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NEW DRUG DEVELOPMENT IN BIOPHARMACEUTICAL COMPANIES:

The Role of Private and External Funding

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NEW DRUG DEVELOPMENT IN BIOPHARMACEUTICAL COMPANIES: THE ROLE OF PRIVATE AND EXTERNAL FUNDING

Biotech industry is characterized by unique elements as the companies operate in high risk environment attempting to accomplish scientific developments trough lengthy and expensive R&D cycles while facing insufficient funding. Most companies develop new drugs while not generating any revenue, however, the need for funding is critical at each stage of the new drug development process. The overall purpose of this study is to describe the challenges in new drug development and identify main sources of private and external funding for biopharmaceutical companies. The study was conducted as an exploratory research and data was collected by interviewing a Finnish biopharmaceutical company.

To achieve the aim of the study, three streams of literature were reviewed: biotechnology industry, new drug development and private and external funding sources in biopharmaceutical context. Most empirical findings of the study supported existing literature. This study emphasises the importance of funding in new drug development and venture capital and alliances with Big Pharma were identified as the main sources of private and external funding for biopharmaceutical companies. Key findings were that early-stage drug development can attract venture capital and value can be created already at early stages of drug development making the company profitable. This thesis contributes to the already existing body of literature and offers a practical description of challenges in new drug development and private and external funding sources.

KEYWORDS:

Biotechnology, Biopharmaceuticals, New Drug Development Process, Private Finance

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LIST OF ABBREVIATIONS

FDA	Food and Drug Administration (USA)
EMEA	Medicines Evaluation Agency (EU)
IND	Investigational New Drug Application
IP	Intellectual Property
IPO	Initial Public Offering
NDA	New Drug Application
NME	New Molecular Entity
PLC	Product Life Cycle
R&D	Research & Development
VC	Venture Capital

1 INTRODUCTION

1.1 Background

Biotechnology has been widely regarded to be of vital importance to the economic growth of most national economies, in fact, it has been increasingly recognised as " one of the most promising frontier technologies for the coming decades" and furthermore, and it can serve both private and public needs (European Commission 2002). Moreover, biotechnology contributes to job creation, competitiveness in the EU and promotes economic development (European Commission 2007).

Various researchers and studies (for example, Champion 2001; Baker 2003; Arantes- Oliveira 2006; Hine & Kapeleris 2006; Khilji et al 2006; Pisano 2006; Vanderbyl & Kobelak 2007) have showed biotech industry is characterised by unique elements as the companies operate in high risk environment attempting to accomplish scientific developments trough lengthy and expensive R&D cycles while facing insufficient funding.

The concentration of this thesis is on biopharmaceuticals, in other words, in new drug development. The new drug development process is long and expensive: on average the process takes 14 years and the huge costs associated with successful drug development can come to $800 million to $1 billion (Champion 2001, 110; Hine & Kapeleris 2006; Pisano 2006, 117). Moreover, most companies develop new drugs while not generating any revenue due to lack of marketable products, which is why only few biotech companies have created substantial cash flows or have become profitable (Pisano 2006, 118). However, the need for funding, in particular external funding is critical at each stage of the new drug development process (Brännback et al 2004, Khilji et al 2006, 533). The current trend experienced in the industry is that venture funding from investors is becoming 'tranched', particularly in the early rounds of funding,

meaning funding is distributed between defined milestones rather than the company receiving the money up front; in addition, although there are less capital available to companies, they are expected to do more with their resources (Ernst and Young 2011).

Considering the above, the process of attracting private and external funding to support new drug development process became of interest. Therefore, this study wishes to explore the challenges of new drug development and the role of private and external funding in new drug development process in biopharmaceutical companies.

1.2 Purpose

The purpose of this thesis is to study the need of private and external funding in new drug development in biopharmaceutical companies. To accomplish this, the following research questions were set:

1. What are the challenges in new drug development process in biopharmaceutical context?

2. What are the main sources of private and external funding in new drug development process?

1.3 Structure of the Thesis

In an attempt to satisfy the two research questions, three streams of literature were reviewed: biotechnology industry, new drug development process and private and external funding sources in biopharmaceutical context. From this a theoretical understanding was gained to support in the collection of primary data. Primary data was collected by a semi-structured interview, in which challenges of new drug development process and matters surrounding private

and external funding were discussed. The interview was audio-recorded and after this transcribed.

This introductory chapter is followed by Chapter 2 which consists of the literature review of overview of biotechnology industry, new drug development process and private and external funding sources in biopharmaceutical context. Chapter 3 describes the research methods used in this thesis in more detail. Chapter 4 presents the findings of the research and Chapter 5 includes the conclusions of this thesis. References can be found listed at the end of this thesis.

2 LITERATURE REVIEW

This literature review comprises of three streams of literature: biotechnology industry, new drug development process and private and external funding sources in biopharmaceutical context.

Biotechnology "involves use of living organisms or parts of living organism through biological processing to develop new products or provide new methods of production". Biotechnology industry includes a variety of fields, for example, medicine, and agriculture, food processing and environmental maintenance. (Hine & Kapeleris 2006, 19). The focus of this thesis is on the development of biopharmaceuticals. The term biopharmaceuticals was initially defined as "a class of therapeutic protein produced by modern biotechnological techniques" but the developments in the industry within the last 30 years have altered the definition to “a protein or nucleic acid based pharmaceutical substance used for therapeutic or in vivo diagnostic purposes, which is produced by means other than direct extraction from a native (non-engineered) biological source”. (Walsh 2002, 2). In other words, the focus of this thesis is on new drug development.

2.1 Overview of biotechnology industry

At the centre the biotech industry are the direct participants such as start-ups, established companies, investors and customers. These core players are linked by institutional arrangements such as markets for capital, products and intellectual property and the industry is regulated by strict rules and regulations and intellectual property (IP) rights. (Pisano 2006, 115-116.) The structure of biotech industry seems to be similar to that of other high technology industries, such as IT, however, various researchers and studies (for example, Champion 2001; Baker 2003; Arantes- Oliveira 2006; Hine & Kapeleris 2006; Khilji et al 2006; Pisano 2006; Vanderbyl & Kobelak 2007) show the biotech industry is characterised by unique elements as they operate in high risk environment attempting to accomplish scientific developments trough lengthy and expensive R&D cycles while facing insufficient funding. Moreover, most companies operate without generating any revenue, which is why only few biotech

companies have created substantial cash flows or have become profitable (Pisano 2006, 118).

At the core of the unique characters of developing biopharmaceuticals is the lengthy and expensive R&D cycle: on average the process takes 14 years and the huge costs associated with successful drug development can come to $800 million to $1 billion (Champion 2001, 110; Hine & Kapeleris 2006; Pisano 2006, 117). In addition, new drug development process includes high risks. The conventional concept of product life cycle (PLC) consisting of launch, growth, reaching maturity, decline and withdrawal (Howard & Hine 1997 as per Hine & Kapeleris 2006, 134) is not appropriate for biotechnology, as in most areas, and specifically is the case of developing biopharmaceuticals, there are no tangible products which would have reached the market and their progress cannot be estimated by turnover cycles of a product. Therefore, it is more appropriate to use the concept of research and development (R&D) pipeline to describe the development stages from research and discovery to development and eventually to the ultimate aim of commercialization. (Hine & Kapeleris 2006, 133-136). Essentially, research and development (R&D) can be defined as "the introduction of and the development of new ideas" (Worthington & Britton 2003, 143, 497). The new drug development process detailing the R&D development stages are described in detail in the Chapter 2.1.1.

