, and that attracts a lot of good brains also from Scandinavia. In the US there are so many rich individuals that backs up companies, because they make money on other people.”

(The CEO of Pharma 1)

The CEO of Pharma 1 added that not only is it harder to get funding from Scandinavian investors, you receive funding under very different conditions. In this respect, the Scandinavian investors are more conservative in how much they grant. This is something the CEO of Pharma 1 thinks is unfortunate, because as shown in a previous quote, not investing enough in the R&D can have dire consequences.

“If you ask them [the US investors] for 10 million dollars, they say: “Are you sure 10 million dollars is enough? You know what? Maybe we should put in 20? Just to make sure there's enough.” Their mindset is just completely different. The Scandinavians will say: “Oh, you need 10? Well, why don’t we give you 3?”

(The CEO of Pharma 1)

Looking at the investment culture on a national scale, the northern parts in the Nordics are geographically separated from investors and industry, which are usually found near the capitols in the south, as mentioned by the Marine CM in section 5.6.8. The Marine CM wasn’t sure about the exact reason but stated that either capital is actually scarce or companies communicate poorly.
The CEO of Non-Pharma 2 stated that Scandinavian biotech companies offer great technology, but usually lack the ability to market it properly.

“I think Scandinavian [biotech] companies generally are not good enough on marketing. They are very good at technology in many ways, but not good enough on marketing. So generally, I would say that that’s where the greatest potential for improvement lies.”

(The CEO of Non-Pharma 2)

In section 5.6.8, the Agriculture CM described the investment culture in this cluster as very conservative and averse of sharing ownership with private investors. Companies would rather choose a slower development, taking bank loans, than letting in private investors, even in form of minority shareholders.
6 Analysis and Discussion

How do biotech SMEs structure their business model to cope with the challenges of the industry? To answer the research question, this chapter contains a discussion of how the characteristics of the business models are related to the industry’s challenges.

The previous chapter presented the empirical data that resulted from the interviews. In this presentation we made a distinction between the SMEs that develop non-pharmaceutical products and the SMEs that develop drugs. This distinction is made because challenges differs, which results in different business models for pharmaceutical SMEs and the non-pharmaceutical ones.

6.1 Comparison of Pharma and Non-Pharma

What are the differences and similarities between pharma and non-pharma? Section 1.2.1 referred to the American FDA’s definition of drugs. Both pharmaceutical and non-pharmaceutical products are biological products, but pharmaceutical drugs metabolize in the body and non-pharmaceutical products do not. Based on this distinction, we gathered data from two SMEs doing drug development and two SMEs developing non-pharmaceutical products. The purpose behind this was to explore how their business models might be similar or different, and why.

We could see great similarities between both pharmaceutical companies. The non-pharma companies shared as well similarities, but not as strong as the pharmaceutical ones.

6.2 Overview of the Business Models

The characteristics for the building blocks of each company was presented in chapter 5. The characteristics are summarized in Table 5 to outline the main differences and similarities between non-pharma and pharma. The data from Pharma 1 and Pharma 2 are grouped into the ‘Pharma’ business model and the data from Non-Pharma 1 and Non-Pharma 2 are grouped into the “Non-Pharma” business model:

<table>
<thead>
<tr>
<th>Building Block</th>
<th>The Pharma Business Model</th>
<th>The Non-Pharma Business Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key activities</td>
<td>R&amp;D</td>
<td>R&amp;D</td>
</tr>
<tr>
<td></td>
<td>Financing</td>
<td>Financing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marketing and sales</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Production</td>
</tr>
<tr>
<td>Key resources</td>
<td>Patent</td>
<td>Patent</td>
</tr>
<tr>
<td></td>
<td>Capital</td>
<td>Capital</td>
</tr>
<tr>
<td></td>
<td>Network</td>
<td>Network</td>
</tr>
<tr>
<td></td>
<td>Know-how in R&amp;D</td>
<td>Know-how in R&amp;D</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Know-how in Marketing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Know-how in Production</td>
</tr>
</tbody>
</table>
Value proposition [VP] | Defining VP takes years | Defining VP relatively short, since R&D can happen at University
---|---|---
Customer segments | Big pharmaceuticals (distributors) | Distributors and end users (end users = businesses)
Customer relationships | Personal Distant One-time transaction Short-term | Personal Close Continuous collaboration Long-term
Channels | Conferences Personal references | Conferences Personal references Word of Mouth
Key Partnerships | University Venture capitalists CROs | University Parent company Government Research Institutes Customers Suppliers
Revenue Streams | Private funding | Private funding Government funding Sales
Cost structure | R&D (clinical trials) | R&D (product development), Marketing

Table 5: Non-pharma and pharma characteristics per building block.
6.3 The Pharma Business Model

The most apparent challenge of the industry is the R&D process. For pharmaceutical development it is 10-20 years long (Pisano, 2006, p. 117), overall costs on average 900 billion USD (Kola & Landis, 2004, p. 711) and outcomes are highly uncertain. As Pharma 2 put it: “It’s a gamble”. As we could see in the interviews with two non-pharmaceutical companies, their R&D process is 3 months up to 5 years (Non-Pharma 1), estimated costs are lower and uncertainty to the outcome is also lower. One factor that prolongs the process and increases the costs are the extensive regulatory framework around pharmaceutical drug approval (VC, IP advisor). To ensure the use is safe in human, the product is tested extensively in clinical trials. The following business model (Figure 7) shows the results of our findings for each building block, which will be explained in the following. The order in which each building block is explained based on the biggest challenges of pharma SMEs, to show the logic how these shape the pharma business model.

