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GROWTH POSSIBILITIES OF BIOTECHNOLOGY COMPANIES FOUNDED IN THE 21ST CENTURY IN FINLAND

– A case study

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GROWTH POSSIBILITIES OF BIOTECHNOLOGY COMPANIES FOUNDED IN THE 21ST CENTURY IN FINLAND – A CASE STUDY

This study is about the growth possibilities of Finnish biotechnology companies founded in the 21st century: a case study of three drug development companies. The purpose of this study is to find out if the financing opportunities have changed after the burst of the IT bubble in the early 2000s. This study presents the reasons behind the changes in the finance opportunities and how they have affected the new start-up companies and the industry.

Organizational growth served as a theoretical base in this study. The stage models of growth by Kazanjian were used to describe the development and critical problems in technology-based SMEs. Measurements of growths and how growth is achieved are also introduced

The qualitative research method was used in this study, because it allows a more in-depth view about the subject. To obtain the needed qualitative data, three case studies were conducted. The case study was seen as the best option for this research, since information was wanted on the performance of biotechnology companies founded after the year 2000.

The results showed that financing has indeed become more difficult to obtain after the slump in the economy. However, the case study companies were doing relatively well and showing constant growth even though the companies are not completely satisfied with the amounts of financing they had received.

The biotechnology companies and industry would benefit greatly from increases in financing. With more resources, biotechnology companies could achieve growth faster and develop more products in a shorter time period. The growth of the biotechnology industry would also mean growth in the economy and of course patients would benefit from the new drugs developed.

KEYWORDS:

biotechnology industry, pharmaceutical companies, financing, growth, stage models of growth, organizational growth, measuring growth

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2000-LUVULLA PERUSTETTUJEN SUOMALAISTEN BIOTEKNIIKKAYRITYSTEN KASVUMAHDOLLISUUDET - TAPAUSTUTKIMUS

Tämä tutkimus käsittelee 2000-luvulla perustettujen suomalaisten biotekniikkayritysten kasvumahdollisuuksia. Tukimus perustuu kolmen lääkekehitysyhtiön haastatteluihin. Tutkimuksen tarkoituksena on selvittää ovatko alan rahoitusmahdollisuudet muuttuneet 2000-luvun alun IT-kuplan puhkeamisen jälkeen.Tutkimuksessa esitellään syyt rahoitusmuutosten takana ja sen vaikutukset uusiin biotekniikkayrityksiin.

Tutkimuksen pohjana käytetään organisaation kasvua. Kazanjianin kasvun vaihemallia käytetään havainnollistamaan teknologiapohjaisten PK-yritysten kehitystä ja kriittisä ongelmia. Tavat, joilla kasvua voidaan mitata ja kuinka kasvu voidaan saavuttaa esitellään myös.

Tässä tutkimuksessa käytettiin kvalitatiivista tutkimusmenetelmää, sillä se mahdollistaa syvällisemmän näkemyksen aiheesta. Kolme tapaustutkimusta tehtiin halutun datan keräämiseen. Tapaustutkimus koettiin parhaaksi tutkimusmenetelmäksi, sillä informaatiota haluttiin vuoden 2000 jälkeen perustetuiden biotekniikkayritysten kasvusta.

Tuloksista ilmeni, että rahoituksen saamisesta on todellakin vaikeutunut talouskasvun laskun myötä. Tutkitut yritykset osoittivat kuitenkin kohtalaista suorituskykyä ja jatkuvaa kasvua, vaikka nekään eivät olleet täydellisen tyytyväisiä alan rahoitusmahdollisuuksiin.

Biotekniikkayritykset ja koko toimiala hyötyisivät suuresti lisärahoituksesta. Suuremmilla resursseilla biotekniikkayritykset pystyisivat kasvamaan nopeammin ja kehittämään enemmän tuotteita lyhyemmässä ajassa. Biotekniikkatoimialan kasvu merkitsisi myös kasvua koko taloudelle ja potilaat hyötyisivät uusista lääkkeistä.

ASIASANAT:

biotekniikka, biotekniikka toimiala, lääkekehitysyhtiöt, organisaation kasvu, kasvun vaihemalli, rahoitus, kasvu, kasvun mittaaminen

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LIST OF ABBREVIATIONS (OR) SYMBOLS

BLA	Biologics license approval
CEO	Chief Executive Officer
DNA	Deoxyribonucleic acid
EMA	European Medicines Agency
FDA	Food and Drug Administration
ICT	Information and Communication Technology
IPO	Initial Public Offering
IPR	Intellectual Property Rights
IT	Information Technology
NDA	New Drug Application
R&D	Research and Development
SME	Small and Medium Enterprise

1 INTRODUCTION

1.1 Research proposal

The purpose of this thesis is to find out how the changes in the public funding of companies have changed the growth possibilities of new start-up companies in the Finnish biotechnology sector in the new millennium. This research continues on the subject of Laura Heinonen's Doctoral Thesis (Ph.D.Econ.) "*On the pursuit of growth in the biotechnology-based companies: The role of public financing in the start-up process of Finnish drug development companies*" (2009). The main findings in the previous study show that currently the public funding in Finland for drug development companies is not sufficient enough and larger companies have difficulties obtaining it. The growth model of biotechnology companies used in the study will also offer the theoretical base for this research.

This study was conducted with the hypothesis that the public funding in Finland is not sufficient enough for new start-up companies, which hinders their growth process. These assumptions were studied with the following research questions:

1. What kind of financing new biotechnology companies have received in each of their growth stage?
2. Have the financing opportunities changed when compared to the earlier study that concentrated in companies founded in the 1990's?
3. What are the reasons for the possible change?
4. How have the finance opportunities affected the growth process of the biotechnology companies?

Section 1.2 introduces biotechnology and the biotechnology industry. Biotechnology as a scientific field is defined and the industry's past, present and future explained. This section helps the reader to understand the biotechnology

sector and its specific characteristics. This information is relevant later on in the research, when the case studies are introduced.

The theory section of this study is divided into subsections that define growth as an organizational process. The theory of Stage model of growth by Kazanjian (1988) is used to better understand the different phases a company goes through in its life cycle and what are the issues that need to be addressed. The theory section also presents how growth is measured and what are the different means to achieve growth. The focus of this study is on the first two stages of growth (*conception and development* and *commercialization*) in the biotechnology start-up companies. The measures of growth are defined in order to understand the results of the case studies and what means of growth the studied companies use.

In methodology, the research methods used in this particular study are presented as well as the reasons for using them alongside with their advantages and disadvantages. The section also describes the tools that were used in the data collection process and details about the process itself. The data in this research was collected by using the qualitative method that allows a more human oriented approach. Three companies were chosen and interviews with their representatives were conducted. The cross comparison of the companies is made using the information gathered in these interviews.

The discussion section introduces the biotechnology industry in Finland along with the industry's players and financial opportunities for companies. The current economic condition, affected by the IT bubble and Great Recession, has had an impact on the industry and caused some strategic changes in the field. The case study companies are then introduced with the results from the case studies and the cross-case analysis.

In the conclusion section, the findings are collected in one. The possible errors in the data collection process are also taken account. The section also explains future possibilities of continuing the research on this area in much the same way as this study was based on an earlier study.

1.2 Background

The biotechnology industry is a fairly new, constantly evolving industry. The industry can be divided into three different areas: health, industrial and agricultural and in this research the focus will be on health related biotechnology. Distinct characteristics separate the industry from other knowledge-based industries and these characteristics are introduced in the following chapters. The scientific process of drug development is also presented shortly.

1.2.1 Definition

There is no single way of defining the biotechnology industry. This is because the industry changes so fast and it can be defined differently every decade. Defining the industry is also challenging, because the term "*biotechnology*" covers so many different functions and fields. The most commonly used definition is the one of Organization for Economic Co-operation and Development (OECD), which describes biotechnology 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 (OECD 2001).

The biotechnology industry is still considered a fairly new and emerging part of the economy (Hermans, Löffler, Stern 2009:64), for example in 2002 the US revenues of the whole industry were equal to those of Microsoft (Zhang & Patel 2005:10), even though the first biotechnological applications were already in use thousands of years ago to provide different commodities. For example the manufacturing of beer is a biotechnological process using yeast (Hine & Kapeleris 2006:19). Since the days of early biotechnological processes we have moved from applying macro level biotechnology, like animal breeding and crops, to working in the field at a micro level, focusing on studying the organism's smallest parts (Biotechnology Industry Organization 2008:1).

The modern biotechnology industry emerged in the latter part of the 1970's due to three major events. In the 1970s the recombinant technology of DNA was developed, the life science industry was noticed, which resulted in significant increases in public and private funding and the guidelines for intellectual property (IP) rights were created (Hermans, Löffler, Stern 2009:62). The development of the recombinant technology of DNA enabled scientists to make slight modifications in biological systems to produce wanted results in treating illnesses (Friedman 2008:11). At the same time the importance and potential of the life science industry became apparent to the investors, causing fundamental increases in the public and private funding (Hermans, Löffler, Stern 2009:62). A court case in 1980 set the ground rules on the matter whether micro-organisms made by humans were patentable. The IP rights were secured and the biotechnology companies were able to profit from and do business with their findings (Hermans, Löffler, Stern 2009:62).

Since the start of the biotechnology industry in the late 1970's, the industry has changed rapidly, which portrays the constant need for change and adaptation that is typical for the industry. From the antibiotics of the 1970s to the rise of the personalized medicine market we are experiencing today, the biotechnology industry has evolved rapidly to cater to the growing needs of the society (Hermans, Löffler, Stern 2009:64). The industry has to continuously face challenges in the global markets. Currently the main issues are the significant increases in the costs of drug development and the regulatory issues that complicate the approval of drugs in different markets. Biotechnology is also used in increasing amount to prevent illnesses before they need to be treated aggressively. The biotechnology industry is constantly growing and now the focus is on China and India and it is expected that these countries will become the future drivers of the industry (Burrill, 2007).

1.2.2 The three areas

The biotechnology industry can be divided into three different areas that are related but clearly distinct: *red, green and white*. Red is the health-oriented

biotechnology, green is agricultural biotechnology and white is industrial biotechnology (Hine & Kapeleris 2006:3). This study concentrates on the red or health-oriented biotechnology since it was also the focus area in the study of Laura Heinonen and it is the most important field of biotechnology in Finland with 52 % of the market share (Scientific American Worldview 2009:41).

Health-oriented biotechnology is focused on how a healthy body is affected by a disease. Health and disease are complex concepts, but gathering more knowledge of their molecular basis makes it easier to develop methods for the treatment and prevention of diseases, as well as diagnosing them. Health-oriented biotechnology aims to provide the health care system with “quicker and more accurate diagnostic tests, therapies with fewer side effects and new and safer vaccines” (Biotechnology Industry Organization 2008:32).

Agricultural biotechnology is becoming increasingly important as the world's population continues to grow significantly in the future. Mankind has always used plants and animals as a source of food and their byproducts for things like clothing and fuel. The agricultural biotechnology industry is working on keeping up with the demand, since the United Nations Food and Agriculture Organization estimates that the existing farmland needs to double in order to keep up with the current prognosis of population growth. Some of the most important biotechnological advances in this field help to increase crops with fewer fertilizers and reduce water consumption as well as controlling pests in an environmentally friendly manner (Biotechnology Industry Organization 2008:41).

The industrial biotechnology can be seen as the third wave of biotechnology focusing on industrial sustainability. It aims at a reduction in pollution levels and resource consumption by using clean technologies and developing the current processes available. In practice these applications mean, for example, moving away from nonrenewable materials, avoiding processes that produce toxic waste and the reduction of greenhouse gases. Industrial biotechnology is seen as the answer to reaching industrial and environmental sustainability. It is already turning production processes more efficient in several industries and

can result in transforming the industrial sector in the same way the pharmaceutical and agricultural sectors have changed over time (Biotechnology Industry Organization 2008:63).