The study of Nosella et al (2006, 9) noted the structure of the biotech industry has developed into more complex environment, but the study identified the following business models for biopharmaceutical companies: new biotechnology companies, fully integrated companies, manufacturing companies and service firms. The new biotechnology firms perform research activities and when reaching lead optimisation they license their outputs, for example, new drug candidates, to other companies. A fully integrated company has a strong pipeline and performs all the activities of the R&D pipeline thus covering all the development stages from target identification to commercialization. Manufacturing companies concentrate on the later stages of the R&D pipeline

by carrying out production and commercialization activities. Service companies supply biotech products and sell their research services to other companies.

In addition to funding being one of the critical success factors for the industry (Vanderbyl & Kobelak 2007, 69) successful biotechnology companies also have a clear business plan, a strong product development model, a clearly planned exit strategy for the investors and an experienced management team (Kulkami 2005). According to various researchers (for example, Baker 2003, 287; Brooks 2003, 26; Hine & Kapeleris 2006, 178) developing multiple products concurrently can spread the high risks involved in new drug development. The study of Vanderbyl & Kobelak (2007) emphasizes the importance of knowledge assets as a critical success factor as the knowledge assets support keeping up a continuous pipeline. This is supported by Ireland & Hine (2007, 688) as the capability of transforming intellectual capital into a product will have an effect on the growth of the company.

2.1.1 New drug development process in biopharmaceutical context

The new drug development process in biopharmaceuticals does not differ greatly to the one of pharmaceutical industry. However, traditional drug discovery uses treatment as the foundation for drug development, biopharmaceuticals start by identifying genes connected with a specific disease (Hine & Kapeleris 2006, 191).

The new drug development process in biopharmaceuticals combines scientific research and technical development leading to commercialisation of a new drug. Thus, the new drug development process includes three stages: research/ discovery, development and commercialization.

In research/discovery stage, three leads are identified: genes connected with a disease (gene identification), target proteins resulting in the disease (target identification and validation) and new molecules preventing the disease (lead identification) (Champion 2001,110; Hine & Kapeleris 2006, 191). At this stage,

first patent applications are filed. It is necessary to secure patent protection for the discovered leads to limit competition (Hine & Kapeleris 2006, 42,50, 118).

Discovery stage is followed by development stage. The development stage involves pre-clinical and clinical testing. In pre-clinical stage the testing is performed on animals to test for toxicity. After pre-clinical testing, an Investigational New Drug Application (IND) is filed if there is evidence of safety and efficacy of the drug. An appropriate regulatory body has to approve the application before the product development can continue to the next stage, clinical testing. (Champion 2001, 110; Hine & Kapeleris 2006, 38, 180, 191, 193, Khilji et al 2006, 530.)

Clinical testing is further divided in to three stages: Phase I, Phase II and Phase III. In Phase I the safety, dosage and side effects of the new drug are monitored by trialling it on 20-30 clinical trial subjects (healthy individuals). In phase II the efficacy and side-effects are assessed on 100-300 clinical trial subjects (patients). In phase III the effects of long-term drug use are examined on 1000-6000 clinical trial subjects (patients) as the new drug is compared to existing therapies and drug combinations. (Hine & Kapeleris 2006, 38, 191-193, Khilji et al 2006, 530). The phases occur sequentially and a phase cannot occur if the previous phase has not been completed successfully. Of the three phases, Phase III takes the longest to complete and is the most expensive to conduct (Hine & Kapeleris 2009, 193).

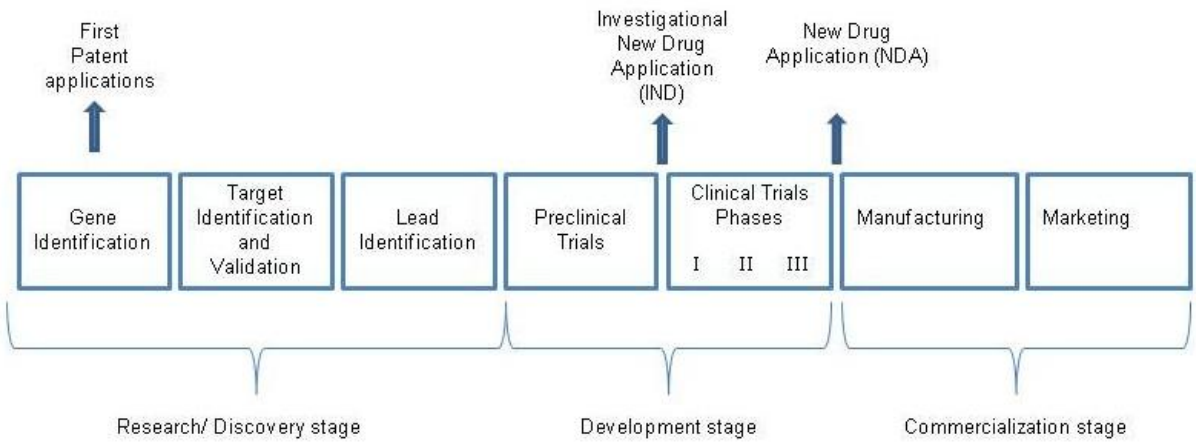
If the clinical tests have been completed successfully and with favourable results, New Drug Application (NDA) is filed. The appropriate regulatory body will then review the application. If the product receives market approval, the market launch can begin. (Hine & Kapeleris 2006, 38, 180, 135, 193; Khilji et al 2006,530.)

The commercialization stage consists of manufacturing and marketing the drug. A company must find ways to economically manufacture the product and build a strong market strategy. The commercialization stage normally commences at

the late stages of clinical trial. (Champion 2001, 110; Hine & Kapeleris 2006, 38, 193.)

As a conclusion, the new drug development process is a lengthy and complex process (Champion 2001, 110) consisting of multiple stages. The stages of the development process are collated in Figure 1. Furthermore, drug development can be seen as emphasising the development of the findings of fundamental research (Brännback et al 2004, 32).

Figure 1 New drug development process in biopharmaceutical context



Source: Based on Champion 2001; Hine & Kapeleris 2006; Khilji et al 2006.

The drug development process is traditionally described linear, however, as Hine & Kapeleris (2009, 191, 193) note, there may be overlapping of the different stages or they may happen in parallel, for example, after a lead candidate has entered the clinical trials, preclinical development may sometimes continue and preparations for manufacturing often happens in parallel with pre-marketing at the late stages of clinical trials.

The following chapter will describe the challenges in new drug development process in biopharmaceutical context in more detail.

2.1.2 Challenges of new drug development process in biopharmaceutical context

New drug development process described in the previous chapter is faced with great technical and commercial uncertainty and the level of risks involved at each stage of the development process is high. Furthermore, the process is long and expensive: on average the process takes 14 years and the huge costs associated with successful drug development can come to $800 million to $1 billion. (Champion 2001, 110;Hine & Kapeleris 2006; Pisano 2006, 117).

New drug development is shadowed by profound and consistent uncertainty. The safety and effectiveness of a drug can only be established through the long and highly regulated development process. (Pisano 2006, 119.) The development process is effectively a "hugely expensive trial-and-error process" (Champion 2001,113). Of 5,000 screened lead candidates, only 250 may reach pre-clinical testing. Of those 250 leads, just 5 will enter clinical testing and ultimately only one will become an end product, the marketable drug. (Champion 2001, 113, Hine & Kapeleris 2006, 126; Pisano 2006, 119.) The study of DiMasi (2001, 303) supports this as it shows half of leads will fail at phase II. Thus, it is evident that the success rate for a lead candidate passing all the stages to commercialization is very low due to the high chance of failure. According to Pisano (2006,119) failure can be expected as the most likely result of new drug development process. To summarize, the uncertainty involved in drug development "translates in to high, long term risks" (Pisano 2006, 119).