![Figure 7: The pharma business model.](image)

A long R&D process means first of all that there are no sales and that most activities in the company are research related. Regarding the sales, companies rely on funding. This affects the building block of **revenue streams**, which describes the financial capital that can be generated by the company (Osterwalder & Pigneur, pp. 40). The funding can come from the university and public funds in the beginning, but as soon as more extensive studies are conducted, such as the clinical tests, usually private capital is required from VC’s or business angels (VC). We could see that the cost structure shifts over the life time of the company. The early research can be done with smaller funds at the university (Consultant), but the further the research gets in the clinical tests, costs increase dramatically (Pharma 2). Acquiring funding is intertwined with the research, which is the **key activity** that keeps the pharma Biotech business model working (Osterwalder & Pigneur, 2010, pp. 36). Doing the research, creating new viable data, allows the companies to apply for new funding (VC). For instance, showing that your product is not
toxic is required before a company can even apply for testing in human, as well as finding an investor who might be interested in it. With the costs increasing, acquiring larger amounts of private capital for the later research stages becomes necessary. The acquisition of capital becomes an increasingly important key activity, compared to earlier stages where smaller sums were acquired with possibly less effort.

Since the research activity is crucial to generate revenues for the company, we look at the necessary key resources and key partnerships supporting it. The key resources for a R&D heavy company is intellectual (Osterwalder & Pigneur, 2010, pp. 34) and from qualified personnel (Renko et al, 2005, p. 264). To be able to drive the research further, experienced personnel is key (Pharma 1) and the created knowledge has to be legally protected (Pharma 2). Pharma 1 and Consultant saw another key resource in a network, which is relates to the building block of key partnerships. In the following is described how the building block is shaped in pharmaceutical biotechs to support the key activities and key resources.

The key partnerships are the network surrounding the firm, possibly optimizing economy of scale, reduction of risk and supporting the acquisition of resources and activities (Osterwalder & Pigneur, 2010, pp.38). Both Pharma 1 and 2 were still involved with the university, but it was unclear to which extent the university contributes to the ongoing R&D. However, in terms of acquisition of resources, most personnel come from the university and the product usually is discovered there (Pharma 1, CRO). As we saw in the previous paragraph, producing viable data is crucial to acquire funding for the next steps in research. At this point, the uncertainty of the R&D process becomes a major challenge. The complexity and limited knowledge of biological systems inherit that outcomes are uncertain. As Osterwalder & Pigneur (2010, pp. 38) see one function of key partnerships in the reduction of risk, networks can play a crucial role. Using specified clinical research organizations (CRO) or manufacturing organizations (CMO) supports the planning and execution of the the research process. Since these organizations are specialized in their area, they can reduce the risk of the research process due to their knowledge and experience with quality standards. Inter-firm cooperation seemed to be rare. According to Pharma 2, their product is so specialized that there is no use in cooperating, since others lack the expertise. OCR mentioned a scenario where companies have complimentary skills, such as one doing the application of the other company’s drug. Agriculture CM mentioned cooperation in a context of “neutral” tasks, such as shared infrastructure. Not having more information, we assess the role of inter-firm cooperation as less present in pharmaceutical biotech company’s business model. For the early process of the pharmaceutical company, the incubator can be supportive to general support, for instance administrative matters, and applying for the first funds (VC, CRO). We could see that the role of the incubator faded as the company progresses. Another aspect is the “intelligent capital” (Pharma 2) or “competent capital” (Marine CM). This describes a financial resource that in addition has knowledge about the R&D. Therefore, investors can shift into a role of partnership where they can support the development process (Marine CM).

The long and risky R&D process has major implications for the value proposition, of the product, a set of benefits for the customer (Kotler et al, 2010, p. 15). Upon discovery of a new product, its value proposition is completely unclear (CRO) and even in the last clinical phase III, a product can fail. It is in addition relatively clear to companies, what value proposition a new product has to offer, since the characteristics of a new product
have to be within the regulatory framework for new drugs. The company has to show that the product is safe to use in humans and that it has a better effect than existing drugs. The parameters by that are clear and transparent. That is why the pharmaceutical biotech business model is so “back heavy” and the customer focus is not as present as one would expect from other industries. Customer segmentation, relationship and channels of communication play a subordinate role.