1.2.3 Industry characteristics

According to Hine and Kapeleris (2006), there are nine distinctive characteristics of the biotechnology industry:

- Medium to very long product development lead times
    - The product development process is considerably long due to the nature of the industry: for a product to be completed it takes 10-15 years of different stages of production, including pre-clinical and clinical trials on humans to ensure the safety and effectiveness of the product. Because the production processes are long and complicated and the industry is very competitive, biotechnology presents high risks to investors (May 2009:7).
- Capital-intensive
    - Due to the various different stages of the development process, developing a drug averages at more than 800 million euros, including possible failures (Biotechnology Industry Organization 2008:38).
- Highly regulated
    - Different governmental bodies, for example FDA in the US and EMA in Europe, regulate the production processes to guarantee the safety and effectiveness of pharmaceuticals and to ensure that the drugs available in the market are safe, correctly marked and mutually comparable (Friedman 2008:109).
- Extensive skill sets and technical knowledge required
    - Biotechnology industry is very knowledge-intensive and human capital is important for the companies that rely on innovation. Due to the nature of the industry education is highly valued and a small Finnish biotechnology company typically consists of ten

employees, five of them having a doctoral degree (Hermans, Kulvik, Tahvanainen 2006:23).

- One of the most research-intensive industries in the world
    - The growth of the biotechnology industry is based on new innovations, (Friedman 2008:14) which is why European biotechnology companies spent 3 370 million dollars on research and development in 2009. The number shows slight decrease from previous years, but this is due to the economic crisis (Ernst&Young 2010:61).
- In many cases ethical clearance is essential, especially for animal/human testing
    - The industry faces challenges because of the complexity of ethical issues connected with the trial stages. In recent times especially animal testing and stem cell research have caused controversy and become a political issue as well (Biotechnology Industry Organization 2008:82).
- Intellectual property protection is an essential element of success for most biotechnology companies
    - To secure the competitive advantage it is essential for biotechnology companies to protect their intellectual property, as product development and testing are costly. The development of a new product is time consuming and expensive but, copying already existing and tested innovations is comparatively cheap, therefore the intellectual capital is crucial in the industry (Friedman 2008:97).
- Strong linkages and strategic alliances established with universities, institutions and other biotechnology companies
    - It is usual for biotechnology companies to be located in clusters around universities, which are centers for the research and education in the industry. The education ministry in Finland has also established bio-centers around these universities and in 2001

half of Finland's biotechnology companies were located in these bio-centers (Luukkonen, Tahvanainen, Hermans 2004:15).

- Outside financing is crucial and a large amount of time and resources is directed to raising capital
    - When it takes up to 15 years to get a new drug into the market to start making profit, it is necessary for the company to constantly look for new financing resources to cover the costs of up to 800 million euros. These costs are scattered throughout all the different research and development stages (Hermans, Ylä-Anttila 2004:112).

(Hine and Kapeleris 2006:20)

1.2.4 The scientific process

This chapter will shortly present the complexity of the scientific process of drug development a biotechnology company goes through. The purpose is to provide the reader with the necessary knowledge to fully understand the latter part of this research. The process of drug development is briefly explained from discovering the lead compound, taking it through clinical animal and human trials to demonstrate its safety and efficacy to getting an FDA approval before finally launching it to the markets.

The *discovery* stage begins with the identification of a molecular process that has an effect on the condition that the scientists want to find a treatment for. The sources of new therapies can sometimes be surprising. Drugs that were meant for treating other illnesses prove to have different effects during the clinical trials. The possible new drug is called a *lead compound.* For example the lead compound for Viagra was found when a drug for treating angina showed curious side effects (Friedman 2008:40-42).

The lead compounds from the discovery stage are then entered into *pre-clinical developments* like animal, cellular and biochemical tests that are used to

determine the dosage and whether the drug would be suitable and safe for humans. Sometimes a drug candidate that works well in a laboratory environment does not translate well when tested in a clinical setting. The cells might not react with the drug as expected or the liver might even transform the drug into toxins. Animal testing is a crucial step, because if a compound shows negative effects on animals, it will not be suitable for humans either, even if positive results on animal testing do not always guarantee success on human trials (Friedman 2008:42-44).

Clinical trials consist of three different phases of trials on humans. *Phase I* includes a small group (<100) of healthy individuals to guarantee the safety of the drug and get information on the right dosage. In *phase II* the drug is tested on a group of 100-300 individuals suffering from the condition the product could treat. This phase continues to gather data on safety, but also proof of efficacy. In *phase III*, a large group (1000-5000) of patients with the condition is tested. In this phase, more evidence of efficacy is obtained alongside with possible side effects of long-term use (Biotechnology Industry Organization 2008:39-40). Clinical trials on humans to determine safety and efficacy of the drug are required in order for the drug to achieve FDA approval (Friedman 2008:44).

Approval process is reached if a drug successfully completes the clinical trials. The FDA (Food and Drug Administration) in the USA needs to grant an approval for the product prior to marketing (Friedman 2008:44). While the FDA approval should guarantee the drug to be safe, if there are no better treatments for a severe disease, an approval can also been given to products with harmful side-effects, for example HIV drugs (Horn 2004). The drug is approved, if the FDA considers that ”a product's benefits to users will outweigh its risks” (ibid.). The FDA approval can be applied by filling out a *new drug application* (NDA) or a *biologics license application* (BLA) (Biotechnology Industry Organization 2008:40).

Post approval includes the *phase IV* trial, which continues to monitor the products safety after it has been launched to the markets (Friedman 2008:44).

This has to be done because the clinical trials are not extensive enough for detecting rarer side effects. If any unfavorable events occur, the law requires them to be reported to the FDA (Biotechnology Industry Organization 2008:40).

2 THEORY

2.1 Organizational growth

Growth has been studied by many researchers. But it does not have a single definition which would make it simple to understand. The theory of this research introduces organizational growth, the way in which companies grow. Different stage of growth are presented to get a better idea of how growth happens throughout a company's life-cycle, as well as the financing a company needs at each stage of its growth. Growth can happen in various ways and it can have various measurements, which are also introduced.

2.1.1 Defining growth

The Oxford English Dictionary defines growth as ”the action, process or manner of growing; both in material and immaterial senses” and in an economic sense ”a relation between the rates of increase in capital and the working force, such that *per capita* output (not necessarily consumption) is rising.” In economic context a more practical definition of growth would be the increased production capacity of a community that is caused by multiple factors. Growth can be drawn from various different sources, with the three most important being improving technologically, increasing revenues and a higher level of human capital (Carneiro 2006:51).

In a study of executives and Masters of Business Administration (MBAs), growth was identified most commonly as the key point of business success (Hubbard & Bromiley 1995 in Weinzimmer, Nystrom and Freeman 1998:235). But organizational growth does not just happen; a successful company needs to

have certain qualities to back it up. The company has to see opportunities for growth instead of thinking that their business is already mature. Growth should not happen just for the sake of growing but be profitable while remaining sustainable and capital efficient. Company leaders should create and encourage the mindset of growth and this mentality needs to be reached throughout the different levels of the company. Growth needs to be seen more as an opportunity than a challenge, because in the end it is more risky to stay behind in a constantly changing market (Charan 2000:7).

Traditionally, growth has been linked with getting bigger and expanding the operations, and in business sense this means the rise of sales growth, higher profits and increase in stock prices. A growing shareholder value is seen as the essential reason for doing business (Tomasko 2005:11-12). Growth is increasingly important in the modern world and the business leaders should start focusing on growth and not only on operational excellence, because it can be said that companies have two choices: grow or die (Charan 2000:6). But in today's economy, growth can be defined in a different way. It no longer needs to be about getting bigger but more about moving forward and achieving full potential instead of maximum size (Tomasko 2005:1-2).

Like there are many ways of defining growth, various factors can also be defined as reasons for organizational growth; it can be a managerial objective or a necessity to keep the business productive. In a globalized world, the internationalization and expansion of markets requires companies to grow if they wish to keep their market share or strengthen their market position. Companies in capital intensive industries are typically large, because small companies are unable to carry out the more money consuming product development projects. Growth can also be used as a defensive strategy to respond to the actions of competitors (Worthington & Britton 2003:220).

To better understand the process of growth companies go through, life cycle and growth stage models have been created. In the next chapter the idea behind the *Stage model of growth* by Kazanjian (1988) is presented together

with the different stages in the growth process and how this particular model can be applied to biotechnology companies.

2.2 Stage model of growth in technology-based companies

The stage model of growth is also known as the life cycle model. This model helps to understand how sales and profitability change over time (Worthington & Britton 2003:494). The model can be used to describe the development of a single product, a company or even a whole industry. In this study the focus is on the changes and different stages a company goes through with a special focus on the technology-based companies.

For decades, the growth process of organizations has been a topic of interest for researches who want to find out what is the factor that makes some companies grow and succeed while other ones fail. To understand the problems and possibilities in organizational development, the growth stage model has been developed to point out the critical issues a company has to overcome in each stage to be able to move forward (Lester & Tran 2008:72).

When studying growth in technology based companies, a stage model of growth by Robert K. Kazanjian (1988) is often used. The stages of development and critical problems in each stage are presented in his research of technology based SMEs. The stage model of growth by Kazanjian is applicable only to the initial internal growth of new, technology based ventures that are working in a non-limiting market condition. In the model four stages can be recognized: *conception & development, commercialization, growth and stability* (Kazanjian 1988:261).

The following definitions of the four stages are done according to Kazanjian (1988), but also from a biotechnology company's viewpoint. In this research the focus is on the first two stages of organizational growth, the conception and development and the commercialization stages that together form the start-up stage of a biotechnology company.

Stage 1 - The conception and development stage is characterized by invention and the process of research and development of a product. At this stage the focus is on the technical rather than organizational issues and the company lacks structure and formality. The problems that the company needs to overcome at this stage are developing the new technology and gathering further resources (Kazanjian 1988:262-267).

In the field of biotechnology, the conception and development stage normally occurs in an academic environment like universities, but small bio-tech companies can grow also in science parks and biotechnology incubators. The companies in this stage are usually small with few employees that are all part of the research and development of new therapies (U.S. Department of Labor 2004:16).

Stage 2 - The commercialization stage is reached when initial funding has been received and the focus shifts from research and development into early production and plans are made for the product to be introduced to the markets. At this stage the company still does not need many full time employees and in order to save money, contract employees can be used to provide their expertise. Problems that the company needs to overcome at this stage are related with the initialization of the production, and the market potential of the product (Kazanjian 1988:263-267).

At this stage in a biotechnology company the product is tested in clinical trials and it goes through the regulatory approval process. The company seeks financial help mainly from venture capitalists or other equity investments. The main challenges for a bio-tech company in the industry are to secure the venture capitalist funding and passing the process of regulatory approval. This stage is especially tricky to pass and since achieving the regulatory approval takes a lot of time and involves many risks it is difficult to attract investors. Sufficient funding is crucial to continue the development of a new drug and therefore investors are usually asked to invest in a product the scientists believe to be potential, but that will not bring profits in the near future. Together with the

conception and development, these two start-up stages can take up to 15 years to produce a new drug (U.S. Department of Labor 2004:16-17).

Stage 3 – The growth stage occurs when the product is already on the market and is showing success, which normally leads to the steady growth of the company. At this stage the company struggles with trying to keep up with the growing market share and sales and has to make adjustments in the production process to keep up with the demand. At this stage the organizational functions also become increasingly important (Kazanjian 1988:264-267).

When a bio-tech company finally releases a drug to the commercial market it enters the growth stage while continuing developing other products in the pipeline. During this stage the amount of employees grows because in a biotechnology company, only at this stage more full time employees are required for functions like sales and marketing rather than technology based functions (U.S. Department of Labor 2004:17).

Stage four – Stability is reached when the fast growth of the previous stage stabilizes and the company needs to try to find further growth. At this stage the company should focus on their internal control and possibly replace the founder with a professional manager with more insight to the business operations. New sources of growth can be found from the development of a new product (Kazanjian 1988:265-267).

A high level of global competitiveness defines the maturity stage of biotechnology companies and not many modern companies are able to reach this stage. Mature companies have a large amount of employees, because they are responsible for all the functions beginning with the research and development stage (U.S. Department of Labor 2004:16-17). Company maturity also signifies sales revenues which means they are able to finance their upcoming projects themselves relatively well and makes them independent from outside investors (Friedman 2008a:140).