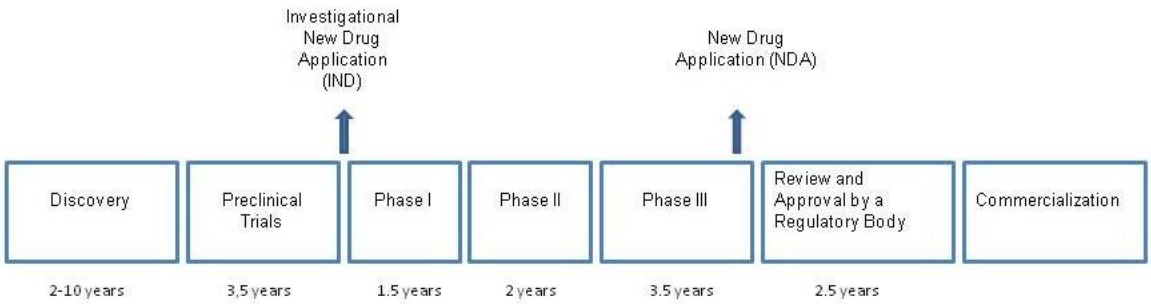
The study of DiMasi shows that efficacy was the main reason for research termination of first IND filing with 37.6% closely followed by economic reasons with 33.8% and safety problems accounted for 19.6% of the terminations. At the later stage developments main reasons for terminations were economic reasons (39%) followed by efficacy issues (32%), safety issues being the third highest reason (16%) for terminations. (DiMasi 2001, 304). According to CMR International (as per Brännback et al 2004, 33) efficacy (22.5%), portfolio considerations (21.7 %), clinical safety (20.2%) and toxicology (19.4%) were all

on a par with each other as being the main reason for termination in drug development process. The importance of economic success in drug development process is thus evident.

On average, the drug development process from discovery to commercialisation takes approximately 14 years (Hine & Kapeleris 2006). As described in chapter 2.1.1**,** the new drug development process consists of various stages, which must be followed to be able to bring a drug to the market. The long lead time to production is partly due to the nature of biopharmaceuticals as new drug development process is highly regulated by regulatory bodies (Hine & Kapeleris 2006, 38): Medicines Evaluation Agency (EMEA) in the EU and the US Food and Drug Administration (FDA) in the US. The regulation and approval of new drugs consist of various stages making the process time-consuming (Hine & Kapeleris 2006, 178). The timeframe for the approval process differs dramatically between countries; however, approval times for New Molecular Entities (NME) are not less than 12 months in any country (Hine & Griffiths 2004, 142; Hine & Kapeleris 2006, 39). It must be noted, however, that this is only one of the activities in the long R&D cycle (Hine & Griffits 2004, 142), but most importantly, the ability to eventually commercialize a drug is dependent on the approval of a regulatory body (Hine & Kapeleris 2006, 178- 179). The Figure 2 shows the average time different stages take in the new drug development process.

The lengthy development process also denotes a long waiting time from initial investment to return on the investment for investors. Thus the length of the new drug development process can be an obstacle in attracting funding. For example, venture capitalists (VCs) usually have a timeline of three years for an investment, which is a noticeably shorter time than the time it takes to develop a drug. In addition to conflicting with the funding, the long R&D cycle also clashes with rewarding of risks. (Pisano 2006, 119).

Figure 2 The average length of different stages in the new drug development process



Sources: Adapted from Hine & Kapeleris 2006; Khilji et a 2006.

The biopharmaceutical companies operate "in a climate with minimal resources but requiring huge investments to develop technology and secure intellectual property (IP) rights" (Vanderbyl & Kobelak 2006, 68). On average, bringing a drug to a market costs £500 million (Champion 2001, 110) but the costs can rise up to $800 million to $1 billion (Pisano 2006, 117). There is no great difference in the costs of a new drug development between major pharmaceutical companies or biopharmaceutical companies (Pisano 2006, 120). However, Brännback et al (2004, 33) estimate the cost of a new drug development only to be 100-250 million Euros in a right context, of which as much as 60% is credited to clinical development. To attract a vast amount of funding from investors the company has to make the new drug development process into an attractive investment opportunity, although a tangible product does not exist. The need for external funding is critical at each stage of the development process (Khilji et al 2006, 533) to process through the R&D cycle,

however, the need for funding may vary depending on the stage of the development.

While biopharmaceutical companies are developing their drugs, in other words, progressing through the R&D cycle, and they are not creating any revenue due to lack of marketable products, they are faced with an 'equity gap' as they cannot meet the high development costs associated with new drug development process. The gap is a result of "perceptions amongst potential investors about the relative balance between the risks associated with a potential investment and the potential returns from that investment" (Harding & Cowling 2006, 117). This is associated with the reasons why only few biotech companies have created substantial cash flows or have become profitable (Pisano 2006, 118).

For a biotech company to be successful, it should aim to develop multiple products concurrently (Baker 2003, 287). This is supported by Hine & Kapeleris (2006, 178) and Brooks (2003, 26) who note companies with only one product in the pipeline are most vulnerable due to the risks involved in the new drug development. In addition, Vanderbul & Kobelak (2007, 72) note that a differentiated pipeline can help to offset the high failure rate. However, Champion (2001, 114) estimates the cost of continuous drug pipeline to be between $2billion to $5billion a year in research alone. Most companies do not have resources for this (Brooks 2003, 26). As a result, the cost of developing multiple products may force a company to choose which development project to pursue further. The decision is based on interpreting results from various stages of the drug development and the verdict made may vary between individuals and companies (Pisano 2006, 122). However, Brooks (2003, 26) also warns of having too vast pipeline of developments at early stages as this may not attract investors due to concerns over not creating later stage value. In addition, Champion (2001, 110, 111) notes that company's position in the process determines its profit potential and the margins are small at the early stages of development.

Champion (2001,113) believes that companies must find means of improving the pace and cost effectiveness of the whole drug development process. This is further supported by Baker (2003, 287) according to whom new drugs must be brought to the markets in a timely manner to provide funds for further discovery and development. The new drug development process is highly regulated by regulatory bodies, which restricts the degree of control the biopharmaceutical companies have over the R&D cycle. However, reducing the R&D cycle is the only way to provide for greater investment returns before patent expiry. (Hine & Griffiths 2004, 142).

