



**How can risk minimising strategies influence the firm's value of health care Start-Ups?  
The relevance for the decision process of Venture Capitalists.**

-

**A first approach based on the Israeli market.**

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## Abstract

When screening projects for potential investment placements, Venture Capitalists have to base their decision on the information provided in the business plan. The aim of this study is to make VCs aware of the influence of various factors which are discussed in business plans, such as the management team and risk minimising strategies. In order to do this, the business plans of four companies which received investment placements were analysed. The analysis revealed the two main success factors to be industrial experience and a filled product pipeline. The results also suggested that the business plan in its current form may not cover all the information needed for an optimal result. However, since this work is only a first approach further research needs to be carried out.

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### 1. Introduction

#### 1.1. Relevance of the theme

*“Understanding valuation means understanding the company, the process of valuation, the external and internal influential factors and the dynamics of valuation”<sup>1</sup>*

Risk management is one of the theoretical and practical centrepieces of financial management. Hitherto, risk management has concentrated mainly on publicly traded companies, which usually have a (long) history of financial reports. However, during the days and months following the collapse of the “new economy” hype, the need for such tools “tailor-made” for investors focusing on rapidly developing and/or young firms became apparent<sup>2</sup>. Many Venture Capitalists (VCs), and other private equity investors, lost billions of dollars as they became entangled in the clutches of “me-too-investment” phenomena<sup>3</sup>, funding start-ups based on dubious business models. Despite these losses, the VCs’ business model remains unchanged, as do their investment decision criteria.

The business of Venture Capital is twofold: on the one hand, the VC has to evaluate, and subsequently invest in, suitable companies; on the other hand, they are assisting with the management of their portfolio companies. The focus of this thesis is on the former, i.e. the evaluation process for potential investments<sup>4</sup>.

Research literature on the VC decision-making process dates back to the early 1970s. Until now, the main methodologies used have been post hoc, such as surveys and interviews. The main drawback of such methodologies is that they involve post hoc rationalization and bias, especially as the literature indicates that “experts” tend to rely on intuition<sup>5</sup>. Such results may in fact be the reason for the reluctance of private equity investors to change their investment criteria.

It is generally agreed that private equity investors, such as VCs, are experts in the new venture-funding realm. However, there is room for improvement regarding their decision

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<sup>1</sup> Peter Friedli (2000) in Wipfli (2001)

<sup>2</sup> Although representative material from which meaningful data can be derived is still difficult to acquire, it should only be a partial explanation of the lack of interest the academic world has shown in this “niche” area of risk management until recently.

<sup>3</sup> Stein (2002)

<sup>4</sup> For more details, see Chapter 1.2

<sup>5</sup> Zacharakis/Meyer (1998)

process, since the nature of the Venture Capital market prevents the process of company valuation from being an “exact” science. In fact, the final decision is frequently the result of the chaos of human reactions, leaving ample room for the psychology, hopes and fears of the stakeholders as well as the current fashion of the general VC and stock markets. Evidence<sup>6</sup> also suggests that investors’ investment decisions are influenced by the so-called “new economy”<sup>7</sup>.

Zacharakis/Meyer (1998) argue that, other things being equal, the VC’s performance is a function of two factors:

1. the quality of the investment decision
2. the effectiveness of its management support system on the portfolio companies.

Hence, if the VC firm is able to improve the quality of its investment decision, it should see an improvement in its overall performance. Although there are differing opinions about the actual percentage of VC-backed start-ups that fail to reach profitability, there is a consensus that this level is too low. Considering the billions invested each year, even a modest improvement in the failure rate can have a substantial impact on a venture portfolio return. However, in order to do this, VCs have to be able to access effective risk management tools for the evaluation stage. This work aims to provide the VC with a deeper insight into the key factors influencing the value of health care-based life science start-ups. This insight may in turn reduce the risk of investors’ assigning their (non-)monetary resources to a suboptimal project.

### **Why Biotechnology?**

The industrial focus of this work is the (human) health care-based life sciences, such as biotechnology<sup>8</sup> or medical technology. There are a number of reasons for this choice:

- Due to its rapidly developing underlying technologies, the biotechnology industry is one of the most research-intensive sectors worldwide. In German industry, for example, 34% of all human resource (HR) expenses are R&D-

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<sup>6</sup> Tz. (2000)

<sup>7</sup> The “new economy” has occurred every few years since the Second World War (e.g. in the 1980s, the hardware industry was also dubbed the “new economy”).

<sup>8</sup> In this thesis, the term biotechnology will be used for those sectors concentrating on pharmaceuticals and other human health care-related issues only, disregarding veterinary, agricultural and industrial/environmental biotechnology sectors.

related; companies with fewer than ten employees often have up to 70% of their employees focusing on R&D<sup>9</sup>. In addition, the industry's need for specialists willing to work in new and innovative companies<sup>10</sup> results in very high HR expenditure levels. Continuing with the German example, in 2000 the average biotechnology company spent € 40,000 – €50,000 per employee on R&D<sup>11</sup>, which is approximately 50% higher than the average level in the pharmaceutical industry<sup>12</sup>.

- While most industry sectors have suffered from economic slowdown, investors have refocused their attention on the life sciences, a sector Venture Capitalists shunned only a few years ago. According to Calandra (2001), VCs have realised that biotechnology and biopharmaceuticals are relatively safe while offering a strong potential for handsome returns. Right now, the economy is seeing a large amount of private equity fuelling this industry. In Germany again, an average of 50 to 60 new start-ups were established annually between 1999 and 2002, leading to a phase of rapid expansion<sup>13</sup>. Fuelling this growth were unprecedented levels of private sector investment placements, which nearly doubled between 1999 and 2000, reaching €2.3 billion<sup>14</sup>. This development has laid the foundations for the very young German biotech arena; in fact, according to Mietzsch (2000), 57% of all biotech-companies are less than five years old.
- Biotech and pharmaceuticals do indeed look poised to do well in the future. For instance, some 300 new drugs which will pass through the FDA approval process<sup>15</sup> during the next few years are draining major pharmaceutical pipelines. Since start-ups often have competitive advantages in areas such as basic scientific research<sup>16</sup>, they are likely to benefit from this trend. Furthermore, scientists are already intensely involved in research for so-called personalized

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<sup>9</sup> Statistisches Bundesamt (2001)

<sup>10</sup> Most firms working in this area have a very short financial history, thus making it risky for employees to evaluate the potential bankruptcy risk their employer is facing

<sup>11</sup> Statistisches Bundesamt (2001)

<sup>12</sup> The pharmaceutical industry is traditionally an R&D investment-intensive industry, with an average HR expenditure level of €26,500 p.a. and per employee.

<sup>13</sup> Müller et al. (2002)

<sup>14</sup> Müller et al. (2002)

<sup>15</sup> Many companies view the FDA approval proceeding as an international quality control standard and are aligning their R&D standards towards these.

<sup>16</sup> Coe (2004)

medicine, i.e. drugs based on an individual's genetic makeup, which are expected to be introduced onto markets within the next ten years.

### **Reasons for the high risks involved with start-ups**

The advent of the internet economy, in conjunction with the technological revolution in telecommunications, biology and other sciences, has led to unprecedented rates of businesses forming. Pioneering entrepreneurs have been a further major driving force behind the growth of the life sciences industries. Life science start-ups usually pursue innovative projects, which, although often highly profitable, tend to be very risky. In fact, complete business failure is not uncommon<sup>17</sup>. A major factor contributing to the high failure rate is that entrepreneurs are often faced with various challenges when starting a new venture:

- Since the owners' monetary resources tend to be rather limited compared to those needed for a typical start-up investment, which often lies in the multi-million dollar area, particularly in sectors such as biotechnology or medical devices, external financing is needed.
- The entrepreneur can typically boast a successful scientific career, but will rarely have any commercial or managerial experience.
- The superior technological knowledge and proprietary information of a team frequently makes it difficult for external financiers to evaluate the project (or company) and monitor its progress.
- The accessibility of superior Venture Capital is still considered an obstacle - especially in Europe.

In addition, biotechnology start-ups often require more than just monetary funding to develop their business from ground zero. The management team often requires the VC's aid on fundamental issues such as employee quality and motivation, customer needs, product development, and marketing. Some uncertainties VCs have to consider include<sup>18</sup>:

- **Technical uncertainty:** including abandonment of the project, ineffectiveness of the product, cost uncertainties for technical reasons, e.g. extension of clinical tests.

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<sup>17</sup> Robinson (1987), Timmons (1994)

<sup>18</sup> Hillerström (2001)

- **Legal and regulatory uncertainties:** including non-issuing of pending patents, effects of the competitor's patent strategy who may find another compound based on the same mechanism of action.
- **Regulatory uncertainties:** including the risk of non-approval by the regulatory authorities during any of the drug discovery and development stages.
- **Business risk:** such as market acceptance, demographic changes, size of the risk premiums to be paid or changes in the interest rate, which in turn influences the discounted cash flow<sup>19</sup>.
- **Competition uncertainties:** e.g. the investment and patenting behaviour of competitors – which could influence the firm's market potential. Other risks include losing a patent litigation or time-to-market.

A key challenge for firms, especially those inexperienced in the development-to-market process, is reserving enough money for the clinical development stages. Managers often fail to plan for this important and costly process<sup>20</sup>. Since such companies often hold their financial assets as cash, these funds are quickly depleted (or “burned”) by high personnel and materials expenses associated with R&D.

**The resulting (financial) profile of biotech start-ups renders traditional valuation approaches inadequate. Although these models are often viewed as universally applicable, they cannot be expected to yield and/or suggest reliable value indications for all companies in every industry; this is especially true when evaluating start-ups that are based in such innovative fields as medical technology or gene therapy.**

In fact, spending too much money and building too large an infrastructure are common demons for the biomedical investor. Injecting capital as needed by the start-up could circumvent this. In fact, McNeil (1999) indicates that such an investment strategy benefits not only the start-up but also the VC, as it enables a 35% portfolio return, which is believed to be a prerequisite for VC funding.

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<sup>19</sup> See chapter 1.4.1

<sup>20</sup> Müller (2002)

### 1.2. Context/classification of the theme

Venture Capital literature dates back to the 1970s and can be divided into the following five categories<sup>21</sup>:

- **Institutional Framework:** deals with the typology of Venture Capital firms, i.e. the characteristics of different VC-phases (e.g. early vs. latter stage, MBO/LBO vs. IPO) and analysis of the various financing sources of Venture Capital.
- **Venture Capital Process:** investigates the problems that arise from screening, valuation and contracting procedures.
- **Venture Capital Monitoring:** deals with challenges that arise after the investment has been placed and includes such issues as information asymmetry, agency problems, and corporate governance.
- **Investment Realization and Performance:** As the company matures it reaches the so called “exit-strategy phase”, which could involve a private placement, MBO, LBO, merger, acquisition, or IPO. Another aspect of this theoretical arena concerns the performance of Venture Capital. However, due to the confidentiality of the Venture Capital business, the available data is very sparse and must effectively be disregarded.
- **Alternative Financial Sources:** deals with the informal sector of the VC-business, such as Business Angels and other institutional investors, e.g. banks, and corporate M&A activities. Central problems discussed are the different weightings of risks (market vs. agency risk) and different levels of involvement (e.g. hands-off/hands-on policy<sup>22</sup>).

Following these classifications, the focus of this thesis is on the venture capital process (see Diagram 1.1), and to be more specific the initial screening. During the initial screening phase, the VC evaluates the material provided by the start-up; this is usually a business plan. If the VC decides to continue investigating the opportunities presented by the proposed project, then an interview with the management team, a due diligence, a negotiation process and, finally,

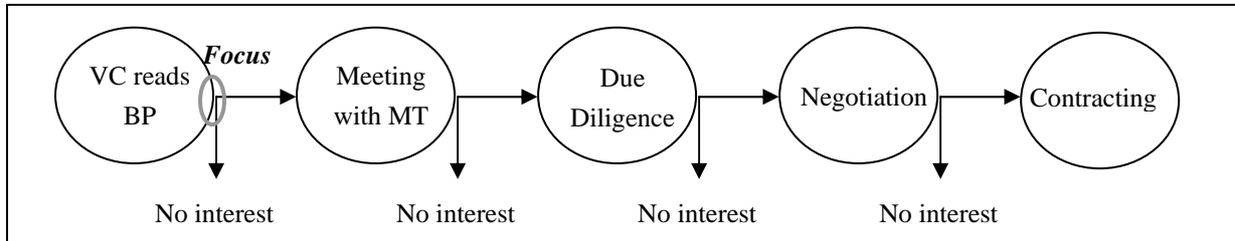
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<sup>21</sup> Wipfli (2001)

<sup>22</sup> e.g. Gorman/Salman (1986), Wipfli (2001). MacMillan et al. (1989) described it as laissez-faire, moderate and close trackers

the actual contracting and investment placement will follow. At each step, the VC may decide to abandon the project. Diagram 1.1 depicts a very simplified version of this process.

**Diagram 1.1: Venture Capital process**



Source: Own

Furthermore, this thesis only analyses start-ups which are involved in biotechnology, medical technology or other innovative products/services in the health care arena.

Although the relationship between the management team and its company's value has been researched quite thoroughly, no study relevant to biotechnology or the health care market has hitherto been carried out. Conversely, literature on the relationship between risk-minimising business strategies and the valuation of companies is virtually non-existent, especially pertaining to patents and the product pipeline. Ample research studies are available with regard to general decision criteria; however, the test samples either have not included any health care-related start-ups or only a few.

The table below (Table 1.1) lists a summary of current literature dealing with the various aspects to be analysed in this thesis, as well as a small overview of literature dealing with general decision criteria in Venture Capital business. These studies are not arranged according to academic significance, but chronologically.

**Table 1.1: Literature overview of management, alliances, patents, pipeline issues and general new firm valuation issues<sup>23</sup>**

Year	Author	Theme
Management Team		
2000	Gemünden/Konrad	Unternehmerisches Verhalten
1998	Galais	Motive und Beweggründe für die Selbständigkeit und ihre Bedeutung für den Erfolg
1994	Cooper et al.	Initial human and financial capital as predictors of new venture performance
1994	Robinson/Sexton	The effect of education and experience on self-employment success
1993	Baum et al.	Nationality and work related interactions: a cultural contrast of Israeli and US entrepreneurs' versus managers' needs.
1993	Rosenstein et al.	The CEO, Venture Capitalists, and the board
1990	Gomez-Meja et al.	Influence of Venture Capitalists on high technology management
1990	Keeley/Roure	Management, strategy, and industry structure as influences on the success of new firms: A structural model
1988	Rosenstein	The board and strategy: Venture Capital and high technology
1980	Lachman	Toward Measurement of entrepreneurial tendencies
Pipeline		
1996	Deeds/Hill	Strategic alliances and the rate of new product development: an empirical study of entrepreneurial biotechnology firms
1996	Zahra	Technology Strategy and new venture performance: a study of corporate-sponsored and independent biotechnology ventures
1994	Zahra	Business strategy, technology policy and company performance
1993	Zahra et al.	Technological choices within strategic types: Toward a conceptual integration
Patents		
2003	Hirschey	Tech Stock Valuation: Investor Psychology and economic analysis
2002	Keeley/Roure	Management, strategy, and industry structure as influences on the success of new firms: A structural model
2001	Hirschey/Richardson	Valuation effects of patent quality: A comparison for Japanese and US firms
1990	Griliches	Patent Statistics as economic indicators: A survey
1989	Griliches et al.	Patents: Recent trends and puzzles comments and discussion.
Alliances		
2004	Witt	Entrepreneurs' networks and the success of start-ups
2003	Welter	Strategien und strategisches Verhalten von KMU
2002	Nicholson et al.	Valuation of Biotech companies under the light of biotech-pharmaceutical alliances
2002	Kelley/Rice	Leveraging the value of Proprietary Technologies
2002	Witt/Rosenkranz	Netzwerkbildung und Gründungserfolg

<sup>23</sup> Research studies which have focused on more than one criterion are listed under "general criteria".

2001	Hoffmann/Schaper-Rinkel	Acquire or ally? - A Strategy framework for deciding between acquisition and cooperation
1999	Miles et al.	Dangers of Dependency: The impact of Strategic alliances used by small technology-based firms
1998	Lerner/Merges	The control of technological alliances: an empirical analysis of the biotechnology industry
1996	Deeds/Hill	Strategic alliances and the rate of new product development: an empirical study of entrepreneurial biotechnology firms
1994	McGee/Dowling	Using R&D cooperative arrangements to leverage managerial experience: A study of technology-intensive new ventures
1991	Lyons	Joint Ventures as Strategic choices - a literature review
1989	Gomes-Casseres	Joint Venture in the face of Global Competition
1989	Jorde/Teece	Competition and Cooperation: Striking the right balance
1988	Datta	International Joint Ventures in the face of Global Competition
General Decision Criteria		
2003	Scheibehenne et al.	Venture Capital für die Biotechnologie: Eine empirische Analyse der Vergabekriterien
2002	Kaplan/Stömberg	VC's decision making and monitoring criteria
2002	Weber/Diekes	Risikokapitalgeber in Deutschland: Strukturmerkmale, Entscheidungskriterien, Selbstverständnis
2002	Zott/Amit	Business strategies and company valuation
2001	Hillerström	Real options to value biotech companies
2001	Weihe et al.	Bedingungen erfolgreicher Existenzgründungen...
2001	Wipfli	Unternehmensbewertung im Venture Capital-Geschäft
1999	Schefczyk	Erfolgsdeterminanten von Venture Capital Investment in Deutschland
1998	Frei	Diplomarbeit: Stufenweise Finanzierung und Neubewertungsproblematik von Venture Capital Projekten
1998	Zacharakis/Meyer	A lack of insight, do Venture Capitalists really understand their own decision process?
1995	Zacharakis <sup>24</sup>	VC-Investment Decision
1994	Fried/Hisrich	Toward a Model of Venture Capital Investment Decision Making
1994	Karakaya/Kobu	New product development process: An investigation of success and failure in high-technology and non-high-technology firms
1993	Fried et al.	Research note: Venture Capitalists' investment criteria: A replication
1992	Bates/ Bradford	Factors affecting new firm success and their use in Venture Capital financing
1992	Dourtiaux	Emerging high-tech firms: how durable are their competitive start-up advantages?
1987	MacMillan et al.	Criteria distinguishing successful from unsuccessful ventures in the venture screening process
1987	Stuart/Abetti	Start-Up ventures: towards the prediction of initial success
1985	MacMillan et al.	Criteria used by Venture Capitalists to evaluate new venture proposal

Source: Own

<sup>24</sup> In Wipfli (2001)

For the reasons explained in the previous section, this research study will concentrate on health care-related market segments only. Furthermore, the empirical study will be based on Israeli start-ups, as Israel is one of the leading countries in global biotechnology, both in terms of the number of start-ups as well as revenue generation<sup>25</sup>. The main challenge to the empirical analysis is the limited data available, which not only results from the young age of this industry but above all from non-disclosure agreements between start-ups and VCs. In addition, the nature of the surveyed success factors, in conjunction with this insufficient data, makes it rather difficult to ascertain whether or not these factors are *ex post* long-term key success factors.

**In brief, the aim of this thesis is to make VCs aware of the influence of various factors which are discussed in business plans, such as the management team and risk-minimising strategies,. This deeper insight may then be translated into meaningful risk management tools for the initial screening process and beyond.**

In fact, the author believes that this study will make significant contributions to initial company valuation in several aspects. First, this work endeavours to establish the importance of various risk-minimising strategies. It is therefore to be viewed as a first approach to establishing whether the surveyed factors can be used as an indicator for the long-term success of a start-up. These indicators may in turn be used as risk management tools for VCs evaluating biotechnological and other health care market-based start-ups. In addition, this study aims to enhance and further develop existing research studies by outlining various skills and knowledge belonging to the management team, which is a key factor considered by VCs.

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<sup>25</sup> A portrayal of the Israeli biotechnology industry is given in Appendix 4, Chapter 8.4

### 1.3. Structure

The final part of this chapter focuses on the success factors which will be examined<sup>26</sup> in greater detail in the theoretical and empirical part of this thesis. In the subchapters of 1.4, the factors that are generally taken into account by VCs<sup>27</sup> will be discussed first, followed by a discussion of why the author feels that the factors investigated in this thesis are of importance when evaluating possible risk factors in healthcare-based start-ups.

The subsequent two chapters reveal the structure and important aspects of the VC and biotechnology industry respectively, in greater detail.

Chapter 3 addresses the theoretical framework of issues concerning the management team of a start-up and risk-minimising business strategies, i.e. alliances, the product pipeline and patents. The author believes that these strategies should be thoroughly evaluated by VCs, as they present strong forms of competitive advantages and thus should lead to a company value increase by means of reducing the discounting rate.

The final part of this work presents direct evidence of these factors, and reviews other possible factors of influence, such as the target market and the financial analysis provided in the business plan. As the aim of this work is to provide a tool for VCs at the initial screening stage, i.e. when reviewing the business plan, the only information that is used for the analysis is the data presented in the business plan. The test sample is made up of four such Israeli start-ups which have provided their business plans. This will be explained in further detail in Chapter 6, which outlines the research design. The analysis itself includes a review of each firm's business plan and a comparison of the test samples. The analysis reveals some unexpected issues with respect to all factors analysed; these issues and their implications will also be discussed in Chapter 7.

The Appendices (Chapter 8) outline various aspects which, although containing interesting background facts, are not essential for the analysis. Appendix 1 (Chapter 8.1) presents an outline of the generally accepted structure of the business plan. Chapter 8.2 (i.e. Appendix 2) addresses the issues of SWOT analysis, an essential tool in coming to understand the advantages of the individual firms, which should form the basis of the strategy design. As will

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<sup>26</sup> both theoretically and empirically

<sup>27</sup> and that has been the main focus of past research studies

be explained in the following subchapter, one such strategy is alliances. Thus, Appendix 3 (Chapter 8.3) will delineate the various types of alliances. Further, although Israel has built up one of the leading biotechnology industries globally, little is known about its structure and other important aspects, such as government programs, which are outlined in Appendix 4 (Chapter 8.4). Finally, Appendix 5 (Chapter 8.5) focuses on the Israeli VC market.

#### 1.4. Deduction of the determinants of the value of young enterprises

Investors are faced with a multitude of challenges and have to evaluate numerous factors. When assessing the potential rate of returns associated with a prospective start-up investment, investors not only have to evaluate the “usual” factors but are faced with the fact that start-ups usually have no or only marginal profits, which is especially true for the biotechnology sector. In addition, start-ups usually only have a very limited range of products and services. Another limiting factor is that, due to the novelty of these markets, their cycles and structures are seldom comparable to traditional and/or existing markets. Witt/Rosenkranz (2002) indicate that the venture success of start-ups is usually based on the business/product idea, the entrepreneur’s position on planning and information acquisition, the approach to attaining resources, and the launch strategy.