2.2.1 Financing growth

Companies in emerging industries are proven to be more innovative due to the constant pursuit of growth and success. Besides being an emerging industry, the biotechnology industry is also capital-intensive. Research and development in biotechnology are especially costly and without significant investments, it is impossible for the companies to grow. The biotechnology industry is an important part of national economies and mankind benefits from its products, which makes financing important (Hine & Kapeleris 2006:60). This chapter will present the financing opportunities in the different stages of a company's growth.

In this study, a pattern found by Heinonen (2009) is used to determine the financiers in each stage of a company's growth. Figure 1 offers the theoretical base for this information. The financiers of each stage are briefly explained, but they will be discussed more thoroughly in section 4.2 in connection with the case study companies.

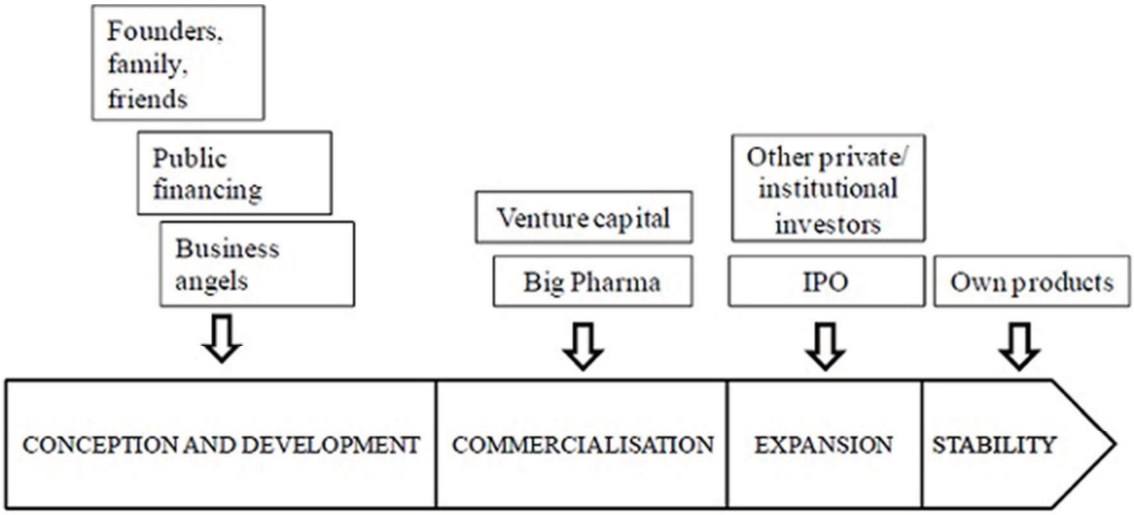

Figure 1: The financing of drug development companies in each growth stage (Heinonen 2009:69)

In the conception and development stage some initial financing for new bio-tech companies is provided by the founders together with their friends and family. However the capital needed is larger than what this group can provide, so professional investors like business angels and venture capitalists offer financing and business expertise to promising new companies (Friedman 2008a:134). There are two major public institutes in Finland offering companies money in the conception and development stage. Tekes and Sitra are the largest public equity loan providers and together their loans cover almost 70 % of the financing of SME biotechnology companies (Tahvanainen & Hermans 2004:94-95).

In the commercialization stage, biotechnology companies mainly seek financing from sources like venture capital financiers and Big Pharma companies. Venture capital companies invest their clients' money on potential projects to gain profit. By investing a significant sum they will also become board members and are able to take part in the business decisions of the company (Klausner 2009). Leading pharmaceutical companies, or Big Pharmas as they are called collaborate with small biotechnology companies by buying the rights for a single product or acquiring the whole company to get access to the innovative IP (Malik 2009:818).

Biotechnology companies in their growth stage (called expansion stage in the figure) receive financing from private investors, institutional investors and IPO. Private investors used at this stage are mainly banks that offer loans. This financing option is not used earlier, because the risks in the product development stage in this sector are very high. Companies that are already more or less settled and have some tangible capital are able to pay back the loan even if a project fails (Hermans 2004:77). Companies can also sell their shares to the public in the stock exchange to facilitate their growth. This method of financing is called initial public offering (IPO) (Friedman 2008:150-151). Because of the economic condition, IPO's are becoming a rarer form of seeking financing (Booth 2009:705).

In the stability stage, the company's own products will start to make profit once they are launched and the company does not need outside investors anymore. The patent protection of a drug will typically last for about 12 years after the FDA approval and after this other companies can start to use the IP of a drug to make their own, usually cheaper products (Friedman 2008:48).

Receiving sufficient financing in each growth stage is a prerequisite for the growth of a single company and the whole biotechnology industry. Financing is needed for different areas of the company; the research and development is an expensive stage, but money is also needed for the commercialization activities of a new product to ensure its commercial success and ability to receive revenues (Hine & Kapeleris 2006:22-23).

2.3 Measurements of growth

Organizational growth has been a great interest to many researchers and there are a lot of studies on the subject; however there is a lack of consistent theories about measuring organizational growth and the company performance (Birley & Westhead, 1990), which leads to confusion about what organizational growth really means (Whetten, 1987:341). To reach reliable results on the matter, the most important step is to determine the concept of growth, whether it is connected to sales, employees, assets or something else (Weinzimmer, Nystrom, Freeman 1998:237). This chapter continues with the discussion of the measurements of performance, what it means in a traditional sense and how it translates to the growth process of biotechnology companies.

The traditional way of measuring growth is by focusing on the financial performance of the company. Increased profit, sales, productivity and return are used as a means to estimate the success (Ghalayini & Noble 1996). This method of measuring worked well in the industrial era, in which it was developed, but it does not bring the kind of answers to match up with the skills and competencies the modern companies are interested in (Kaplan & Norton 1992:71). Kaplan and Norton (1992) developed a growth measurement system

called the *balanced scorecard* to illustrate the needs and interests of today's business environment. This scorecard combines financial, internal business, customer and innovation and learning perspectives that together give a quick and comprehensive overview of a company (Kaplan & Norton 1992:71).

In this study, financial performance as a measurement of growth is not relevant since all of the companies researched are SMEs in their conception and development stage. In their early years of operations, SMEs are rarely expected to generate any profit (Mcdougall, Robinson, DeNisi 1992:268-269) and this is especially true when talking about the biotechnology industry. This is due to the fact that the development process of a single marketable product can take up to 15 years (Hermans 2004:78). The biotechnology companies are far from the ones in the industrial era, because their mode of operation is knowledge intensive rather than focused on manufacturing large amounts of a single product. This is why it takes years to see growth measured by financial means.

To better understand the growth in knowledge based industries, Cumbry and Conrod (2001) have conducted a research trying to identify the most important measures of performance in biotechnology companies. The result was that financial information does not provide a realistic overview of the growth in companies in the biotechnology industry, but the focus should be more on the non-financial factors that are more value-relevant. The growth of a biotechnology company, at least in their early stage, is impossible to measure from profit, since it can take years before the company brings in any revenue. Better indicators are the size of the potential market, milestones reached in the product development, the number of employees and the human capital acquired as well as alliances (Cumbry & Conrod 2001:269).

2.4 Achieving growth

A company can pursue growth using three different strategies: *internal development, strategic alliance* or *acquisition*. Each of these strategies entails advantages and disadvantages and it is important to determine which strategy

to use depending on the given situation (Weinzimmer 2001:178). This chapter will present these strategies and their applicability in the biotechnology industry alongside with the virtual business model that is an increasingly popular way for biotechnology companies to seek growth.

All of the case study companies in this research use a *virtual* or *semi-virtual* business model as a growth strategy. The virtual business model is based on the idea that the company only has a limited amount of employees, the key personnel, who manage the core operations of the project while everything else is outsourced. The use of this business model has become increasingly popular, especially among the new start-up companies, because it is a way of saving money and achieving results more quickly. The key to success in this model is to choose a leadership team with the abilities to manage the relationships with the partner organizations to build trust so that minimum supervision is required (Chew 2010). Using the virtual business model is an important strategic step, because it makes a company more capital efficient (Booth 2009:707).

Internal development is a strategy where a company pursues its growth opportunities by itself. This means that the company should grow internally without joining forces with a company from outside its operations in the form of partnerships or acquisitions. If a company wants to use the internal development strategy to expand to a new market, the company needs to do everything from market analysis, setting up new facilities, increasing operations, and manufacturing the products to financing it all. Growing internally requires a lot of resources and a significant amount of financing but it can also be very effective when it is successful (Weinzimmer 2001:179).

Almost all companies implement the internal development strategy to their pursuit to grow. This does not mean that the company necessarily multiplies its operations, but hiring new employees and acquiring assets is also seen as internal growth. Companies nearly always begin their growth process with some

sort of internal development and afterwards move to joint ventures or acquisition (Weinzimmer 2001:178).

In the biotechnology industry, companies that have implemented the internal development strategy are using *vertical integration* as their business model. The integrated business model makes it possible for companies to control everything in their value chain. But to be able to maintain this infrastructure, the companies need to be aware of and prepare for high risks and requirements for financial capital. The first big pharmaceutical companies like Genentech used an integrated business model, and it was a business model all the new companies wanted to adapt to. (Hine & Kapeleris 2006:79).

Strategic alliance as a strategy of growth is implemented by partnering with another company. Sometimes a company does not have the required resources to grow internally, which makes them seek out partners from outside the company. Partnering makes growing easier and quicker for companies that do not have enough money or knowledge to do it by themselves and waiting to acquire these qualities could be fateful. Many types of strategic alliances exist and the most common ones are *franchising, licensing and joint ventures* (Weinzimmer 2001:184).

Franchising is the arrangement where the rights of a company (franchiser) are sold to another company (franchisee), who then markets the product or service. The most typical form of franchising is trade name franchising, where the franchisee operates under the name and guidelines of the franchiser, whose popular trade name will help the franchisees business operations. Big chains like McDonald's and Burger King use this strategy (Worthington & Britton 2003:209). *Licensing* is an agreement where a company (licensor) authorizes another company (licensee), usually in another country, to use their patents, copyrights or other intellectual property in return of royalty payments (Worthington & Britton 2003:210). *Joint venture* can be used as a business venture that is jointly owned by more than one company or a contractual

agreement that involves more than two parties (Worthington & Britton 2003:211).

Almost all of the companies in the biotechnology industry use licensing as a strategic alliance in the growth process. In the modern world, there are only a few fully integrated biotechnology companies that do everything themselves, so it is rare for a company to develop a drug from discovery to the approval stage on their own (Ben-Menachem 2008:91). The case study companies in this research are also using strategic alliance and licensing as their way to achieve growth. All of them identify themselves as early-stage developers and users of a virtual business model, which means they only take part in the initial research and development process and continue in the future by licensing them out.

Acquisition is a strategy of growth where instead of growing internally or partnering with others, a company can simply buy another firm. This is the most risky way of growing, since it requires spending a lot of money buying another company, and the acquisition might not even bring any profit in the end (Weinzimmer 2001:178). In the acquisition process it is important to identify the right kind of candidate to acquire and take into consideration that some companies are more expensive than others, depending on their qualities (Weinzimmer 2001:191).

In the biotechnology sector, acquisition is a strategy mainly used by big pharmaceutical companies that are industry leaders. These companies have rather weak pipelines and their research and development process lacks innovative ideas. To maintain their market share and grow, Big Pharma companies acquire small and innovative biotechnology companies to strengthen their pipelines (Malik 2009:818).

3 METHODOLOGY

This section presents the methods of collecting data that were used in this study. The methods are also defined and the reasons for choosing them as well as their advantages to other ways of data collection are discussed and explained. The research as a process is also introduced in this section as well as the criteria used when choosing the case study companies.

3.1 Qualitative data collection

This research was conducted using the qualitative data collection. This method is better suited for this study than the quantitative method that uses mostly numerical data, because the focus was more on non-numerical data. Quantitative research is more interested in summarizing statistical explanations and characterizations while qualitative research offers profound descriptions and presents causations (Ten Have 2004:5). In a research where the focus is on finding out reasons and explanations to certain events and the opinions of human beings, qualitative research offers more in depth sight to the issues. This is because in qualitative research, more interpretative results are wanted. Nothing should be treated as self-evident; meanings of events should be looked into with contextual interpretation (Ten Have 2004:4).