2.2 Private funding sources for biopharmaceutical companies

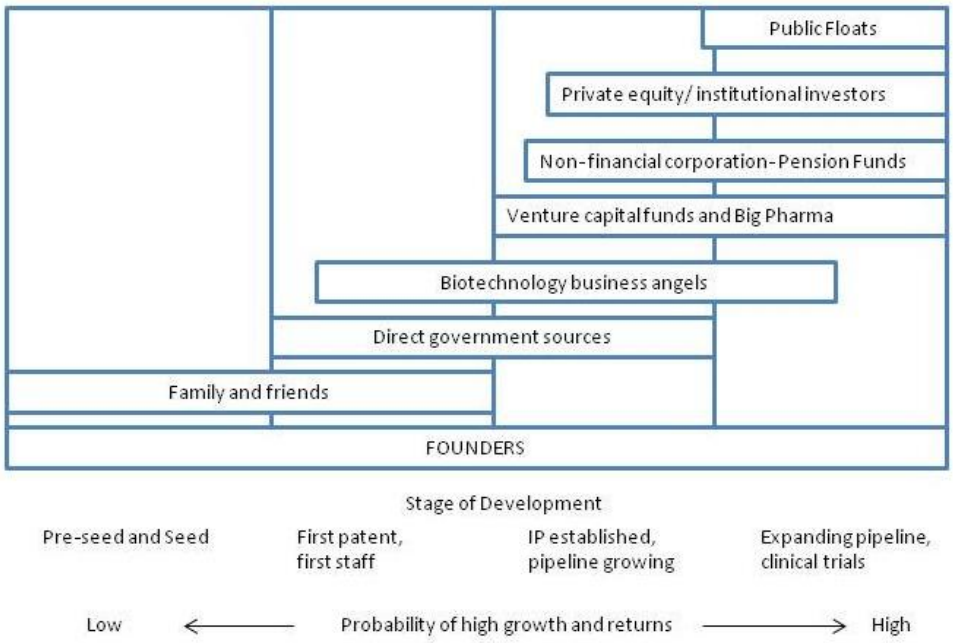
Due to the nature and challenges of new drug development process described in the Chapter 2.1.1 and Chapter 2.1.2, the need for external funding is critical at each stage of the development process (Brännback et al 2004, Khilji et al 2006, 533). This chapter reviews literature of external funding from private sources to investigate how it raises to the challenges of new drug development process.

2.2.1 Overview of funding strategies of new drug development process

Biopharmaceutical companies' needs for financial resources can be characteristics as follows: despite having high development costs, they are not generating any revenue, the demand for finance is taken in steps instead of the demand developing gradually and high growth requires large amounts of capital (Gabrielsson 200, 3). Traditional sources of finance are usually unsuitable for biopharmaceutical companies, especially debt financing is considered unsuitable at the early stages of drug development. For example, banks are unlikely to fund early stages of drug development due to the high risks involved as the risk/return ratio is not favourable. (Whitehead 2003, 245). Thus venture capital (VC) funding is an important factor in the industry (Hine & Kapeleris 2006, 78).

The funding of drug development process can come from several sources: primary funding from founders, family and friends, pre-seed and seed funding from business angels and government, venture capital (VC) funding and Initial Public Offering (IPO). Each of these sources has distinct characteristics, different criteria, motives and level of involvement in drug development process. (Hine & Kapeleris 2006, 49, 54; Gabrielsson et al 2004). The informal venture market of business angels and friends and family is considered to be extensively larger than the formal venture market of banks, financial institutions and other institutions (Hine & Kapeleris 2006, 78). In addition, alliances with Big Pharma are a common way of organising funding in the industry. Figure 3 shows the typical equity and investment funding for biotech companies. The different sources of private and external funding will be discussed in more detail in chapter 2.2.2.

Figure 3 Source of equity investment funding for biotech firms

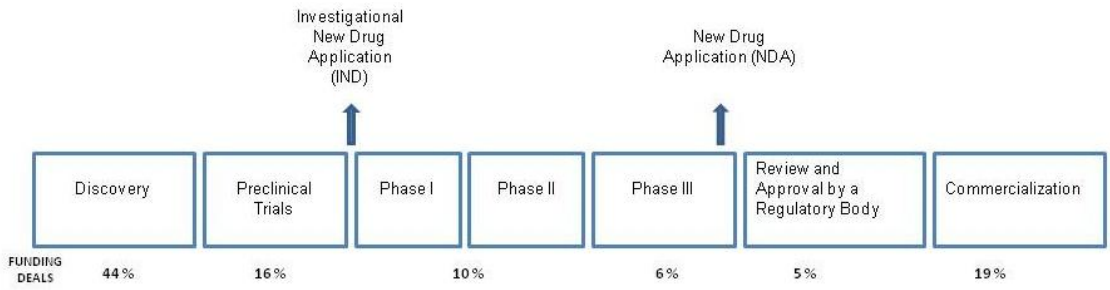


Source: Based on Hine & Kapeleris 2006.

Biopharmaceutical company often receives pre-seed and seed funding from the government for example, in forms of specialised programs, grants and fiscal benefits and as the company grows finance is often sought from private sources. (Arantes-Oliviera 2006,68; Hine & Kapeleris 2006, 51). As this thesis concentrates on private sources of funding, the option of gaining funding from public sources, for example, government grants, is outside of the scope of this thesis and thus is not discussed further.

The major types of venture capital (fixed capital, working capital and growth capital) are not appropriate criteria for funding high technology ventures, which is why stage of funding and furthermore amount of funding with stage of development are often used as defining criteria (Hine & Kapeleris 2006, 49). Internationally , most funding deals are done at discovery phase at 44 per cent, 16 per cent are done pre-clinical stage, followed by 10 percent of funding deals at phase I and phase II. Further 6 percent of the funding deals are done in phase III, with 5 percent being done at registration and 19 percent after launch. (Allant 2004, as per Hine & Kapeleris 2006, 49). Figure 4 summarises the funding deals at each development stage.

Figure 4 Funding deals at each development stage



Source: Based on Allant 2004 as per Hine & Kapeleris 2006.

According to Khilji et al (2006, 531) most funds available are concentrated on R&D activities during pre-discovery stages, nevertheless, the lack of a tangible product weakens the investment opportunity for private investors. Consequently, when a tangible product is available, the investment opportunity becomes more attractive to the venture capitalists, business angels and corporate venture funds. In situations, where the availability of high risk and long-term funding solution is scarce, a biopharmaceutical company may have to opt to short-term revenue activities while simultaneously or in place of going through long and expensive drug development process (Arantes-Oliviera 2006,65).

2.2.2 Sources of private and external funding in new drug development process

2.2.2.1 Founders, Family and Friends

Primary funding sources consist of private individuals: the founder, family and friends. Most often cash to build up facilities is provided in exchange of equity in the firm. These sources of investment are most often used at the discovery stage. However, the expensive R&D related to drug development, high burn rates and the need for facilities such as scientific expertise and equipment lead to a remarkable equity gap in funding which cannot be covered by founders, family and friends. (Hine & Kapeleris 2006, 52.)

2.2.2.2 Business Angels

Private business angels may provide further seed funding to the company. Business angels are wealthy private investors. Most often the investment savvy business angels invest only 5 to 15 per cent of their possible investment portfolio into high- risky ventures. This suggests business angels do not invest what they can't afford to lose and, in addition, the amount invested in high-risk ventures is proportional to the health of their investments on the wide markets. (Whitehead 2003, 242.) In particular, early-stage companies are usually

dependant on the business angels to provide funding at the start in order to attract more wide investment base in the future (Vanderbyl & Kobelak 2007, 72).

Due to the complex nature of biotechnology industries, business angels are less common in comparison to other industries. The business angels need to have the scientific knowledge to understand the investment, enough capital to afford the high costs of the investment, patience due to the long R&D cycle and tendency to endure the high risks involved with the investment. (Whitehead 2003, 242.) Often business angels invest in companies in the same sector (Hine & Kapeleris 2006, 52) in which they have experience and feel confident in. In addition to funding, business angels provide management expertise to the company they have invested in (Hine & Kapeleris 2006, 52).

Furthermore, business angels' contacts can prove to be valuable to a biotech company as they often lead to syndicates of investors. Syndicate of investors is a group of like-minded private investors. The syndicate spreads the investors' individual risks as they are investing smaller individual amounts which collectively add up to the amount of funding sought. In addition, business angels invest to a wider portfolio through a syndicate spreading the risks more. Before investing in a company, a due diligence is conducted to assess the investment opportunity in the company. (Whitehead 2003, 243.) Due diligence is defined by the "process of evaluation a prospective business decision by investigating relevant financial, legal, and other important information about the other party" (Osborne & Petheram 2010, 109). Investing through a syndicate includes advantages for both the business angels and the company: investors spread their risk and gain better valuation based on an effective group bargaining power and the company attracts the investment and saves time and money by attracting investment from many simultaneously (Whitehead 2003, 243).