Segmenting customer groups to offer each group a distinct offer (Osterwalder & Pigneur, 2010, p. 20), which are for pharmaceutical Biotech SMEs big pharma companies (Renko et al., 2005, p. 252). The distinct offer is however relatively clear: the product has to show a proof of concept and address enough patients to be financially interesting. Therefore, customer segmentation happens on a smaller scale, looking into which big pharma might be specialized in a certain category of drugs. The marketing efforts done by the company are more of a fine-tuning, getting in touch with possible customers and including adjustments to their research. Because the customer segmentation and in general a market perspective plays a subordinate role, the companies relationship and communication with possible customers differs from other industries. Customer relationship, considering acquisition, growth and retention of customers (Kotler et al., 2010, p. 19) and creating a customer experience (Osteralder & Pigneur, 2010, p. 28) is less relevant since companies sell their product only one time. Acquiring customers is obviously still important, but since big pharma are depending on innovations from Biotech SME’s to supply their product pipeline, there is a mutual interest. Whether they can be acquired as customers is driven by the proof of concept that results from the research. This process is only driven by facts, wherefore creating a customer experience seems less relevant. Growing and retaining customers are also less relevant since there is one product sold one time. After sale, companies remain sometimes in a partnership with a big pharma, to support the knowledge transfer of the patent (IP Advisor). Channels include communication, sales and distribution (Osterwalder & Pigneur, 2010, pp. 26). Communication happens sporadically on a personal level. They can meet physicians, CRO’s and investors on certain events to gain personal contact and marketing insight (Pharma 1 & 2, VC, CRO). This represents most of the marketing intelligent companies get and market efforts they do. The distribution plays a less important role when transferring intellectual property. The sales process is relatively standardized (Pharma 2) except the exact price is based on negotiations.
6.4 The Non-Pharmaceutical Business Model

To look at the non-pharmaceutical business model, we start at the same point of R&D process and show how its different nature leads to different implications in their business model compared to pharmaceutical Biotechs. Non-Pharma 1 has a production development process that takes 3-6 months, constantly acquiring new products coming from the university. Non-Pharma 2 developed its product over the course of 10 years, but continuously develops its application in possible other areas. Non-Pharma 1 does not have to deal with high uncertainties, since the products function is clear when they acquire it. Non-Pharma 2 probably faced risk of uncertainty at the beginning of their research as well. In terms of costs per product, Non-Pharma 1 and 2 are probably below the R&D costs of pharmaceuticals. One aspect is the regulatory framework in pharmaceutical development, that lengthen the process and increase costs drastically. Regulatory framework for non-pharmaceutical products is less strict. In general, the non-pharmaceutical products can differ in terms of how much knowledge is required to create a product. The higher specialized the product and the more knowledge a product requires, the higher can get the R&D related costs, such as qualified personnel (Agriculture CM). This will also relate to the number of products in the company’s portfolio. The main difference between Non-Pharma 1 and 2 is that Non-Pharma 1 has multiple products, for which it outsourced the R&D process. Non-Pharma 2 has one product, which required relative long and high R&D costs. Our results for the Non-Pharma companies are summarized in the following figure 8. The order in which each building block is explained is based, just as the previous pharma SME model, on the challenges and how they shape the business model.

Figure 8: The non-pharma business model.

Looking at the possibility to earlier generate sales than pharma, the non-pharmaceutical business model shifts from the research-heavy one in Pharma 1 and 2, to a more customer focused one. Revenue streams can consist of around 50% of sales and 50% of public funding in cooperation with the national research council. Different to pharmaceutical
companies, non-pharmaceutical companies can make a public offer at the stock market to raise funds (Consultant, OCR, IP advisor). Research is still part of the key activity, however due to the possibility to sell a product, Non-Pharma 1 & 2 put more effort into marketing than Pharma 1 & 2. In terms of costs, we don’t see the pattern of dramatically increasing costs in non-pharmaceutical biotech as we see in the pharmaceutical companies that are going through clinical tests. The pressure to acquire external private capital is lower, both Non-Pharma 1 & 2 were funded by their umbrella corporation and the national research council.

Since the key activities of Non-Pharma include more marketing efforts, required **key resources** differ. They still require qualified personnel, but their skills are required in research related topics as well as marketing. As Non-Pharma 1 stated, knowledge about customer needs becomes a crucial resource, to lead marketing efforts. And this is where Non-Pharma, as opposed to Pharma 1 & 2, puts building blocks around the customer into their center. Non-Pharma 1 has to constantly reestablish their product’s **value proposition** to fit their customers’ needs. To achieve this, they constantly seek out feedback from its customers, as Non-Pharma 2 does with its end users. Major difference to the pharmaceutical biotechs is that non-pharma companies can send products out to test to their customers. This allows the companies to adjust their value proposition to the customer needs (Agriculture CM, Non-Pharma 1) and evaluate the market potential of a possibly new product.

Since there are repeating sales, Non-Pharma 1 & 2 seek to establish a close **customer relationship** to improve their product, grow and retain customer segments. The close relationship is crucial in the fast changing industry and to monitor future needs of customers (Non-Pharma 1). This also results in a different use of **channels** compared to Pharma 1 & 2. Communication happens on different levels, websites, ads and conferences. Most important is the personal communication and word of mouth (Agriculture CM, Non-Pharma 1 & 2). For pharmaceutical biotechs the same efforts would be less relevant. Pharma 1 & 2 focus on the R&D and sporadic exchange with big pharma is at early stages sufficient. High marketing efforts are unlikely to persuade big pharma, which will make a fact drive assessment of the potential pharmaceutical product. As mentioned previously, Non-Pharma 1 & 2 have sales, which results in the physical distribution of their product. In terms of **customer segmentation**, we saw more diverse customer groups for non-pharmaceutical companies, where Non-Pharma 2 deliver B2B as well as B2C in some cases. According to Marine CM, non-pharmaceutical companies can serve both customer groups.