In order to systematise the valuation process, Beike et al. (2000) have listed the valuation criteria that should be considered when valuing shares of growth companies. As the valuation of growth companies should be identical regardless of the IPO status of a start-up, these criteria have been displayed in Diagram 1.2:

**Diagram 1.2: Valuation criteria of growth companies/shares**

<i>Plausibility of business model</i>	<i>Management qualities</i>	<i>Strong internal growth</i>	<i>Conservative accounting methods</i>	<i>Valuation/ market multiples</i>
<ul style="list-style-type: none"> <li>▪ When will the start-up become profitable</li> <li>▪ Is the business able to grow its profits above average levels</li> </ul>	<ul style="list-style-type: none"> <li>▪ Is the management acting consistently aggressively, and planning for future</li> <li>▪ Is the management able to focus on profitable business units</li> </ul>	<ul style="list-style-type: none"> <li>▪ Are profits increasing due to M&amp;A activities or internal growth</li> <li>▪ What is the revenue/ profit margin that is generated through any M&amp;A activities</li> </ul>	<ul style="list-style-type: none"> <li>▪ Is the company using an aggressive or conservative accounting style</li> <li>▪ How far are the valuation leeway’s used</li> </ul>	<ul style="list-style-type: none"> <li>▪ Are margins and multiples above industrial average</li> <li>▪ If the company is not profitable, what is the make-up of the revenues</li> </ul>

Source: Beike et al. (2000)

In addition, a (theoretical) analysis of the company valuation includes all aspects of business administration, and hence factors to be analysed include: finance, marketing, human resources, management, politics, corporate identity, production, logistics, possible lucrative alliances, attractiveness of the company within the VC and/or general financial market (incl. already invested equity) and the chosen exit strategy.

Although this is only a small list of those factors, it is not feasible to conduct a thorough analysis of *all* important factors in any single research study, especially a thesis. Furthermore, as the current focus of academic research in this area generally rests on factors such as sales and sales forecasts, measurements of risk and suitability valuation techniques, this thesis only examines factors which may strengthen a firm's market position. Although this research only concentrates on these aspects, a concise outline of sales, discounting factors and the most common valuation techniques is provided in Chapter 1.4.1.

Venture Capitalists utilize a variety of modus operandi to help identify and limit risks, while attempting to improve the reward-to-risk ratio of ventures they have decided to invest in<sup>28</sup>. A common requirement for prospects seeking private placements is a detailed business plan which clearly identifies various factors such as the ultimate size of the anticipated market, likely competitors, and whether a market for an untried product actually exists.

As highlighted above, the business plan, which is a key element in obtaining initial funding, is usually the first source of information presented to potential investors. This document, which in effect is no more than a statement of strategy, is carefully scrutinised by Venture Capitalists<sup>29</sup>. After the investment placement, some VCs will assume a "board of directors" position at the portfolio company and will assist with any necessary adjustment of the business plan if the start-up is seeking further rounds of funding<sup>30</sup>.

Various challenges arise when attempting to predict the performance of a new firm. Cooper (1993) highlights the fact that prediction methods are contingent on environmental developments, which are difficult, if at all possible, to predict. Although all firms are

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<sup>28</sup> Ruhnka/Young (1991)

<sup>29</sup> see Chapter 8.1 (Appendix 1) for an outline of components included in the business plan

<sup>30</sup> Rosenstein (1988)

impacted by environmental influences, the author believes that new ventures whose risk is concentrated upon a few products – sometimes only just one, which may still have to prove itself in clinical test phases – often serve quite narrow markets, and hold only a few key resources, e.g. patents. It follows that even companies which have both competent managers and a well-considered strategy may fail due to unforeseen environmental changes and a lack of funds to “ride out hard times.” These factors may cause the performance of a new firm to change rapidly, making it hard to identify predictors of good or poor performance.

### 1.4.1 Factors generally investigated by VCs

As mentioned previously, several so-called key success factors are usually taken into account by private equity when evaluating investment proposals. A multitude of literature sources, both academic research as well as general literature which has been devised for entrepreneurs who are seeking investment placements, have highlighted the importance of the target market and sales strategy, financial analysis, and product description sections<sup>31</sup>. Furthermore, academic literature also indicates that the calculated value of the start-up is dependent on the discounting factor and financial assumptions, which are based on the sales forecast. Since both these factors are the foundation of valuation methods, this section will outline these three factors: the sales forecast, the discounting factor and valuation methods.

#### **Sales strategy/forecast**

According to the research conducted by Wells (1974), Poindexter (1976), Tyebjee/Bruno (1984)<sup>32</sup> and Zacharakis/Hofer (1998), the attractiveness of the market a company is aiming to enter is a crucial investment criterion. Thus, it is safe to assume that VCs avoid investing in the “wrong” industry or betting on a technology risk in an unproven market segment. This means that, regardless of the talent or charisma of individual entrepreneurs, start-ups rarely receive backing from a VC if the business is satisfying needs in a low-growth market. The exception to this rule is investment into so-called “concept” stocks, which are companies which are very promising, but in which it takes an extremely long time to succeed, e.g. biotechnology. In this industry, the challenge for the VC is to identify entrepreneurs who can advance a technology to a certain stage – e.g. FDA or EUMEA approval – at which point the company can be taken public or sold to a major corporation.

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<sup>31</sup> e.g. Wipfli (2000), Heidenreich (2002), Schlech (2000), Weitnauer (2001)

<sup>32</sup> Hall & Hofer (1993)

From their research, Streans et al. (1995) concluded that companies with broadly focused strategies have a higher survival chance than a company with a narrow market focus. However, this may not be true for the biotechnology market, where many niche markets have had no industrial players thus far. One of the reasons may be because no company has yet found a suitable product to satisfy the need of this market. In addition, many companies focus on the major markets as they believe that these are easier to access, despite facing (strong) existing and potential competitors.

As stated above, the current work does not evaluate the research and evaluation methods or the effects of varying sales figures on the company's value. Readers interested in this are recommended to turn to Meffert (1972,1992, 1999, 1998, 2000), Broda (2002), Baumgarth (1999), Hüttner (1982), Bruhn (1997), Diller (1998), Kotler et al. (1996), Paley (1999) or Czinkota/Kotabe (2001).

### **Discounting factor**

As asserted above, Venture Capitalists are long-term investors who are willing and able to bear the risks of this engagement. As a return, a relevant risk premium is expected, which is derived from the initial investment input and the selling price at the exit. Indeed, even though start-ups are renowned for their high risk, they are also well-known for having an unusually high return on investment. Robinson (1987) states that one of the most common objectives for VCs is to realise a return on investment of between 25% and 40% within a five to six year time horizon.

In order to evaluate a project, VCs vary the discounting factor used for calculating the company's value at that time, which decreases over time<sup>33</sup>. This discounting factor is made up of four components, which are as follows<sup>34</sup>:

- Risk-free interest rates
- Weighted cost of capital (WACC)
- Surcharge for especially difficult ability to sell (liquidity surcharge)

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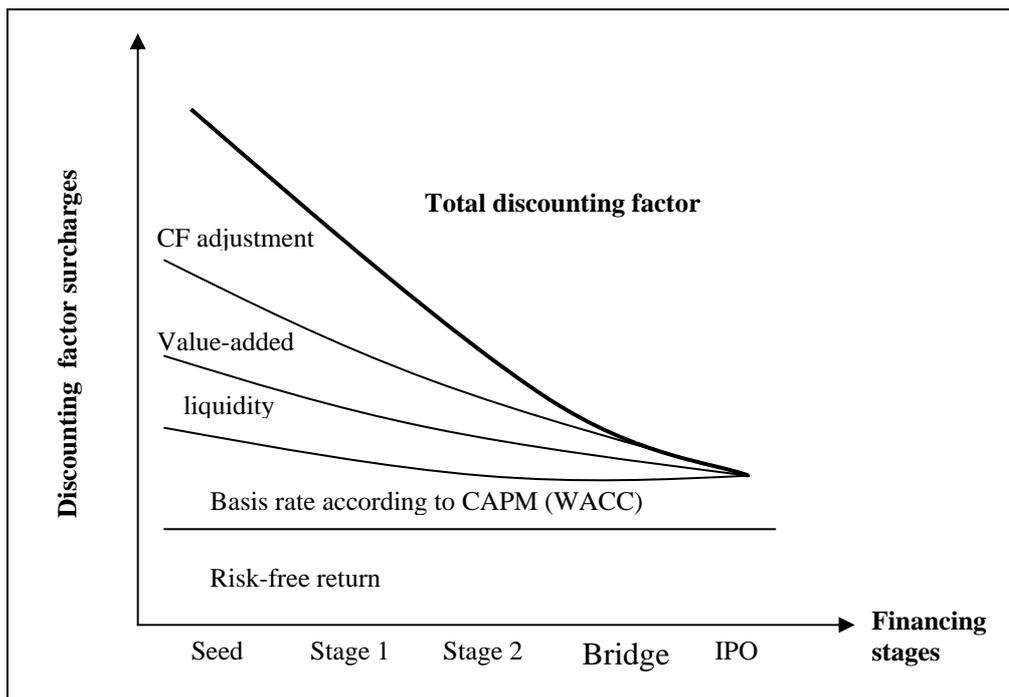
<sup>33</sup> Frei (1998)

<sup>34</sup> Wipfli (2001), Frei (1998)

- Surcharge for the contribution of the VC towards the value increase (value-added premium)
- Surcharge for the adjustment of the free cash-flow

The following diagram (Diagram 1.3) shows how these Venture Capital-specific components decrease, leaving at IPO only the systematic risk plus the risk-free premium.

**Diagram 1.3: Components of the factors**



Source: Wipfli (2001). Frei (1998). VentureValuation (2002)

In current research, e.g. Wipfli (2001) or Frei (1998), it is assumed that Venture Capital projects are only financed by the owner's equity. It follows that a weighting based on the owner's and foreign equity, the so-called weighted average cost of capital (WACC), is redundant or even irrelevant. Thus, the discounting factor only considers the opportunity costs for the owner's equity.

Taking all the above factors into account, it becomes clear why VCs are looking for high return-on-investment values: not only are they investing in projects which have high systematic risks, the projects are also associated with components of illiquidity together with a requirement for value-added services. Readers further interested in this should turn to Wipfli (2001) for a discussion of the reasons related to the question as to why there is no general

procedure for evaluating risks involved in VC projects. However, the above explanation should provide an adequate understanding of the complexity of the problem and of how these components relate to each other.

### **Valuation methods**

The final part of the investment process (prior to contracting) is to examine the projected financial statements and draw conclusions from them. There are many analysts who argue that start-ups cannot be valued, since they have no history and in some cases no products or services to sell, but only an idea. Damodaran (2002), however, concedes that, although it is more difficult to value young firms than established ones, the fundamentals of valuation do not change.

The problem involved in estimating an appropriate value for an early stage company is that during the first rounds of investment the founders usually bring few assets in the form of equity. In extreme cases, the start-up's main assets are its intellectual property, (pending) patents, the team's experience and/or an idea.

Venture Capital projects usually have a negative cash flow<sup>35</sup> at the early stages of their development. On the other hand, as explained above, these high risk levels should lead, in the long run, to high returns. In addition, often only limited historical data is available, making it even more difficult to use standard valuation methods which are based on positive cash flows. Further, unlike listed companies, there is usually no market which could be utilised to value the company through "a third party."

It is generally agreed that the information needed to calculate the firm's value is derived from three sources:

- The current financial statement is used
  - to determine the profitability of a firm's investments
  - to determine the level of reinvestment for generating future growth and
  - for all inputs required in any valuation
- Revenue/earnings and price history may be used as an analysis of
  - the cyclicalities of the firm and growth levels
  - price history may also be used for risk measurement

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<sup>35</sup> Cash flow refers to retained profits plus depreciation during a set period

- The firm's competitors or peer group is
  - used to gain an understanding of the competitiveness of the company
  - needed to estimate key inputs on risk, growth, and cash flows

However, in the biotechnology industry VCs find themselves running into other information problems. First, biotech start-ups have not been in existence for very long, thus there is a very limited history. Second, their current financial statements reveal very little about the component of their assets' expected growth, which is a main contributor to value. Finally, these companies are often the first of their kind on the market and thus have no real competitor or peer group against which they can be measured.

Many VCs who have decided to invest in these kinds of firms argue that, although they are difficult to evaluate, the fault lies with the valuation models themselves. Since investors have complained that conventional valuation techniques are not suitable for valuing start-ups, they have come up with new or adapted ways, based on the limited information available, of justifying the prices paid for these stocks. However, even though this is a very interesting and crucial aspect, as iterated above, it is not the focus of this work. Here it should only be emphasised that, according to Frei (1998), the major technique used is DCF followed by the Venture Capital method. Readers further interested in this subject should turn to Wipfli (2001), Damodarant (2002) or Sontheimer/Matzen (2002) for a discussion of the issues associated with valuation methods and start-ups.

It is interesting to note that Laitinen (1992) tried to develop a model that would aid in predicting the failure of a firm, using only financial ratios<sup>36</sup>. He did so because he believed that his model “deals with the symptoms of failure rather than the causes”<sup>37</sup>. The results of this quantitative analysis showed that it is possible, to some extent, to predict the failure of a newly founded firm as early as the first year after its foundation. It also revealed that the best predictors proved to be the stockholder-capital-to-total-capital-ratio (i.e. the indebtedness), the cash-flow-to-net-sales-ratio (i.e. revenue financing), and the cash-flow-to-total-debt-ratio (i.e. the sufficiency of revenue financing to pay financial obligations).

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<sup>36</sup> Laitinen (1992) did not take factors such as the management team, the product or the market into account

<sup>37</sup> Laitinen (1992)

Laitinen (1992) further states that the risk of failure increases with high indebtedness, insufficient revenue financing and a large size in the first year. Hence it follows that, in order to reduce the risk of failure, the top management team should use less debt of financing and pay special attention to generating a sufficient revenue stream in the initial stages. Furthermore, starting with a smaller sized firm may also be less risky to start business operations. Although these conclusions may be relevant for many companies, they do not seem to be suitable for life science companies, which usually generate large sums of debt in their initial phase prior to being able to actually produce any revenue stream.

Furthermore, Laitinen (1992) uses actual data produced by a company. The company does not have historical financial data for a business plan, especially if it is seeking first-round financing. It would thus be interesting to retest Laitinen's (1992) model using life science companies exclusively, and to investigate whether this method is also applicable to business plans. However, due to the focus of this thesis, and in light of the available test sample, this valuation option will not be investigated further.

### 1.4.2 Missing Factors

Although different statistics available quote that the failure/mortality rate among newly founded firms is very high<sup>38</sup>, recent years have shown that VC-backed start-ups have not been spared either. An emphasis on the factors outlined above, in conjunction with the management team, may in fact beguile many into believing that these should be the main, if not only factors, which investors should consider when evaluating investment proposals. However, the high failure rates seem to suggest that other factors should also be taken into consideration when evaluating both the probability of survival and the firm's potential.

Previous research studies have indeed endorsed this train of thought. For example, MacMillan et al. (1985) claim that the most important product characteristic appears to be some form of proprietary protection. In a later study, MacMillan et al. (1987) identified two major criteria that are predictors of venture success: the extent to which the firm is initially insulated from competition and the degree to which there is a demonstrated market acceptance of the

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<sup>38</sup> For example Robinson (1987) states that statistics universally show a failure rate of in excess of 50% among newly founded firms during their first five years. Timmons (1994) states that the level of venture failure during the first year of incorporation lies at over 20% while rising by 66% within 6 years.

product. This position is supported by the findings of Fried et al. (1993) who have duplicated McMillan et al.'s (1985) study. Fried et al.'s result criticised the fact that VCs have fine-tuned their focus to market acceptance, while shifting away from their main focus on potential rates of return and quick exits. In fact, when considering the factors underlying market acceptance, such as enjoying clear competitive advantages, e.g. through exclusive alliances or patents, it may be argued that these focus modifications represent a more realistic view of a venture's potential. In fact, the analysis by Scheibehenne et al. (2003) revealed that 40% of their interviewees thought patents to be a critical criterion for equity placements in biotechnology companies. Further, Kahle/Bouncken (2002) point out that alliances are vital for start-ups and young companies in general.

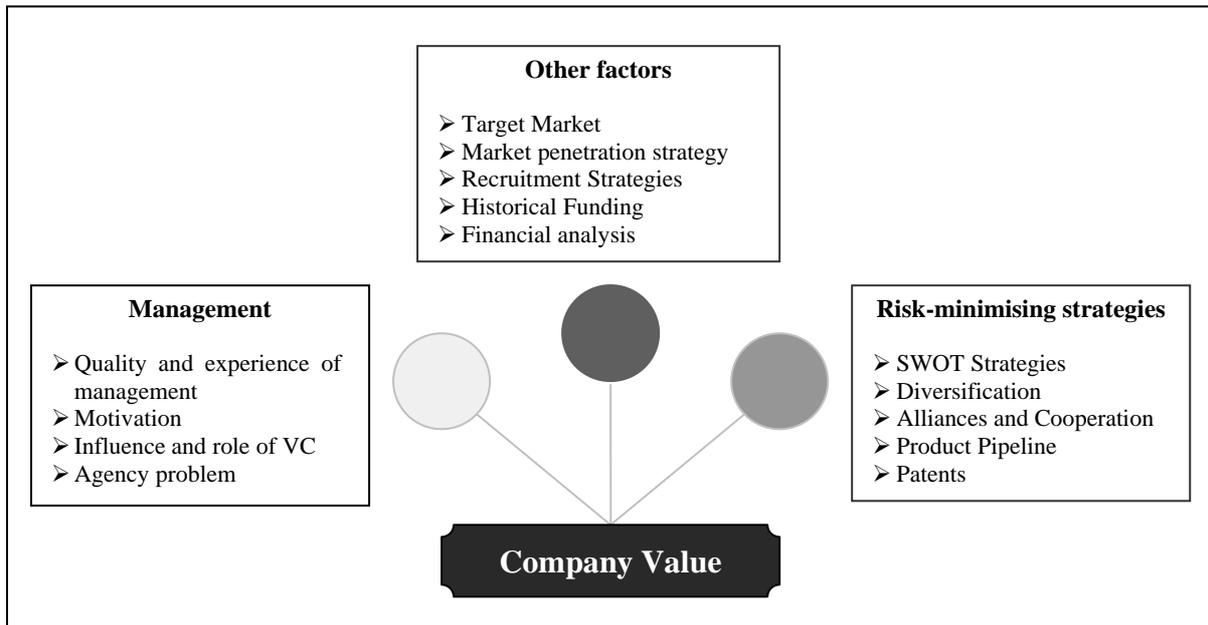
In addition, authors such as Timmons (1977) and Dubini (1989) have indicated that the success of a new venture is influenced by the fit between entrepreneurial team characteristics and the characteristics of the product and market. Finally, Meyer (1998) also denoted that the two main reasons for failure are rooted in the management team's missing, incomplete or even incorrect knowledge of the market, economic, financial, and other business-related issues, together with overvaluing a product idea.

Some of the above arguments form the basis of the reasoning behind the choice of factors to be evaluated. Since it has proven difficult to determine the key influential factors, due to the vast number of options available, the priorities were chosen in connection with the data provided in a business plan.

As avowed previously, various factors of the management team have been suggested to be of the utmost importance for the survival and success of a company. The aspects that will henceforth be discussed are on the one hand linked directly to the management team as well as to the influence and the role of the VC. With regard to the choice of risk-minimising strategies which in turn improve the firm's competitive advantage, the empirical study focuses on the importance of alliances, the product pipeline and product protection via patents. Finally, other factors that are discussed in the business plan will also be evaluated in order to reveal other potentially interesting issues. These factors are related to the start-up's target market and its penetration strategy as well as financial issues. The author believes that all factors referred to should have a profound influence on the company value, which will be

expressed as the current state (i.e. the time during which the empirical analysis was carried out). This has been outlined in Diagram 1.4.

**Diagram 1.4: Key determinants on the company value of a start-up**



Source: Own

As indicated in Chapter 1.3, a literature review of the main factors, i.e. management and risk-minimising business strategies, will be presented in Chapter 3. In the third part of this work, the impact of these business aspects on the company's value will be empirically studied.

Having established the importance of the issue in the VC process, the specific focus as well as the structure of this thesis, the following Chapter will investigate the nature of the Venture Capital business and industry.

### 2. The VC Market

*“Now is also a good time to be starting a biotech company because the Venture Capitalists are looking for companies with real technology”<sup>39</sup>*

The focus of this chapter is to portray the nature of the Venture Capital business and to review the global Venture Capital market. This Chapter begins by outlining the two concepts of private equity and Venture Capital. This is followed by a general overview of the Venture Capital business and the type of project which VCs are usually interested in. The final section presents recent developments in the global Venture Capital industry. Readers interested in a further account of the developments of the Israeli Venture Capital market should turn to Appendix 8.5.

#### 2.1. Definitions

It is always difficult to define concepts that are not only developed by practice but also have different meanings in an international setting. Further, in a dynamic environment such as that of Venture Capital, the theoretical definitions usually lag one step behind “reality.”<sup>40</sup> Due to the scope of this thesis, a variety of standard definitions and explanations will be given; however, there will be no discussion of each definition. The next section shall simply be used to avoid any ambiguities which may arise.

#### **Private Equity**

Private equity has become a major source of funding, while establishing itself as a recognised asset class within many institutional portfolios. In fact, monies committed to private equity funds have increased dramatically<sup>41</sup> despite the collapse of the “new economy.”

According to Bancel (2002), the EVCA’s definition of private equity is an investment placement in securities through negotiations. Often categorised as an “alternative investment”, private equity entails a wide spectrum of investors. In Europe, the top four sources of private equity are banks (25%), pension funds (22%), insurance companies (13%) and corporate investors (10%)<sup>42</sup>. However, Schulte (2002) indicates that other sources of equity are available

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<sup>39</sup> Nelson in Agres (2001)

<sup>40</sup> Bader (1996)

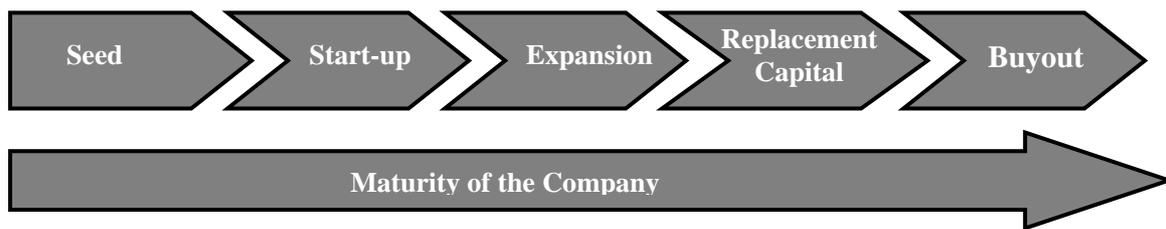
<sup>41</sup> Bancel (2002)

<sup>42</sup> EVCA in Bancel (2002)

for companies. In addition to internal financing, there is also the option of “normal” bank credits.