The accessibility to business angels is dependent on the maturity of region's biotech industry. In major biotech industries there is a large pool of angels compared to the smaller pools of maturing and immature biotech hubs. In less

mature biotech industries the importance of informal investors, such as business angels, is high (Hine & Kapeleris 2006, 52).

Business angels make investments in the areas in which other investors, such as institutional investors, are reluctant to invest i.e. in risky investment opportunities and thus filling the equity gap. Thus funding provided by business angels is most often needed at the early stages of drug development process, especially in the pre- clinical stage when probability of high growth and returns are low to medium and the risks are high. (Hine & Kapeleris 2006, 38, 52.) Due to the informal nature of angel funding, the amounts of investments are difficult to establish (Hine & Kapeleris 2006, 52), however, the investments most often are below £1 million (Whitehead 2003, 244). Table 1 broadly describes the characteristics of business angels.

Table 1: Characteristics of business angels

Business Angels
Below £1 million
Very dependent on the individual investors
Have a personal interest in the business
Forgiving (i.e. may invest although management team is not complete)
Very limited funds - follow-on funding is unlikely

Source: Based on Whitehead 2003.

2.2.2.3 Venture Capitalists

Venture capital is defined as "being investment in unquoted firms usually associated with high risk and in its original sense primarily directed towards young, often technology based firms with high growth potential" (Christensen & Christensen 2003, 156). Venture capitalists (VCs) are professional fund managers, who manage funds for other investors, such as banks and pension funds. (Whitehead 2003, 243; Hine & Kapeleris 2006, 53). However, there are

differences in venture capital definitions in official statistics: in Europe later stage equity financing is included in venture capital, but in the US it is not (Christensen & Christensen 2003, 156). Venture capital, also known as risk capital, is usually in the form of equity (Hine & Kapeleris 2006, 53), however, it could also be in forms which are related to the profits of the company, for example, converting it to shares or rendering a return (Christensen & Christensen 2003, 156). VCs rarely fund early-stage drug development due to the high risks involved and generally back up companies in the later stages of the development. (Hine & Kapeleris 2006, 50, 53). Venture funding events are usually called rounds.

The VCs' motive is to make a significant return on their investment, which translates into a healthy profit and as a result, deals below £1 million are usually regarded as economically unviable (Whitehead 2003, 244). The VCs thus make investments at the stages of clinical trials, when the risks are lower than in the previous stages, and the probability of high growth and returns are higher (Hine & Kapeleris 2006,38, 50) and the need for funding is greater. However, due to the vast amount of money required to bring a drug in to the market, not even the largest VC funds can provide all the financing as they have to spread their risks (Pisano 2006, 119). Moreover, VCs usually expect the investment to provide a return within three to ten year-period (Hine & Kapeleris 2006, 53; Pisano 2006, 119).

Venture capital investment decisions take usually from 2 to 12 months (Hine & Kapeleris 2006, 53). Similarly to the syndicate of private investors, the VCs conduct a thorough due diligence to assess the investment opportunity in the company, stressing issues such as science base, business plan, company strategy and management team (Whitehead 2003, 244, Brooks 2003, 23). In addition, they assess previous development success and critical mass of the company (Brooks 2003, 24). Long negotiations in relation to equity and milestones usually take place prior to investment decision (Hine & Kapeleris 2006, 53).

In addition to funding, VCs bring a network of experienced contacts, such as accounting and law firms, and professional managers to help the company. Furthermore, VCs themselves bring reputation that has effect on the profile and credibility of the company. (Davila et al 2003, 691.) The VCs usually insist on a significant role in the operations of the company, for example, a board position or involvement on day-to-day operational management. (Christensen & Christensen 2006, 156; Whitehead 2003, 244; Hine & Kapeleris 2006, 53). The position of a VC in the company depends on the degree of development of the company (Hine & Kapeleris 2006, 53).

Usually the VCs invest in specific sectors (Whitehead 2003, 244; Hine & Kapeleris 2006,53), however, most often VCs spread their risk by having a portfolio approach, in other words, mixing their investments, or syndicating investments with other investors (Hine & Kapeleris 2006, 53).

VC funding events are not only a source of funding; it is also an positive indication of the quality of the development, bringing more credibility and thus decrease the uncertainty of the development's possibly success (Davila et al 2003, 691, 692, 706). This is further supported by Christensen & Christensen (2003, 156) who state that it appears the development of companies is positively affected by venture capital. Furthermore, investors often see themselves vital for success of a company as they can provide insights of the company the management cannot produce themselves (Fischer & Reuber 2003, 53).

Historically, VC investments appear to be dependent on the maturity of region's biotech industry; VC investments are more successful for example in the US, where the stock market is more mature and the supporting conditions for VC investments are more favourable alongside with conditions supporting entrepreneurship (Giesecke 2000; Arantes-Oliviera 2006, 65). Arantes- Oliviera also notes the problem of investors lacking specialised knowledge of the biotech industry (2006, 68). Table 2 broadly describes the characteristics of venture capitalists.

Table 2: Characteristics of venture capitalists

Venture Capitalists
Above £1 million
Very sector- specific
Professionalism throughout the business required
Strong management required
Strong IP rights expected
Board position
Large equity stake
Experts in getting most out of a deal

Source: Based on Whitehead 2003.

2.2.2.4 Initial Public Offering

International Public Offering (IPO) is where the company is listed publicly on a stock exchange (Hine & Kapeleris 2006, 54). IPO's function is to raise capital for the company (Deeds et al 1997, 38). Moving to IPO places major financial and managerial demands on the company such as strict reporting and accounting processes and the cost of IPO is significant. Usually IPO is one of the last sources of funding and is considered at the late stages of clinical trials. (Hine & Kapeleris 2006, 38, 54). An obvious correlation exists between the amount of money invested in a company prior to IPO history and its value at IPO (Brooks 2003, 278). Historically biotechnology has had major success in relation to public offerings in 1999 and 2000, however, there were major failures in 2001 and 2002 with investor confidence increasing from 2004 onwards. (Hine & Kapeleris 2006, 54).

2.2.2.5 Alliances with Big Pharma

As noted in chapter 2.2.1 a strategic alliance with a large pharmaceutical company, Big Pharma, is a common way of gaining funding in the biotech industry. Most often a strategic alliance is required to launch the product to the market (Hine & Kapeleris 2006, 19). Strategic alliances are based on monetizing intellectual property (Pisano 2006, 117) by licensing out patented intellectual property (IP) or by forming collaboration, partnerships and joint ventures. Licensing means the transfer of IP either on exclusive or non-exclusive basis. Licensing IP can occur at any stage of the development process, where as collaboration is generally formed at an early stage and a joint venture is established at a later stage. (Hine & Kapeleris 2006, 72-73.)

Strategic alliance can benefit a biopharmaceutical company by securing funding and resources (Hine & Kapeleris 2006, 23) but also by broadening its capabilities (Champion 2001,113). The structure of the alliance and the position of a biopharmaceutical company in a strategic alliance depends on the stage of the development and in-house possibilities of the company, for example, a company in early stages of development can give away ownership of any targets identified keeping the rights to a royalty interest, but as the company moves down the value chain they are able to maintain more control and an ownership stake over the products becoming more 50-50 alliances. (Champion 2001, 113; Hine & Kapeleris 2006, 138).