Regarding this study, qualitative data collection methods were seen as being able to offer better results as a whole. Even if the research is centered on received financing, the numerical data is not the most important information. Numerical and statistical data were used as secondary data but the focus was more on what happened, when it happened and what the effect of this was. In qualitative research case studies can be seen as a means to find generalizations to different circumstances (May 2002:9). Case study was used in this research and the next chapter presents this research strategy.

3.2 Case study

Case study was chosen as a research strategy in this particular study. It is defined by Robson as "*a strategy for doing research which involves an empirical investigation of a particular contemporary phenomenon within its real life context using multiple sources of evidence*" (Robson 2002:178) and by Stake as "*the study of the particularity and complexity of a single case, coming to understand its activity within important circumstances*" (Stake 1995:xi). The case study method was chosen for this research because it has the ability to answer the questions "why", "what" and "how". The method suits this study, since more in-depth information about the selected companies was wanted (Saunders, Lewis, Thornhill 2003:93).

To execute this study and collect primary data, structured interviews were used as the method of data collection. The structured interview was selected because it is a good way to collect valid and reliable information that is applicable to the set research questions and objectives (Saunders, Lewis, Thornhill 2003:245).

The structured interview can be identified with the use of a standardized set of interview questions. The interview is conducted by reading each question to each interviewee with the same tone of voice to avoid any bias and then recording the answer. During structured interviews, the social interaction between the parties is limited to the clarification of questions: there should not be any other factors that might change the setting of the different interviews. However the interviewees are encouraged to talk about the themes as freely as they want (Saunders, Lewis, Thornhill 2003:246).

Structured interviews are frequently used in descriptive studies and explanatory studies (Saunders, Lewis, Thornhill 2003:248). Descriptive studies are used when it is necessary to accurately portray persons, events or situations. Explanatory research studies a situation to explain the relationships between different variables (Saunders, Lewis, Thornhill 2003:97-98). In this research

characteristics of both of these studies can be found. The goal is to give a clear picture of the current state of the biotechnology industry and the players in Finland, but also to explain the relationships between these variables and what sort of effect they have on each other.

When doing a scientific research, special attention must be paid in order to give the study reliability and validity. To achieve a reliable study it is important to make sure that the results are replicable. This means that all the steps of the study as well as the resources used need to be recorded. Validity can be measured by making sure the collected data actually measure what they are supposed to measure and that the research findings are answers to the original research questions. As this research is a follow up on the study made by Laura Heinonen, it is important to follow her research design to reach the right kind of answers.

3.3 Implementing data collection

This research was conducted in order to determine whether the changes in the economic environment and in the criteria to receive public funding of new drug research companies in Finland has had an effect on the companies' chances to grow and reach their full potential. The research is based on an earlier study, where all the case study companies were already matured, so this research can be repeated in the future to see the whole picture of the Finnish drug development environment in the new century.

The companies used in this study were selected from BioFinland's catalogue of 2009-2010 that lists all the operating biotechnology organizations in Finland. This catalogue indicates the foundation year of the company and after finding the ones that fit the criteria, a further internet search was made to see if the company had a working internet site and if it showed any recent activity by the company.

The following criteria were used when selecting the companies for case study:

1. Company has to be in the biotechnology industry, more specifically focused on drug discovery and development.
2. Company needs to be currently active in the biotechnology sector.
3. Company was founded in the new millennium.

In the end four companies were chosen and e-mail inquiries were sent out to find out whether the company was willing to take part in the study and be interviewed over the phone or in person. Three out of four companies agreed to answer. One of the interviews was conducted in person and the other two over the phone because of the distance between the interviewees and the interviewer. The fourth company never replied to the e-mail inquiry that was sent to them.

During the interviews, the interviewer followed a series of per-determined questions and the interviewee could freely answer the questions. The questionnaire used was based on the same questions that were asked in the study made by Laura Heinonen with slight modifications to better fit this study.

The setting of the interviews varied slightly from one interview to another. In the first phone interview, the interviewee asked to have the questions beforehand and also the interviewee who answered the questions in person saw the question form before the interview. Another factor affecting the interview is the fact that the people that were interviewed were in slightly different positions in the company. In two of the cases, the interviewee was the founder or co-founder of the company and in the third case, the interviewee was the Chief Executive Officer (CEO) who was hired two years after the company was founded. It could be said that the two founders might have more in-depth view on the company history since they have been part of it since the beginning. In this study, however, it could not be seen that one of the interviewees had been with the company for a shorter time, since all of them gave very valid and detailed answers.

The interviews were conducted in Finnish for clarity reasons: all of the interviewees and the interviewer are Finnish and using English would have made the interviews more complicated. During the interview a recorder was used with the consent of the interviewees, because it would have been fairly difficult to make notes as quickly as the answers were given and interrupting the answering from time to time would have disturbed the interview. The answers were later analyzed and translated by the interviewer using the recordings as source-material.

Some problems arose when the answers were being analyzed, since one of the interviewees felt that giving out certain data was not possible for security reasons and in all of the cases the time line of the company was bit difficult to follow. This is partly because not all of the events were given in one continuous answer, but the information was scattered through the entire interview. This is why secondary data like the Internet and news were used in order to gain a better picture of the companies.

4 DISCUSSION

4.1 The biotechnology industry in Finland

This section will discuss the biotechnology industry in Finland and specific characteristics that have made the growth of the industry possible in the past few decades. The different players in the Finnish market are also being presented.

Finland has a history of supporting the development of knowledge-based industries with public investments in research and development, which is the reason for the success of the Information and Communication Technology (ICT) sector. In the 1980's, the biotechnology industry was selected to be a priority in the future, which has proven to be a wise decision (Academy of Finland 2002:7).

Biotechnology industry has similar characteristics with the ICT sector that indicate similar possibilities for success. They are both engines for technological innovation and have great chances to go global (Hermans & Kulvik 2007:3). Biotechnology has great potential of becoming one of the industrial pillars in Finland alongside the forest, machine and electronic industries, but this will still take decades (Hermans, Kulvik, Ylä-Anttila 2005:134).

The biotechnology sector in Finland has grown rapidly since the end of the 1980s and 75 % of all Finnish biotechnology companies were founded after the year 1990 (Luukkonen, Tahvanainen, Hermans 2004:11). The fast growth of the biotechnology industry continued until the end of the century, but has significantly slowed down in the last decade (Hermans, Kulvik, Tahvanainen 2006:15). However, the number of biotechnology companies in Finland is still considerably large when compared to the number of companies in the EU (7 %) to the amount of the population of Finland in the EU (1,3 %) in 2003 (ibid.). The majority of Finnish biotechnology companies are SMEs, even though Finland is considered to be a biotechnology intensive country. The companies typically have difficulties expanding and reaching their full market potential (ibid.).

Health oriented biotechnology is the biggest field in Finland when compared to the other two, agricultural and industrial, with 52 % of the market share (Scientific American Worldview 2009:41). Pharmaceutical industry and R&D are the most important activities, with 60 % of the SMEs focusing on them and this market has high expectations of growth because of the research developments and aging population structure (Hermans, Kulvik, Tahvanainen 2006:15). Drug development holds high success opportunities, but at the same time the R&D process is very risky and due to different regulatory practices, global marketing is difficult (ibid.).

The growth of the biotechnology sector in Finland was made possible by investments made on research and development projects. Since 1988, the Ministry of Education has supported the biotechnology industry with different funding programmes that have been directed mainly towards bio-centers

working alongside universities. Tekes and the Academy of Finland have also played a significant part in the growth of the industry by offering public finance. The received financial support has been important but not nearly sufficient enough to cover all of the funding needed. The combined funding from Tekes, Academy of Finland and the Ministry of Education has been merely 400 million euros from the late 1990s to the beginning of the 2000s, when the amount of money needed to manufacture a single drug can be up to 800 million euros (Luukkonen, Tahvanainen, Hermans 2004:12-13).

In Finland, it is easy to point out the cities in which most of the biotechnology companies have been established and formed so called *clusters*. This has not happened by accident, since there is a university in each of these cities. They are an important part of education in this field and therefore also sources of qualified workforce close by. The biggest clusters in Finland can be found in Helsinki, Turku, Kuopio, Oulu and Tampere. Over half of the biotechnology companies are situated in these clusters. The companies and universities frequently work together on research and development projects and many companies have been formed around discoveries made in universities (Luukkonen, Tahvanainen, Hermans 2004:12-13).

Finland has many different public and private financing sources for knowledge-intensive companies. The next chapter will present these different financial players in the Finnish biotechnology industry.

4.2 Finance opportunities

The biotechnology industry is a capital-intensive area of business and every step in the research and development process of a new therapy requires a lot of funding and different financing options are available for the companies. All of the different financing options come with advantages and disadvantages that might have a significant impact on a company's future growth and success (Hine & Kapeleris 2006:54). Financing can be obtained from public and private

sources. Some of the possible financing opportunities for biotechnology companies in Finland will be presented in the next chapters.

4.2.1 Public financiers

The Foundation for Finnish Inventions (Keksintösäätiö) is a foundation that helps Finnish start-up companies or private persons develop their inventions and innovations into business ideas. It also provides free guidance from business experts. It was established in 1971 as a private foundation that is financed primarily by state subsidies channeled through the Ministry of Employment and the Economy (www.keksintosaatio.fi).

TE-keskus (Työ-ja elinkeinokeskus) is a work and business center that operated in various cities in Finland from 1997 to 2009 helping SMEs and advancing the technological and internationalization. The centers also provided companies with consultant services by Tekes. The name of the center has since been changed to ELY-keskus (Center for Economic Development, Transport and the Environment) and the operations have also been reduced (www.ely-keskus.fi).

Tekes (teknologian ja innovaatioiden kehittämiskeskus - the Finnish Funding Agency for Technology and Innovations) is the most important organization in Finland offering public funding that supports innovative projects and R&D. Tekes offers capital loans, which are a suitable option in high risk projects in the biotechnology industry, even though they are more expensive than traditional debt. Unlike traditional debt, they need to be defined in the company balance sheet as equity capital, which prevents the company from going bankrupt if a project fails. Typically, the projects receiving investment from Tekes are research-intensive in promising early stage companies, for example research and development of new drugs in biotechnology companies (Hermans, Kulvik, Tahvanainen 2006:36-39).

Sitra (Suomen itsenäisyyden juhlarahasto - The Finnish Innovation Fund) is an independent public foundation that operates under the auspices of the Finnish

Parliament. By law, Sitra is required to promote the development and growth of Finland's economy as well as support international competitiveness. Sitra gives financing to projects that promote sustainable well-being. The funding for the operations of Sitra comes from endowment capital and capital investment returns. Sitra has had three pre-seed programs that were meant to help companies in their start up process. *Liksa* was a funding service together with Tekes that helped with the development of a business plan. This program was however terminated in 2004. *Intro* was created as a marketplace where promising companies could present their business ideas to possible venture capitalists and business angels. *Diili* was the third program by Sitra targeted to starting companies and the goal of this program was to offer strategic knowledge for the company to back up the technological knowledge the company already had. Today Sitra does not have any of these programs anymore, but pre-seed financing program, with similar goals, has been set up by VeraVenture (www.sitra.fi).

Finnvera offers financing for start-up companies and companies in their growth, internationalization and exporting process with the main focus on the development of SMEs by venture capital investments. Finnvera is owned by the State of Finland and it provides the financing by sharing the risks with other finance providers like banks (www.finnvera.fi).

VeraVenture is the subsidiary of Finnvera that offers venture capital investments. The direct investments are directed to innovative companies in their start up stage by Seed Fund Vera, which operates under the management of VeraVenture. The goal of the venture capital investments it makes is to help promising Finnish companies to reach international success (www.veraventure.fi).

Finnish Industry Investment (Teollisuussijoitus) is a governmental company that grants venture capital and private equity investments to businesses in their growth stage. Their main goal is to promote business, employment, internationalization and economic growth in Finland regardless of the industry.