In order to differentiate between the different types of private equity sought by firms, five general categories have been established, outlined in Diagram 2.1 and the description below.

**Diagram 2.1: Stages of private equity placement**



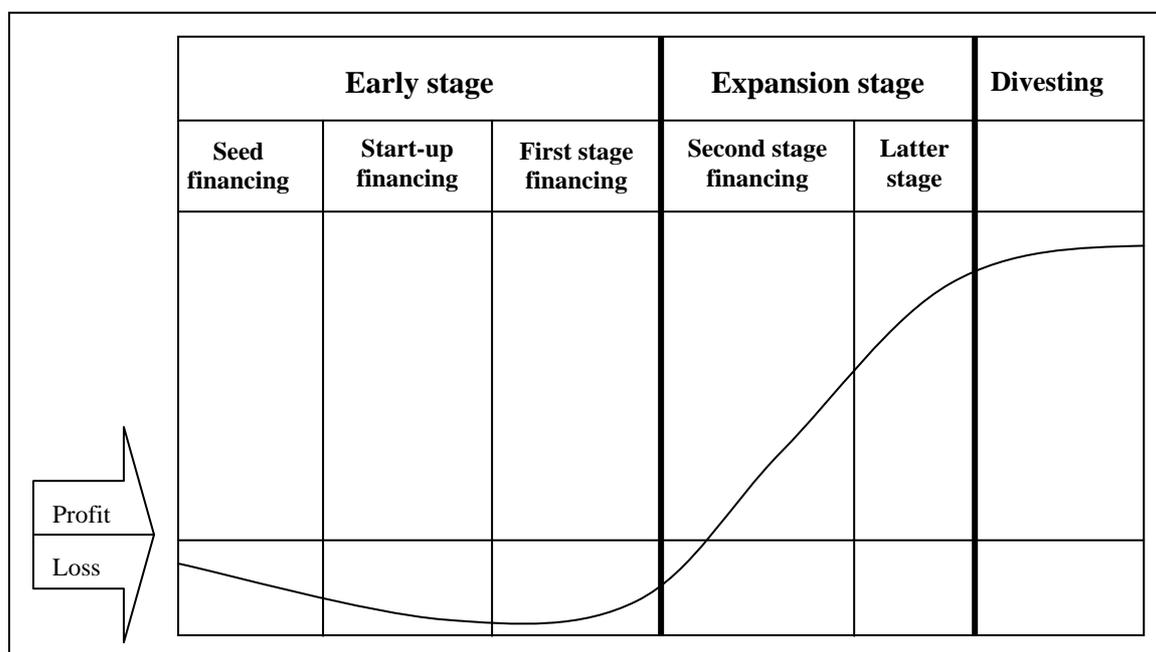
Source: Bancel (2002)

- **Seed stage:** At the initial development stage, seed financing is granted to entrepreneurs who have devised a first concept but do not own the resources to research, assess and initiate first development efforts.
- **Start-up stage:** Contrary to popular belief, start-up capital is only provided for product development and preliminary marketing efforts. Although a company may already have been established, start-up capital is often transferred to the entrepreneurs who are in the process of setting up the business. An additional feature of companies seeking such capital is that the firm is generating any sales revenues and thus profits.
- **Expansion stage:** Expansion capital is transferred to companies which have managed to reach or surpass the break-even-point and wish to expand their production capacity, market or product development, and/or to provide additional working capital. Expansion capital may also be used for bridge financing and business recovery efforts.
- **Replacement Capital:** This type of capital is sought by business owners wishing to regain higher shares in a firm by purchasing shares from third party investors, such as VCs or business angels. Nevertheless, it may also be sought by entrepreneurs wishing to refinance the firm’s debt and therefore reduce the gearing level.

- **Buyout:** Typically, a buyout involves acquiring a significant portion or majority of control over a business, normally entailing a change of ownership. This type of investment usually targets established companies with a proven track record.

Each financing stage is known to have its unique profit/loss profile. Diagram 2.2, which was developed by Schmidtke (1985), depicts both the development stages of Venture Capital projects and the appropriate profit/loss profiles which can be expected at the various financing stages. This model is based on the typical, ideal development of a start-up.

**Diagram 2.2: Ideal development of VC projects and the appropriate profit/loss profile**



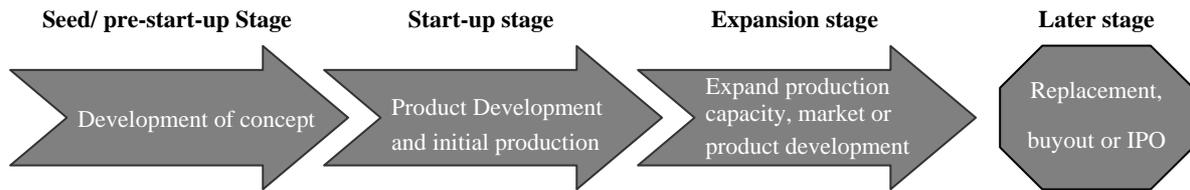
Source: Schmidtke (1985) in Frei (1998), Peisel/Hanny (2002), Sontheimer/Matzen (2002), Wicht (2003)

Since the decision process of VCs does not vary between the stages,<sup>43</sup> this thesis will not differentiate between the different stages.

The above financing stages can be directly compared with the phases of the formation process of a start-up, which is depicted in the flow diagram (Diagram 2.3) below:

<sup>43</sup> Frei (1998)

**Diagram 2.3: Company formation process**



Source: Based on Kahle/Bouncken (2004), Witt/Rosenkranz (2002), Witt (2004), Peisl/Hanny (2002)

## Venture Capital

Venture Capital is just one of several finance resources available for start-ups. The US definition of Venture Capital differs from the European one. In the US, Venture Capital is linked to equity-related investments in either start-ups or companies involved in high growth cycles. Furthermore, the national Venture Capital association of the United States (NVCA) describes Venture Capital as money provided by professionals who invest both funds and management in young, rapidly growing companies which have the potential to develop into significant economic contributors<sup>44</sup>. In Europe, on the other hand, Venture Capital refers to a more general concept and includes any commitment to unquoted companies seeking financing capital for any development stage.

Venture Capital can therefore be viewed as an alternative form of investment for both the entrepreneur and the investor. For entrepreneurs, Venture Capital is usually the first type of external equity placement<sup>45</sup>, since it does not, unlike classic financing resources from banks, require any form of securities<sup>46</sup>. Although viewed favourably, the lack of securities is taken into account when VCs are composing a start-up's individual risk level. Furthermore, Venture Capital usually aims to achieve high levels of return on investment from capital gain, rather than interest rates. This capital gain is sought via the chosen exit strategy of an invested company. Although VCs typically prefer an IPO<sup>47</sup>, as it enjoys higher returns than other forms of exit, Amit et al. (1998) criticised the fact that the majority of exits perceived were internal, e.g. MBO.

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<sup>44</sup> NVCA (2002)

<sup>45</sup> Henderson (1988)

<sup>46</sup> Weitnauer (2001)

<sup>47</sup> Weitnauer (2001)

Additional definitions have also been provided by the academic world. For instance, Liles (1974)<sup>48</sup> defines Venture Capital as an investment in:

- any high-risk financial venture
- unproven ideas, products, or start-up situations
- growing companies which are unable to raise funds from conventional public or commercial sources
- major publicly traded companies, and possibly obtaining controlling interest in such companies, where uncertainty is significant.

A further definition has been provided by Perez (1986), Pratt (1987) and Gupta/Sapienza (1992)<sup>49</sup>, who argue that VCs are organisations which finance the founding and early growth of new enterprises which do not have access to other sources of funding, such as retained profits or the stock exchange.

Furthermore, Green (1991) has argued that Venture Capital is perceived as a type of direct investment in the securities of either new speculative firms or technologically oriented enterprises undergoing international expansion. It is also characterised as a high-risk investment with large returns expected in dividends and capital gains. Weitnauer (2001) has expanded this definition by adding that Venture Capital is a long-term, management-supporting investment in an innovative, high-growth, young enterprise.

**In this report, private equity and Venture Capital have been used as synonyms and refer to equity investment for the first two stages of a company's development, i.e. the seed and start-up stage.**

## 2.2. The nature of Venture Capital

Due to the high costs involved in transforming an innovative idea into a feasible project in the health care arena, a major problem which start-ups face is a lack of sufficient funds<sup>50</sup>.

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<sup>48</sup> in Green (1991)

<sup>49</sup> all in Zacharakis/Meyer (1998)

<sup>50</sup> Tyková (2000)

Additionally, most biotechnology start-up owners are usually not seasoned managers, representing a further challenge. While banks generally monitor the financial health of their clients, Venture Capitalists also thoroughly check the business strategy, offering a joint provision of long-term capital<sup>51</sup> and managerial experience<sup>52</sup>.

Venture Capitalists seek to control or manage risk<sup>53</sup>. They often do so by taking an active advisory role, having a say when principal decisions are made, being able to make managerial and human resource decisions, providing their portfolio companies with necessary contacts when/if needed, while providing management and technical assistance in the areas of planning, personnel, marketing and finance. A further means to controlling the risk involved in any of their investment placements is from various financing structures and investment strategies, including portfolio diversification, information sharing, networking, and specialisation<sup>54</sup>.

Since VCs usually have vast managerial experience with and knowledge of specific industries, it is common for Venture Capital firms to specialise. This specialisation may focus on specific industries, geographical regions or certain risk-return criteria. This combination is believed to facilitate the evaluation of uncertain projects. In fact, an empirical examination of the Canadian Venture Capital arena by Amit et al. (1998) showed that VCs had disproportionate representation in industries that are thought to have high levels of informational asymmetry.

Although there are differing opinions concerning the actual time VCs spend per annum per client<sup>55</sup>, VCs must identify and attract new deals, monitor existing deals, allocate additional capital to the most successful deals, and assist with exit options. Astute VCs are able to

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<sup>51</sup> Given the industry's reward system, the VC investor is usually locked into an investment for a five to seven year time frame – for companies in the biotechnology industry this could be even longer – in order to develop a significant business. However, due to the dynamic process of risk capital, an investor seldom remains involved for over ten years.

<sup>52</sup> Henderson (1988)

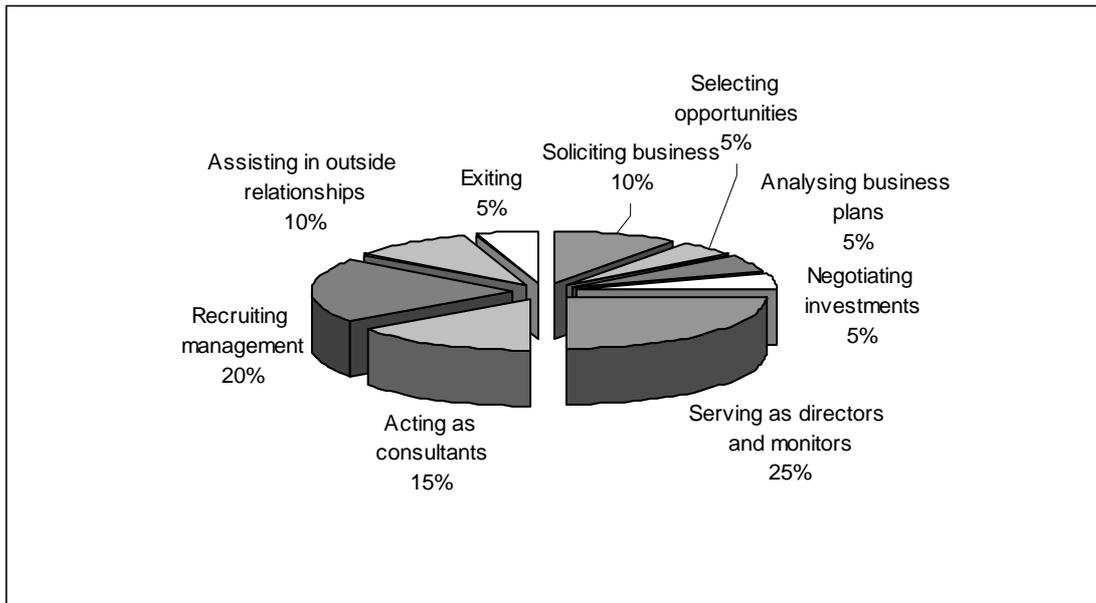
<sup>53</sup> MacMillan et al. (1985), Norton/Tenenbaum (1993)

<sup>54</sup> Bygrave (1987, 1988), Norton/Tenenbaum (1993)

<sup>55</sup> Robinson (1987) states that this can range from 2 to 450 days per annum per client. On the other hand, Zider (1998) estimates that a VC does not spend more than 2 hours a week with any one company, assuming an average of 2,000 working hours per annum and 10 portfolio companies per VC.

allocate their time wisely among the various functions and deals. In fact, Zider (1998) points out that most VCs have to distribute their time among many activities (see Diagram 2.4).

**Diagram 2.4: How Venture Capitalists spend their time**



Source: Zider (1998)

In conclusion, it is fair to state that, far from being simple passive financiers, VCs foster growth in their portfolio companies by both passive and active involvement in management issues as well as strategic marketing and planning. Venture Capitalists are thus entrepreneurs first and financiers second.

Finally, it has to be stressed that, according to Schulte (2002), only a small percentage of start-ups seek Venture Capital. Indeed, the study revealed that about 80% of the test sample did not consider Venture Capital to be a viable option as a source of finance, mainly due to the loss of ownership. However, this result can largely be disregarded, as it is unclear what percentage of this sample was active in the biotech and related markets.

### **Venture Capital Decision process**

The decision criteria used by VCs have received much attention within entrepreneurship literature, since selecting firms which promise high future profits is a very difficult task. In fact, when considering an investment, the technical and business merits of the proposition are

carefully screened. According to the OECD, in 1996 VCs only invested in about 5% of the submitted proposals<sup>56</sup>.

VCs assess the probability of success or failure by evaluating information surrounding a venture. One major challenge they face is that, due to the nature of the industry, the VC is generally forced to evaluate other issues rather than concentrating on a “pure” financial analysis. This is due to the lack of meaningful financial history which the entrepreneur is able to present to a potential investor. The VC is thus known to focus on issues such as the management team, the originality of the idea, and the structure of the relevant market. In the section below, several research results will be presented. These will not be discussed but merely stated, so as to provide the reader with an understanding of the complexity involved in this decision-making process.

Libecap (1986) indicates that Venture Capital markets differ from other financial markets because of the importance of information asymmetry and the associated high risk level which are inherent in entrepreneurial activities. There is general uncertainty regarding the new product and processes, management abilities, and long-term market conditions which affect contracts between all parties involved. Additionally, entrepreneurs have an information advantage, since they know more about their product than the VC. In response to these risk and asymmetrical information problems, Venture Capital financing is often a sequential process, involving contingent contracts and several levels of funding<sup>57</sup>. This procedure benefits both parties, allowing VCs to limit their investment until more information is obtained, while allowing entrepreneurs to renegotiate on more favourable terms if the promised developments have been met.

The analysis by MacMillan et al. (1985) revealed that VCs appear to assess ventures systematically in terms of six categories of risk management. These are the risks of:

- losing the entire investment
- being unable to bail out if necessary
- failure to implement the venture idea
- competitiveness
- management failure

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<sup>56</sup> Tykiová (2000), Scheibehenne et al. (2003)

<sup>57</sup> Carelton (1986), Libecap (1986)

➤ leadership failure

Interestingly enough, MacMillan et al. (1985) stress that VCs are well aware of the importance of the entrepreneur/management team, which is also a main decision criterion<sup>58</sup>. However, the main tool for evaluating a company's potential is still the business plan, which reveals little about the characteristics of the entrepreneur. In fact, Henderson (1988) claims that the two most important considerations for the equity investor are the management team and the product's market potential. Robinson's (1987) study confirms the above claims that a major emphasis on the quality of the top management team in evaluating new deals was universal priorities.

Additionally, MacMillan et al.'s (1985) analysis also indicated that the most important product characteristic appears to be some form of proprietary protection. On the other hand, VCs claimed that the need for the product to be "high-tech" was not important. This is very surprising, given that most VC placement is performed in some kind of high-tech arena, including communication, Internet technology, biotechnology or medical devices<sup>59</sup>. Furthermore, according to this study, the only critical market requirement is a high growth rate.

The research carried out by Riquelme/Rickards (1992) confirmed that during the screening stage VCs focus on a small subset of criteria in a non-compensatory process, i.e. that an unacceptable value for one criterion cannot be offset against a high value for another one. The most important criteria during the screening phase seem to be the entrepreneur's experience in the industry, in-depth knowledge of the product (e.g. advantages over competitors, technical, production and cost feasibility), and the existence of a prototype or unique features of the product<sup>60</sup>. Riquelme/ Rickards (1992) point out that the screening phase tends to use judgmental rather than analytical methods<sup>61</sup>.

Furthermore, Elango et al. (1995) claim that the earlier the investment stage, the greater the interest in potential investments built upon proprietary products, product uniqueness and high

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<sup>58</sup> see for example MacMillan et al. (1985), Fried et al. (1993), Cooper et al. (1994), Zacharakis (1995), Frei (1998), Schefczyk (1999), Weber/Diekes (2002), Wipfli (2001)

<sup>59</sup> See Chapter 2.3

<sup>60</sup> Riquelme/Rickards (1992)

<sup>61</sup> Riquelme Rickards (1992)

growth markets. On the other hand, late-stage investors are more interested in demonstrated market acceptance. They revealed that, after the investment was made, earlier stage investors attached more importance to spending their time evaluating and recruiting managers. It was also claimed that earlier stage investors sought ventures with higher potential returns<sup>62</sup> – a 42% hurdle rate of return for the earliest stage investors versus 33% for the late-stage investors<sup>63</sup>. On the other hand, late-stage investors were found to spend more time evaluating a potential investment; however, there was little difference in the amount of time the VC spent assisting the portfolio company once the investment had been made. In addition, Amit et al.'s (1998) study discovered that VCs favoured later-stage to early-stage investments.

### 2.3. The Venture Capital Market

By all reasonable measures, the Venture Capital market has grown at an incredible rate over the past few years, despite the setback caused by the collapse of the new economy. The continuous growth of private equity activity since 1997 was marked by an unprecedented acceleration during the year 2000, then a slow-down during 2001, before refocusing and slowly picking up again in 2002. Investors' interest in technology investment, the main engine of growth between 1997 and 2000, has been almost completely lost. This is highlighted by VCs' focus on Internet and telecommunication technologies. However, the expectations of rapid growth which these industrial sectors promised did not materialize.

According to PricewaterhouseCoopers (2001), the year 2000 saw a new global record in private equity and Venture Capital investment of at least \$177 billion, an increase of 30% over the 1999 figure of \$136 billion. The total private equity and Venture Capital invested equated to over 0.6% of the world's GDP (up from 0.5% in 1999). According to Thomson Financial/ Venture Economics<sup>64</sup>, VC investments slowed down by 58% to \$50 billion during 2001, from \$121 billion in 2000. Technology investment still made up the bulk at \$113 billion, representing almost two thirds of all investment<sup>65</sup>. The top country by investment was the USA (\$153.9 billion), followed by the UK (\$16.3 billion), France (\$6.9 billion) and Germany (\$5.7 billion).

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<sup>62</sup> Elango et al. (1995)

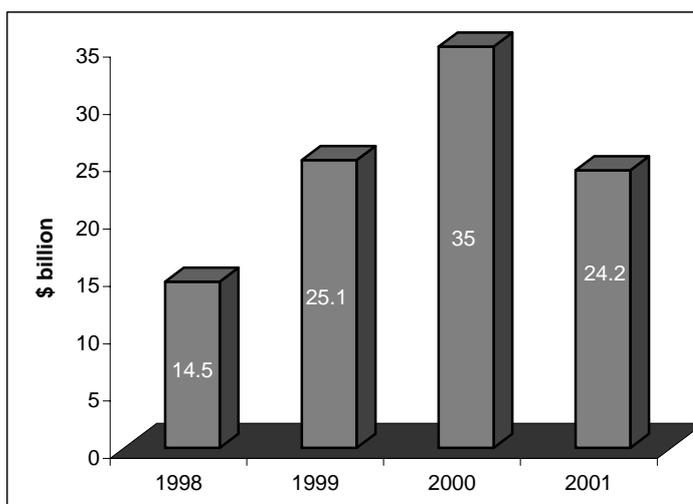
<sup>63</sup> According to Henderson (1988), VCs are funding projects promising a return on equity of 30% to 50%

<sup>64</sup> Stein (2002)

<sup>65</sup> PricewaterhouseCoopers (2001)

As shown in Diagram 2.5, Western Europe enjoyed a level of investment of \$32 billion in 2000, representing a 20% increase over 1999 and computing to nearly 0.4% of the European GDP<sup>66</sup>. The record-breaking growth trends seen in 1999 and 2000 have been curbed on the premise of a global economic recession during 2001. During 2001, European start-ups were able to obtain 30.9% less private equity placement compared to 2000's investment levels<sup>67</sup>.

**Diagram 2.5: Total European equity investment, 1998 – 2001**



Source: EVCA (2001C)

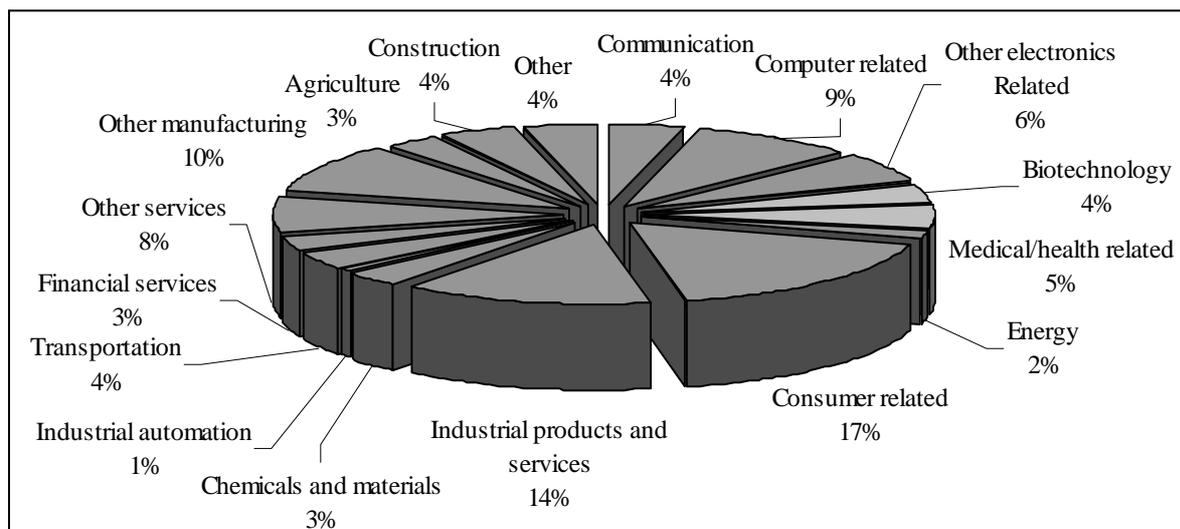
Diagram 2.6 illustrates the make-up of the European VC market, revealing which sectors VCs found most interesting. The sectors on which VCs concentrated their investment placements were industrial-related and consumer-related products.