From the point of view of Big Pharma, alliances with biopharmaceutical companies effectively mean outsourcing their R&D and most often it is in those areas where it is missing expertise (Pisano 2006, 117, 120), in addition, they are thus spreading their own risk.

However, as the research of Khilji et al (2006, 535) found out, forming strategic alliances can be a complicated process due to the patented information and scientific discoveries. However, practically every new biopharmaceutical company has to form at least one alliance with Big Pharma, while most of the companies will have to form numerous alliances (Pisano 2006, 117).

Furthermore, an investment from or a collaboration with a large pharmaceutical company not only contributes to the growth of a company but it also brings credibility to the biopharmaceutical company. In countries where large pharmaceutical companies do not exist, large foreign companies should be attracted to that country to ensure investment in biopharmaceutical companies. (Arentes-Oliviera 2006, 67).

3 RESEARCH METHODOLOGY

In this chapter, the research design will be explained, data collection process will be described after which the limitations to this study are discussed. This is followed by a brief introductory of the researched company.

3.1 Research design

An exploratory study gives means to find out "what is happening; to seek new insights; to ask questions and to assess phenomena in a new light" (Robson 2002, 59). By using the method of exploratory research this study can identify the main challenges in new drug development and find out how the private external sources of funding raises to the challenges while trying to seek new insights in to the relationship between these two issues. The three primary means of conducting exploratory research are searching literature, interviewing experts in the research field and/or conducting focus group interviews (Saunders et al 2007, 133). This thesis used the first two first techniques. Previous literature concerning biotechnology industry, new drug development and private and external funding sources in biopharmaceutical context were studied in detail; a combination of journal articles, books, websites of biotechnology companies and organisations related to the industry.

Due to the sensitive nature of the topic of the thesis, quantitative data was difficult to find due to this information not being public and using only qualitative techniques was considered to be adequate in trying to satisfy the research questions, thus an interview was chosen for this purpose. Also, as it was important to understand the reasons to my research participant's opinions, it was necessary to conduct a qualitative interview (Saunders et al 2007, 315). The interview was the main and only method for data collection. The interview was based on list of themes and questions (Saunders et al 2007, 312) while at the same enabling flexibility on clarifying given answers further and presenting additional questions. The conversation was kept within the chosen themes and questions to ensure the validity of the data. The chosen themes and questions included the company's history, the type of products/ services the company

offers, characteristics of the pipeline, internal capacities, market factors and innovative performance of the company. The semi- structured interview with the company representative lasted approximately 1 hour, and was audio-recorded and after this transcribed (Saunders et al 2007, 475). The transcription was done manually. Categories were developed based on the themes in the interview and units of data were attached to relevant categories (Sanders et al 2007, 480).

In choosing the interviewee, importance was placed on the direct experience of the interviewee to obtain information relevant to this study. The company representative, the interviewee, chosen for the interview was the CEO of the company due to the CEO's vast and direct experience in development projects from discovery to commercial success as part of the current company and also as part of previous companies having been involved in drug development for over a decade.

It is recognised that there are various limitations to this study. The research would have greatly benefited from having multiple cases to assist with generating a wider understanding of the matters researched. This was the intention of the researcher; however, due to the sensitive nature of the research topic, companies were not willing to discuss matters relating to their private and external funding sources and thus they could not be included in the research. Therefore, this research has no basis for scientific generalisation. In addition, some limitations are related to the availability of data. Some of the data on private and external sources of funding is not public and thus could not be analysed. Revealing this information was left up to the representative of the company, however, due to non-disclosure agreements between the company and the co-operative partners some of the information may not have been revealed. The limitations described may have had an impact of the outcome of research.

3.2 Company profile

The researched company operates in Finland and was founded after 2004, which is considered to be a turning point from financial aspects in biotech industry due to the market conditions. The company is a privately owned and backed by venture capital. The company concentrates on discovery, preclinical research and early development of novel therapeutics. The company's pipeline is based on internal research and inventions. Currently, the company has five products in the pipeline. The company has successfully received both public and private external funding for their drug developments and the amount received has been approximately 5 million Euros. They have received around half of that from Finnish public sources and half from venture capitalists. R&D spending since founding the company has been approximately 3 million Euros. They are currently partnered with a large pharmaceutical company. The company employs less than 10 people. The company has applied intellectual property rights for three of their molecules.

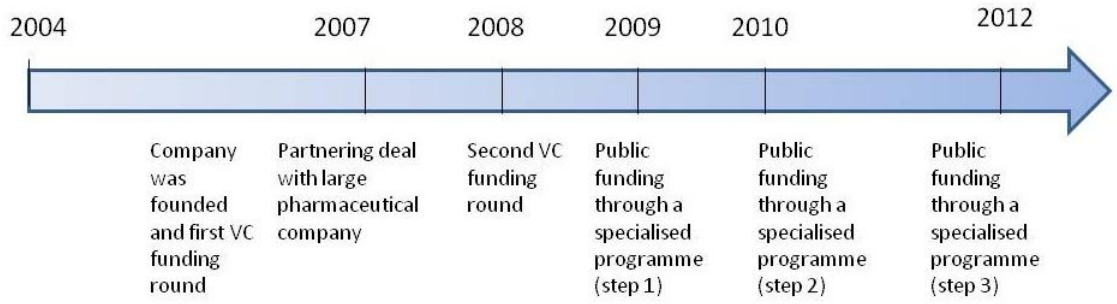
4 FINDINGS

In this chapter the data gained from the interview conducted with the company representative will be presented.

New drug development process described in chapter 2.1.1 is faced with great technical and commercial uncertainty and the level of risks involved at each stage of the development process is high. Furthermore, the process is long and expensive: on average the process takes 14 years and the huge costs associated with successful drug development can come to $800 million to $1 billion. (Champion 2001, 110; Hine & Kapeleris 2006; Pisano 2006, 117). Due to the nature and challenges of new drug development process, the need for external funding is critical at each stage of the development process (Brännback et al 2004, Khilji et al 2006, 533). The company stated funding is one of the most important factors contributing to the success of the company. The company had received a VC funding round in 2008, which meant they have

not had an urgent need to actively seek for new financing deals; however, a considerable amount of time is still currently being spent on planning funding strategies: "If you miss the window of opportunity due to funding, you can ruin the future of the company". Therefore, funding is of most importance to the success of a biopharmaceutical company. Figure 5 presents the company's funding milestones in a chronological order.

Figure 5 Timeline of company's funding milestones



The company named access to capital and access to international markets as the most significant barriers to their R&D activities. However, as the company has been successful in attracting both public and private funding, the interviewee did state they do not feel access to capital has been a major issue for them. However, as they are not in dealings with any regulatory issues and they have always had highly skilled people within the company, they have not experienced challenges with access to skilled human resources, although this is generally a problem in Finland.

The earlier a failing compound as development target is terminated the more resources can be saved by a company. The leading reason for terminations of new drug developments is economical reasons, both at the early-stage developments and but also increasingly at later stage developments (DiMasi 2001, 304; CRM International as per Brännback et al 2004, 33.) which would indicate economical and competitive advantages of a new drug are not considered carefully enough at the discovery stage, although companies should

focus on the these advantages from early on (Schmid E. & Smith D 2005). However, the interviewee confirmed the commercial and competitive advantages are taken into consideration before a development process has even started as it is crucial for them to be aware of the competitive clinical advantages of a compound when it is compared to rivalling compounds in the future as they cannot waste their resources on a compound which does not have commercial or competitive advantages.