As described by Jonas & Clifford (2005, p. 807), collaboration is one of the success factors for Biotech SMEs. We see compared to Pharma 1 & 2 more possible **key partnerships** with universities and other companies. In early stages, the incubators can offer valuable support in many areas, such as first administrative steps, market evaluation and help to access early funding (OCR, VC). The consultant described the network of a company as valuable source the get an evaluation on a product. Renko et al., (2005, p. 807) see also the network as an important source of market intelligence, especially in smaller companies where resources are scarce and extensive market evaluations are difficult to conduct. The university played a vital role for Non-Pharma, not only because they purchase their products from it, but also because the university supports in some cases the product development process. Interfirm cooperation seems to be more likely
than in pharmaceutical products, although they usually remain on more “neutral” grounds (Agriculture CM) as shared infrastructure for example.

6.5 Discussion of Emerging Themes

As we could see for Non-Pharma 1 & 2 projects can be funded up to 50% by public funding, political decisions can therefore have a direct impact on their business. This increases the relevance of the public funds and results in a dependency by northern companies on the political climate and how much funding the government offers. In addition, Agriculture CM mentioned the different business culture, where the companies in this cluster tried to avoid private investors and the shared ownership resulting from such an investment. This can lead to a slower business development, which companies take over shared ownership, according to Agriculture CM under his cluster. Both factors together, dependency on public funding and unwillingness to have shared ownership could increase companies’ exposition to political decisions on in- or decrease funding possibilities.

An emerging theme was that there is a cultural difference between Europe and US. Europe has a conservative investment climate with lower investments, where in the US, investors “think bigger” (Pharma 2). It was interesting to see, that the investment climate in the less populated north was seen as more difficult as in the south (Marine CM), and to seek investment most companies visit events in the south to establish personal contacts (VC), which were seen as crucial networking (Agriculture CM). The question is: why do companies in the north struggle with financing? Information technologies advance constantly and the products are mostly intellectual, which means they can be communicated easily, and Biotech is one of the most global industries (Pharma 1). The location should therefore be less relevant. Marine CM argued, that either financial resources are scarce or communication by the companies is lacking. As we heard from informants (Pharma 1 & 2), acquiring capital is not easy but definitely possible, we come to the conclusion that there might be an issue with the communication on the companies’ side, on which Non-Pharma 2 agreed on, for in his perspective Norwegian Biotech SMEs. Personal Networks and word to mouth marketing were seen as crucial to get access to the market (Agriculture CM, Non-Pharma 2). Personal contacts could affect greatly the communication, although the industry is global and communication in a digital age is easier than ever.
7 Conclusion

This chapter first presents our research findings, which is the section where we provide an empirical answer to the research question of this thesis, namely: “How do biotech SMEs structure their business model to cope with the challenges of the industry?”. This is followed by theoretical contribution, where we indicate how the findings contribute to theory. We then discuss managerial implications and give suggestions for future research. Lastly, we discuss limitations.

7.1 Research Findings

The objective of this thesis was to find out: “How do biotech SMEs structure their business model to cope with the challenges of the industry?” In order to answer this research question, the business model canvas was used to describe the companies’ business model and how their business models relate to the challenges which we identified. The major and most prominent challenge which we identified was the R&D process, with its length, costs and uncertainties. Our main finding is that the degree of length, costs and uncertainty of the R&D processes for the companies’ products directly affected key activities and revenue streams, which consequently influenced the shape of the other building blocks in their business models. In short, the summarized answer to our research question is therefore that biotech SMEs structure their business models by altering their key activities and key resources. The length, cost and uncertainty of their R&D processes is in essence what decides which activities the SMEs perform and which resources are the most important for them to acquire. A more elaborate explanation to the main finding is presented in the following:

Although all four companies work with biological compounds, their business models differed greatly depending on their products’ field of application. The reason for that is the degree of R&D length, cost and uncertainty. This lead to the distinction between pharmaceutical SMEs and non-pharmaceutical SMEs.

The pharmaceutical SMEs are developing medical products for use in human, which comes with strict regulations and rigorous clinical tests to ensure the products’ safety, and which dramatically increases the R&D length and cost. Uncertainty follows from the complexity of anatomy, because it is near impossible to know exactly on beforehand how the medical product will behave or perform in the clinical trials. Uncertainty is further enhanced by the need for funding from private investors and partnerships with big pharma companies, because agreements with these actors are rare and very difficult to acquire. The pharmaceutical SMEs cope with these challenges by highly specializing their operations and resources. Their key activities are characterized by that they do only one product development process at the time, and their key resource is the research personnel, who are highly specialized in the narrow discipline needed to develop the product. All other resources, perhaps except a CEO to take care of the administration of activities and acquisition of resources, are outsourced in order to keep costs and investments down.