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<sup>66</sup> PricewaterhouseCoopers (2001)

<sup>67</sup> EVCA (2001A)

**Diagram 2.6: European VC activity sectors**



Source: EVCA (2001B)

However, the above diagram also clearly exhibits an interest from investors in the various life sciences markets. When viewed together, Biotechnology (4%) and health-related industries (5%) amount to quite a considerable market share.

Having established the importance of the issue in the VC process, which is the specific focus and structure of this thesis, the following Chapter will investigate the nature of the Venture Capital business and industry.

### 3. The Healthcare-Based Biotechnology Market

*“In this time, biotech has become a very attractive space to invest”*<sup>68</sup>

Despite early successes and failures, biotechnology research projects in medicine and agriculture have grown at a phenomenal rate. Biotechnology has become a key focus of the “new economy” and is recognized for its broad technology platform of innovation across many industrial sectors, including health care, manufacturing, agriculture, energy, and environmental management.

This Chapter will begin with common definitions and explanations of biotechnology in general and its three broad sub-divisions. The second part will examine recent developments in the medical-related biotechnology market. Finally, an outline of both the characteristics of such companies and the common bio-pharmaceutical product development procedures will be provided.

#### 3.1. Definition

Since there is no homogeneous definition of biotechnology, this Chapter, like the previous one, will state a variety of standard definitions and explanations so as to avoid any ambiguities. Again, it will not include any discussion of each definition.

According to the OECD, biotechnology is “the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living and non-living materials for the production of knowledge, goods and services.”<sup>69</sup>

A standard definition is provided by Standard & Poor’s, who define biotechnology as “the practice of using biological and engineering data to solve problems arising in the relationship between man and machine.”<sup>70</sup> However, the company points out that, due to current industrial practice, the word commonly refers to the application of biological and biochemical science to large-scale production, for the purpose of modifying human health, food supplies, or the environment.

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<sup>68</sup> Cohen (2002)

<sup>69</sup> OECD (2002)

<sup>70</sup> Saftlas/DiLorenzo (2000)

Fildes (1990) provides an interesting definition, stating that biotechnology is not an industry, but a set of tools affecting an entire range of industries. Freier (2000) seems to be basing his explanation of biotechnology on Fildes, asserting that biotechnology should be viewed as a new “technology system”, i.e. a fusion of diverse technologies whose combined innovations have enabled the birth of a new industry.

These definitions/explanations imply that biotechnology is not one large industry focusing on medical applications, but rather a number of large, very dissimilar industries which have been gathered under the umbrella term “biotechnology.” In fact, when exploring biotechnology, it becomes apparent that it has revolutionised the medical diagnostics field by providing accurate and relatively inexpensive tests for a wide spectrum of diseases, as well as for consumer market products (such as home pregnancy tests<sup>71</sup>). In addition, biotechnological advances in agriculture have led to new, genetically engineered bio-pesticides, crops and seeds which are upgrading the food chain, while other products are making for a better environment through improved methods of hazardous waste disposal and water purification. Biotechnology is also playing an increasingly important role in crime detection through greater use of DNA testing.

While healthcare is said to remain the principal market, biotech products are also expected to widen applications in agriculture, food processing, environmental control, and forensics. Standard & Poor’s estimated that in 1999 human therapeutics accounted for about 75% of industrial sales, human diagnostics for 20%, agricultural products for 5%, and other products for 5%<sup>72</sup>.

Currently, three broad biotechnology sectors have established themselves, which are not only different in their focus, but differ also in market size, social acceptance and their ability to find Venture Capital financing:

- The prevalent biotechnology industry deals, as previously indicated, with medical-related issues, such as pharmaceuticals, diagnostics and gene therapy. This area is also commonly referred to as the “red” biotechnology sector. As the industry has grown, biotech companies have sought to apply an increasing body

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<sup>71</sup> BIO (2002)

<sup>72</sup> Saftlas/DiLorenzo (2000)

of knowledge to understanding the disease process, in order to develop analogues of natural molecules as well as completely new and powerful drugs. As stated above, that is the focus of this thesis.

- Another eminent area in biotechnology deals with the well-being and modification of both plants and animals. In fact, the successful cloning of the sheep “Dolly” is a very prominent example of the “green” biotechnology sector. In addition, agro-biotech companies have sought to develop crops which are resistant to insects, pesticide and drought, have a longer shelf life, and offer increased nutritional value (functional foods), or animals producing more meat or other products, such as milk.
- The third, and mainly unknown, sector concentrates on adapting biotechnological methods and products to industrial and environmental needs and processes. Currently, the mainstream focus in this sector is twofold. First, companies are focusing on the analysis and breakdown of harmful chemical substances which have polluted, or potentially will pollute, the environment (i.e. water, air, soil). Secondly, companies are seeking methods of creating renewable resources. In fact, several companies are researching methods of growing plants, such as rape or sunflower, which yield higher than average levels of oil, or oil which contains certain qualities required for special purposes, as a substitute for crude oil.

The genetically modified products of today’s biotechnology industry are indebted to groundbreaking research in genetics and molecular biology conducted over the past five decades. Although people recognised the potential of genetic research very early on in helping to find cures for hereditary diseases, many also feared that genetic research might result in the accidental creation and release of deadly new pathogens into the environment. Even today, genetically modified agricultural products are still banned in many countries. In Europe and elsewhere, opponents continue to raise practical and philosophical concerns about the use of genetics in agriculture, cloning and other emerging areas.

### 3.2. Recent market developments

#### **The biotechnology market**

The biotechnology industry comprises many different practices, some of which involve the modification of genetic material. Many of the basic principles used by the biotechnology industry today have been employed for thousands of years – bacteria, fungi, and other living organisms have long served to induce needed chemical reactions to process certain foods and beverages. Decades prior to the advent of genetic engineering, scientists sought to produce medicines made from living organisms on a large scale. The significant difference over the last two decades is that scientists have learned to manipulate organisms at the genetic level. Their advances have facilitated the creation of new products in medicine and agriculture, in addition to the mass production of substances otherwise available only in trace amounts.

Over 250 million people worldwide have been helped by over 130 biotechnology drug products and vaccines approved by the U.S. Food and Drug Administration (FDA)<sup>73</sup> – 70% of all approved biotech medications were approved over the last six years<sup>74</sup>. There are more than 350 biotech drug products and vaccines currently in clinical trials targeting over 200 diseases, including various cancers, Alzheimer’s disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis<sup>75</sup>. Diagram 3.1 depicts the actual segments of these Biotech pipeline drugs.

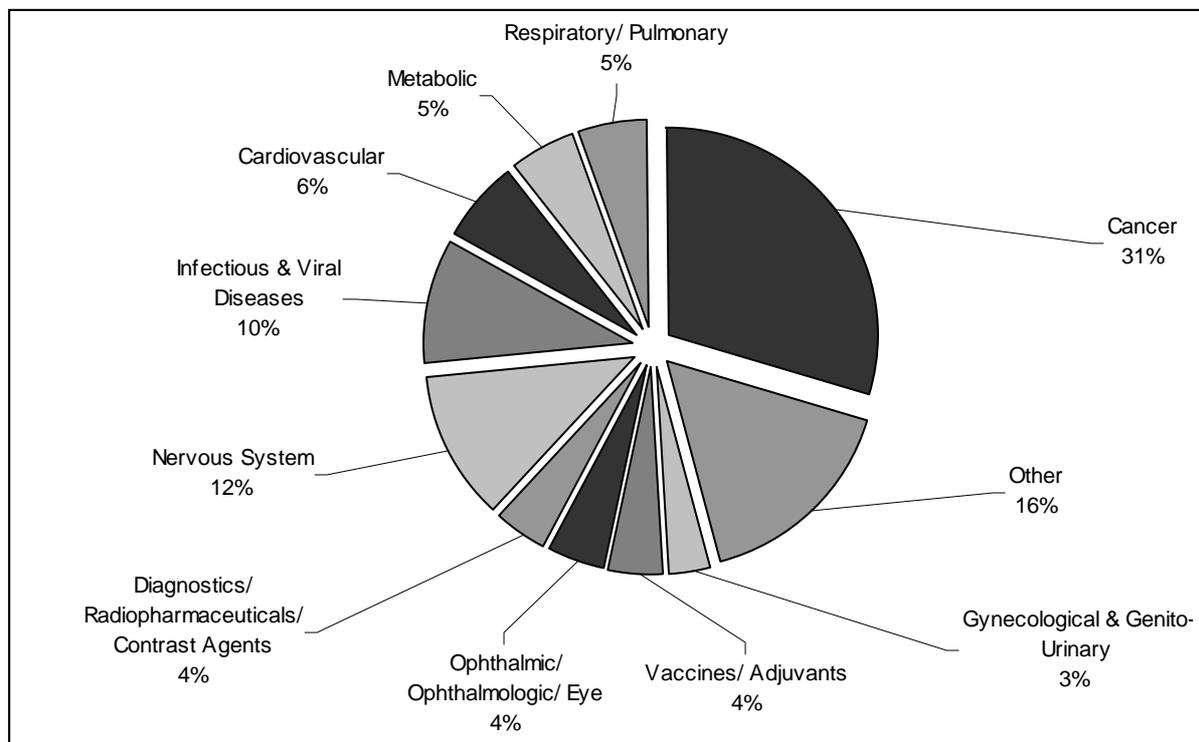
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<sup>73</sup> Calandra (2002), BIO (2002)

<sup>74</sup> BIO (2002)

<sup>75</sup> Calandra (2002)

**Diagram 3.1: The Biotech Pipeline – Phase III Clinical Trials**



Source: Ernst&Young (2001)

In the US, 117 genetic drugs could be found on the market in 2001; about 300 new medications are being evaluated in clinical studies phase III, of which 50% aim at the fight against cancer. In Europe, 48% of all drugs are biotechnology-based; Germany's genetically engineered drug market made up 7.3% of the German drug market in 2001, with a turnover of about €1.1 billion.<sup>76</sup> During 2000, the volume of the German diagnostic market reached nearly €1.3 billion, about 35% of which was due to biotechnology-based diagnostics<sup>77</sup>.

Globally, the revenue for genetically engineered medicine has reached \$16 billion<sup>78</sup>; according to the European Biotechnology Association – EuropaBio – this sum will reach nearly \$40 billion by the year 2005, enjoying a growth rate of 18%. Experts also anticipate that by 2018 half of all drugs available will have biotechnological roots<sup>79</sup>. In diagnostics, several hundreds of biotechnology-based products could then be found<sup>80</sup>.

<sup>76</sup> EuropaBio (2001)

<sup>77</sup> EuropaBio (2001)

<sup>78</sup> EuropaBio (2001)

<sup>79</sup> EuropaBio (2001)

<sup>80</sup> EuropaBio (2001)

### **Private Equity**

Biotechnology is not only considered the darling of the investment sector nowadays, but already held this status once before during the early 1990s<sup>81</sup>. When biotechnology entered the stage in the 1980s, it became the instant darling of investors. But when those same investors realised that it would take years and numerous false starts to deliver the new breed of miracle drugs to market, interest waned. This resulted in an apparent lack of interest by investors during the late 1990s, mainly because a) the ROI of biomedical portfolios lagged behind those of the technology portfolios and b) the biotech market was experiencing a consolidation era. By the mid 1990s, investment money all but dried up for biotech as high-tech's siren song of quick profits bewitched many Venture Capitalists. The investment thaw actually started some time in 1999. However, historically the people who made investments in the life sciences sector have made reasonable returns, as biotechnology has proven to be a slow but steady investment<sup>82</sup>.

By the end of 1999, the US biotech industry saw 169 deals bring in \$1.7 billion<sup>83</sup>; the European Capital Venture arena saw roughly the same amount during 1999<sup>84</sup>. However, these investments soared in 2000 to \$3.6 billion in the US and to \$3.8 billion in Europe. Nevertheless, it is difficult to say for certain how much of this investment was due to a general interest in anything which investors found worthwhile or in a specific interest in this market sector. On the other hand, the fact that the area of health care performed comparatively well during the recession of 2001 and beyond suggests that these investments may actually have been an indication of an increase in interest in this area and a general desire to invest.

According to Growthink, US health care companies received over \$1.5 billion in equity funding during the first quarter of 2002, representing 19.7% of the total venture dollars invested<sup>85</sup>. During the first three quarters of 2001, the health care market raised \$1.9 billion in the US<sup>86</sup>, over \$750 million of which was in biotechnology, over \$400 million in medical devices and equipment, and \$14 million in health care services.

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<sup>81</sup> McNeil (1999)

<sup>82</sup> Calandra (2001)

<sup>83</sup> Calandra (2001)

<sup>84</sup> EVCA(2002)

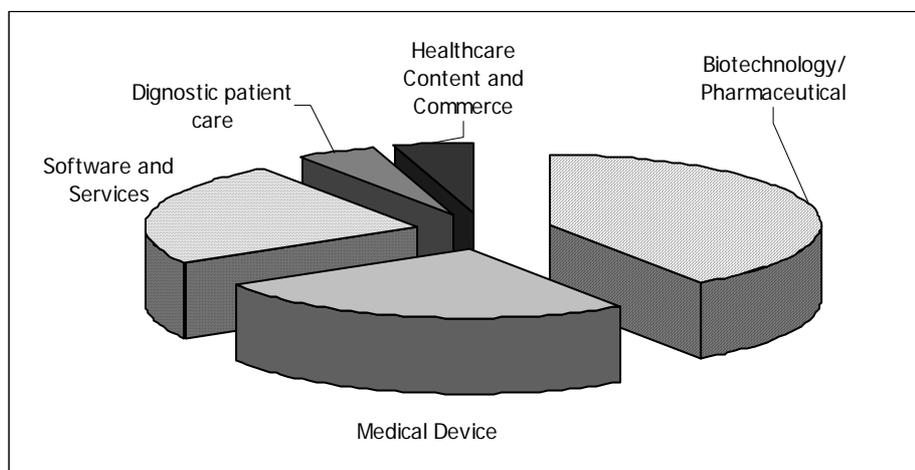
<sup>85</sup> Growthink Research (2002)

<sup>86</sup> Calandra (2001)

During 2001, 610 privately held US biotechnology, life science and health care companies received over \$7 billion in Venture Capital<sup>87</sup>. This sector, which is often referred to collectively as the “health care sector”, experienced a phenomenal year, particularly in light of declining Venture Capital investments nationwide. As other sectors waned, the health care sector flourished. During the first quarter of 2001, fewer than 10% of the companies receiving Venture Capital were in the health care field, receiving less than 10% of the total dollars invested. However, by the fourth quarter, over 21% of the companies receiving funds could be found in the health care arena, and health care’s percentage of total venture dollars grew to nearly 24%.

According to Growththink Research (2002), over 40% of the companies funded in the health care sector were in the biotechnology or pharmaceutical fields, while medical device companies (26%) and software and services companies (24%) comprised much of the balance (see Diagram 3.2). Diagnostic patient care, health care content and commerce venture each accounted for less than 5% of the year’s venture financing.

**Diagram 3.2: Market Share of the US Healthcare sector**

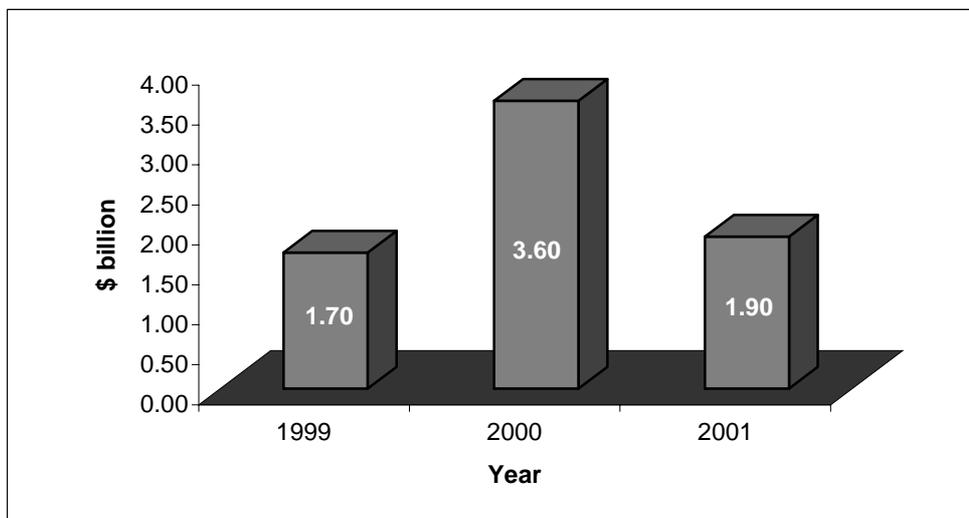


Source: Growththink Research (2002)

Diagram 3.3 depicts the levels of VC investment placements in the years 1999 – 2001. The rapid increase from 1999 to 2000 may be explained by the shift in the VCs’ attention away from high-tech/communication projects to biotechnology. On the other hand, a general slowdown in VC funding which could also be felt in the biotechnology sector existed during the same period.

<sup>87</sup> Growththink Research (2002)

**Diagram 3.3: US Venture Capital Investment in Biotechnology**



Source: Cohen (2002)

During 2002, over half of the companies funded in the US health care sector were biotechnology or pharmaceutical ventures<sup>88</sup>. In the US, the total VC placement during the first quarter of 2002 was over \$6.2 billion, of which biotechnology received over \$750 million, medical devices and equipment over \$400 million and health care services \$14 million<sup>89</sup>.

In addition, according to Venture One, US Venture Capitalists invested \$777 million in drug discovery during 2001, or about \$260 million per quarter. This was down from \$358 million per quarter in 2000, but still much higher than the moderate amount invested in 1999, which amounted to \$144 million per quarter<sup>90</sup>.

According to Ernst and Young (2002), British biotech companies enjoyed 39% of all Venture Capital money invested in European biotech during the first half of 2001, which amounted to approximately \$240, in comparison to the \$255 million collected during the fiscal year of 2000<sup>91</sup> (see Diagram 3.4). According to EVCA (2001C) statistics, about \$35 billion were

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<sup>88</sup> Growththink Research (2002)

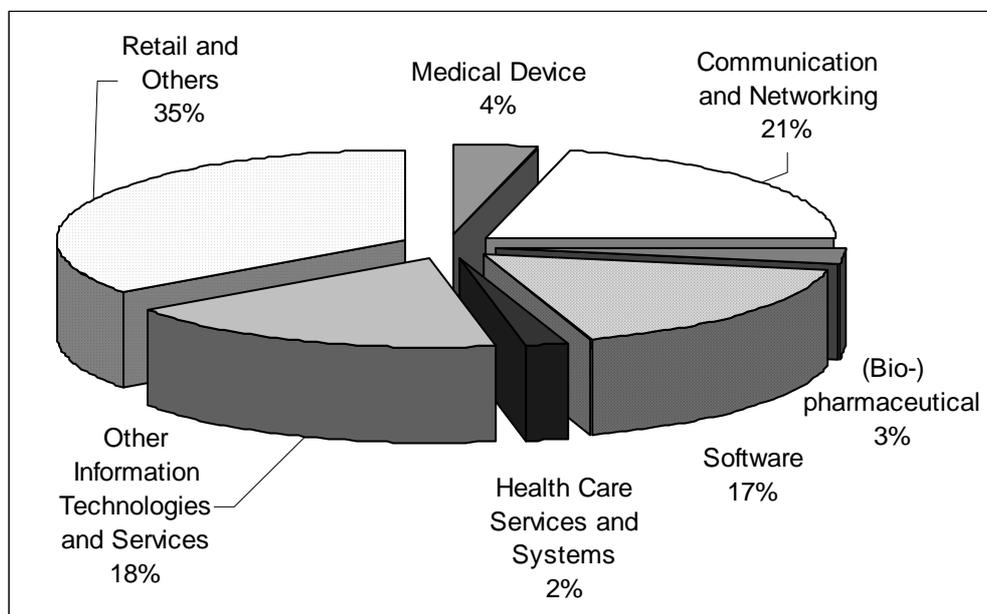
<sup>89</sup> Venture Economics

<sup>90</sup> Park (2001)

<sup>91</sup> Cohen (2002)

invested in 2000, 11% of which was represented by biotech and medical, reporting a staggering 129% growth in that year.

**Diagram 3.4: Breakdown of European VC Healthcare Placements in 1999**



Source: Ernst & Young (2002)

Despite a very challenging market, the health care industry enjoyed an increase in equity placement during 2000 and 2001; its median pre-money valuation rose from €7.5 billion in 2000 to €7.8 billion in 2001<sup>92</sup>. The reason for this can be attributed to the fact that at that time businesses relying on intellectual property and protected by high barriers of entry – such as biopharmaceuticals – were better equipped to weather the difficult times of 2001. Companies positioned in these areas flourished in countries with economies and infrastructures to support them – mainly the UK, Germany, France and Sweden. It is therefore not surprising to find that these four countries, which made up 71% of European investment in 2000, accounted for 76% in 2001<sup>93</sup>. Just as most European investment is directed at four countries, it is also concentrated in four core industries: biopharmaceuticals, software, consumer and business services, and communication. Even though the largest individual sector is software – which has replaced consumer and business services – with 29%, biopharmaceuticals were able to

<sup>92</sup> Zemel/Harmston (2002)

<sup>93</sup> Zemel/Harmston (2002)

increase their share of investment from 8% to 17%<sup>94</sup>. In 1998, biotechnology received only 2.4% and medical devices 4.7% of the total European equity placement<sup>95</sup>.

### 3.3. The Biotechnology Company

This section addresses the unique characteristics of a biotechnology firm which can be explained by the product development process. For this purpose, it will begin with an overview of the specific features of a firm operating in the medical-related biotechnology sector. This will be followed by an outline of the product development procedures that are required by regulations, and which the company has to abide by in order to gain approval, be it from a national authority (e.g. FDA in the US) or an international one (e.g. EUMEA in Europe). It is common practice for a company to acquire several licences, as each country has its own specific regulations.

#### 3.3.1 Characteristics of Biotechnology Companies

In the red biotechnology market, therapeutic and drug development can be a very drawn out and costly process. Bringing a drug to market often takes 10 years and costs \$550 million or more<sup>96</sup>. It is clear that the product cycles in biotechnology are very different from high-tech or other industries.

Like pharmaceutical companies, the biotechnology industry is not as susceptible to economic cycles as other industries. In countries such as the US, UK, Germany, France or Israel, where the market is highly developed, growth in demand for biotechnology products is fairly constant from year to year. Although the industry is peopled with companies which remain unprofitable and continue to struggle for financing, several trends suggest that the biotechnology industry is poised for solid long-term growth.