Various researches have suggested that in order for a biopharmaceutical company to be successful it should aim to develop multiple products simultaneously as companies with only one product in the pipeline are most vulnerable due to the risks involved in the new drug development process. (Baker 2003, 287; Brooks 2003, 26; Hine & Kapeleris 2006, 178; Vanderbul & Kobelak 2007, 72). The interviewee did support this view: "I do agree that having only one product in the pipeline is too risky and it is a no-go for the investors, however, at the same time, it is not good to have too of a diverse pipeline either, you will only lose you focus and you will definitely run out of resources- it is all about getting the balance right." The interviewee also stated they seek external consultancy opinions on managing their pipeline with the resources they have to maintain a realistic pipeline.

Although the view of finding the correct balance within the pipeline had also been represented in the literature review, Brooks (2003, 26) warns of having a too vast pipeline of developments at early stages, not because of running out of resources, but because this may not attract investors due to concerns over not creating later stage value. The interviewee took a contrary view to the matter: "This is a very traditional way of thinking- nothing is worth of any value until you have the actual product in your hand- and our company wants to question this way of thinking." The company has no intention of taking their compounds themselves further than the end of non-clinical stages. In fact, the company believes this will be a better solution for them profitability -wise as the interviewee explains: "Of course I understand it means the absolute value of the drug is not 600 to 800 million Euros, however, I do believe we get a better

return on our investment by taking the compounds only to pre-clinical stages when considering the resources spent on it versus the return we will receive, rather than if we would invest a further 20-40 million Euros ourselves and taking the compound to phases I and II, when the return on investments for us is smaller. This outlook is somewhat contrary to the views of Champion (2001, 110) who notes that notes that company's position in the process determines its profit potential, however, the margins are small at the early stages of development.

The company has currently five products in the pipeline, which for them is the right balance at the moment. Baker (2003, 287) states a biotech company has to be able to deliver repeated innovation to maintain competitive advantage "as continuous pipeline is the lifeline of the company". The study of Vanderbyl & Kobelak (2007) emphasizes the importance of knowledge assets as a critical success factor as the knowledge assets support keeping up a continuous pipeline. The interviewee did not mention funding as a reason for having a full pipeline, instead the interviewee stated the sole reason for the company to be constantly able to innovate and thus being able to keep their pipeline full is their network: "We have fully committed experts working for us and we are constantly innovating or someone has heard of us through our academic or corporate network and that way we become involved in new development processes".

Venture capitalists rarely fund early-stage product development due to the high risks involved and generally back companies up in the later stages of the development: the investments are usually done during clinical trials when the risks are lower than in the previous stages, and the probability of high growth and returns are higher (Hine & Kapeleris 2006, 38, 50, 53). However, the researched company only concentrates on the discovery, preclinical research and early development of novel therapeutics and has been successful in gaining venture capital already at very early stages of drug development. Successful biotech companies have been deemed to have a clear business plan, a strong product development model, a clearly planned exit strategy for the investors and an experienced management team (Kulkami 2005). VCs

conduct a thorough due diligence to assess the investment opportunity in the company, stressing issues such as science base, business plan, company strategy and management team (Whitehead 2003, 244, Brooks 2003, 23). In addition, they assess previous development success and critical mass of the company (Brooks 2003, 24). The CEO strongly believes the reason for the company having attracted funding from venture capitalists lies with the team and their experience: "We had experience of the industry and its participants through previous businesses before we founded the company and we also spent a considerable amount of time on building a credible, diversified and experienced team before we even approached the investors, so the risk for the investors to invest in us was smaller. If your team is not credible, you will not attract funding from any source... The people are very important criteria for the investors. I would say that you can make a project which is based on an average science a success with the right people and vice versa; a brilliant science project will not be a success without the right people." Thus, it can be concluded that venture capitalist place a great deal of importance on credible and excellent team requiring professionalism throughout the business and strong management. However, the interviewee stated that IP rights do not play a significant role in the investment decisions: "Of course you must have or have applied for IP rights for the compound as this protects your product, however, investors do not have the understanding or the willingness to start valuing IP rights at the time of making the deal, it is know-how that is valued more."

Venture capital in Finland is scarce (Invest in Finland 2011, 6) and historically, VC investments appear to be dependent on the maturity of region's biotech industry; VC investments are more successful for example in the US, where the stock market is more mature and the supporting conditions for VC investments are more favourable alongside with conditions supporting entrepreneurship (Giesecke 2000; Arantes-Oliviera 2006, 65). Arantes- Oliviera also notes the problem of investors lacking specialised knowledge of the biotech industry (2006, 68). The interviewee agreed that venture capital in Finland is immature and the main challenge being there are not enough participants in the Finnish market. However, the interviewee noted a change in investors' knowledge and

understanding of the requirements in the industry: "... this is an area where there has been a significant increase within the last ten years." In Finland there is no room for "me-too" type of products as the interviewee describes: "... the products must be unique in reality, although at the same time they cannot be too complex to understand and they have to be applicable to a considerable population". Internationally, the challenge in VC markets is to attract the investment as many venture capitalists are not ready to invest due to high risks involved and huge disappointments experienced previously which is why drug development is usually excluded of VC investments. Table 3 summarises the findings on venture capital.

Table 3 Findings on venture capital

Venture Capitalists	
Very sector- specific	New drugs have to be unique but not too complex to understand. Investors' understanding of the industry has increased.
Professionalism throughout the business and requirement for strong management	The importance of excellent and skilled team (experts) is emphasised.
Strong IP rights required	IP rights must exist, but investors place more importance on know-how.
Availability dependant on the maturity of region's biotech industry	VC market in Finland is immature; not enough players, only few active participants.

A strategic alliance with a large pharmaceutical company, Big Pharma, is a common way of gaining funding in the biotech industry. Strategic alliance can benefit a biopharmaceutical company by securing funding and resources (Hine & Kapeleris 2006, 23) but also by broadening its capabilities (Champion 2001, 113). In countries where large pharmaceutical companies do not exist, large foreign companies should be attracted to that country to ensure investment in biopharmaceutical companies (Arentes-Oliviera 2006, 67). The view that large pharmaceutical companies provide funding, resources and broadens the

company's capabilities was supported by the interviewee who stated the partner of choice must complement the company's own skills and know-how and thus have capabilities, experience and know-how in clinical development, regulatory affairs and commercialisation of a drug. The importance of international presence of a large pharmaceutical company was emphasised.

Practically every new biopharmaceutical company has to form at least one alliance with Big Pharma, while most of the companies will have to form numerous alliances (Pisano 2006, 117). The alliances with Big Pharma are very important for small biopharmaceutical companies at early stage development, which is portrayed by the fact that the interviewee named "increasing the value of their company to attract a large international pharmaceutical company to an alliance" to take their non-partnered compounds to clinical stages as their main strategic goal.

An investment from or a collaboration with a large pharmaceutical company not only contributes to the growth of a company but it also brings credibility to the biopharmaceutical company (Arentes-Oliviera 2006, 67). The interviewee fully agreed: "We have been able to build credibility as a company in the market and the best reference of the credibility is the fact we have been able partner one of our very high-risk developments and the development is still going strong."

5 CONCLUSIONS

The research aim of this thesis was to describe the main challenges in new drug development process and identify the main private and external funding sources of new drug development process. For the most part, the empirical findings of this study seemed to support existing literature. However, some findings open possibilities for future research.

The significance of this thesis is mainly managerial as it puts forward more practical description of challenges in new drug development process and main funding sources of new drug development. From theoretical point of view, this thesis adds to the already existing body of literature on new product development and funding.