The non-pharmaceutical companies in this thesis developed products used in diagnostic and in animals. The R&D processes for these products can be cheaper and shorter, since they do not need to follow an extensive regulatory framework to guarantee safety in
human use. As a result, the non-pharmaceutical SMEs in our study are able to generate revenues from sales and are more customer centric than the pharmaceutical SMEs. Hence, the key activities of the non-pharmaceutical SMEs are more diverse, including marketing and production as important activities next to R&D, in which they can develop several products simultaneously. Likewise as the pharmaceutical SMEs, the non-pharmaceutical SMEs have their research personnel as their key resource, but also the marketing personnel is crucial in order to secure revenues. Also the marketing personnel require high formal competence.

The pharmaceutical SMEs develop one product in one very long, very costly and very risky process and then sell it one time, wherefore they are less customer centric and more research orientated. Looking at figure 9, the discovery-to-market line by Nosella (2006, p. 208), it is easy to see how the characteristics of the R&D process is related to whether a company includes a customer orientation or focuses mainly on research activities.

![Diagram of business models' position in the discovery-to-market process](Adapted from Nosella, 2006, p. 208).

The more basic and applied research a company does, the further away it is from the market (right side in figure 9). This is where Pharma 1 & 2 spend most of their company’s lifetime, until they sell their product to a big pharma which does the development process for the market. This explains why building blocks concerning the customer have less relevance for these companies, namely customer segmentation, customer relationship and channels. As already argued in the analysis, the basic function of customer segmentation is to identify certain customer groups to serve their needs. In case of pharma SMEs, it is relatively clear what the needs of the very few big pharmaceuticals are. The product has to surpass the pre- and clinical tests according to regulations. It is then that the pharma SMEs, if their product is successful, might be able to choose between a few interested big pharma companies. This is an underlying mechanism, that an extensive regulatory framework sets the parameters for customer needs, then effects customer relationship and channels. There is no point for the pharma SMEs to create a strong and intensive customer
relationship. Either the product fulfills the regulatory requisite, or it is worthless to the big pharma. An intensive customer relationship is not going to make the big pharma buy a failed product for hundreds of millions of dollars. Lastly, channels have also very little relevance, since distribution and communication with the customer have little relevance.

To cope with the challenges of the industry, pharma SMEs have to focus on their R&D. The building blocks of key activities, key resources and key partnerships are crucial for the company to survive. The activity to drive the research forward is most important, since new valid results are necessary to get further funding. The mechanism of more results leading to more funding determines the surrounding building blocks of key resources and key partnerships. Knowledge and patents drive and protect these results. Key partnerships like universities can support the resource of knowledge and CROs or CMOs can help to reduce risks and costs, since they are specialized in research and manufacturing. In summary, pharma SMEs cope with the challenges by investing all their efforts in the research process and the customer side of the business model plays a subordinate role.

Looking at figure 9, non-pharma 1 & 2 are positioned more on the right side, closer to the market. These companies, although they deal with biological compounds, don not require to fulfill regulatory requirements like Pharma 1 & 2. Therefore, the R&D is less costly and lengthy. This allows them to actually market a product faster. Both SMEs are involved with the product development process and act directly on the market, wherefore the building blocks surrounding the customer become more relevant, compared to the pharma SMEs. Non-pharma 1 & 2 can generate repeated sales to different customer groups, wherefore customer relationship, channels and value proposition become crucial. For the non-pharma companies, R&D is still an important activity, however through their ability to have repeated sales, they need a more customer-centric business model.

This customer focus can still vary within the field of non-pharmaceutical biochemical products. Non-pharma can include various different products with varying degrees of necessary knowledge to develop. It appeared from the interviews with the non-pharma companies and Marine CM, that the more R&D a product requires, the smaller is the number of products, and the longer the time spent on R&D (figure 10).
Non-pharma 1 had a broad product portfolio and the development of a ready product takes 3-6 months, because most R&D happens at the university from which they buy the product. By leaving the research process to the university, Non-pharma 1 effectively avoids a big part of the risk involved in the basic research for new products. Left with the product development, Non-pharma 1 can have new products ready for the market in a few months, giving the opportunity to focus on customer related building blocks.

Non-pharma 2 has one main product and conducted the research themselves, which took up to 10 years to commercialize. During that time, the company conducted basic and applied research to put it in the context of the previous figure 9 of discovery-to-market process. Therefore, a non-pharmaceutical company can have in its lifetime a period where it has a more research centered business model, before the product gets ready to market and customer perspective becomes more relevant in the business model. The result that non-pharmaceutical companies have a more customer centric business model has therefore to be seen in the status of the company. If the company is involved in basic and applied research, the business model might be more similar to the research orientated business model of pharmaceutical SMEs. This is an important aspect, already mentioned in the delimitations. Non-pharmaceutical biochemical products are less regulated than pharmaceutical products and can come in various forms. Our research results for the non-pharma business model has therefore be seen in the context of the research stage the company is involved in.