Since the beginning of its operations, the total amount of investments made by the Finnish Industry Investment adds up to a total of 670 million euros (www.teollisuussijoitus.fi).

4.2.2 Private financiers

Founders, friends and family are the primary source of funding for a new company. However, the funding that can be raised through this channel is far from sufficient since a new biotechnology company needs a significant amount of capital from the very beginning of its operations. The rate at which the company burns money is also higher than in other industries (Hine & Kapeleris 2006:50-51).

Venture capitalists manage the funds of other investors with the goal of high returns. They are experts in the development stage of companies and in exchange for the chance to invest and become shareholders in the company; the venture capitalists offer their business expertise (Friedman 2008:148).

Business Angel investors are typically wealthy individuals who have succeeded in business and want to help new companies in the same sector to grow by providing start-up capital (Friedman 2008:147). The availability of angel investors depends on the maturity of the region. The more mature the industry is, the easier it is to find business angels (Hine & Kapeleris 2006:52-53). The biotechnology industry in Finland is not as mature as, for example, that of the US so the use of business angels is much rarer.

Private investors can be for example banks and financial or other kinds of institutes that offer short and long term debt financing to companies. Normally private investments are used at a later stage in the company's development, like expansion or buy-outs. These investments are also less risky than the venture capital investments in the start-up stage (Hine & Kapeleris 2006:54).

IPO (Initial Public Offering) is the initial sale of shares a private company makes by listing on a public stock exchange that turns it into a publicly traded

company. By listing publicly, a company can potentially raise a large amount of capital, but the preparation for IPO can take a lot of money, time and managerial resources that can affect other ongoing projects (Friedman 2008:150-151).

4.3 Economical factors

When conducting a scientific research about a certain industry, it is also important to take into consideration the changes and trends in the economic environment that might play a role inside the industry. The economic crisis of 2008 and the burst of the IT bubble in the early years of the new millennium are some of the outside factors that need be explained when wanting a realistic picture of the biotechnology industry today. Especially the IT bubble has had an effect on the biotechnology industry's financing opportunities in the 2000s. The impact of the current economic crisis is yet to be seen.

4.3.1 IT bubble

The IT bubble was born when Internet technology was introduced to the business world in the mid-1990s. The Internet made it possible for companies to reach the global market and audience more cheaply and effortlessly than ever before, which is why many business plans based on this opportunity attracted huge amounts of investments and funding. The investors saw their opportunity in these Internet-based companies and the demand for the shares quickly exceeded the supply, making the companies worth hundreds of millions of euros even without any actual information on their financial performance (Tassabehji 2003:224).

The entrepreneurs in the IT field had great trust and expectations in their Internet-based companies, which led to the spending on technology and marketing spiraling out of control when they used money they didn't even have believing in huge profits in the future. By this time the venture capitalists

stopped funding these companies that were showing no financial returns (Tassabehji 2003:225).

New companies were launched constantly and soon the market was so saturated that the consumers couldn't differentiate between the Internet sites anymore. It became impossible to attract paying customers to cover the huge costs. During the IT bubble, profits and sales were expected to rise at an unrealistic rate and the high stock prices were a representation of this. When the share prices started to plunge as a result of mounting losses, many of the big companies of the time went bankrupt, for example Jippii in Finland. The burst of the IT bubble was a good reminder for entrepreneurs and venture capitals that the most important part of a business plan are financial objectives that are possible to achieve and sustain (Tassabehji 2003:225).

4.3.1.1 The impact on the biotechnology industry

During the rise of the information technology industry in the 1990s, the private capital markets developed and also brought financing to the biotechnology sector in the end of the century. After the IT bubble burst in 2001, the situation in the financial market changed. At the end of the 1990s there were high hopes of taking biotechnology companies to the public capital markets in a very early research and development stage, but only a few of these companies were able to make the transition before the burst of the bubble, for example Biotie (Luukkonen, Tahvanainen & Hermans 2004:13). The change in the capital markets was a problem of the whole western world. In the US, the venture capital investments dropped to a half in 2001 when compared to the previous year (Lerner 2002:26).

After the burst of the IT bubble taking early stage biotechnology companies to the public capital market was no longer a possibility and the private capital investors were not able to secede from the biotechnology companies according to plan. This has been the main reason for the difficulties in receiving new funding and therefore the decrease in the number of founding of new

biotechnology companies. Private capital investors have become increasingly cautious and investments are mostly directed towards companies that are past the pre-clinical stages and already in the market making profit (Luukkonen, Tahvanainen & Hermans 2004:13-14).

4.3.2 Great recession

The current worldwide economic situation, called the *Great Recession*, is the biggest financial and economic crisis the world has faced since the *Great Depression* of the 1930's (Gylfason et al. 2010:11). By the fall of 2008, the crisis had become a worldwide financial panic even though the first indicators of the crisis were detectable a few years earlier already (Blinder & Zandi 2010:2).

The first signs of the forthcoming economic slump could be seen in 2006, when the house prices started to fall and mortgage loans rise in the US. In 2007 this lead to important mortgage lenders to stop buying mortgages and related securities. Later that year several mortgage lenders and banks filed for bankruptcy and liquidated related hedge funds. The biggest turning point came in September of 2008 when the authorities in the US let one of the oldest investment banks, Lehman Brothers, go bankrupt, causing a global credit freeze (Hemerijck, Knapen, Doorne 2009:13).

These events were then followed by the evaporation of liquidity, expanding credit spread, slumping stock prices and the failing of various important financial institutes (Blinder & Zandi 2010:2). The damages in their financial statements caused restricted credit in financial institutes and households to cut back their spending. This continued in a spiral, further damaging the financial statements when investment and trade declined along with the rise of unemployment. The massive collapse of the economy happened at such a great speed causing panic and extreme uncertainty that it managed to even deepen the recession when investors and consumers radically changed their behavior in order to hold on to their own capital (Commission on Growth and Development 2009:5).

The OECD reports the global economy and financial markets to be normalizing, but unemployment rates are still very high in many countries and it will take time and international collaboration to fully get over the Great Recession (OECD 2010). It is rare for a crisis to hit stock market, banking and housing simultaneously like it has now and this situation forecasts a longer and deeper recession (Claessens, Kose, Terrones 2008:4-5). When a recession has been this strong, it is preferable to be critical about the fast improvement of the economy and in the future, aftershocks can still be expected (Hemerijck, Knapen, Doorne 2009:14).

4.3.2.1 The impact on the biotechnology industry

Supporting a new project is always a risk for the financiers, but especially in the biotechnology industry. The length and complexity of the drug development process means that the risks are especially high. Throughout the biotechnology industry's history, the risks have always been there, but after the start of the capital crisis in 2007, investors have been more interested in opportunities with lower risks. This is a major problem in an industry where developing just one new product can cost up to 800 million euros (Biotechnology Industry Organization 2008:38). If the capital cannot be raised, companies need to delay or even stop some development projects that one day could have been a useful new therapy helping millions (May 2009:7)

The situation is especially difficult in the US, where the financial crisis started, but the current situation in Europe is similar to that of the US. The companies selling products in the market are not considerably affected by the crisis, since they can get finances from the profit of the drug. This is why it is important for a company in the bio-tech industry to have at least something on the market, even if the product is not a top seller, because in a situation like this, all profit is needed. For new companies just starting their business, getting the initial financing could prove to be very difficult. Also mid-stage companies in the middle of trials often need a lot of money and the trials can get terminated due

to a lack of finances, which is an opportunity for Big Pharma companies to come in and buy the valuable intellectual property (May 2009:7-8).

The current market condition has been a great shock to the whole world, but the biotechnology industry has in fact been in a negative atmosphere throughout the last decade since the burst of the IT bubble (Booth 2009:705). The current economic situation being as low as it is now, has been one of a kind in the biotechnology industry's 30 year-history and it is yet to be seen how much it has affected the future of this important industry (May 2009:8).

4.4 Changes in the finance opportunities

In the beginning of the 21st century the financial market experienced a downfall with the characteristics of a recession, when the rapid financial growth of the previous seven years came to a turning point in 2001. Similarly to the recession of the early 90s, the economic growth experienced a 5 % drop in 2001. The areas most affected by this change were the ICT sector and the biotechnology sector. During this time the R&D funding also experienced cutbacks for the first time since 1991 (Työministeriö 2003:77, Hietanen 2004:3-4).

Before the downturn, financing was more accessible to companies. The atmosphere was more opportunistic, which led to the public financiers supporting various projects quite freely. There were no strict rules or restrictions on the allocation of funds and all of the funded projects were expected to be successful. Affected by the downturn, some financiers have changed their criteria and strategy (Heinonen 2009:109).

In 2006 Tekes made a strategic lining about the financing of biotechnology companies, where a realistic business model became an increasingly important factor, underlining the business competences of the company CEO's (Hendolin 2011). This means that Tekes will focus on even fewer companies in the future to guarantee their success. At the same time many companies with interesting

inventions will be left without financing because the lack of business knowledge results in shortcomings in their business plan.

In 2011 Tekes announced its new strategy that also brings some changes in the criteria for receiving financing. This strategic change is so new that it has not yet had an impact on the case-study companies, but in the future they also might experience some effects, as will the companies that have still not been even founded. Some of the strategy changes that will also affect the biotechnology industry are that Tekes will cut down the amount of projects it finances, but increases the monetary support it gives on the continued and chosen projects. The new focus will be on pioneers and innovative projects. Tekes will also support new start-up companies by taking more risks, which means that possibilities of both success and failure will increase (www.tekes.fi).

Together with Tekes, Sitra is seen as the biggest financial source for Finnish biotechnology companies. However, Sitra has also made changes in its strategy which makes it unavailable for new companies. Because sufficient financing is such an important factor in the growth of biotechnology companies, Sitra has decided to focus on companies that are already on its portfolio and will not make investments in new companies. This is of course beneficial for the companies that are now receiving more money from Sitra, but new start-up companies are left to look for other options (Heinonen, Sandberg 2008:292).

4.5 Case studies

The following section focuses on the case study companies. First the companies will be presented with the focus on indications of growth, both financial and non-financial. The companies were also asked to describe how they feel about the current economic situation in Finland and how it is affecting them. The companies, location of the company, their representatives and the representatives' position in the company are:

- BioCis Pharma, Turku – Dr. Lasse Leino, CEO and founder of the company
- Medeia Therapeutics, Kuopio – Dr. Milla Koistinaho, CEO and founder of the company
- Hermo Pharma, Helsinki – Mr. Juhani Lahdenperä, CEO

4.5.1 BioCis Pharma

BioCis Pharma Ltd. (BioCis) was founded in 2003 by doctors Lasse Leino and Jarmo Laihia. It is a drug development company focusing on research and development of novel pharmaceutical products for inflammation, allergy and cancer. The company uses a virtual business model and therefore outsources almost all of the R&D activities requiring major resources, while staying responsible for the planning and managing of the product development activities. The business idea is to conduct the drug development projects from the preclinical stage until proof of the drug being efficient has been obtained in the Phase II stage of clinical trials. After the clinical trials, the product is out-licensed to Big Pharma companies. BioCis expects to receive revenues of the product from upfront payments, milestone or maintenance earnings and royalty fees from the licensed products.

The company is the result of research that the founding members had done since the beginning of the 90s in a university, which grew into an idea that the discoveries could be commercialized. The commercialization process was started by collaborating with a technology transfer company in Turku in the hopes of finding licensing partners. In the end this proved to be unsuccessful and it was decided that an entirely new company could be established around the discovery.

Dr. Lasse Leino tells that the development projects have proceeded according to plan, although slower than originally expected, which has been caused by financial issues. In a company where finances have to be constantly searched for, the projects will be delayed if there is not a sufficient amount of money to be

invested in the projects. ”*The speed of product development is mainly regulated by financing. These past two years we have had to slow down the projects due to scarcity of financing*”. Along the way BioCis has also eliminated some projects, because of the lack of financing and resources. BioCis currently has three products in its pipeline: A dermatological emulsion cream for *atopic dermatitis*, eye-drop medicine for *dry eye syndrome* and a cancer treatment for *bladder cancer*. During the 6,5 years of its operations the product development has gone from early pre-clinical phase to the 2b phase in the most advanced project, the dermatological cream.