The concentration of this thesis was on the development of biopharmaceuticals, in other words, in new drug development. This thesis consisted of literature review starting with an overview of biotech industry describing the new drug development process and related challenges, identifying the private and external funding sources for biopharmaceutical companies in Chapter 2, followed by detailed explanation of the research methods used in Chapter 3. Findings of the research were presented in Chapter 4 and this Chapter will conclude this thesis. Recommendations for future research and list of references can be found at the end of this thesis.

This study acknowledged that biotech industry is characterised by unique elements as the companies operate in high risk environment attempting to accomplish scientific developments trough lengthy and expensive R&D cycles while facing insufficient funding. Moreover, most companies operate without generating any revenue, which is why only few biotech companies have created substantial cash flows or have become profitable. (Champion 2001; Baker 2003; Arantes- Oliveira 2006; Hine & Kapeleris 2006; Khilji et al 2006; Pisano 2006, Vanderbyl & Kobelak 2007). This study accepted that the traditional concept of product life cycle (PLC) is not appropriate for biotech companies and concept of research & development (R&D) pipeline describing the development

stages from research and discovery to development and eventually to commercialization (Hine & Kapeleris 2006, 133-136) would be more appropriate. The lengthy and expensive R&D cycle is a unique character of the industry affecting the whole drug development process and on average the process takes 14 years and the huge costs associated with successful drug development can come to $800 million to $1 billion (Champion 2001, 110; Hine & Kapeleris 2006; Pisano 2006, 117). The need for external funding is critical at each stage of the drug development process (Brännback et al 2004, Khilji et al 2006, 533). This study showed that funding is of most importance to a development process and planning funding strategies is one of the main activities in biopharmaceutical companies. In addition to funding, previous literature identified that successful biotechnology companies also have a clear business plan, a strong product development model, a clearly planned exit strategy for the investors and an experienced management team (Kulkami 2005). The study of Vanderbyl & Kobelak (2007) emphasizes the importance of knowledge assets as a critical success factor as the knowledge assets support keeping up a continuous pipeline. In line with Vanderbyl & Kobelak, this study highlighted the importance of academic and corporate networks to be able to keep innovating and thus being able to maintain a full pipeline. This finding is important, as the ability to deliver repeated innovation, in other words having a continuous pipeline, is the "life line of a company" and assists in maintaining competitive advantage (Baker 2003, 287).

This study described the stages of the lengthy and complex new drug development process in detail from research and discovery to development and to commercialization. The process starts by gene identification, target identification and validation and lead identification after which first patent applications are filed. The development stage includes pre-clinical and clinical testing. After pre-clinical testing on animal models, an Investigational New Drug Application (IND) is filed if there is evidence of safety and efficacy of the drug. Clinical testing is divided into three stages: Phase I, Phase II and Phase III. The phases occur sequentially and a phase cannot occur if the previous phase has not been completed successfully. If the clinical tests have been completed

successfully and with favourable results, New Drug Application (NDA) is filed. The appropriate regulatory body will then review the application. If the product receives market approval, the market launch can begin. The commercialization stage consists of manufacturing and marketing the drug. (Champion 2001; Hine & Kapeleris 2006; Khilji et al 2006).

New drug development is shadowed by profound and consistent uncertainty as the safety and effectiveness of a drug can only be established through the long and highly regulated development process and failure can be expected as the most likely result of the development process (Pisano 2006, 119.) Main reason for research termination at early and later stage developments are economic reasons (DiMasi 2001, 304) which highlights the importance of economic success in drug development. This study showed that economical and competitive advantages of a new drug are considered by companies before the development process even starts.

Various researchers have suggested that in order for a biopharmaceutical company to be successful it should aim to develop multiple products simultaneously as companies with only one product in the pipeline are most vulnerable due to the risks involved in the new drug development process. (Baker 2003, 287; Brooks 2003, 26; Hine & Kapeleris 2006, 178; Vanderbul & Kobelak 2007, 72). The study found that having only one product is too risky, however, pipeline should not be too diverse either and the balance between having too many and not having enough developments is of most importance.

Although the view of finding the correct balance within the pipeline had also been represented in the literature review, Brooks (2003,26) warns about having a too vast pipeline of developments at early stage, not because of running out of resources, but because this may not attract investors due to concerns over not creating late stage value. However, this study took a contrary view to the matter. Although a drug's absolute value cannot be 600 to 800 million Euros at the early stages, the study drew attention to the fact that value can already be created at the non-clinical stages through this making a company profitable as this will offer better returns on investment for the company than when

developing the drug further themselves. The view of "nothing is worth any value until you have a product in your hand" was deemed to be slightly old-fashioned, but traditional, approach to drug development.

The study understood the traditional funding sources are usually unsuitable for biopharmaceutical companies due to the nature of drug development. The drug development process shape the biopharmaceutical companies' funding needs and three unique characteristics could be identified: despite having high development costs, they are not generating any revenue, the demand for finance is taken in steps instead of the demand developing gradually and high growth requires large amounts of capital (Gabrielsson 200, 3).

To attract funding biopharmaceutical companies have to become an attractive investment opportunity for the investors. However, the lack of a tangible product weakens the investment opportunity for private investors and consequently, when a tangible product is available, the investment opportunity becomes more attractive (Khilji et al 2006, 531).

The funding of drug development process can come from several sources: primary funding from founders, family and friends, pre-seed and seed funding from business angels and government, venture capitalist funding and Initial Public Offering (IPO). Each of these sources has distinct characteristics, different criteria, motives and level of involvement in drug development process. (Hine & Kapeleris 2006, 49, 54. Gabrielsson et al 2004). Alliances with Big Pharma are also a common way of organising funding in the industry. This study found that venture capital funding and alliances with Big Pharma are the most important private and external funding sources for a biopharmaceutical company.

Venture capitalists rarely fund early-stage product development due to the high risks involved and generally back companies up in the later stages of the development (Hine & Kapeleris 2006, 38, 50, 53) however this study showed that companies which concentrate only at the early stages of the development process are able to attract funding from VCs. VCs conduct a thorough due

diligence to assess the investment opportunity in the company, stressing issues such as science base, business plan, company strategy and management team (Whitehead 2003, 244, Brooks 2003, 23). In addition, they assess previous development success and critical mass of the company (Brooks 2003, 24). This study highlighted the importance of a credible, diversified and experienced team as criteria to attract funding from VCs. The study also showed that although IP rights must exist, investors place more value on know-how. It was identified that although venture capital market in Finland is immature, investors' knowledge and understanding of the industry has improved within the last 10 years.

This study confirmed what was describes in previous literature on alliances with Big Pharma: they are a common way of organising funding for small biopharmaceutical companies and in addition to securing funding and resources, it also benefits a biopharmaceutical company by broadening its capabilities (Champion 2001,113; Hine & Kapeleris 2006, 23). It was identified that the partner of choice must complement the biopharmaceutical company's own skills and know-how and thus have capabilities, experience and know-how in clinical development, regulatory affairs and commercialisation of a drug. The importance of international presence of a large pharmaceutical company was emphasised. An alliance with Big Pharma was shown to be one of main strategic goals of small biopharmaceutical companies and should an alliance take place, it will bring credibility in the market to the biopharmaceutical company.

While acknowledging the limitation of this thesis, this study was restricted to Finland and thus it would be interesting to compare private and external funding in various countries as depending on the maturity of countries' biotech industry the findings may vary. In addition, if this research was to be continued, it would be interesting to look further into the findings of this study which were in contrast with previous literature; creating value already at the non-clinical stages of the development process and through this making a drug development company profitable.

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