Most biotechnology companies are generally engaged in so-called “upstream” activities<sup>97</sup>, mainly in R&D. While they provide products and services to businesses in a multitude of

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<sup>94</sup> Zemel/Harmston (2002)

<sup>95</sup> EVCA (2002)

<sup>96</sup> Agres (2001)

<sup>97</sup> Saftlas/DiLorenzo (2000)

industries, most are still in the development stage, and thus do not have commercial products presently.

Being independent and entrepreneurial, biotechnology firms usually pursue high-risk opportunities which apply cutting-edge science to practical problems, and are thus becoming increasingly dependent on technology to further their quest. On the downside, most firms are confronted by many problems and disappointments along the way, while the industry is renowned for its high rate of bankruptcy.

Even though most literature only talks about the uniqueness of companies based in the so-called red biotechnology industry, this does also apply – more or less – to companies based in the other biotechnology industries.

It has been highlighted several times that not every biotechnology company is dealing with the same markets, and that these companies can pursue various business models, thus facing different risks. One example is that of biopharmaceutical companies. Generally, these companies either work independently or in conjunction with a large pharmaceutical company. These companies often have to tackle various risks – the development as well as the approval risk. Statistically speaking, their failure rate lies at 90%<sup>98</sup>.

Technology providers which enable companies to carry out the actual R&D processes face another problem. First, the barriers to entry are relatively low in this market, which has led to a highly competitive marketplace. On the other hand, the actual products usually suffer from a very short life span – only a short period of time elapses before a new, better, more efficient, or cost-effective technology is introduced onto the market.

The third group which can be found are those which provide information in the field of genomics - these companies provide databases or other content. The highest risk facing this biotech segment is associated with the lifespan of the patents and other intellectual property.

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<sup>98</sup> Thies (2001A)

3.3.2 The Bio-pharmaceutical product development process

In order to understand some of the basic factors for the biopharmaceutical industry, this section will provide a short overview of the steps involved in bringing a drug to market. The biopharmaceutical approval process is both lengthy and costly. Total development time varies, averaging 7 to over 14 years to advance from the pre-clinical development stage to marketing approval<sup>99</sup>. Studies of the development process indicate that most new products cost between \$200 and \$500 million to fully develop<sup>100</sup>. Based on these astronomical figures, the industry-wide high concerns about this process are understandable. The effort to discover and develop new therapeutics generally consists of nine distinct steps: target identification, target validation, screening development, secondary screening, lead compound optimisation, pre-clinical trials, clinical trials – phase I, II and III – and regulatory submission and review. Table 3.1 presents a very simplified overview of these phases:

**Table 3.1: Overview of biopharmaceutical drug development**

	Research	Pre-clinical	Clinical Studies			Approval
			Phase I	Phase II	Phase III	
<b>Years</b>	2 or more	3-6	1-1.5	2	3-3.5	up to 2.5
<b>Success rate</b>	0.2%	25%	70%	50-63%	85-94%	75-90%
<b>Average cost</b>	\$2-\$50m	\$1 - \$3 m	Total \$250 m			

Source: Freier (2000), Sontheimer/Matzen (2001), BIO (2002)

**Early discovery and pre-clinical development**

Pre-clinical work is estimated to take up about 40% of the time and 42% of the costs required to bring a new compound to market. While it is common to focus on a drug company’s clinical development pipeline, industry insiders know that many of the hurdles encountered during drug development occur before the compound enters the clinic. Pfizer’s rule of thumb implies that it takes about seven million primary screen candidates in order to produce one new chemical entity<sup>101</sup>.

Contemporary research tools and techniques developed through molecular biology, chemistry, and other related disciplines are now being applied to discovery and early development

<sup>99</sup> Freier (2000), Fildes (1990)

<sup>100</sup> Saftlas/DiLorenzo (2000)

<sup>101</sup> Saftlas/DiLorenzo (2000)

activities. New capabilities in R&D improve the chances of discovering more effective medications, while reducing the overall time and cost of the process. The key steps in the R&D process<sup>102</sup> of biological drugs are described below<sup>103</sup>:

- **Target identification:** Ultimately, most diseases are attributed to underlying genetic defects. During target identification, researchers focus on identifying genes and their respective products thought to be responsible for causing a particular disease. For infectious diseases, micro-organisms need to be characterised. The ultimate goal of this step is to find and isolate potential areas for therapeutic intervention.
- **Target validation:** Once a prospective disease target is uncovered, its role in the disease in question must be determined. Researchers use various methods, such as differential gene expression, tissue distribution analysis, and protein pathway studies, to verify the target's significance in the illness.
- **Assay development:** An assay, or drug candidate screen, must be constructed to detect the activity which potential treatments have on the target. Ideally, a drug development screen should be cost-effective, fast, accurate, easy to perform, quantitative, and amenable to automation. Some screens can be reused for other drug development studies, while many others must be tailored to specific targets or sets of therapeutic compounds which will be tested.
- **Primary screening:** Once the assay is ready for use, the drug developer will conduct tests with a library of chemical compounds in an attempt to modulate a validation target. Researchers look for a predefined minimum level of activity against the target. Compounds that meet or exceed these criteria are termed *hits* and will be included in subsequent screens.
- **Secondary screening:** This procedure is focused on confirming the activity, measuring the potency, and assessing the selectivity of hits from the primary screen. In this way, a drug developer identifies the most promising drug

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<sup>102</sup> Saftlas/DiLorenzo (2000)

<sup>103</sup> For the purpose of this thesis, the steps to be taken for approval have been chosen to follow the FDA regulatory steps, as these are often viewed as the industrial standards. It should be noted that the regulations are very similar internationally. Also, before a drug is approved in a country it has to be submitted to the national ministry in charge of approving new drugs. The difficulty in getting a drug approved varies considerably – for example, the UK is known to have very lean regulations, while Germany is renowned for its very strict and long-whined approval process.

candidate in terms of their pharmacological characteristics. Most secondary screens are performed manually and therefore consume significant resources.

- **Lead optimisation:** By re-screening compounds several times through the secondary screening process, researchers attempt to zero in on candidates with the best chance of safety and therapeutic efficacy. New libraries of compounds which possess superior structure-activity relationships are generated. The optimisation process can include up to 10 or more iterations on previously optimised groups of compounds.
- **Pre-clinical studies:** Prospective compounds which exhibit the greatest activity within the least chance of toxicity are called leads. Leads move on to a set of FDA-mandated tests, which are necessary before human clinical trials can be initiated. The tests primarily involve animal studies which must prove a compound's safety in terms of potential carcinogenicity and other toxic consequences. Additionally, drug developers use pre-clinical testing to assess the preliminary effectiveness and other pharmacological properties of a compound. A sponsoring drug company must submit the results to the FDA as part of an Investigational New Drug Application, which is a formal request for permission to begin human clinical trials.

### Clinical Trials

The drug approval system in the US is one of the most stringent in the world. Drugs produced through biotechnology must undergo the same lengthy testing process designs to show product safety and efficacy. The clinical testing period in humans usually consists of three phases and uses about 70% of the R&D equity needed to bring a new drug to market<sup>104</sup>.

- **Phase I:** During Phase I, the manufacturer gives the drug to a relatively small number of healthy people to test its safety. Small doses of the drugs are administered first. If this initial test appears successful, the dosage is slowly increased to determine its safety at higher levels.
- **Phase II:** During Phase II, the drug is administered to patients suffering from the disease or condition the drug is intended to treat. This second round of tests is designed to evaluate the drug's effectiveness and safety, and generally includes a larger sample population and a lengthier test period than Phase I.

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<sup>104</sup> Freier (2000)

- **Phase III:** Phase III is the most complex and rigorous testing phase, which requires a very large group of patients to verify the safety, effectiveness and optimum dosage required of the drug. Physicians closely monitor patients to determine efficacy and identify adverse reactions. Usually during Phase III (and often also during Phase II) randomised, blind and double-blind tests with placebo control are implemented to remove any chance of bias.

The FDA estimates that out of every 20 drugs entering clinical testing, an average of 13 or 14 will pass the clinical Phase I tests, of which only 9 will make it through Phase II, and only one or two are likely candidates to survive the rigorous Phase III trials. Thus, only 5% to 10% of drugs entering clinical trials are ultimately approved for marketing<sup>105</sup>.

### **Regulatory filing and review**

Once the clinical testing has been concluded, the manufacturer analyses all the data and submits a Biological License Application or a New Drug Application to the FDA if the data successfully demonstrates its safety and efficacy. The application is a compilation of the research conducted, and needs to disclose all details of the product's formula, production, labelling, and intended use. On average about 18 months elapse between the time a manufacturer submits an NDA and the time the FDA approves the drug.

Once a drug has been approved, the FDA continues to monitor the drug closely. Often, after the marketing has begun, the manufacturer submits supplementary applications requesting approval to use the drug for additional indications. The FDA also determines the drug's official labelling, including a detailed description of the drug, its composition, indications, contraindications, and side effects. This information is included in a drug's package insert. Sometimes the FDA requires additional studies, Phase IV, to evaluate long-term effects if side effects or other unexpected developments come to light only after the drug has been widely used. The FDA also holds the right to recall a product.

The FDA sometimes allows for experimental drugs still in clinical trials to be made available to seriously ill patients through its Investigational New Drug treatment policy. This provision enables manufacturers to sell drugs (on a cost recovery basis only) which have not yet passed

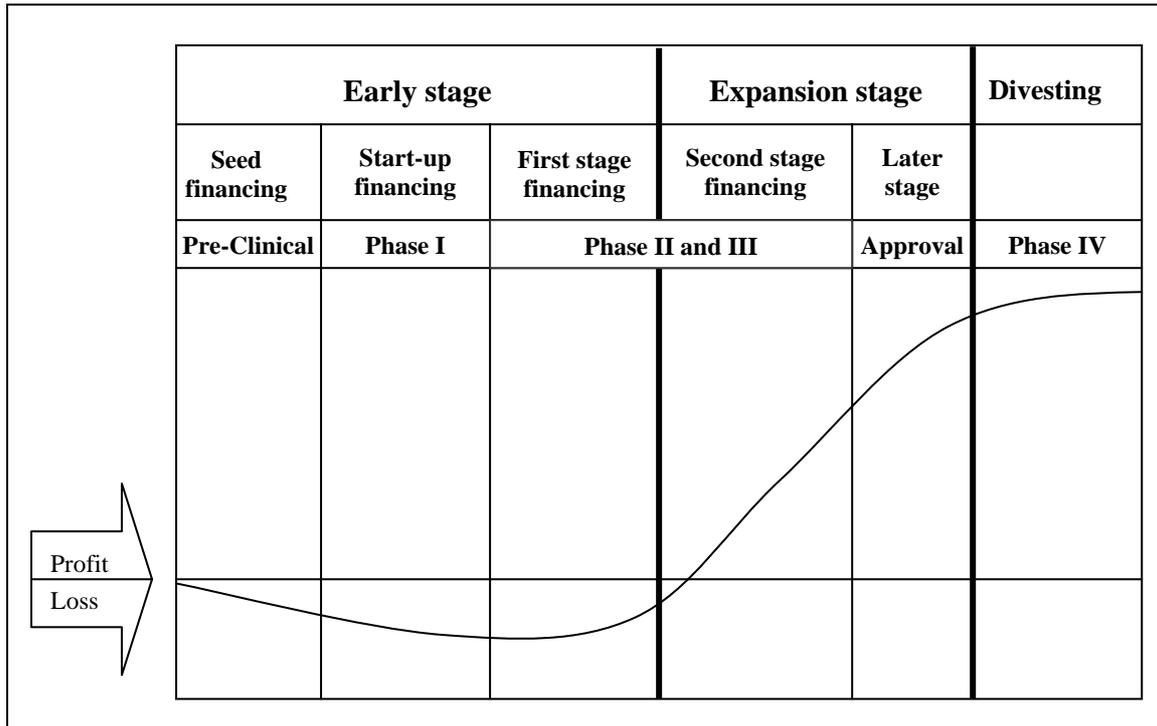
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<sup>105</sup> Saftlas/DiLorenzo (2000)

all three phases of testing to patients with life-threatening diseases, provided that Phase I clinical studies have been successfully completed.

Diagram 2.2 (p.27) can be adapted to the product development process of (bio) pharmaceutical products.

**Diagram 3.5: (Bio)pharmaceutical product development and the Venture Capital cycle**



Source: based on Scheibehenne et al. (2003)

Diagram 3.5 shows very clearly that Venture Capitalists only expect a (bio)pharmaceutical start-up to become profitable during Phase III, i.e. during the expansion stage. This is in fact no different from any other industry, as during Phase III the product has already proved itself on a small scale.

The purpose of the preceding outline of the nature of the VC and biotechnology market was to make the reader aware of the challenges facing VCs and start-ups. The following section will focus on various issues relevant to the empirical study.

#### 4. Literature review

The two broad factors analysed, management and strategy, follow the results of Krüger (1989), who proposed that these two factors are eminent for the success of a venture<sup>106</sup>. This section reviews some of the research results of prominent studies which have focused on the area of interest of this thesis, and which the VC may evaluate from the information provided in the business plan. As indicated in Chapter 1.3, the results discussed below will serve as a basis for the empirical research conducted in Chapter 6.

This Chapter will begin by reviewing management team-related issues, such as industrial knowledge and educational background. This will be followed by an analysis of the influencing factors patents and product pipeline, including a discourse on diversification. Issues concerning strategic alliances, such as liability of newness, will be discussed in the final section.

##### 4.1. Management

*“Even in a high-tech industry, management skills are more important than technology”<sup>107</sup>*

As previously mentioned in Chapter 1.4, VCs and academic scholars have generally identified the management team (or entrepreneur) as the most important factor, and have drawn attention to the fundamental importance of the entrepreneur<sup>108</sup>. Prior to the empirical analysis, therefore, this section summarises the results of various research studies focusing on a range of management-related issues, which underlie the empirical examination.

##### 4.1.1 Quality and experience of the management team

The significance of both the quality and experience of the management and scientific team for the company’s long-term success has been the focus of a multitude of academic studies<sup>109</sup>. As indicated in the first part of this work, the existing biotechnology sectors produce diverse and

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<sup>106</sup> In fact, the study by Krüger (1989) revealed that strategy is the most important factor for both the success and the failure of a venture, while the management team is an equally strong factor for a venture’s failure.

<sup>107</sup> Weiss in Wipfli (2001)

<sup>108</sup> Herron/Robinson JR. (1993)

<sup>109</sup> e.g. Wipfli (2001), Dubini (1989), MacMillan et al (1985, 1987), Gomez-Meja et al. (1990)

complex strategic challenges for senior management. The rapidly changing industry, concurrent with the challenges of the different growth stages, necessitates diverse entrepreneurial skills. Furthermore, in conjunction with requirements dissimilar to other industries, vast differences exist between single-life science markets, such as genetic engineering and minimally invasive diagnostic technology. It is therefore imperative that the management team constitutes insightful and astute individuals who are capable of adapting to any set of circumstances. On the basis of these considerations, there is an evident prerequisite for managerial quality appraisal, including the experience, talent, and character of each team member<sup>110</sup> during the (initial) screening process. The research results of previous studies are highlighted in the following paragraphs.

Several studies have been designed to determine the most important criteria used by VCs to decide on funding new ventures<sup>111</sup>. One prominent example is the survey of MacMillan et al. (1985), which revealed that 50% of the most important valuation criteria were correlated to the entrepreneur's experience and personality. Moreover, evidence of staying power and the ability to handle risk were also identified as fundamental personality characteristics. Further, the investigation by MacMillan et al. (1985) provided support for a thorough familiarity with the target market, leadership capabilities and a track record relevant to the venture being fundamental requirements. A rather unexpected result revealed by MacMillan et al (1985) is the VC's apparent lack of concern about the entrepreneur's reputation.

The work by Weber/Dierkes (2002) substantiates the above arguments and records the following management investment criteria (Table 4.1):

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<sup>110</sup> Davis and Stetson (1985), Weber/Dierkes (2002)

<sup>111</sup> e.g. Chandler/Hanks (1993), Fried et al. (1993), Zacharakis & Hofer (1998), Gorman/Sahlman (1989), Wipfli (2001)

**Table 4.1: Management investment criteria according to Weber/Dierkes (2002)**

Criteria	Importance	
	Very important	Important
Industrial experience of the management team	43%	43%
Leadership abilities of management team	38%	42%
Management's ability to recruit high quality employees	32%	47%
Good "chemistry" between VC and management team	34%	35%
Communication skills of management team <sup>112</sup>	32%	36%
Complete management team	32%	33%
New-venture skills of management team	8%	26%

Source: Weber/Dierkes (2002)

Numerous reviews of these issues, e.g. Wells (1974), Poindexter (1976), Tyebee/Bruno (1984)<sup>113</sup>, Fried et al. (1993), Hall/Hofer (1993) and Zacharakis/Hofer (1998), have confirmed the findings of MacMillan et al (1985) and Weber/Dierkes (2002)<sup>114</sup> using empirical investigative methods. All authors have specified that both background/experience and managerial capabilities are elementary investment decision criteria. In fact, Gorman/Sahlman (1989) proposed that the senior management team is the principal contributing factor to a venture's failure, although rarely the main cause. Gorman/Sahlman's (1989) study reinforced a similar assertion made in a second analysis by McMillan et al. (1987)<sup>115</sup>.

<sup>112</sup> including negotiation skills, which Wipfli (2001) believed to influence the value of a company.

<sup>113</sup> all three in Hall/Hofer (1993)

<sup>114</sup> In fact, the opposite is true in many cases, i.e. that the work from MacMillan et al (1985) and especially Weber/Dierkes (2002) support previous research results.

<sup>115</sup> The work by MacMillan et al. (1987) revealed that there are three broad classes of unsuccessful ventures:

the venture team is lacking in experience or staying power, the product has no prototype, and/or there is no clear demand for the product.

the venture team is very well credentialed, but the venture faces early competition and the team has no staying power and runs out of steam.

the team has exceptional staying power and demonstrate that a market exists (through perseverance) only to lose the market to competition due to lack of product protection.

It is surprising to find that VCs still fund some ventures which belong to the first category. One reason may be that these firms receive equity placements at times when so-called "me-too" investment placements are quite common (e.g. during the high-tech boom/bubble during the late 1990s).

This research also showed that there are four types of successful companies, namely:

The following paragraphs have been grouped under three subheadings and follow the subheadings used in the later analysis.

### **Market knowledge and industrial experience**

Weihe et al. (2001) investigated the correlation between the company's success and the market knowledge of the management. In fact, their research sample revealed that 84% of successful managers had acquired market knowledge, while in unsuccessful ventures only 44% of the managers had done so. Hence, it may be argued that market knowledge is a main success factor. A possible reason suggested was the general way the management team is able to use and acquire information. These results are concurrent with the conclusions drawn by Siegel et al. (1993) and Gemünden/Konrad (2000). Both treatises have acknowledged management experience and industry knowledge to be predominant factors in the screening and valuation process. The following empirical analysis should thus reveal these two factors, market knowledge and industrial experience, to be the main success factors.

### **Education, business accomplishment and reputation**

Davis et al. (1985) emphasized that the VC's investment decision is frequently based on a positive feeling about the management team, while a central aspect is the individual's personal attributes. Evidence entailed an ex ante appraisal of management team qualities concurrent with high risks and an in-depth knowledge of psychology. Nevertheless, several researchers<sup>116</sup> asserted that several qualities are undoubtedly measurable, e.g. an individual's business and educational attainment, and the support team's reputation (such as attorneys,

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- a well-qualified management team with the staying power needed to face competition
  - although the management team is not a well-qualified management team, the product enjoys a high level of protection and turns out to be highly successful
  - the typical "market-makers", i.e. a team with exceptional perseverance which demonstrates the need for their product and thus creates a market for it, and which also uses some form of product protection once the market demand has been demonstrated
  - the final class of successful ventures is a small group of "low-tech" products in which distribution skills are essential. MacMillan et al. (1987) believe that these products tend to be consumer goods.

When comparing the first three types of successful ventures with the three types of unsuccessful ventures it is apparent that these are very similar, with the exception of some flaw within the management team.

<sup>116</sup> Bates/Bradford (1992), Dourtiaux (1992), Robinson/Sexton (1994)

accountants, consultants). Venture Capitalists have to rely on questioning previous co-workers, superiors and clients to obtain the necessary information<sup>117</sup>.

Furthermore, a survey by Bates/Bradford (1992) found that attractive human capital traits at business entry for entrepreneurs include high educational attainment, owners who are in the middle-age range, and those who have a family business background. Dourtiaux (1992) demonstrated the positive short- and medium-term impact of initial company size, available capital, past experience in marketing and finance, the founder's age, market structure, and similarity with the market served by a previous employer.

The work of Robinson/Sexton (1994) examined the effect of education and experience on becoming self-employed and the success of such a move. They revealed that both experience and the level of education have a strong, positive correlation with the probability of becoming self-employed and the success of individuals in terms of earnings. The difference between these two factors' correlation coefficient was the intensity of the effect on both probability and success.

In addition, Sandberg/Hofer (1987) learned that new venture performance is influenced by industrial structure, venture strategy and the top management team's characteristics. The authors obtained the maximum results when observing the interaction of all investigated factors, rather than each factor in isolation. Although this analysis confirmed that investors pay great attention to the top management team, it revealed that the biographical characteristics of each entrepreneur had little impact on new venture performance. However, the authors emphasised in the study that the conclusions do not imply that the entrepreneur is insignificant, but rather that the biographical profiles are not a key success factor. On the basis of this research, the results of the empirical examination should reveal factors pertinent to the management team to be important, but not the educational background.

### **Other factors**

With regard to a complete management team, the investigation by Davis et al. (1985) asserted that, although a full team with experts covering each area is preferred, VCs also favour entrepreneurs who are confident enough to realize that they do lack the necessary skills or network over acquiring seasoned professionals.

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<sup>117</sup> Davis et al. (1985)

The research of Stuart/Abetti (1987) indicated a strong negative correlation between an initial quantified success and market attractiveness, i.e. companies operating in small/slowly growing markets demonstrated a higher success rate compared to companies focusing on large/rapidly expanding markets. A positive correlation also exists between the top management's entrepreneurial characteristics, the team's experience, new business requirements for the initial quantified success, and subjective success. However, the authors repeatedly emphasised the fact that their test sample was rather small and included only a small number of companies orientated towards new technology.

Zider (1998) provides an outline of an entrepreneur's ideal profile as envisaged by the VC:

- qualification in a "hot" area of interest
- diverse sales or technical advances such as FDA approval with reasonable probability
- is able to tell a compelling story and is also presentable to outside investors
- recognises the need for speed to an IPO for liquidity
- understands the need for a team with a variety of skills and therefore sees why equity has to be allocated to other people
- has a good reputation and can provide references demonstrating competence and skill
- works diligently towards a goal but maintains flexibility
- has a good relationship with the investors
- understands the cost of capital and typical deal structures and is not offended by them
- is sought after by many VCs
- has realistic expectations about process and outcome

In conclusion, it is safe to assume that, with regard to the business to be undertaken, an understanding of the marketplace (including market needs, threats and opportunities) as well as product/service, production and distribution requirements are all fundamental to a company's success. The business plan is generally considered to be a good starting point to explore the management team's knowledge of potential customers' needs and to find where (and if) a market niche can be established rapidly.