In summary, we’re confident that our description of pharmaceutical SME’s business model is relatively accurate. In order to overcame the challenges of the industry, they have to focus on driving their research forward. Customer related building blocks play clearly a subordinate role. Non-pharmaceutical companies can be more diverse in their business model, due to less legal regulation. Their business model can vary, depending on how much research is required for their products. The longer the R&D, the more similar their business model might look like for the pharmaceutical business model. The shorter the R&D, the more resources can be used to focus on marketing the product. However, the major difference between pharma and non-pharma is that non-pharma
SMEs are able to market their products by themselves. Pharma SMEs cannot bring their product to the market without selling it to the big pharma, since the costs are too high. Therefore, to survive, pharma SMEs need to drive their research to be able to sell it once, while non-pharma SMEs can profit from repeated sales to survive.

7.2 Theoretical Contribution

In terms of the knowledge gap, our literature research indicated that the few articles we found investigating biotech through the lens of a business model, did not agree on a classification of biotech nor used the same dimensions of the business model for their analysis. In this thesis we tried to show clearly the theoretical perspective we take using the business model, in terms of the management field of innovation (Zott et al., 2011, p. 1021) and on the instance and taxonomy level of Osterwalder et al.’s (2005, p. 5) hierarchy. The business model canvas was clearly stated as the concept we use to describe the companies, which is a concept including more parameters than other models and is the one of the most recent business models. We therefore hope that by clarifying and positioning our use of the business model canvas, to contribute to a more common language in the field of business model research. We also think that our description of current companies can contribute as a first step of research of business models in the fast developing biotech industry. By describing and laying the foundation of a common language in the business model research, future researchers can take it a step further and explore possibilities of business model innovation and strategic implications. The major societal implication would be to improve business models in biotech, where future drugs, alternative fuels and materials are developed, which can contribute to the progress of society.

7.3 Managerial Implications

Looking at the managerial implications, the description of the business model can help to allocate resources in a more meaningful way. Looking at the pharma SMEs we identified, their focus on the research side, the value creation. Driving the research keeps these companies alive, wherefore management has to take actions to support it. The management of these SMEs is usually a researcher, who not necessarily has a background in business management. By no means do we see that as a deficit, a researcher can probably easier obtain a business management mindset, then a business manager could do the research. However, it implies a different language when talking about managerial implications, especially since we the authors are business students. We therefore want to look at the managerial implications in a very practical way, and look at actions that can be undertaken by the researchers who usually manage their SMEs.

Talking about the research in pharma SMEs, we look again at the building blocks directly supporting it, key resources and key partnerships. Knowledge as a key resource is obtained through qualified personnel. Team members that can contribute with their expertise are crucial, especially in this intellectual property heavy industry. But not only can experienced personnel contribute with research knowledge, they can also contribute with network and knowledge about the process. People experienced in the industry could be placed as board members to give guidance to the various steps of the regulatory process, which was especially pointed out by the CRO. Setting milestones and creating a plan can be crucial to efficiently progress in the long R&D process. The network that
experienced personnel might have can also be utilized, which overlaps with the point of key partnerships. This network might give access to other actors, like VCs, CROs or different consulting services. From the interviews we heard that there are differences in the quality of these partnerships. Pharma 1 mentioned the intelligent capital, meaning investors who are familiar with the industry and are able to support processes with knowledge. The other impression we got from our results is the tendency to outsource services (Pharma 2). This makes sense considering that the product can fail in each step of process, wherefore companies avoid long term liabilities. The managerial implication can be to outsource activities, to be able to focus on driving the research. As Pharma 2 already does it, these activities include administrative tasks, legal and financial issues.

In terms of key partnerships, keeping ties to the university and incubator can help to receive early funding and expertise in research and help with early administrative tasks. Companies specialized in research or manufacturing (CRO & CMO) can support structuring the R&D process and reduce risks due to their specialization. They might help to reduce risk because there are familiar with the regulatory standards. Researchers facing these extensive research standards for the first time might make mistakes, which leads to invalid results. Leaving these processed to specialized companies might be more expensive, but might improve the efficiency in the research process. Especially considering that most funding only supports one research step at a time (VC), efficient use of scarce capital is important.

Non-pharmaceuticals might have different managerial implications, due to the fact that these companies carry a product to the market and are directly involved with their customers. This requires personnel dealing with marketing and sales. Besides these obvious personnel implications, Non-pharma 1 & 2 reported that the industry is rapidly changing and progressing. Non-pharma 1 tries to keep a very close relationship to their customers, to get insights about future needs and sends test products out. Constantly improving and maintaining customers is a challenge, especially since other countries and legal systems allow researchers to work more freely. For instance, China and the UK have less strict regulations and ethical restraints in certain areas, which can be huge future challenge for companies in Scandinavia, who are bound to a different legal system. To counter this, the non-pharma SMEs in this research project positioned themselves in a niche, where their product is difficult to replicate. They invest a lot of effort into marketing and keeping their customers close.

The factor of communication, mentioned earlier in the emerging themes, appears also to be relevant to managers. Most communication is personal and Agriculture CM mentioned that without a personal network, their market is difficult to access. Establishing a personal network in the industry might therefore be an important factor to access markets.