4.5.1.1 Factors contributing to growth

The company started its operational activities in January 2004 after 1,5 years of seeking financing. BioCis received an early stage financing and a start-up business loan from Tekes and won locally a business plan competition called Venture Cup in 2004. The discovery of a potential drug lead, will to commercialize and successful funding in the start-up phase made it possible for BioCis to start its operations. After these indicators of success, the company started to operate full-time in January 2005. The company started with three employees: the two founding members and a biotech engineer working in the laboratory. Today the company has 6 employees.

In the early days of the company, BioCis received TULI investment, which is granted in order to promote new research-based business ideas and to expedite the commercialization process. The program is coordinated by Tekel and funded by Tekes and the investment at that time was 10 000 euros/ project. At the time of the start-up process, BioCis also received pre-seed funding from Liksa, a project by Sitra and Tekes for developing business. The maximum amount of funding a project could receive was 40 000 euros (Grundsten 2004). BioCis also received an establishment loan from Tekes, maximum of 100.000 euros/company, and after that found venture capital investors.

BioCis has successfully followed a traditional path to find financing in the start-up stage. After the initial stage, the financing has been mainly gathered from venture capital investments and product development loans from Tekes. Since the beginning, BioCis has received altogether several product development loans from Tekes as well as gone through several financing rounds to gather venture capital investments. Between 2004 and 2010 BioCis has received over 2 million euros from Tekes as product development loans: 124 900 euros in 2010, 471 017 euros in 2009, 801 077 euros in 2008, 22 994 euros in 2007, 578 975 euros in 2006 and 49 150 euros in 2005 and 2004

The CEO feels that receiving public finance has been a crucial part of getting the company started and attracting the interest of private investors. Without it the company would have taken a lot longer to start or it might have been impossible to start the company at all. The public financing has also been a part of the company's overall financing.

In the fall of 2007 Biocis received an investment of 1,5 million euros from Finnish Industry Investment Ltd. and the Swedish investment company Karolinska Development. With the investment, BioCis was able to speed up their product development projects and start the first clinical study of the dermatological cream. This was the first time Karolinska Development invested on a Finnish biotechnology company (www.teollisuussijoitus.fi).

By the end of 2007 BioCis was chosen as the Business Incubator Company of the year. The competition rewards companies that have grown in technology incubators. BioCis was chosen because it filled out the criteria by showing cost-efficiency in the product development and the business model BioCis uses was seen as being innovative and providing a competitive edge. The competition was arranged between 2004 and 2009 by TEKEL, the Finnish Science Park association to honor successful new companies (www.tekel.fi).

In the fall of 2008 BioCis received almost 1,6 million euros for research and development. The funding was targeted for speeding up the clinical phase I/II program of the company's dermatology product. The product development loan

was granted jointly by Tekes and a Swedish Venture capital company, Midroc New Technology AB. The fund was predicted to cover 70 % of the costs of the clinical trials (www.mainialehti.fi).

In the spring of 2011, BioCis announced that they would start extensive phase IIb clinical trials on their cream for atopic dermatitis with about 150 patients. The cream has gone through 4 clinical trials in the last three years and has shown to be very promising. BioCis has a lot of market potential with this therapy, since there are not many similar products at this late stage of the development, but the product won't reach the market until 2012 at the earliest (www.biocis.com).

The company has not been using any specific way of measuring the success of the projects internally. The measuring system is more human-based and consists of “how the project feels by following the progress made”. Dr. Leino also feels that the financiers do not have any specific measurements of success. The financiers have a place in the company board and through that they are able to follow the progress of the company.

Lasse Leino says that the objectives of venture capital financiers are normally similar: to make more money. Sometimes there can also be secondary objectives like supporting Finnish know-how, but these secondary objectives tend to vary among the financiers. He is disappointed by the strategic support that the company has received from its financiers to obtain contacts and financing: ”*Before I was participating in business operations, I used to have the idea that venture capitalists would give a great deal of strategic support that we have not received. I do not know if we have especially passive investors or what is the issue*”. Public money has been directed towards supporting the preclinical, early stage research. Tekes has made a policy outline that it will not finance phase 2 clinical trials, which Leino thinks is ”ridiculous” because it is the stage that requires the most financing.

Leino told that the growth possibilities of the company are very much connected with the current financing environment. *"It would be ideal if the company would be able to grow internally through sufficient financing, but I do not think it is*

possible, so growth could be achieved through fusions or similar kind of inter-company activities". He does not see enlisting in the stock exchange market as a current concern for any Finnish drug development companies.

4.5.1.2 Views on the environment

Public financiers and the public sector, like Tekes, do not understand the special characteristics of the industry very well and their perception of the financing need of the biotechnology industry in different stages is not realistic, according to Leino. "*The process is seen as very simple*". They do not understand the value chain or the time it takes to make profit. He sees the drug development industry in Finland to be in a weak state mainly because of the structural problems connected with lack of the financing opportunities. Leino finds it impossible for companies to receive financing from international sources, if the financing received from Finland is insufficient. This has led to the Finnish biotechnology companies to be very small in size, because even if there is potential to do more, the lack of resources prevents the companies from having more than a few ongoing projects. This situation is not likely to change soon and the lack of financing will continue to eliminate potential companies from the market, so the future of the industry does not look so bright either, says Leino.

To improve the situation, Leino feels that the sources of public financing in Finland need to change their perspective when it comes to financing drug development companies. He sees Finland as an excellent environment for the biotechnology industry because of the education and experience of the workforce, good infrastructure of service organizations and as opposed to common belief, its relatively cheap wage level. But if the financing bodies fail to understand the special characteristics of the industry, the drug development activities could end in Finland due to the lack of financing and all the promising companies will become foreign-owned. If the situation would go as Leino predicts, it would be a great loss to the Finnish economy. The biotechnology industry is constantly growing and it has a potential of bringing high profits and boost the economy of the country.

4.5.2 Medeia Therapeutics

Medeia Therapeutics Ltd. (Medeia) was founded in 2006 by Doctor Milla Koistinaho. It is a drug discovery company that focuses on discovery and early development of products for indications in central nervous system (CNS) and oncology. The company uses a semi-virtual business model, meaning that all of the non-core business functions are outsourced while the company stays in control of the intellectual property and key technology assets as well as strategic partnership. The business idea of Medeia Therapeutics is to develop very early stage drug discoveries further independently but to search for a commercial partner at a very early stage of product development to share the technological and financial risk related to the drug development process. Today the company has 5 full-time employees.

The founding members of Medeia Therapeutics have worked together at a university and gathered their scientific know-how there, but the product-development portfolio/commercialized discovery doesn't stem from an academic background. The motivation to start a new company came from the new discovery and the thought that IPR (Intellectual Property Right) could be created around the discovery. What facilitated the founding of a new company was the commercial experience the founding member had from previously having a company in the same field (but with a different business model and business idea) and the fact that the existing network could be used in the new company.

Medeia Therapeutics was established around developing one research finding that was commercialized very early on, but currently the company has four larger projects in their pipeline. The research & development pipeline currently focuses on finding treatments for age-related neurodegenerative diseases, like Alzheimer's disease, Parkinson's disease, Multiple Sclerosis and Amyotrophic lateral sclerosis (ALS). Dr. Milla Koistinaho explains that there has been some prioritizing with the projects, but none of them have failed technically or commercially as such. The growth of the product development portfolio from

one to four projects has been enabled by increases in resources when a considerable investment was made by an international venture capital investor, Inventi Capital, in the fall of 2008 and Tekes' Young Innovative Company grant in 2009 strengthened the growth

4.5.2.1 Factors contributing to growth

In its first year of operations in 2006 Medeia received 40 000 euros from the late TE-Keskus as an investment and start-up aid. Around this time, Medeia also had its first financing round attracting Seed Fund Vera Ltd. as a capital investor for the company. The company has also taken a part in a growth programme by Technopolis Venture, receiving 40 000 euros for developing its business activities. Since the start of its operations, the company has received around 1,5 million euros from Tekes as research and development loans: 254 102 euros in 2007, 334 211 euros in 2008, 250 879 euros in 2009 and 688 299 euros in 2010 (www.tekes.fi).

Koistinaho tells that receiving public financing has almost been a prerequisite for private financing in Medeia. For the company, to show that it is able to obtain private financing from Tekes and Finnvera has been a positive attribute when attracting venture capitalists.

Medeia completed its second financing round in 2008. During this round the Finnish-German Inveni Capital Ltd., that focuses on funding companies in the life science industry, was the leading investor and became one of the venture capital companies backing Medeia along with Seed Fund Vera Ltd., who also continued financing the company. During the two financing rounds it has been part of, Seed Fund Vera Ltd., which operates under Veraventure Ltd, has made capital investments in total of around 500 000 euros and Inveni Capital Ltd. invested 1,5 million euros in Medeia. The CEO states that the private venture capital investors have offered strategic support, but the public investors have not played a strategic role.

In 2009 Medeia was accepted to the Young Innovative Company (YIC), which is a program funded by Tekes. The program supports innovative and growth orientated Finnish companies by offering a fund of up to 1,25 million euros in two to three phases for business development activities. Medeia received a grant of 250 000 euros in their first phase. This money was directed to developing the product portfolio and building strategic partnerships. In 2010 the company was awarded the second phase grant of 650 000 euros on the grounds of achieving previously set goals about business developing and internationalization. Therefore, in total Medeia has received 900 000 through this program to this date.

In 2007 Medeia made its first commercial agreement with Orion, one of the biggest pharmaceutical companies in Finland, to work on one of their most advanced programs. The agreement has been a major strategic achievement for Medeia and it was expanded in 2010. Medeia will continue looking for new partnerships with global biotechnology and pharmaceutical companies to further advance the clinical trials of the products and eventually help with the launch of the products. During the partnership Orion will be conducting the clinical trials of the products. Medeia will receive revenues from sign-up and R&D milestone payments and royalties.

The measuring of the projects' success is done internally. Before even starting the product development process, a specific plan has been laid out. The plan defines how the project should progress and it has been divided into certain milestones concerning technological advancements and how the drug development phases are progressing. ”*Measurements of growth and the company’s value have been the ability to create new IPR to support the know-how and being able to create actual value to the company by leaving patent applications”.* From time to time the company also measures the direction of growth by contacting possible future clients to see what level of interest they have.

The financiers have also used internal performance indicators and reports. A seat in the board of directors has provided a chance for the venture capital investors to follow the company's operations. And public financing like the Seed Fund Vera requires a bi-annual report. ”*There has not been a need to show how the pipeline projects are progressing, but the operational follow-up has been very informal, the information gets around at the board of directors”.*

The company operates in very early stage drug development and this is when the financiers have come along. During their first financing round, the company received funding from Seed Fund Vera, whose motivational basis on financing were to help company's start-up stage. ”*At that point we already had our first commercial agreement but they (Vera) believed that by giving us this boost, it would be possible for us to multiply our operations”.* Medeia's other financing round has clearly been more growth and internationalization orientated, with the focus on filling the pipeline.

4.5.2.2 Views on the environment

The CEO says that the current availability of financing is not sufficient by any means. ”*I see that especially for seed stage companies, the possibilities for capital investments are practically close to zero*”. Koistinaho thinks that, even though the financing is not sufficient enough, public financiers like Tekes are able to understand the special characteristics of the biotechnology industry, but they lack the ability to take risks. Tekes understands how the industry works but is still not ready to make positive financing decisions. ”*Perhaps they try to fit all the different industries into the same mold even if they have recognized the differences between the inbuilt characteristics of different fields”.*

Dr. Koistinaho feels that the current stage of the drug development industry as a whole is positive. The trend is that big companies are increasingly in-licensing and over half of their revenues at the moment come from these partnered products: ”*Networking and partnerships with small innovative companies is the current trend and I see our place in that network as essential and important”.*

Koistinaho thinks that despite the favorable trends in the industry, Finland is a rather poor environment. This is because the market is so small and the state of financing unfavorable. There are practically no early stage investors other than Seed Fund Vera and because the market is not developed in Finland, the amount of capital investors is small and there are extremely few business angels. It is also difficult to attract international partners, because there is not enough strategic knowledge and experience. ”*In Finland we do not have many professionals who have acquired knowledge in big companies and would come back here to help smaller companies*”.