Taking all the above lines of reasoning into account, one can agree with Saftlas/DiLorentzo (2000), who expostulated that a biotechnology company should ideally employ people who have helped to develop and commercialise pharmaceutical products at large pharmaceutical companies or at successful biotech firms<sup>118</sup>. The management team should also have some operational experience, as understanding and appreciation of the steps and costs involved in the drug development process is important. This insight should lead management to allocate its limited funds to projects offering the highest returns on investment.

Furthermore, when considering these results, the empirical analysis of this thesis should demonstrate that the business plans examined will adduce strong managerial skills and in-depth market knowledge linked with relevant industrial experience. It should also be observed that start-ups with a rather weak or suboptimal management team will not have survived since the investment placement was made.

#### 4.2. Business Strategy

*“Strategy is always a subject of timing and circumstances”*<sup>119</sup>

As explained in the introductory chapter, several strategic choices are considered to be value-enhancing. They include the patent policy of a company, its product pipeline, as well as its strategic network. In this chapter, the strategic network is based on “official” alliances and co-operations, and does not include the management’s personal network. Although this is indeed a very important factor and has long been the focus of academic interest<sup>120</sup>, it is not the focus of this thesis. Since entrepreneurs do not publicise their personal network in the business plan, this factor simply cannot be evaluated and is therefore not relevant to the current study.

As for the previous subchapter, a summary of previous research results and opinions of renowned experts regarding the three business strategy factors evaluated has been provided. The subsequent propositions will be used as a basis for the empirical examination. Interestingly enough, although the importance of these three factors in the VC decision-

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<sup>118</sup> It seems safe to assume that this assertion holds for all types of healthcare companies, such as medical technology

<sup>119</sup> Fildes (1990)

<sup>120</sup> for example Ostgaard/Birley (1996) in Witt (2004) or Ibarra (1998), Kahle/Bouncken (2002), Brin (2005)

making process has been indicated by previous research, e.g. Weber/Dierkes (2002) and Scheibehenne et al. (2003), these issues have rarely been analysed in the context of the VC process.

Before opening the discussion, the definition of risk-minimising strategies as used in this dissertation must be clarified. For the purpose of this work, the three strategies favoured by VCs, i.e. patents, the firm's product pipeline and alliances<sup>121</sup> with other players in the industry, are termed as risk-minimising.

#### 4.2.1 Patents and Product Pipeline

Thus far, the author is unaware of any study which has examined the extent of existing patents and/or product pipeline for an initial company valuation. The only exception may be Scheibehenne et al. (2003), who included the patent situation as well as the size of the product portfolio<sup>122</sup> in their evaluation. Although one of the focuses of their research was to determine the reasons why business plans of biotechnology start-ups were unsuccessful in the screening process, the study was based on interviews only and did not evaluate successful and unsuccessful business plans in themselves. Furthermore, even though a number of research studies have been conducted on both issues, they have hitherto been connected with establishing alliances. The results and significance of these past studies will be discussed in the next subsection.

### **Patents**

Knowledge and innovation are essential production inputs within the biotech and life sciences sector<sup>123</sup>. For this reason, companies in this industry seek to increase their intellectual capital while striving to find measures to protect it<sup>124</sup>. These approaches are referred to as information, knowledge and innovation management. Although a full discussion of this topic lies outside the frame of the current paper<sup>125</sup>, we will address the two most prominent practices, namely patenting and strategic alliances<sup>126</sup>, e.g. strategic networks.<sup>127</sup>

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<sup>121</sup> The word alliance and cooperation will be used interchangeably

<sup>122</sup> They do not indicate what kind of products were included, i.e. what stage a product had to reach in order to be included in the product portfolio.

<sup>123</sup> Oliver (2001), Maurer (2002)

<sup>124</sup> Kahle (2004) Rohnke (2002)

<sup>125</sup> For further discussion, see Nonaka et al. (1995, 2001), Oliver (2001)

<sup>126</sup> See also Chapter 5.2

While there are many ways in which a company can protect its gains against technological investments<sup>128</sup>, patenting is among the most widely used<sup>129</sup>. A patent is an exclusivity right to an inventor to prevent their product being produced, commercialised or utilised in any other way, such as licensing it to other parties<sup>130</sup>. Patenting is necessary to ensure that entities, such as the creator of an innovative product, receive a return on their R&D investment through a monopoly status for a given period. Patents therefore help to delay imitation by other firms and protect the venture's gains from R&D spending and product introductions<sup>131</sup>. Levin et al (1987)<sup>132</sup> observed that patenting represents the most effective means of protecting new ventures' technological resources, as other means may not be very feasible. They also suggested that patents held by the technologically orientated venture are often the firm's most marketable assets.

Keeley/Rice (2002) indicated that a new firm could attract or seek partners having resources it needs to leverage the advantages of this knowledge when patenting its technological knowledge. It may therefore be argued that patents enable the start-up to pursue technology and product development activities which extend beyond the boundaries of the internal organisation. This suggests that technology portfolios may reveal benefits beyond their value to the firm's internal development efforts<sup>133</sup>. A further advantage of patents is that they create a barrier to entry for potential competitors.

Hirschey (2003) argued that one of the most useful measures of the pace of inventive activity is the number of patents granted to a specific firm over a given time period. The widespread use of patent statistics stems from the fact that long-available patent data is derived from an objective and slow-changing standard. A wide body of economic research has documented the strong relationship between patent numbers and R&D expenditure, which implies that patents are a good indicator of differences in inventive activity across firms<sup>134</sup>. Unfortunately, while

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<sup>127</sup> Sydow (1992) in Doloata (2002), Dolata (2002)

<sup>128</sup> Kahle (2004) has investigated some of these, including (inter)national patents, or special security systems in place.

<sup>129</sup> Adler (1989), Bell/McNamara (1991), Dussauge et al. (1992), Kotabe (1992), McGrath (1994), Teece (1986), Utterback (1994), West (1992) in Zahra (1996)

<sup>130</sup> Hacking (1986)

<sup>131</sup> Hacking (1986), Teece (1986) in Zahra (1996)

<sup>132</sup> in Zahra (1996)

<sup>133</sup> Keeley/Rice (2002)

<sup>134</sup> Griliches (1990) in Hirschey (2003)

patent statistics remain a unique and valuable resource for studying the process of technical change, problems are still encountered when patents are used as a proxy for the pace of inventive output at the firm level<sup>135</sup>.

While all patents must meet objective criteria in terms of novelty and utility, not all patents have the same technical scope nor do they have the same economic significance. Patent scope depends on how inventions are linked to one another and the extent to which rapid advances require a diversity of technical and non-technical inputs. The broad or narrow scope of a given patent determines the ability of competitors to produce substitutes without fear of infringement suits and helps define the amount of “monopoly power” enjoyed by a patent holder. Patents which are readily identifiable with end products tend to be more valuable than the average patent. Many low-value patents cover intermediate processes which, in themselves, do not lead directly to marketable products. Therefore, despite research documenting the generally robust, positive effect of patent statistics on the market value of the firm, not all patents create equal value in the eyes of investors. Furthermore, as Hirschey (2003) has highlighted, the use of patent statistics in economic research has been impeded by the fact that patents vary in their economic importance or value. Simple patent counts are thus not fully informative with regard to the economic value of innovative output<sup>136</sup>. It follows that the influencing factor, although important to a venture’s success, should not be a major success factor in the empirical research study.

In addition, important differences exist among firms in terms of their propensity to patent. According to Griliches et al. (1989)<sup>137</sup>, no one-to-one relationship between R&D expenditures and patenting activity could be proven. In his research, Böhringe (2002) revealed that small companies are less prone to utilising patents for product protection, as they are often not willing or able to invest in attaining patent protection. These results have been substantiated by a recent investigation by Kahle (2004). A second motive for this ambivalence to invest in patent protection, as stated by Böhringe (2002), is that many small-sized companies do not believe that patents are necessary or that they will provide the firm with any competitive advantage. However, a study by the German Fraunhofer-Institute<sup>138</sup> in 2003 revealed that an increasing trend towards patent applications can be deduced from the present data. The

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<sup>135</sup> Hinchey/ Richardson (2001) in Hirschey (2003)

<sup>136</sup> Hirschey (2003)

<sup>137</sup> in Hirschey (2003)

<sup>138</sup> BMBF (2004)

rationale presented in this study is that a growing number of small companies understand that patents will improve their bargaining position when negotiating with potential cooperation partners or investors. Nevertheless, it has to be emphasised that none of these studies revealed how many biotechnology companies were included in the test sample or what percentage of small biotechnology companies decided to forgo the option of patent protection. In view of the above arguments, and the general set-up of the biotechnology market (see Chapter 3), it seems safe to assume that the results of the qualitative research study will reveal that the majority, if not all, of the investigated start-ups have applied for patent protection.

### **Product Pipeline/ R&D**

Firms operating in highly uncertain and rapidly changing environments need to maintain technological expertise, particularly when competitiveness is dependent on product innovation<sup>139</sup>. Thus, an important aspect of a venture's technology strategy is the rate at which a firm develops<sup>140</sup> and introduces new products onto the market<sup>141</sup>. In an industry consisting of commercial high technology firms, such as life sciences, these two characteristics have been, and are still, seen as major success factors. Some advantages which frequent product introductions may generate have been given by Zahra (1996), which meet customers' needs, generate profits, and even pre-empt competition.

This supports the claim of Acs/Audretsch (1990)<sup>142</sup>, who drew attention to the fact that rapid product introductions may enhance a firm's ability to differentiate itself from its competitors. Other significant advantages resulting from a fast turnover of products developed and commercialised may be early access to cash flow, external visibility and/or early market share. However, not only start-ups benefit from commercialising new products. Especially in the pharmaceutical industry, companies are permanently seeking new products so as to obtain and maintain any first-mover advantage. In fact, in the pharmaceutical industry the effectiveness of patent protections leads to patent races in which a "winner-takes-it-all" scenario exists. Deeds/Hill (1996) argued that a strong relationship exists between the rate of new product development and the achievement of first-mover advantage. They also

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<sup>139</sup> Penrose (1959), Clark (1987), Itami (1987), Nelson (1991) in Keeley/Rice (2002)

<sup>140</sup> Zahra (1996)

<sup>141</sup> Adler (1989), Ali (1994), Bell/McNamara (1991), Burrill/Lee (1992), Dussauge et al. (1992), Kotabe (1992), Lefebvre et al. (1992), Zarah/Covin (1993), Zahra/Sisodia/Das (1994) all in Zahra (1996)

<sup>142</sup> in Zahra (1996)

underlined the fact that first-mover advantages may be of special importance in industries where patent protection is weak. Some of these benefits may be market pre-emption, reputation effects or experience curve effects<sup>143</sup>.

In 2004, Coe evaluated the relationship between R&D investment and the pipeline productivity of pharmaceutical companies. This analysis led to the conclusion that a linear relationship exists between these two factors. Coe (2002) demonstrated that the theoretical belief that greater R&D efforts should increase the probability of successful product development is not tenable. Furthermore, Coe (2004) stressed that size alone does not enhance the ability to achieve higher productivity. On the contrary, she postulated that higher investment levels in R&D, with no other support, would only generate higher revenues and not higher returns. The author continued by recommending that pharmaceutical companies employ an alternative growth strategy to solve their productivity crises. Coe considered a so-called “networked pharma” as a suitable substitute<sup>144</sup>.

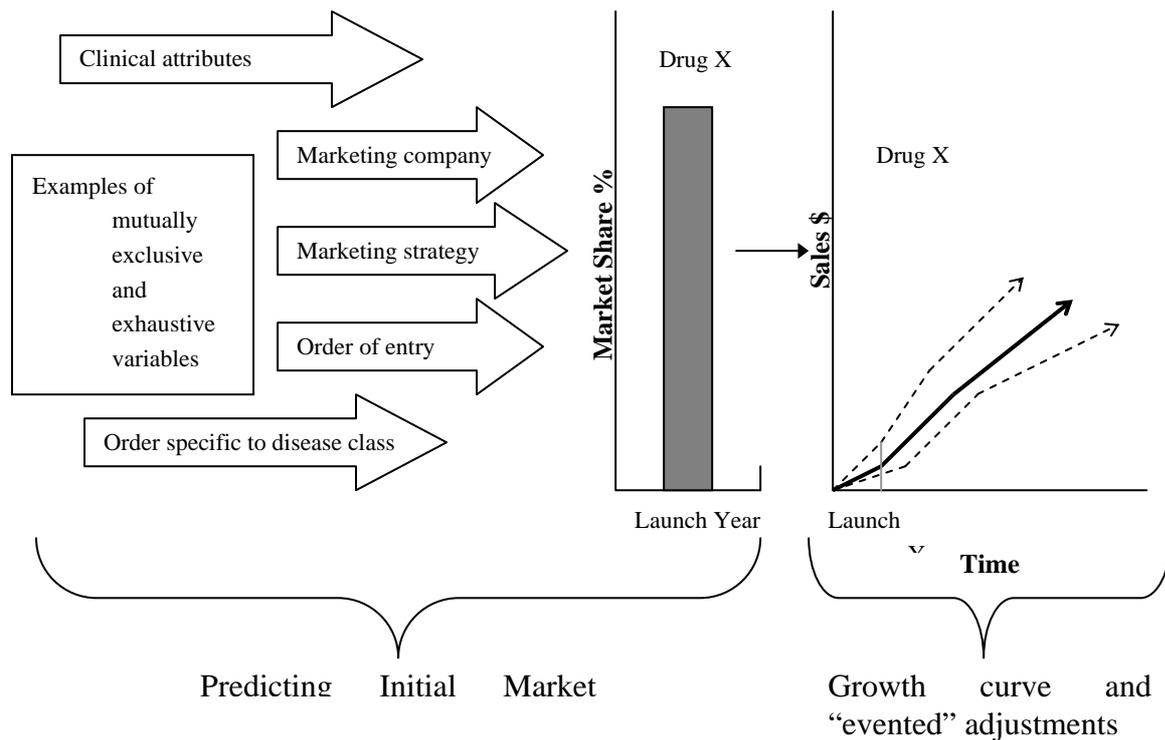
Although Scheibehenne et al. (2003) argued that a too small product portfolio may lead to an unfavourable decision for a start-up seeking private equity, the impact of the product pipeline on the initial company valuation of biotechnology start-ups has not yet been investigated. Nonetheless, the author found two practical applications for product pipeline valuation used by different companies.

Diagram 4.1 depicts the method used by the company Datamonitor, a leading research and analysis company, when estimating the future growth of pipeline products.

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<sup>143</sup> Deeds/Hill (1996)

<sup>144</sup> See Chapter 5.2 for an explanation and discussion

**Diagram 4.1: Overview of Datamonitor's health care pipeline drugs forecasting approach**

Source: Datamonitor (2003)

The concept used by Datamonitor is set out to highlight the drivers of sales growth. In this model, three key stages involved in forecasting the potential market share of a pipeline product are highlighted. First, the market share at launch is estimated, after which a growth curve is applied to the initial market share. Finally, a scenario analysis is performed, i.e. the sales forecast is manipulated (or "evented") to incorporate possible future factors likely to influence the sales of the new product. Although this method is quite straightforward, it is more likely to be applicable for products entering an existing market where information for a forecast such as the market structure is available.

A different method has been devised by Houlian Valuation Advisors (HVA), which seeks to determine a company's value based on the phase of development of its product(s)<sup>145</sup>. The company argued that, in direct contrast to established companies, the value of an early-stage life science company might increase even though the company sustains substantial and continual losses. HVA also stressed that start-ups often hold a product portfolio which is far from being marketable, but that this underlying "technology value" increases as a life science

<sup>145</sup> Robin/Malak

start-up progresses through its life cycle towards becoming a viable company<sup>146</sup>. For value indications under this approach, HVA applied a value matrix<sup>147</sup> of recent financial and development phase information for comparable companies.

The proxy used by HVA was the invested capital-to-market capitalisation approach. Their underlying assumption was that market capitalisation is based on valuations by industry analysts, who have already considered the potential market size, the likelihood of governmental approval (e.g. FDA), and the projected introduction data of a company's developing products. HVA argued that since life science start-ups seldom generate adequate cash flows to support their R&D efforts, they must rely on invested capital in order to advance their products. As the product development continues<sup>148</sup>, the certainty of success and of receiving the anticipated cash flows increases substantially, resulting in a corresponding increase in the firm's value. On the basis of comparable company ratios, HVA viewed the monetary amount of the invested capital as a representation of the start-up's progress, since it could not have reached its current state of development without the placement of such capital.

A study by Stuart/Abetti (1987) has shown that, despite the tendency of technologically orientated entrepreneurs to emphasise R&D and technological advances, a negative correlation exists between initial success and R&D intensity. Similarly, in their exposition, product uniqueness, which the authors claimed to be dependent on R&D intensity, did not appear to be a significant factor in determining initial success. Stuart/Abetti (1987) drew the conclusion that a company should focus its limited resources on marketing efforts once the functional advantages of the firm's product had been demonstrated. However, these results may be influenced by the fact that Stuart/Abetti (1987) used a small test sample, which included only a limited number of new technology-orientated start-ups. Furthermore, it is questionable whether life science companies were included in the test sample.

Additionally, valuation effects of corporate research and development (R&D) expenditure have long been used to provide useful, albeit indirect evidence of the economic consequences

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<sup>146</sup> while its products proceed through successive milestones

<sup>147</sup> The matrix includes each comparable company's market value, market value less cash (the technology value), invested capital, products under development, and the corresponding development phase of each product.

<sup>148</sup> HVA does not include the risk of potential setbacks

of the firm's inventive and innovative activity<sup>149</sup>. For example, Hirschey/Weygandt (1985) were among the first to use market-value data to establish the importance of R&D as a source of intangible capital. The authors also showed that R&D expenditure has consistently large and positive influences on the market value of all size classes and document that the strength of this relationship is inversely related to firm size. Like current cash flow information, data on R&D spending appears to help investors form appropriate expectations concerning the magnitude and variability of future cash flows.

### **Diversification**

When companies are considering expanding their marketability, they may do so in various ways. One available option is to expand the product or service offerings into new geographical regions, or to enter into new markets with a new product/ technology altogether. Diversification is often used as a growth choice and is an indicator of how the venture competes with its technology<sup>150</sup>.

Generally speaking, there are three types of diversification:

- Vertical
- Horizontal
- Lateral

Vertical diversification is the inclusion of services or production steps within the supply chain. Strategically speaking, the mechanism of upward integration is especially useful for companies with platform technologies that have reached their limitations in terms of adaptability. Thus, the inclusion of other services may in the long term increase the profit margin.

In this industry, horizontal diversification denotes when a substance or a technology is used for completely different segments of the health care market. One famous example is Aspirin. Aspirin is used for pain management. However, this substance is also used to lower high temperature or by patients suffering from certain heart problems. The problem with this

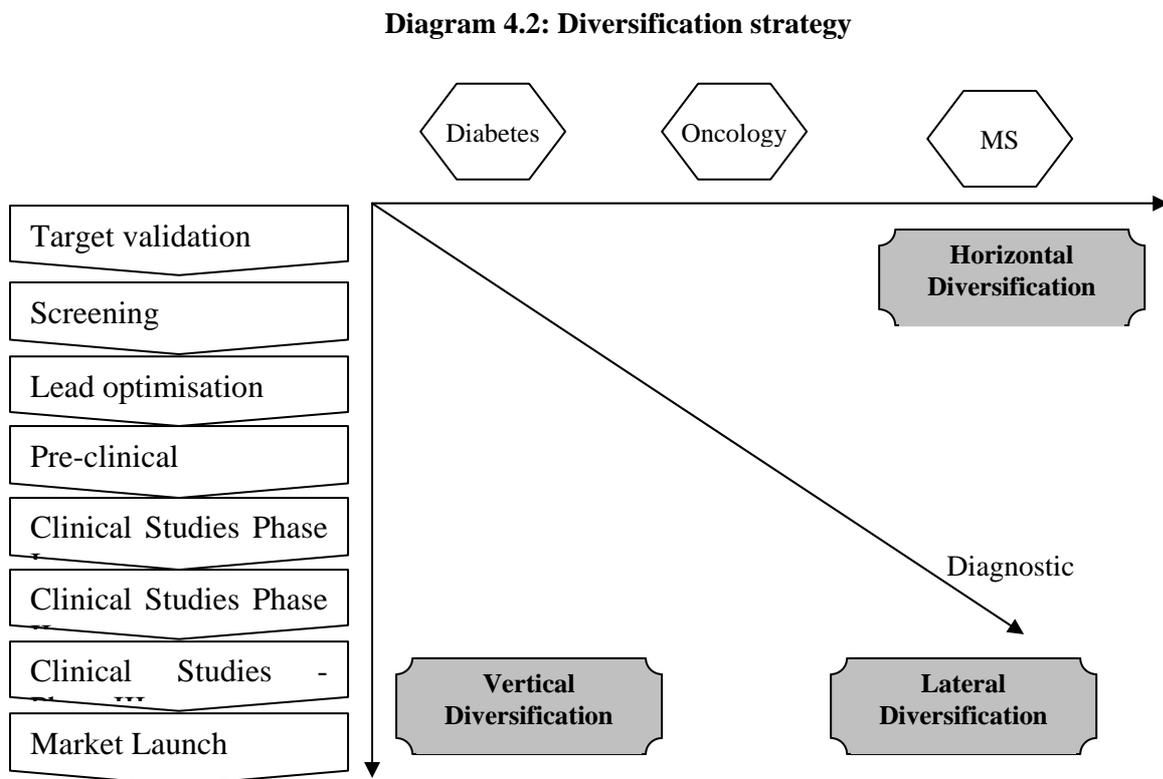
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<sup>149</sup> Hirschey (2003)

<sup>150</sup> McCann (1991)

strategy is that young biotech companies usually lack the managerial, human resource and financial resources required for the R&D of more than just one indication field.

The intensified merger of therapeutic and diagnostic areas has led to so-called lateral diversification, i.e. the migration of companies' competence into completely new areas. Even though this strategy is not a common one, development in various research areas, such as pharmacogenomics<sup>151</sup>, already points in this direction. An example of these diversification strategies is provided in Diagram 4.2.



Source: Müller/Herstatt (2002)

These rather generic strategies need some further fine-tuning with regard to the “how-to” strategy. In order to implement a diversification strategy, a company has several options:

- Evolution/ Growth
- Alliance and Cooperation
- Acquisition
- Merger

<sup>151</sup> Pharmacogenomics deals with the reciprocal action between genes and the active substance, or active substance candidate.

Even though all of these options are viable options, for the purpose of this thesis only the second option, i.e. alliances and cooperation, will be investigated further. The reason for this is that only the second option is of real interest to a VC when valuing a proposed project.