7.4 Future Research

Three interesting issues developed from the conducted research: issues of culture, communication and possible strategic shifts. These developed from the section of emerging themes, where we mentioned issues that matter to the business model, but are not directly related to any specific building block.

Considering culture and communication, one could think that location should not influence the acquisition of funding too much in the globally acting biotech industry.
However, throughout our interviews, culture and communication appeared to be an issue. The interviewees (Pharma 1 & 2) clearly described how the investing culture in the US offers more capital than in Europe. This phenomenon could be interesting to investigate. Within Europe we saw that norther areas have difficulties to receive funding, which might be due to lack of communication (Marine CM) or due to the unwillingness to share ownership (Agriculture CM). Reasons and implications of these factors could be another interesting area for future research.

Regarding strategy changes, we could see that chances of failure are relatively high for pharmaceutical companies. As mentioned by Consultant and Marine CM, pharmaceuticals can change to non-pharmaceutical if they fail for instance in the clinical tests. For example, a company could start to apply their product in the non-pharmaceutical area of food supplements. It could be interesting to investigate companies taking this shift and how the business model might change from a research focus to a more market orientation and what implications this might have. This shift is immensely disruptive for the business model, opening new tasks in the company dealing with customer related building blocks and the actual delivery of value. Finding a company in this process could make a very interesting case.

At this point we would like to reflect briefly on our research process, to possibly support students doing future research in this area. As business students with no background in biotech, there was much to learn about the biotech industry. Every interview gave us new insights and we had to constantly add or change information provided in this thesis, up until the very last day. For future research, it is therefore important to early on contact interviewees and allow them to give feedback on your results. If you have no background in biotech, it is impossible to grasp all the details that might matter for your research project in the beginning. Having a good relationship with your interviewees allows you to benefit from their expertise and ultimately improve the quality of your research work. Trying to get in touch with experts or companies can be tricky in this area, due to their fear of espionage. It is crucial to be transparent from the beginning, how you are going to use the data in terms of anonymity and non-disclosure agreements. Getting in touch with companies is another tricky issue. Our starting point was one personal contact, from which we received recommendations to other companies. Other than that we recommend to simply ask family and friends, if they know possible interview candidates, which surprisingly brought up an interview in our research process. Other than that, calling or personal visits can be effective. E-mails are easily deleted and we recommend to only send it in case someone cannot be reached by phone.

Regarding the interviews, we could see a learning curve as well. Having an interview for an hour with an expert, while we were fairly unexperienced, was challenging. We recommend to include in the transcription process a reflection of the interview style. This helped us to lead better interviews and receive better information.

7.5 Limitations

In this chapter we also want to see our thesis in a critical light and take a closer look at the limitations. First, limitations from the projects methodological stance are discussed and secondly, limitations of the researchers themselves. The main theme of the limitations
is the generalizability of our findings, which is often an issue with qualitative research (Bryman, 2012, p.407).

From a methodological perspective, the thesis is positioned in terms of ontology on a scale between subjectivism and objectivism. We acknowledge that reality can be constructed by its individual social actors, which is a subjective approach, but also consider that reality can be objective and independent from its actors, which is the objectivistic perspective. Since we have the assumption that there is no objective reality independent from its social actors, our findings cannot be applied in a law-like fashion, as it might be possible in natural science. Therefore, applying our findings of business models in other contexts is restricted, since individuals in other situations might experience a different reality due to their subjective construction.

This limitation reoccurs in our epistemological stance, where we choose a pragmatic approach, acknowledging interpretivist and positivist assumptions. With this we take a stance that the nature of knowledge results cannot be purely objective, but neither purely subjective. This means that there is not a single truth applicable to all actors, which again restricts the possibility of generalizing our findings.

We tried to emphasize that the Business Model Canvas and the used method of comparative case studies are highly holistic, trying to investigate the companies’ business model in its context. As a result, our findings should be seen context depended, especially in the field of non-pharma, where product range is much larger and legal restrictions are lighter than in pharmaceutical companies. As discussed in the conclusion, development time of the product is a key factor influencing the business model and should be considered, besides legal conditions, if applying our findings to other companies.

This thesis only uses qualitative data, generated from the interviews. Interviewing and transcribing can cause interpretation errors, as well as translation errors that might have occurred with two non-English interviews. We tried to minimize these errors by sending back the summarized transcription and changes were made with the received feedback. In addition, this self-reported data can be flawed by personal errors and biases, which we again tried to counter by using triangulation methods.

The sample size in this thesis is also a factor which adds limitations to the findings. Due to limited time and access to companies, the sample size is limited. Since it was difficult to achieve access to companies that are willing to talk about their business model, the sample is not randomized. As a result, the findings mostly come from companies in the Nordic countries, and are partly intertwined with each other, because we utilized the personal contacts of each interviewee to arrange new interviews. Although we tried to utilize triangulation to verify the results, there might be tendency that the sample is homogeneous and therefore the results’ generalizability to elsewhere located biotech companies might be restricted. To further test the results, a mixed method could have been useful, where quantitative data and a larger sample could have been used. However, this was not possible due to limited time and access to companies, but might be a possible topic for future research.