4.5.3 Hermo Pharma

Hermo Pharma Ltd. (Hermo) was founded in 2008 by four researchers of neuroscience: professors Mart Saarma, Eero Castrén, Heikki Rauvala and Doctor Henri Huttunen. It is a biopharmaceutical company that focuses on the discovery and development of new drugs for severe neurological diseases. The company uses a virtual business model, outsourcing a major part of its business operations while managing its core functions internally. The business idea is to develop a product and at the end of the process, sell it. The strategy of Hermo is trying to find partners from big pharmaceutical companies during the product development phase that will then take part in the late stage operations from late clinical to marketing.

Hermo Pharma’s drug development portfolio stems from academic background, since all of the founding members work in the University of Helsinki, one as a docent and the other three as professors. The projects had been developed in the university environment, until two of them reached a point in which the academic funding could no longer cover the research costs so a company was built around them. Some of the founding members had previously owned companies, which has helped them to see the commercial possibilities of creating a company that would bring with it the access to public money.

The focus of Hermo Pharma's research and development projects is to find new ways to treat diseases that affect the nervous system. Major diseases of the central nervous system are characterized by their irreversible nature and Hermo Pharma tries to develop drugs that help with the symptoms and possibly prevent the disease from progressing. The two main products in Hermo Pharma's pipeline are meant to treat amblyopia and Parkinson's disease. The product development for the amblyopia treatment is the furthest project in the company's pipeline, at the recruitment stage of phase II, and the possible new therapy for Parkinson's Hermo Pharma develops is at the preclinical proof-of-concept stage. A market for both of these treatments exists and can generate high profits for the company. Amblyopia is a condition effecting up to 2-4 % of the adult population in the western world, and at the moment there are not many products for the treatment of the condition. The market for Parkinson's disease drugs is worth 3 billion dollars and is growing alongside with the aging population.

4.5.3.1 Factors contributing to growth

From 2008 until the end of 2009, the company went through their first financing round and before that it had been financed with small investments. At the end of 2009 the company received a seed-stage financing round jointly from the University of Helsinki fund and Veraventure, worth of 1 million euros. This money enabled the company to be put into operation in early 2010 and Juhani Lahdenperä was hired as a CEO alongside with three outside board members. The company currently has 5 full-time employees.

During its first year of operation the company laid out the strategic plan for the future: the decisions about the possible research and development projects. Since then, two of the projects that had been furthest in the R&D and with most potential value have been chosen as the main focus. At the end of 2010, a permission to start the clinical phase was applied from the authorities and the ethical committee. The permission was granted and the drug will soon enter clinical trials in Finland.

Since the beginning of its operations, Hermo has received altogether approximately 1 million euros from private investors, almost 2 million euros from public sources and 350 000 euros from the Michael J. Fox foundation. The money the company has received from Tekes has not all been used, since venture capital funds are spent first. Money that has been obtained is directed towards the two research and development projects, improvements in quality control and preparing a business strategy.

Tekes has acted a major role in the growth process of Hermo with annual financial support. In 2008, Hermo Pharma received a support grant from Tekes, worth of 40 600 euros to cover 75 % of their costs. In 2009 Tekes gave the company a grant of 52 721 euros to support the company's efforts to initiate business activities. In 2010 Tekes granted the company 150 212 euros to support the business development and to speed up the preclinical development of the amblyopia product. In 2011 Tekes continues to finance the research projects of Hermo Pharma. The research and development fund Tekes granted the company is directed toward the therapy for Parkinson's disease and to support the pre-clinical research program.

The CEO of the company feels that receiving public finance has facilitated private financing. He credits Tekes for making two of their financing decisions with conditions, because this makes it easier to show the aim of the funding to private financiers as well. By changing the investment structure, Tekes has made it easier for the private investors to invest in the company. This has been positive progress.

The company has received a product development loan from Tekes and also venture capitalist financing for the amblyopia project. Hollywood star Michael J. Fox, who has Parkinson's disease and has a foundation that rewards a handful of rising projects a year, gave the company a fund for their Parkinson's disease research. Most of the projects that receive the grant from Michael J. Fox foundation are North American so this can be seen as a very promising

indication for the company's future. Tekes is also another source of finance in the Parkinson's disease project.

In the April of 2011, Hermo announced the establishment of its first industrial partnership with a major pharmaceutical company. This agreement shows strong evidence that the company is moving in the right direction with its projects. The partnership provides Hermo financial investment with added value from strategic knowledge in markets and product development

Hermo has reached the objectives that the company has set for itself in the two projects that it is focusing on. The success of the projects is measured by reaching the milestones in each stage of the drug development process. Reaching these milestones takes a few years at a time so some shorter-term goals have also been set. Tekes has specified criteria for project money, where the drug development process has been divided into sub-phases and Hermo works towards these goals. Reaching these short-term goals will help with their long-term ambitions as well.

The objectives of different investors are similar in many cases: to promote the growth of the company. The motives of the investors can however vary. For example, venture capitalists are looking to make profit whereas the Michael J. Fox foundation is more interested in finding the cure for Parkinson’s disease. The goal is the same, but the motives behind funding the project are different. Depending on the motivational factors of the investor, different performance indicators are also used by the financiers to do follow-up. The venture capitalists are mainly following the company’s growth through financial results and they are interested in when the business side is starting to operate. Tekes has a reporting system for all the projects it is financing and can follow the company through those.

The company is considering acquisition as a strategy of growth in the future, but at the moment they pursue growth through business activity. Expanding operations is more relevant in a few years’ time, but before that the focus is on creating value on the two R&D projects. Strategic alliances have been

discussed and the company is mainly interested in big companies with market contact to share risks. The main goal is to sell the product to a big company.

The CEO, Mr. Lahdenperä, feels that the company has received sufficient strategic support from their investors. The board members' expertise as private investors and the strategic consultant service from Tekes have both been put to good use. ”*Tekes actively takes part on many levels and I have a very positive image of them, even though I know they have received public criticism.”* In the beginning of 2010 Hermo Pharma appointed new members to its Board of Directors. One of these members was Jonathan Knowles, who has had many high-profile positions throughout his career, including serving years as a board member at Genetech, one of the biggest biotechnology companies in the world. He has also recently received Script's lifetime achievement award. Having board members like Dr. Knowles is important for a growing company because of the strategic knowledge and experience they have.

4.5.3.2 Views on the environment

According to the CEO, Finland is a great environment for their business and traditionally there have been many good inventions, but the lack of knowledge on the commercialization of these inventions has hindered their progress and development. ”*We do invent and find things, but in a way maybe we lack the open-mindedness and courage to go and do. The lack of courage and creativeness has prevented us from commercializing by ourselves*”, says the CEO about the weaknesses of the Finnish companies who are afraid of taking risky steps in the fear of losing jobs. As a result he suggests creative thinking to reduce the risks, like spin-up companies. He sees that there are many potentially successful inventions that for some reason or another never reach their full potential, but that the problem is not the financing.

The CEO of Hermo thinks that the public financiers in Finland understand the industry relatively well, because they are following the international markets. One issue is that the reaction to changes and communication is slow in big

organizations, but that is natural. ”*Finnish people like to complain when there is a problem but won't start solving it”,* says Mr. Lahdenperä, who thinks that the public sector understands the characteristics of the industry very well. All the industries are being treated as equals and compared to the IT industry that has had many success stories; the biotechnology industry might need more creativity in the commercialization of the inventions. He says that good projects get a sufficient amount of money in Finland. ”*The financiers need to be told what they want to hear in order to finance, and if you are not sure about the project, the financiers won't be either. You are just deceiving everybody*”, says the CEO, who specializes in communicating and presenting the projects to the financiers.

Juhani Lahdenperä feels that the pharmaceutical industry is undergoing a massive transition and introducing new products to the market has become increasingly difficult. The current trend is that new inventions and innovations are made in small companies or universities and sold to Big Pharmas to control risks. Mr. Lahdenperä identifies three generations of companies in the Finnish drug development history. The first generation being big and old companies, like Orion, that were assigned to make the needed products. After this there was the opportunistic generation, for example Biotie. The problem of the second-generation companies was that there is a lack of business, strategic and operational knowledge in Finland. They tried to achieve the same kind of structure as Orion by handling all the operations. These companies were established by academics without a lot of commercial experience and who were willing to put money on overly risky projects.

Now the Finnish biotechnology industry is on its third generation and the problems of the previous generations are attempted to be solved by seeking strategic knowledge from outside. The companies in the current environment have also started using virtual models where most of the functions are outsourced. The problem of the current generation is the lack of business development knowledge in Finland. *”I have high hopes for the next generation.*

When the current problems are solved, Finnish biotechnology companies in the future are able to operate from start to finish".

4.6 Cross-case analysis

In this chapter, the case study companies are being compared to one another to get a better picture of the similarities and differences they have. This is done so that generalizations could be made about the current state of the biotechnology industry in Finland. The comparisons are made by using the theoretical knowledge of growth acquired in the second chapter. This includes the strategy of growth and the business model used by each of the companies, financial and non-financial measurements of growth and how the companies have obtained financing.

4.6.1 Company foundation

One of the biggest differences between the case study companies is the age. BioCis was founded in 2003, Medeia in 2006 and Hermo in 2008, which means they have been founded within a five year range. If the companies would be in a later stage of their growth, this would not be a major issue. However, all of the companies are still in their conception and development stage, and in the first stage of the company's growth, five years make a great difference in what the companies have even been able to achieve.

BioCis and Medeia share similar characteristics in their founding stages. Both had a drug candidate that was being researched in a university by a founding member, but the companies are not straight continuations to the preceding university research. Hermo on the other hand developed its product in a university and set up a company around it when the academic environment could no longer support the project financially. In each of the companies at least one founding member had had previous commercial experience, so the transition from academic research into a commercial one was not particularly problematic.

4.6.2 Strategy of growth

All of the companies identify themselves as early stage drug research and development companies using a virtual business model and are planning to license out and look for partners for the later stage developing and even clinical trials. The phases of the drug development in which the companies want to license out the operations vary slightly between the companies. BioCis' plan is to work on the project until the drug has shown efficiency in the phase II and then out-license it to Big Pharma companies. Medeia's plan is to develop early stage discoveries independently, but simultaneously look for partner to join in on the project at an early product development phase. Hermo wants to have a partner to join after the product development to take care of the late stage operations and marketing.

All of the companies stated that they are looking for partnerships for their drug development projects to share risks and look for strategic knowledge. BioCis does not yet have any partnerships, whereas Medeia and Hermo do, even though they are newer companies. This could be because BioCis might not be as partnership-orientated as the other ones; the company could be considering it, but not actively pursuing it. Medeia and Hermo on the other hand made it clear that they are looking for more partnerships at the moment, Medeia already having one agreement and after the interview Hermo announced on their internet page that they had signed a partnership deal as well.

4.6.3 Projects

If conclusions were drawn about the progress of the companies' drug development projects on the grounds of the company's years in operation, it could be said that BioCis would have the most advanced product development and the most products in their pipeline, followed by Medeia and then Hermo. BioCis has products furthest along in product development: there are two projects in clinical trials, but the company has only three projects overall. Medeia and Hermo both have four projects in their pipelines and out of the two;

Hermo is further in the development process than Medeia. Hermo is in the phase II clinical trials with its furthest project and going into the clinical trials with the second. Medeia's furthest project is about to reach the pre-clinical phase.

The fact that the results are slightly different from the original hypothesis can be explained by certain factors. If BioCis is seen in this case as following normal development, the two other companies will be compared to its progress. Hermo already has a drug candidate at almost the same development phase as BioCis, even though it has been founded five years later. This could be explained by the fact that Hermos products were already developed quite far in the university and the actual company was not founded until after the development reached a stage, where it was no longer financially possible to continue in the academic environment. BioCis and Medeia on the other hand were founded at an earlier stage of the drug discovery process. Hermo and Medeia also have more products in their pipeline when compared to BioCis. The reason behind this is that Hermo and Medeia have products in their pipelines which are in early research phase while all of BioCis' products are in the pre-clinical or clinical phase. Projects in the early stages can be terminated more easily if they do not show success and the companies might want to make prioritizations in their product portfolio later.