It is usually rather difficult for a biotech start-up to become a fully integrated pharmaceutical company, due to the numerous barriers of entry. Thus, the first option, i.e. evolution, is not a viable option, even though some companies have used it in the past – examples are Amgen, Biogen and Genentech. Notwithstanding, this strategy may be viable for a company focusing on a small niche market where the resources needed are not as high as in other market segments.

The third and fourth option are also not interesting at the valuation stage, as these are only interesting if the company has already undergone a merger or acquisition, which is usually not the case at an early stage. However, if these two strategies are the preferred exit strategies it could influence the VC's valuation.

The author believes that, when focusing on the valuation phase, the strategy of interest should be the number and quality of the alliances the company has already built, as these are good indicators of the value of the company. Issues surrounding the importance and risk of alliances will be discussed in further detail in the following section.

#### 4.2.2 Alliances and cooperation

*The biotechnology field has proven to be highly creative in the area of corporate alliances*<sup>152</sup>

The biotechnology industry is peopled by entrepreneurial start-ups in which the rate of new product development is a critical competitive dimension. However, as Deeds/Hill (1996) have indicated, these start-ups often lack many of the complementary assets required to develop and launch a new product. Moreover, in an industry in which strong patent protection means that the first-mover advantages obtained by those who win the patent races are significant, a strong incentive to enter alliances<sup>153</sup> generally exists<sup>154</sup>. Nicholson et al. (2002) have asserted

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<sup>152</sup> Fildes (1990)

<sup>153</sup> Alliances can generally be described as “arrangements by which firms combine resources to accomplish particular tasks.” These arrangements can take the form of licensing, joint ventures and collaborations. A strategic alliance comprises companies which remain legally

that not only biotechnology companies rely heavily on alliances with pharmaceutical companies to finance their research and development expenditure, while pharmaceutical firms rely heavily on alliances to supplement their internal R&D. Recombinant Capital, which reported that strategic alliances generated three times more capital than equity placements in 1999, in fact supports this statement<sup>155</sup>. Powell et al. (1996) also substantiate this finding by claiming that biotechnology firms without alliance partners are rare<sup>156</sup>.

Coe (2004) has recommended that pharmaceutical companies seek strategic alliances with specialised vendors and (bio)pharmaceutical companies with the intention of outsourcing specific parts of the firm's value chain, such as discovery, product development or even manufacturing<sup>157</sup>. These specialised companies are arguably more efficient and progressive in their specialised field than many pharmaceutical companies<sup>158</sup>. The author stressed that this strategy is not only valuable for established pharmaceutical companies, but also for small (bio)pharmaceutical companies that have yet to start, or have only just started, generating revenue. By building up a network of alliances, both parties usually have access to resources (resource-based view<sup>159</sup>) where and when required. Moreover, Coe's (2004) analysis somewhat supports Kirchoff (1994), who has noted that start-ups in fields such as biotechnology need larger and more international networks than in other industries<sup>160</sup>.

Furthermore, the existence of R&D cooperation between biotech start-ups and large pharmaceutical companies is viewed as a kind of "good housekeeping seal of approval." This approval is more commonly termed as a reduction of the liability of newness<sup>161</sup>. VCs view it

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independent and cooperate to achieve competitive advantages by exchanging or consolidating resources and services. Alliances preserve legal independence and – outside the field of cooperation – even economic autonomy. The alliance can be terminated and their interdependency is confined to the field of cooperation.

<sup>154</sup> Nicholson et al. (2002)

<sup>155</sup> Müller/Herstatt (2002), Nicholson et al (2002)

<sup>156</sup> In Oliver (2001)

<sup>157</sup> Kahle (1987) discusses the required cost-benefit analysis when considering the option of outsourcing part of the firm's value chain. The author has used the problem of "make or buy" with regards to the Galenical form of pharmaceutical agents.

<sup>158</sup> Coe (2004)

<sup>159</sup> For example Tsang (2000), Zündorf (1994), Eisenhardt/ Schoonhoven (1996) in Oliver (2001)

<sup>160</sup> in Witt (2004)

<sup>161</sup> E.g. Bruderl/Schussler (1990), Oliver (2001)

as such, as “big pharma” has already undertaken a due diligence where the technology has been validated<sup>162</sup>.

Alliances are an appealing way for companies to quickly combine distinctive strengths and opportunities<sup>163</sup>. Biotechnology companies can utilise licensing, joint ventures, partnering agreements and acquisitions<sup>164</sup> to gain market access with either existing or new technologies. Furthermore, forging cooperation is one type of strategy which enables a company to gain external resources for growth<sup>165</sup>, technologies and markets effectively<sup>166</sup>. This in turn may help bridge the gap between a firm’s present resource endowment and future expected requirements through the provision of access to external resources<sup>167</sup>. Alliances can provide shortcuts, especially for those racing to improve their R&D and production efficiency and quality control<sup>168</sup>. By joining resources, companies may thus be able to utilise economies of scale and scope<sup>169</sup>.

The advantages of properly utilised alliances over traditional organisational arrangements are manifold, including faster market penetration (Gomes-Casseres (1989))<sup>170</sup>, the sharing of financial risk (Jorde/Teece (1989)), possibilities for technology transfer (Lei/Slocum (1992))<sup>171</sup> and knowledge transfer (Gomes-Casseres et al (2004), Kogut (1998)), and increased

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<sup>162</sup> Müller/Herstatt (2002), Nicholson et al (2002)

<sup>163</sup> Newman (1992)

<sup>164</sup> McCann (1991)

<sup>165</sup> Hoffmann/Schaper-Rinkel (2001)

<sup>166</sup> Keeley/Rice (2002), Hamel et al. (1989)

<sup>167</sup> Hoffmann/Schaper-Rinkel (2001)

<sup>168</sup> Hamel et al. (1989)

<sup>169</sup> Small biotech firms have pioneered new drug discovery technologies, which rely on microbiology and genomics, whereas traditional pharmaceutical companies have a superior expertise in chemistry, which is essential for the formulation of drugs from the lead compounds generated by drug discovery. Pharmaceutical companies are generally larger, have more experience and possibly economies of scale and scope in conducting clinical trials for safety and efficacy, navigating the FDA approval process, manufacturing, marketing and sales. Biotech-pharmaceutical deals may thus be viewed as a vehicle by means of which the parties exchange services, given their different skills and expertise.

<sup>170</sup> The study also sought to provide a framework to aid in the decision-making process of managers seeking joint ventures. Gomes-Casseres (1989) recommend that managers only enter an alliance when the firm needs to do so, in order to expand to compete successfully, but not when it is merely trying to exploit its competitive advantage or when there is a conflict of interests between (the) two partners. They also point out that a firm usually has a strong bargaining position if it brings advanced technology into the relationship or is willing to make major investments.

<sup>171</sup> In Miles et al (1999)

production efficiencies (Datta (1988)). Such arrangements may be particularly suited to early-stage technology firms. Alliances can work to benefit these firms by allowing them to build on their strengths and overcome their weaknesses.

Despite these proposed advantages and increased use of alliances, however, little insight has been gained regarding the overall impact of using alliances on a firm's success. To date, most research on alliances has focused on issues related to the success or failure of the alliance itself (see for example Lyons (1991) or Tyler/Steensma (1995)<sup>172</sup>), or on how and when alliances may benefit early-stage technology-based firms (see Miles et al. (1999)).

Much attention continues to be focused on the use of strategic alliances, particularly for early-stage technology-based firms who may be able to utilise alliances to overcome inherent problems in accessing markets, reaching economies of scale, and/or further developing innovative technologies. However, as the work of Miles et al. (1999) revealed, although seeking alliances is a widespread strategy used by early-stage technology firms in order to exploit their valuable resources while gaining access to markets, there was no performance difference between a firm which was involved in an alliance and one that was not. Further investigations by Miles et al. (1999) showed that only when a firm used the strategy of forming alliances out of choice and not necessity, i.e. to manage resource dependencies, were alliances associated with firm success.

McGee/Dowling (1994) addressed various cooperative arrangements. The most important finding of their work is that the investigated relationship was positive when the new venture's management team was relatively more familiar with the industry, markets and/or with similar technologies. In other words, the results of McGee/Dowling (1994) specify that managers who were relatively more experienced were more proficient at using R&D cooperative activities to strategically position their firms in comparison to their less experienced counterparts. Evidently, these managers were better able to identify the risks and benefits of engaging in such cooperative activities. Additionally, McGee/Dowling (1994) provide preliminary evidence that greater knowledge possessed by the management team may have enabled the new ventures to reduce the costs associated with R&D market transactions. Furthermore, a study by McGee et al. (1995) showed that to leverage external resources

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<sup>172</sup> The study serves as a merger between theory and the practical factors important to the selection of technological collaboration.

through alliances successfully, the potential ally possesses extensive know-how in the area of cooperation.

The work of McGee/Dowling supports the concept devised by Cohen/Levinthal (1990)<sup>173</sup>, which proposes the notion that founders (or the management team in general) will not benefit from alliances if they have not obtained the necessary skills and capacity to absorb the information provided. Based on this assumption, Cohen/Levinthal (1990) argue that various management-related issues such as entrepreneurial experience, social competencies, and level of university education shape the degree of benefit which the start-up can foster from its alliances. Various research studies discussed in Chapter 4 (Management) support this concept<sup>174</sup>.

Furthermore, work by Hoffmann/Schaper-Rinkel (2001) demonstrated that alliances provide advantages with regard to high environmental uncertainty and knowledge dispersion, as they provide greater strategic flexibility and foster rapid learning.

The research of Keeley/Rice (2002) provides an insight into the relationship between a technology-based firm's efforts to build a portfolio of technology resources, the value of which can be understood by potential partners, and its pursuit of development activities extending beyond the boundaries of the internal organisation. The authors hypothesised that new firms were able to enhance their capacity for forming alliances by building portfolios of technologies and increasing the communicability of their value through patents. The findings of this exploration revealed that start-ups who had built up a patent portfolio during the first six years of their existence were more likely to form alliance relationships than those who had failed to do so. These findings are consistent with those of Venktaraman et al (1990) and Eisenhard/Schoonhoven (1996), who all identified firm-specific resources as advantageous to start-ups seeking external relationships. However, Witt (2004) draws attention to the fact that firms diverge in terms of the available resources (both tangible and intangible) and even the size, the company's strategy, the stage of development or the market focus of a start-up may influence the correlation between a company's networking activities (including any established alliances and cooperation) and its success.

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<sup>173</sup> In Witt (2004)

<sup>174</sup> Examples are Bates/Bradford (1992) or Robinson/Sexton (1994)

Deeds/Hill (1996) argued that one way an entrepreneurial firm can increase its rate of new product development is by entering into strategic alliances with firms possessing complementary assets. Their analysis revealed that:

- a firm's rate of new product development is a positive function of strategic alliances which it has entered into,
- but the relationship between strategic alliances and the rate of new product development may not be linear, and
- beyond a certain point, negative returns may set in.

They argue therefore that the relationship between the number of alliances and the rate of new product development may be an inverted U-shape.

One of the reasons for this relationship is that not all alliances will make equal contributions to increasing the rate of new product development. Furthermore, the economic law of diminishing returns suggests that the more alliances a firm engages in, the more likely it is to enter some alliances whose marginal contribution is relatively minor. Such a phenomenon on its own is enough to suggest diminishing returns. Further, Deeds/Hill (1996) argued that poor performance may occur if the firm discovers that the complementary assets provided by the partner are a poor match, fail to live up to the promises made by the partner, or a partner may opportunistically exploit an alliance, expropriating the firm's know-how while providing little in return. Such problems may arise, as the effectiveness of selecting and managing alliance partners is likely to be negatively related to the number of alliances which a firm is managing. Due to information processing requirements, the quality of seeking new partners and the ability to monitor the partners' actions are likely to decline as the firm increases the number of alliances in which it is involved. Consequently, the authors argue that this reasoning leads to the prediction that beyond a certain point alliances will be increasingly vulnerable to poor performance. This raises not only the possibility of diminishing returns to the number of alliances, but also negative returns as the number of alliances increases past some critical point<sup>175</sup>.

Deeds/Hill's (1996) analysis provided fairly strong evidence in support of the relationship outlined above between the number of strategic alliances and the rate of new product

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<sup>175</sup> Deeds/Hill (1996)

development. They concluded that at low levels strategic alliances are positively related to new product development, but as the number of alliances increases, the benefits begin to decrease, and at high levels, the cost of an additional alliance actually outweighs the benefit. Their conclusion is also strengthened by similar results obtained by Pennings/Harianto (1992)<sup>176</sup>.

Kogut (1988) compares the perspectives of transaction costs and strategic behaviour in explaining the motivation to form a joint venture. In addition, the author proposes and develops a theory of joint ventures as an instrument of organisational learning. Chan's (1983) work reveals that entrepreneurs are tempted to offer inferior products when uninformed investors dominate the market, i.e. all investors are facing positive information costs. One suggested reason is that, in the absence of informed investors, the entrepreneurs will find it in their interest to offer less desirable projects leading to the degeneration of the projects undertaken. However, the work by Chan (1983) is lacking in grounded reasoning for this motive.

Lerner/Merges (1998) examined the allocation of property rights in biotech-pharmaceutical alliances, testing the theory developed by Aghion/Tirole (1994)<sup>177</sup>. Lerner/Merges (1998) found evidence that biotech firms with more financial resources retain a relatively large amount of the property rights, which appears to be consistent with an efficient allocation of rights. However, Lerner/Tsai (2000) found that deals signed during periods when it was difficult for biotech firms to raise public or private equity assigned most of the property right to the licensee (usually a pharmaceutical firm), and these alliances were less likely to lead to a drug approved by the FDA. This appears to suggest inefficiency in the allocation of rights, presumably resulting from imperfections in the market for financing biotech deals. Pisano (1997) found that drugs developed by biotech-pharmaceutical collaborations were less likely to reach the market than drugs developed by a single firm, which led him to conclude that biotech companies used their informational advantage to out-license their low-quality products. This suggests a different type of inefficiency – a persistent asymmetry between

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<sup>176</sup> in Deeds/Hill (1996)

<sup>177</sup>The authors argue that proper rights (e.g. the responsibility for managing clinical trials or product manufacturing) should be assigned to the R&D firm when the marginal impact of its effort on the product's value is greater than the marginal impact of the licensor firm's financial investment on the product's value.

biotech and pharmaceutical firms leading to a quasi-lemons phenomenon in the market for deals<sup>178</sup>.

Nicholson et al. (2002), however, have contradicted Pisano's findings. Their research revealed that *"drugs that are jointly developed are more likely to advance in clinical trials than drugs that are developed by a single company, so that the first-deal discount is not consistent with the post-deal performance of these drugs."* They also found that *"biotech companies that sign deals receive substantially higher valuations from Venture Capitalists and from the public equity market, which implies that the discounts are rational"*. It may thus be concluded that a biotechnology company developing its first product may benefit from forming an alliance with a pharmaceutical company, which sends a positive signal to prospective investors. Nicholson et al. (2002) argued that the preponderance of early-stage deals is consistent with their hypothesis that the incremental value from co-development is greatest if alliances are formed early in a drug's life.

They also indicated that an alternative, not mutually exclusive, body of theory focuses on imperfect information and the role of financial intermediaries which can evaluate and signal to markets the quality of other firms (Chemmanur/Fulghieri (1994), Chemmanur (1993), Chan (1983), Campbell/Kracaw (1980), Leland/Pyle (1977)). Pharmaceutical firms can be viewed as performing a similar validating function. If investors (Venture Capitalist and investment banks) have less information than pharmaceutical firms regarding the likely success of a biotech firm's products and the quality of its science and management, then by doing a deal with a pharmaceutical firm, a biotech firm can signal its quality to financial markets.

The analysis of Nicholson et al. (2002) found that biotech companies received a 60% discount for their first deal and a 30% discount for their second deal, and that these discounts were not consistent with the post-deal performance of these drugs. One reason for this may be that, since pharmaceutical companies are (plausibly) better able to evaluate the quality of a biotech company's assets and the capabilities of its management than pure financial intermediaries, the discounted payments accepted by inexperienced biotech firms represent implicit payments to reimburse the pharmaceutical company for the cost of producing information. Since a pharmaceutical company not only takes an equity stake in a small firm but also acquires rights to the assets, the pharmaceutical firm may have stronger incentives to invest optimally in

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<sup>178</sup> in Nicholson/Danzon/McCullough (2002)

information gathering than a Venture Capitalist who takes only a partial and temporary equity share.

The fact that drugs in biotech-pharmaceutical alliances perform better in subsequent trials than products developed solely in-house by biotech or pharmaceutical firms confirms that co-development adds value which is sufficient to outweigh any moral hazard problems resulting from sharing development responsibilities. Nicholson et al. (2002) argue that these findings are inconsistent with Akerlof's lemons hypothesis, and state that biotech companies are able to out-license their least promising drugs due to asymmetric information. Their finding that the discount for first deals does not decline or disappear for latter-stage drugs, when more objective information is available, provides further evidence against Akerlof's hypothesis.

Although biotech companies take a substantial discount on their first deal, this nevertheless appears to be rational, as a deal with a pharmaceutical company sends a positive signal to prospective investors. Nicholson et al. (2002) found that biotech firms which had signed a deal usually received substantially higher valuations from Venture Capitalists and other investors at subsequent financing rounds. Additionally, the magnitude of the premium approximately offset the discounted deal payments accepted previously by the inexperienced biotech firm.

In conclusion, the above literature review suggests that the findings of the following empirical research are likely to show that life science companies will have entered, or are seeking to enter, alliances with strong, well-established companies.

## 5. Data Collection

This thesis is based upon an initial screening and evaluation process, for which the only available information to which the VC has access is the business plan. In view of the question that this thesis is trying to answer the only relevant data acquisition instrument is, hence, the business plan. Since the Venture Capital business is a very confidential business, the data acquisition of such highly sensitive and secret information has proven itself to be without a chance. Unfortunately, the expected scientific use of the results of such a study did not outweigh the contacted companies' fear of unintentional publications of internal documents. Despite nearly two years of repeated inquiries to national and international VC companies, and the support of different associations, only four (outdated) business plans were made available.

The companies surveyed are all of Israeli origin and wrote their business plan in the second half of 2000. All four start-ups were able to obtain an investment placement using these business plans. However, during the past few years not all businesses succeeded in surviving turbulent times.

Given the difficult situation with regards to the data acquisition, a thorough quantitative analysis, the original aim of this thesis<sup>179</sup>, and a correct examination of the hypotheses in a strict statistical sense were rendered unfeasible<sup>180</sup>. Therefore, given the set of data<sup>181</sup>, the empirical research was changed from a quantitative to a qualitative approach. In this case, a systematic text-based analysis will be implemented. More specifically, the author felt that, in view of the question set in conjunction with the available material, an explicated content analysis was the most appropriate method<sup>182</sup>. This decision was based on the fact that the explicated content analysis methodology evaluated the material according to certain criteria<sup>183</sup>, which is the method that will be applied in the analysis below.

The dependent variable in this analysis was defined as the company value, i.e. using the content analysis, the factors investigated were evaluated in view of their possible influence on

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<sup>179</sup> which also explains the structure of this work

<sup>180</sup> In fact, this may also explain the lack of scientific work in this very topical area.

<sup>181</sup> The current state of research, which also does not allow the author to test certain factors using quantitative methods which would reveal any meaningful results.

<sup>182</sup> Lamnek (1988, 1989), Flick/ von Kardorff/ Steineke (2003)

<sup>183</sup> Flick/ von Kardorff/ Steineke (2003)

the perceived company value. Here, the company value is divided into two parts, the first part considering the factors linked to the survival of a company, the second section focusing on the actual profitability of the company. Of course, the results produced should be viewed with great caution, given the very small test sample. Its statistical validity is therefore questionable. However, as the reader will note, some interesting results have indeed come to light.

### **Overview of the companies surveyed**

As mentioned above, the four companies are all based in Israel, which is renowned for its innovation in biotechnology and health care. Since further data collection proved to be unfruitful, the author decided to contact previous clients in order to ask permission to use their business plans. As explained above, only four companies allowed the author to use their business plans on condition that their names would not be revealed nor that any other, more recent material would be used. One reason why the companies could be persuaded to do this was that the business plans were written in cooperation with the author and thus did not include any information previously unknown to her. Since the author has contacted the previous clients, she is also aware of their current status. The companies are:

- **Company 1 (C1):** C1 has developed two proprietary drug delivery platforms with different market applications for each technology. Although this company is still in business, it has not advanced very much since the business plan was written and the equity placement received thereafter.
- **Company 2 (C2):** C2 is developing medical devices. It has developed into a well-known company, not only nationally, but also globally. The business plan was written to obtain financing for its global expansion strategy. At the time, the company had been in existence for some time, but less than 8 years, which for the biotech and medical device market is still tantamount to a start-up stage.
- **Company 3 (C3):** C3 has developed a certain type of packaging that could also be sold to the medical market, although its main alliance partner at the time was based in the health care sector. Despite the rather large potential market applications, the company has since gone bankrupt.
- **Company 4 (C4):** C4 has developed a specialised Internet service site to be used by various clients. Although the company received several investment placements, the site was never launched.

## 6. Evaluation of an Empirical Study

Following the theoretical background discussion, this part of the thesis will focus on the empirical analysis of this work. As explained above, a qualitative approach will be used. In addition to investigating the two broad factors discussed in Part Two, the management team and the business strategy, the last part will investigate other factors which are highlighted in the last subsection.

### 6.1. Management

In Chapter 4, the importance of the management team and various related key factors were discussed. Although a very extensive list of important management characteristics exists, including various managerial skills and character traits, only a few of these can be investigated using available data. In fact, the business plan reveals evidence for only five of these factors, which will be investigated below in greater detail. These factors are:

1. Business experience, e.g. management, financial, logistics, marketing and sales
2. Industrial knowledge/experience
3. Level of education
4. Complete management team or seeking to complete it
5. New venture skills

#### 6.1.1 Experience, e.g. managerial, financial, logistics

In the literature discussion section, the management team's industrial experience was considered to be one of the most important factors for VCs when evaluating a project proposal<sup>184</sup>. All but one company investigated in this thesis, C2, are working together with a scientific advisory board<sup>185</sup>. The companies' scientific advisory board is made up of

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<sup>184</sup> Wells (1974), Poindexter (1976), Tyebjee/Bruno (1984), McMillan et al. (1987), Stuart/Abetti (1987), Gorman/Sahlman (1989), Fried et al. (1993), Zacharakis/Hofer (1998), Gemünder/Konrad (2000), Saftlas/DiLorentzo (2000)

<sup>185</sup> The author knows that all companies are working together with a scientific advisory board. However, Company 2 has refrained from including any details of such a board in its business plan. Since this thesis only investigates details known from the business plan, it must be assumed that Company 2 is not working with a scientific advisory board. If a VC would like to pursue this potential project any further, this may be an area worth investigating.

internationally renowned<sup>186</sup> professionals. Below, both the top management and, where applicable, the board of directors are investigated.