In terms of the researchers’ limitations, as mentioned previously, the access to interviews was difficult. The method of interviewing was also challenging, as it was our first time leading such interviews, which might have affected the quality of the data. Since most of
the interviews were led in English, which was neither the mother tongue of the researcher nor the interviewees, translational errors and misunderstandings might have influenced the collected data.
Reference List


Appendix 1: Interview Guide

Umeå, 2015-03-30

Interview Guide: Business Models of Biotech SMEs

Fransisca Kappfjell Herbst & Julian Tölle
Master Students in Business Development and Internationalization
Umeå University

Introduction

We are doing this interview for our Master Thesis about “The Business Models of Biotech SMEs”. SME stands for “small- and medium-sized enterprise”. A business model is defined as “the logic behind how a firm creates and captures value”. Value creation is to create a product or service valuable to the customer. Value capture is turning products or services into profits.

Our research question is “how do biotech SMEs structure their business model to cope with the challenges of the industry?”. We use a framework named “The Business Model Canvas” to structure the interview guide. This has 9 “building blocks” that are used to map the business models of firms. Our questions are structured around these 9 themes.

Note that we are interested in the structure of your business model. We do not ask for any detailed or sensitive information about your product(s) or service(s).

We bring a copy of a standardized confidentiality agreement which we sign and give to the respondent in the beginning of the interview. The respondent will remain anonymous toward third parties, including our supervisor and the university committee grading the thesis.

Opening questions:

- Which company do you work for?
- What is your role in the company?
- What does the company do?
- Which types of products, or which services?
- How long have you worked in the Biotech Industry?
- How many firms have you been involved with?
- Which kind of products have those firms been involved with?
- What is your educational background?
<table>
<thead>
<tr>
<th>Key Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>- What are the most important activities for the company to be profitable?</td>
</tr>
<tr>
<td>- Why? (Describe more in detail)</td>
</tr>
<tr>
<td>- Are there any challenges with doing these activities?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Key Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>- What are the most important resources for these activities? (Physical / financial / human / intellectual)</td>
</tr>
<tr>
<td>- What are the physical resources you need for doing the activities? (e.g. Laboratory &amp; equipment)</td>
</tr>
<tr>
<td>- What human knowledge or skills do you need for doing the activities?</td>
</tr>
<tr>
<td>- Do you need access to intellectual property (patents) to do these activities?</td>
</tr>
<tr>
<td>- How do you finance the activities?</td>
</tr>
<tr>
<td>- Do you experience any challenges with accessing the resources you need for the activities?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Value Proposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>- When and how did you discover that the technology could be useful for a specific type of customer or user?</td>
</tr>
<tr>
<td>- Did you experience any challenges identifying the customers/ users?</td>
</tr>
<tr>
<td>- Does your technology have any competitors?</td>
</tr>
<tr>
<td>- How does the competition affect the product development?</td>
</tr>
<tr>
<td>- Why would customers buy your product, over others’?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Customer Segments</th>
</tr>
</thead>
<tbody>
<tr>
<td>- When and how did you identify the customers/users of your product/service?</td>
</tr>
<tr>
<td>- Is the person paying for the product/ service also the user?</td>
</tr>
<tr>
<td>- Do you serve different groups of customers/users?</td>
</tr>
<tr>
<td>- Is it difficult to identify the customer/ user?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Customer Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Does your company currently have customers? (Are there any sales?)</td>
</tr>
<tr>
<td>- How would you describe your interactions with (potential) users and customers?</td>
</tr>
<tr>
<td>- Do you plan on how to get new customers and how to keep them?</td>
</tr>
<tr>
<td>- Have you experienced or do you expect to experience any challenges with your relationship to customers/users?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Channels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>How do you plan to sell/how are you selling the product/service? Direct sales or intermediaries?</td>
</tr>
<tr>
<td>How do you communicate with your customers/users?</td>
</tr>
<tr>
<td>Are there any challenges reaching the customers?</td>
</tr>
<tr>
<td><strong>Key Partnerships</strong></td>
</tr>
<tr>
<td>Is the company cooperating with other organizations?</td>
</tr>
<tr>
<td>Does the company depend on partnerships with other organizations? Why? In what way?</td>
</tr>
<tr>
<td>What is the University’s role in the Biotech Community?</td>
</tr>
<tr>
<td>Did you experience any challenges with key partners?</td>
</tr>
<tr>
<td><strong>Revenue Streams</strong></td>
</tr>
<tr>
<td>Does your company sell a product currently?</td>
</tr>
<tr>
<td>How did you plan the prices of your products/services?</td>
</tr>
<tr>
<td>What is the major income source of your company?</td>
</tr>
<tr>
<td>Do your receive financing from third parties? (E.g. Governmental funding, VC’s etc.)</td>
</tr>
<tr>
<td>Did your company face challenges to fund its business?</td>
</tr>
<tr>
<td><strong>Cost structure</strong></td>
</tr>
<tr>
<td>What are the biggest cost factors?</td>
</tr>
<tr>
<td>Are there challenges in managing costs?</td>
</tr>
</tbody>
</table>