4.6.4 Financing

All of the companies have received sufficient financing from both private and public sources to have been able to start the company's operational activities and continue the drug development processes. The CEO's also think that having been able to get public financing from sources like Tekes has made them more attractive to public venture capital financiers.

BioCis has received public financing of up to 150 000 euros from Tekes and Sitra in its start-up stage. Since the exact numbers were not given in the interview, approximates were collected from the Internet. The company has also received research and development loans worth 2 million euros from Tekes

between the years 2004-2010. Together with public money and venture capital financing, BioCis has received investments for the clinical trials of its most advanced product, the dermatological cream. The public financier Finnish Industry Investment Ltd with a venture capital company Karolinska Development made an investment of 1,5 million euros for the phase I trials and Tekes with venture capital company Midroc New Technology invested 1,6 million euros for the phase IIb trials.

Medeia has received 40 000 euros of public financing in its start-up stage from TE-keskus. Another 40 000 euros in the early stage was private money from Technopolis Ventures. As research and development loans, Tekes has granted the company 1,5 million euros in 2007-2010. Tekes' finance program for innovative companies has also granted the company 900 000 euros in two phases to develop their product portfolio and strategic partnerships. Seed Fund Vera that works with public money, has invested 500 000 euros in the company's first and second financing round. During the company's second financing round it attracted private venture capital company Inveni Capital as its other major financier with Seed Fund Vera. It has made an investment of 1,5 million euros.

During its first financing round, Hermo received 1 million euros of public money from the Helsinki University fund and from Veraventure for starting business operations. Tekes has granted Hermo approximately 250 000 euros between 2008 and 2010. Including these two sources, the CEO of Hermo told that they had received 2 million euros of public money. Hermo has gained 1 million euros of Private venture capitalist money and the company has received 350 000 euros from a non-profit foundation.

There are few points of interest that arose from the financial measurements of growth. First of all, Sitra, that has traditionally been one of the biggest public financiers of biotechnology companies, has made investments in only one of the companies, and the investments have both been made through projects that were also financed by Tekes. Sitra's role as a financier of new biotechnology

companies is therefore clearly diminishing. Another point, connected to the theoretical base of financiers in different growth stages, is that all of the companies received venture capital financing already in their conception and development stage. Traditionally venture capital investments are not received until the commercialization stage. Founders, family and friends, business angels and public financing are sources of finance in the conception and development stage, but the case study companies only used public financing. One reason for this is that there are virtually no business angels in Finland.

4.6.5 Strategic support

Receiving strategic support is crucial for biotechnology companies, especially in the commercialization stage. This is due to the fact that in most cases the founders and CEO's are scientists without much business knowledge or experience. The lack of strategic knowledge can cause failure in otherwise promising projects. Traditionally, strategic support can be gained from the venture capital companies who will place a board member inside a company to help and overlook the company's activities.

BioCis and Medeia have not received any strategic support from their investor. This has been a disappointment especially for BioCis, who expected to receive it. The problem was thought to be in the passive investors. Hermo on the other hand has received a sufficient amount of strategic support from its private financiers and Tekes.

Hermo also made a strategic decision at an early stage of hiring a CEO from outside the company. This can prove to be a wise decision, if the founding members can look at their business abilities critically and make the judgment of possibly hiring someone new with the required expertise. Both the business and science side can benefit from this when the scientists focus their unlimited attention on the drug development projects and the CEO focuses only on the business side. This way, activities do not need to be prioritized.

4.6.6 Views on the environment

The industry environment of biotechnology in Finland has recently been under a lot of criticism, especially concerning the actions and criteria of the public financiers. The case study companies were also asked how they see the environment and it became clear that not all of them saw the situation the same way.

All of the companies agreed that Finland is a good environment for this type of business activities, which was to be expected, since Finland is known to be a knowledge-intensive country and the workforce is highly qualified. But the interesting fact was that while BioCis and Medeia criticized the financing possibilities and especially Tekes, Hermo had a different view. Hermos CEO felt that other Finnish companies are criticizing Tekes without any valid reason and acquiring finances depends on the projects' strength but most of all, on communication skills.

4.7 Synthesis

In this chapter, the focus is on answering the research questions that were set out for this study in the research proposal. By answering these questions, the main findings of this study will also become clear. The questions will define what kind of financing was received, how and why the financing opportunities have changed and how this has had an effect on the growth of the companies.

The three case study companies in this research are in the early stages of the growth model, late conception and development stage or in the early commercialization stage. All of them have received public money right before or after commencing their operational activities, which has enabled them to successfully start the company. After the founding, all of the companies continued to have annual research and development loans from Tekes and also attracted venture capitalist companies to invest in their most promising projects.

The companies in the previous study went through their conception and development stage in the late 90s when the economy was strong and the hype around technology-based companies was high. During this time large investments were made on biotechnology industry in the hopes of success. The companies in this study on the other hand went through their conception and development stage around the mid-2000s, after the burst of the IT bubble and during the great recession. The changes in the financial environment have changed the finance opportunities these companies have when compared to older companies in the same field. Both public and private financiers have changed their strategy and will not make investments as loosely in the fear of financial losses if projects fail.

The main reason for the lack of financing for Finnish biotechnology companies is the burst of the IT bubble in the beginning of the 21st century. This made the investors more risk-averse and new companies have difficulties convincing the financiers on the importance of their projects. The recent global recession has also had an impact, but it will take some time to see the full effect it has had on the industry.

The case study companies have shown consistent growth regardless of the economic situation and the scarcity of financing. However, by receiving extra financing they probably would be able to grow faster and develop more products in their pipelines simultaneously. This would be important since having more pipeline products makes the company less vulnerable against product failure. But it should also be noted that since the economic condition changed in the early 2000s, there have not even been many new start-up companies in the biotechnology industry. So the scarcity of finances has definitely hindered the growth of the whole biotechnology industry.

5 CONCLUSION

This section will briefly collate the main points and findings of this research. The section also takes into consideration and analyzes the errors that were made during the process and the possible negative factors affecting the result and gives suggestions for future studies on similar topics.

5.1 Conclusion

The economic downturn of the early 2000s not only changed the way the financiers think, but also the view of the biotechnology companies. Before the companies were implementing business models and growth strategies that included doing most of the operations by themselves. When it became increasingly difficult to receive finances, the companies had to consider other opportunities to cut back costs, which lead to a number of companies to switch to virtual business models and the new start-up companies now tend to implement this strategy from the beginning. This new trend is growing stronger, since venture capitalist investors prefer companies using the virtual business, because the risk-averse investors want to maximize the efficiency for their money (Klausner 2009:127).

It can be argued that the actions of the financial players in Finland have had some negative effects on the biotechnology industry and the new start-up companies. While there is a sufficient amount of financial opportunities for new start-up companies in the form of different projects and funds, there is a slight amount of uncertainty connected to them. While doing this study, it was observed that many of the start-up stage funding programs the case study companies had received money from are no longer functioning the same way. Some of them have been terminated altogether, changed the name or have been moved to operate under another financing source. This constant change can result in uncertainty and confusion when the companies have to constantly

find out where to get the financing and whether there have been changes in their financing.

Especially the public financiers in Finland are trying to adapt to the new condition by making strategy changes. These changes are needed because financing is a crucial element in the growth process of biotechnology companies and the growth of these companies is important for the economy. It is however impossible to please everyone with the new criteria and some companies will inevitably receive less money than others.

The biotechnology companies as well as the financier's changes in policies and operational activities have the same goal, to help the biotechnology industry get through the difficult economic times. There simply is not enough money to be spent on all of the different projects, but the drug development projects cannot be terminated. Money can be saved by the companies by cutting back the operational costs and by the financiers by focusing on less projects and this is exactly what is happening. In the future when the economy will recover the biotechnology industry will hopefully recover as well.

The hypothesis in the beginning of this study was that "the public funding in Finland is not sufficient enough for new start-up companies, which hinders their growth process". The study shows that while this is true, the case study companies have managed quite well. The scarcity of the financing for biotechnology companies has been an issue even before the changes in the economic condition. The drug development process is so long and expensive that the required financing is difficult to find. However, the lack of public financing has had a more grave impact on the whole industry than these three companies. The lack of new companies founded in the new century will be problematic in the future.

In the future it would be interesting to see this research being continued by following the growth of the case study companies. More compatible results with the study of Laura Heinonen could be achieved, if the companies in this research were to be examined again in their stability stage. This future research

should be even more in-depth with accurate financial records of the companies. With this information more accurate conclusions could be made about the impact that the changes in financial opportunities has had when comparing companies founded in the 1990's and 2000's.

5.2 Error analysis

In the course of writing the thesis and collecting the needed data during the analysis stage, it was noticed that not all the necessary information was to be found in the interviews or the Internet pages of the companies in question. The quality of the answers varied from very detailed and extensive to lacking in information. Due to this variation the companies could not be compared as thoroughly as planned.

The research is based on three different biotechnology companies based in Finland. Because the amount of study subjects is fairly small, the results do not offer a holistic picture of the biotechnology field in Finland. During the interview rounds some of the participants wished not to answer questions regarding their financing and development processes, which made it difficult to compare the different companies. Because the results were gathered by using open questions in an interview, measuring them is complex. The data is qualitative, not quantitative, so defining and measuring the growth of the companies is very difficult. The participants gave such different information regarding the growth factors that a comparative analysis on their growth and development is demanding.

There were also differences between the information offered on the websites of the companies, which affected the overall picture. Not all information could be found or gathered on all companies, so the research is based on the common information provided by the interviews and online sources.

All of the interviewees were CEOs but the best answers were received from the CEO that was hired outside the company. The other two interviewees were also

founding members of the companies, which might affect the answers they gave, while the third interviewee had been hired on the grounds of his strategic abilities. Coming from different backgrounds the interviewees might have had different point of view on financing and other strategic matters.

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Questionnaire

Company history

Describe the path of the company from its foundation to the current situation with a special focus on issues such as:

- Progress of the drug development projects
- Number of drug development projects
- Personnel
- External financing
    - Sources of finance
    - Criteria for financing
    - Allocation of financing
- Licensing
- Partnering
- Other arrangements (IPO, M&As)
    - plans for enlisting on the exchange market
    - growth strategy
        - merger
        - buy

Founding of the company

- What was the motivation for starting up this company?
- What is the background of the inventions (university/spin-off/other)?

Business model

- What was the original business model of the company?
    - Licensing, any deals?
    - Is licensing part of the co-operations
- Has the business model changed along the way, if so why?

Projects

- Did you achieve your objectives set for the development projects?
- Did you initiate new projects along the way?
- How was the success of projects measured?

Financing

- What different financing was received?
    - Public? What?
    - Private? What?
    - Tekes? Equity loan? Commercialization loan?
- What were the objectives of the financiers when they first invested in the company
- How would you evaluate the strategic support received from both public and private investors? What kind of support was received?
- What were the criteria the investors used when considering investing in the company?
- How was the financing allocated? (Discovery/development/commercialization)?
- How did the financiers follow-up the operations of the company, what kind of performance indicators did they use?

- What was the influence of the public finance when you were looking for private investors? Has the stricter criteria of public finance effected the private investors in a positive/negative way?
- If your company has not received private finance and operates only with public finance, what do you think are the main reasons?
- In general, how would you evaluate each of the financiers of the company? Is some of them more important than another?

Growth strategy

- What is the company's growth strategy?
- Expand your own unit?
- Merger with another company?
- Buying other companies?
- Plans for additional finances by enlisting in the exchange market?

Industry

- How would you describe the current stage of the drug development industry?
- How would you evaluate public financiers' ability to understand these special characteristics?
- What kind of comments do you have about the current availability of finance? Do you find it to be sufficient?
- What kind of environment Finland is for doing business?
- How does the public sector understand the special characteristics of the industry?