From the details given in its business plan, C1 does not have a top management team, but only a board of directors (with no assigned position) and a scientific advisory board. This does in fact reflect the situation of the company. In fact, the “management team” was made up of two people, the first two to be introduced in the description of the board of directors’ members list; however, this is not clarified in the business plan:

*Founder 1: “... industrial experience entails managing R&D, product development and design of pre-clinical and clinical studies. X holds extensive experience in developing ...has broad experience in patenting ... and has been involved in all aspects of modern drug development from bench to market. ...was involved in the founding team of X (traded on ...). X was also a lecturer at the....*

*Founder 2: “Prior to founding Company 1, he held the position of Senior VP of ..., an Israeli based company that has devoted itself to the development and marketing of .... X’s other professional experience stems from serving as a Managing Director of ..., as VP marketing of ..., serving as a board member and being responsible for marketing and other related activities of ... products and being responsible for the market research department of ...was a co-founder of (3 companies)...*

*Board member: “... renowned specialist in the field of... is a board member and chairman of various committees...holds various teaching responsibilities...is the director of the internship program at the .... X has held nearly 35 national and international presentations since 19X, while having written 30 publications since 19X.”*

*Board member: “... is currently the president and CEO at ..., a newly created biomedical start-up in the field of.... X has worked as the president and CEO at ..., the Vice President at ..., a Venture Capital fund company, co-managing director of ... a management consultancy firm for high-tech start-ups, the general manager at ...”*

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<sup>186</sup> In the specialised individual fields

C2 has included an overview of both its key personnel, i.e. its top managers, and its board of directors. The majority of C2's key management have been with the company for several years, with depth and experience in their respective fields.

CEO: *"X holds over 20 years of executive management experience in Israel and the United States."*

VP Research and Development: *"X is considered a worldwide expert in the field of ..., and is a director of the ... Association... (relevant association). X has lectured widely and has an extensive record of publications in the field. X also holds a staff position at ... University in the ... Department (a relevant department for both the company and the position)*

European Marketing Director: *"X has 20 years' experience in the marketing and sales of (relevant) products worldwide, including over 15 years in management positions... X has lectured at international management courses."*

VP Medical Affairs: *"has held the position of president of the ...Society of ... (relevant society), and is currently on the foreign editorial board of the ... Journal of ... (relevant Journal), as well as being the Department Manager in ... (an Israeli hospital).*

CFO: *"X has over 10 years of experience in financial and business consulting, both in Israel and in the United States. In addition, X has had extensive experience working with business start-ups in Israel."*

VP of Engineering: *"X has over 20 years' experience as a senior engineer in both military and civilian industries."*

Head of Clinical Department and R&D: *"X is experienced in ... (relevant market sector)."*

C2's Board of Directors is comprised of prominent business leaders and representatives of investors. The board of directors includes both a former president of an internationally

renowned pharmaceutical company, the vice-president of a corporate (pharmaceutical) VC, the representative of a VC, the former president of a bank and of an Israeli incumbent as well as several senior managers from C2, to name just a few.

C3 actually included a line stating their awareness of the (complementary) skills of the founders:

*“...Their complementary skills (of the founders<sup>187</sup>) in both technological development and management and proven past track record are sure to provide added value to the Company.”*

The management team, or as the company termed it key personnel, is made up of various professionals with a wide range of management experience:

*Co-founder, chairman of the board, CEO: “... is the owner of one of Israel’s largest and most successful ... firms. He is also the primary investor and chairman of other ... companies.”*

*Co-founder: “...manages the scientific development and intellectual properties of the Company. X has served as the head of several significant R&D projects at the ... (various internationally renowned institutes and universities).”*

*The CFO: “... is a certified public accountant and has been working in this area for the last 10 years. She was a partner in an Israeli book-keeping firm, has worked as a manager in an accounting firm and, prior to joining Company 3, has held the position of a controller in a leading ...company.”*

*VP Marketing: “... has 18 years of experience in business development and international relations as well as having coordinated international ... projects between ... In addition, he is the chairperson of a large Israeli volunteer organization.”*

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<sup>187</sup> the author

Head Engineer: “... *has extensive experience in ... and has worked as a production and quality assurance manager for various international... companies.*”

Clinical trials and research manager: “... *has worked in the area of ... since 19X; he has served as the Director of ... for the ... for 5 years and managed regional... in the centre of Israel. X is also a consultant for ...*”

The company has also aligned with two renowned scientists, who are both working in the field of medicine and were able to assist in testing the suitability of C3’s product for the medical industry.

The founding team of C4 is made up of various seasoned professionals, all with experience in their particular field. For example:

The CFO: “*With a rich finance and business strategy background, X is currently the vice president of a large investment company, which has a market cap of \$X billion and is serving as the Chairman of the Board of Directors of several ... companies. X’s past experience includes international business consultancy, various executive positions and involvement in start-up companies.*”

The CTO: “... *is currently the managing director of ... where he is in charge of project management and ... X has a vast background of internet based ... database knowledge. X designed several such websites during ...He has also developed...* ”

The various marketing, sales and PR team members also hold many years of relevant work experience:

“*Since 19X ... has years of experience in public relations and marketing for ....*”

“*... comes with a vast background in marketing for internationally renowned...*”

“*... has years of experience in the advertisement and media markets via his work with...*”

The founding team members of C4 have stated their understanding of the importance of a complete management team which has obtained the necessary skills and background needed

for the successful execution of such a venture, in addition to a sound scientific advisory board.

C4 states:

*“The Scientific Advisory Board is one of the critical features of the venture. It consists of senior international practitioners, researchers and academics in the field of .... Their role is to:*

- *Ensure that the professional standards are of the highest order*
- *Help build the confidence of users regarding the quality and objectivity of the service*
- *Be a spokesperson for the Company...*
- *Advise generally and act as a bridge with the latest developments in the profession.”*

This statement is followed by a list of the initial members of the scientific advisory board and a short background of each of them.

#### 6.1.2 Industrial knowledge/experience

VCs view industrial experience as one of the most important factors (Weber/Dierkes (2002), Stuart/Abetti (1987), Siegel et al. (1993)). It follows therefore that the management section should spell out each member’s previous industrial experience.

One of Company 1’s managers in particular has truly extensive industrial experience. The second manager has acquired the necessary industrial knowledge from his previous work:

Founder 1: *“... is an expert in the field of ... (including drug delivery systems)... industrial experience entails managing pharmaceutical R&D, product development and design of pre-clinical and clinical studies. X holds extensive experience in developing ...has broad experience in patenting ... and has been involved in all aspects of modern drug development from bench to market. ...was involved in the founding team of X (traded on ...). X was also a lecturer at the....”*

Founder 2: *“...held the position of Senior VP of ..., an Israeli based company that has devoted itself to the development and marketing of ... (similar products)...”*

The majority of C2's key management have been with the company for several years and thus have industrial knowledge. Furthermore:

VP Research and Development: "... is considered a worldwide expert in the field of ..., and is a director of the International ... Association (relevant association). ... has lectured widely and has an extensive record of publications in the field."

European Marketing Director: "... has 20 years' experience in the marketing and sales of ... products worldwide (relevant market and industry sector)..."

VP Medical Affairs: "... has held the position of president of the ... Society of ... (relevant society), and is currently on the foreign editorial board of the American Journal of ... (relevant society), as well as being the Department Manager in ..."

Head of Clinical Department and R&D: "... is experienced in ... (relevant market sector)."

Although C3's management team has obtained a wide array of management skills, it fails to portray its previous experience in this industry<sup>188</sup>, with the exception of the head engineer.

Head Engineer: "... has extensive experience in ... technology..."

As indicated above, C4 is made up of various seasoned professionals. The industry expertise must actually be viewed in two parts, the internet markets and the medical field which the offered internet service will focus on:

The CEO: "... is an expert in the field of ... (the target medical market). Since 19X, he has served as a Professor and trainer in these fields on an international level.... In addition, X has been involved in the development of various ... (relevant products in the target medical market)"

The CTO: "... has designed several such websites. He has also developed a CD... and is the co-author of ... (both the book and the CD are relevant to the target internet market) "

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<sup>188</sup> which it does not have

Marketing/sales/PR: “...since 19X ...has years of experience in public relations and marketing for...(relevant industry).

...comes with a vast background in marketing for internationally renowned...(relevant companies).”

### 6.1.3 New venture skills

According to some authors, new venture skills are favoured by VCs when evaluating potential projects<sup>189</sup>. At C1 both founders had previously established a new company:

Founder 1: “... was involved in the founding team of ... (traded on ...).”

Founder 2: “...was co-founder of X, which is now owned by ..., Y and Z ...”

In the business plan of C2, no information is provided as to whether or not any of the top management had any previous experience with establishing a new venture. However, in the list of the board of directors there are several individuals who have extensive experience in helping with the growth of a start-up (alone two VCs).

At C3 it seems that only one of the co-founders has any experience with start-ups.

Co-founder, chairman of the board, CEO: “...is also the primary investor and chairman of other core-tech and high-tech companies.”

The same seems to apply to C4.

The CFO: “... past experience includes... and involvement in start-up companies.”

### 6.1.4 Complete management team or seeking to complete it

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<sup>189</sup> Saftlas/DiLorenzo (2000), Weber /Dierkes (2002)

As discussed above, Weber/Dierkes's (2002) research has shown that VCs view a complete management team as being quite important. However, as indicated by Davis et al. (1985), although VCs prefer a full team with experts covering each area, they also favour entrepreneurs who are confident enough to realise that they do need help with acquiring seasoned professionals.

As already stressed in the above section, C1 has not only been unable to assemble a complete management team, it has failed to actually create a management team altogether. Although a recruitment strategy is provided, which also includes management team members, it cannot be termed a strategy as it is not very "practical", since it foresees an average annual growth rate of over 100% for 6 years.

Although C2 has successfully assembled a complete top management team, it has also realised that it needs to acquire experienced local professionals when entering new geographical markets:

*"... efficiently and rapidly ..., the Company's management will recruit qualified and experienced local professionals."*

C3 has not only assembled a complete management team who have worked together as a team for some time; its management team also realises the need for expansion in view of their growth strategy.

Although C4 has not assembled a complete management team, which would have been unnecessary in any case, it has indicated in its recruitment strategy that it understands the need to acquire the right personnel in conjunction with its growth strategy.

### 6.1.5 Level of education

According to Davis et al. (1985), one management quality which is measurable is the individual's achievements in education. Furthermore, Bates/Bradford (1992) found that attractive human capital traits at business entry for entrepreneurs include high educational attainment.

Both managers of C1 have obtained university degrees.

Founder 1: “...holds a Ph.D. from the ... in Pharmaceutical science and is a registered Pharmacist.”

Founder 2: “...holds a bachelor degree from the ... and an MBA from ...”

The educational level of the individual team members of C2 are:

CEO: “... holds a B.Sc. in Industrial Engineering and an M.Sc. in Industrial Management.”

VP Research and Development: “holds a BSc. in Mechanical Engineering, and M.Sc. and Ph.D. degrees in Biomedical Engineering.”

European Marketing Director: “... was educated in the disciplines of business administration and management.”

VP Medical Affairs: “...board-certified in the US in Physical Medicine and Rehabilitation and Electrodiagnostic Medicine...”

CFO: “... holds a B.Sc. in Industrial Engineering and Management and completed her MBA degree in the United States.”

VP of Engineering: “... holds a B.Sc. in Mechanical Engineering, an M.Sc. in Operations Research, and a separate qualification in Aeronautical Engineering.”

Head of Clinical Department and R&D: “ ...is a Ph.D. candidate in Biomedical Engineering and holds a M.Sc. in Biomedical Engineering as well as a B.Sc. ....”

C3 did not specify the educational level of each key member of staff. In fact, the only facts which can be determined from the business plan are that the:

- co-founder, chairman of the board and CEO holds a degree in engineering
- co-founder holds the title of Professor
- CFO is a certified public accountant

- VP Marketing: “...holds a bachelor degree from ... and studied medicine both in the US and Israel.”

C4 did also refrain from spelling out each individual educational level, except in one case. The information provided in the business plan is that:

- the CEO is educated to Ph.D. level
- the CTO: “ ... holds a Diploma of Business Administration and IT from the ... and ... ” (two relevant institutions)

## 6.2. Business Strategy

As discussed in Chapter 5 (Business Strategy), a company’s strategies affect the company value in several ways. Nonetheless, as indicated above, this work only focused on three factors, namely:

1. Product pipeline
2. Patents
3. Alliances and co-operations

### 6.2.1 Product Pipeline

The need to develop new products and successfully introduce them onto the market of biotechnology and medical technology companies was discussed in section 5.3. A product pipeline increases a company’s ability to generate cash flows, secure early market share and differentiate itself from its competitors<sup>190</sup>. All companies should therefore not only describe the products which they are currently developing, but also provide an anticipated timetable of their developing and marketing efforts. Where applicable, a list of relevant markets should also be made available.

C1 has identified several markets where both technology platforms can be applied. The company has stated quite explicitly the stage of its development programme for product X, its leading product platform:

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<sup>190</sup> Acs/Audretsch (1990), Deeds/Hill (1996), Zahra (1996)

*“Company 1 is in the process of starting a 2-year R&D program to develop the X products base on ....”*

The company has provided both a summary of the milestones (such as feasibility studies, clinical trials) and explanations thereof:

*“...is expected to state its Phase I clinical trials for X during Q2 2001 to validate the safety of the product. Phase II clinical trials are scheduled for Q4 2001 and will test the efficacy of the product. The company will prepare for the ... approval with Phase III clinical trials during 2003...”*

*“The company anticipates that the ... amendments to... product regulation will occur by the end of 2002. After Phase I, X will be registered with ... as a ... product. Thereafter Company 1 will begin marketing the X products or technology to ... The company will file for ... approval after Phase III clinical trials.”*

Furthermore, the company has also developed a line of off-the-shelf products which are based on this technology, for the following reason:

*“In order to substantiate the X technology, Company 1 has formulated a line of products... The products are currently ready to enter the market...”*

Although the company also discusses its second product platform, including the relevant industries, it does not affirm the further development of products based on this technology. It only states that:

*“... revenue is expected from (... various agreements/alliances – see below)... The company also anticipates that specialty product formulation and product design projects will add to its top-line growth.”*

C2, on the other hand, describes in great detail the products which it is developing, which are all based on their core technology, and the state of development which each product has reached. For example:

*“Research and development focuses on novel applications of Company 2’s basic technology. Company 2 is currently developing devices for .... All these products are developed for both adults and children. Current trial results show... Future generation products will include.... Company 2 expects to launch the X device early in 2002, product Y in 2002 and Z to be available in Year 2003... it expects product Y to be ready for commercialization in 2002.”*

*“Furthermore, the first modules of products for children will be launched in 2002.”*

C3 states its development strategy very specifically:

*“It is assumed that all ... solutions will be developed according to technical requirements of interested companies. Company 3 will be responsible for delivering a working prototype to its customers to show proof of concept.”*

*“The Company has identified the following areas of future R&D activities, which will expand Company 3’s spectrum of potential users.... The Company also plans to transfer from X technology to Y technology.”*

It also gives an account of the current status of the current project:

*“The Company is currently launching ... for ...use. As a first step in the strategy, ... will be provided to ... as a promotional tool. By using the ... will recognize the ... system and will be more likely to purchase it ... In turn, it is projected that sales of the ... will lead to sales ...”*

C4 is planning to offer various services, which are all explained in the business plan, to several different target groups. Although the company has provided an overview of the milestones, it has done so only for the introduction of the site in various geographical regions and not for each service. The only exception is one service package:

*The pilot site will be launched in the fourth quarter of 2000 where it will focus on establishing its brand name in the ... field locally, even though ... will also have access to all ...content. Building a critical mass of ... will position the company as the only extensive supplier of online services in .... The complete ... offering will begin at the beginning of 2001.*

### 6.2.2 Patents

As pointed out in section 5.3., patents are usually the most effective means of protecting new ventures' technological resources<sup>191</sup>. Patents are viewed as a tool in reducing the risk involved in the R&D and marketing process in the biotech arena, as the company's most marketable asset<sup>192</sup>, and as a barrier to entry for potential competitors<sup>193</sup>. This is especially important when a so-called blockbuster drug, technique or device is developed.

It follows that companies developing proprietary products stress that they understand the need for patenting in the business plan. In fact, Company 1 specifies that:

*“The company realizes that patents build very strong barriers to entry and will thus continue to apply for patents for their technologies.”*

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<sup>191</sup> Levin et al (1987) in Zahra (1996)

<sup>192</sup> Levin et al (1987) in Zahra (1996)

<sup>193</sup> Keeley/Rice (2002)

As does C3:

*“To maintain its competitive advantage, Company 3 intellectual property position will be maintained with new patent applications for each innovation embodied of the X technology.”*

Furthermore, C1 and C3 also detail the number of attained and pending patents. C2, on the other hand, fails to specify its intellectual property protection strategy. Finally, since patents are not a viable protection option for C4, it has chosen an exclusive alliance (see below) to protect the novelty of its service offering.

In part II of this thesis, the positive correlation between the product development rate and the number of patents has been highlighted. Thus, although the test sample does not allow for a very evocative statistical statement, the correlation coefficient between the number of (pending) patents and the product pipeline has been calculated<sup>194</sup>. The results indicate a very strong correlation between the two variables (correlation coefficient 0.68), thus corroborating the findings of Hirschey (2003).

### 6.2.3 Alliances and co-operations

In Chapter 5.4, both the importance of alliances and co-operations as a value indicator and the relationships between the patent portfolio, the rate of new product development and the number of alliances of a company were reviewed. Although the actual benefits of alliances for start-ups have not been clarified in academic literature,<sup>195</sup> alliances are still a prevalent strategy used to gain market access and initiate cash inflows. The analysis revealed that a multitude of third party relationships, including potential clients, were classed as alliances. Therefore, every alliance indicated and, if available, the potential benefits derived from this relationship, will be pointed out below.

The so-called “strategic partners” with which C1 was seeking to align were exclusive to marketing and sales and activities.

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<sup>194</sup> The company value was calculated in accordance with the generally accepted DCF method.

<sup>195</sup> However, a consensus seems to exist that a biotech can signal its quality to the finance markets by aligning with a pharmaceutical company.

*“Currently, the Company is actively negotiating with leading ...strategic partners regarding the marketing and development of first generation ... ready to market products. The Company also plans on forging strategic alliances with leading ... companies to deploy ... product during 2003.”*

*“Company 1 is seeking strong strategic partners, mainly well established companies with an existing or growing focus on commercializing novel delivery systems for ... in the ... market of .... These agreements will enable the Company to expose its novel ... product platform potential to the marketplace, via leveraged marketing and distribution. Further, by teaming up with Company 1, these companies will be given the opportunity to be the first movers in providing new, safe and alternative ...delivery systems, thus securing their own competitive stakes.”*

*“These partnerships will:*

- facilitate the introduction of the ... to the ... industry in its targeted niche markets, representing a market opportunity of over ...*
- leverage the commercialisation process by providing a customer base, brand name loyalty and distribution expertise.”*

In addition to describing the partner that C2 would require to be able to implement its international commercialisation strategy, it also portrayed the function of each party:

*“... the Company will deploy a ... network to support and expedite nation-wide coverage. The Company will assemble .... ... are expected to propagate Company 2's products by utilizing their existing channels to the ...target market. Company 2 will approach the relevant ... offering them exclusivity for their respective area...”*

C3 employs the term strategic alliance partners for both commercialisation and development projects. However, it also clearly outlines its expectations of the partner's responsibilities:

*“The Company's business model heavily depends on joint ventures and strategic alliances and collaborative ... with leading ...companies. The assumption is that the partner will finance the R&D costs and pay Company 3 a royalty stream post launch of the value added product”*

Unlike the previous two start-ups, C3 has succeeded in aligning itself with a relevant specialist prior to the second half of 2000:

*“The Company is seeking multinational and multi-market alliances with leading... in all its target markets.”*

*“Company 3 has entered various stages of negotiation with leading international... companies....”*

*“Furthermore, for the development of the ... Company 3 forged professional alliances with leading R&D and distribution companies in Israel, which it is intending to uphold to further develop and maintain the highest quality ... products in the ... industry. The Company’s most significant R&D collaborator is..., a specialist in the field of ....”*

*“Other professional collaborations include expert ...consultants....”*

C4’s business plan includes a very detailed list of existing and potential alliance partners and ,where appropriate, a brief description of each company/organisation. Each subsection is preceded by the following statement:

*“The Company is looking to recruit ... . Strategic alliances have already been forged with the following companies (organisations)... ”*

By the second half of 2000, C4 managed to obtain 15 alliance agreements, including an exclusivity agreement with one organisation, thus protecting its main service offering from competitors.

In fact, the importance of strategic alliances for C4’s survival was emphasised in the “critical success factors” section:

*“In order for the Company to reach critical mass fast, its goal is to reach agreements of strategic cooperation...”*

*“The major asset of the company with regards to acceptance with ... will be the extensive source of ... (which can only be provided via alliances<sup>196</sup>)”*

In addition to the above analysis, a quantitative analysis was included. The results were quite surprising, as they revealed a negative effect exerted by alliances on the number of patents

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<sup>196</sup> Added by the author

(correlation coefficient  $-0.37$ ). On the other hand, the influence of alliances on the product pipeline was non-existent (correlation coefficient  $0.02$ ). One interpretation of these results is that they are in line with the findings of Pennings/Harianto (1992) and Deeds/Hill's (1996), who argue that at low levels strategic alliances are positively related to new product development, but that with increasingly more alliances the costs will outweigh the benefit. In other words, these results may in fact confirm the generally agreed belief that too many alliances may be counterproductive. However, attention has to be drawn to the element of the non-significant test sample and the resulting prudence.

### 6.3. Other factors

In addition to the management team and the previously discussed business strategies, other issues concerning the start-up are also discussed in the business plan<sup>197</sup>, such as a detailed description of the product/service, the potential market size, the market share which the company is aiming to capture, the actual and potential competition, the marketing and sales strategy, and a financial section. In the following section, a short investigation of these aspects will be presented.

#### **Product uniqueness and market potential**

In Chapter 1, the importance of a company's target market attractiveness was discussed. First, VCs avoid "unattractive" markets, regardless of an individual entrepreneur's skills or the uniqueness/novelty of the product or service, and usually invest in high growth markets. Therefore, it is not surprising to find that all companies have spent a considerable part of their business plan outlining their prospective target markets. In addition to highlighting the market potential, other issues reviewed include potential direct and indirect competitors, and the unmet market need which the company responds to. Usually, this section is followed by a detailed description of the product.

C1 has decided to discuss the target market, product and marketing/ business strategy for both technology platforms individually.

C2 first highlights the market needs, industrial challenges and the technological concept. The business plan proceeds with a detailed discussion of the market, the market potential and

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<sup>197</sup> see Chapter 8.1/Appendix 1

existing competitors. The market section is followed by a detailed explanation of the product and planning issues.

C3's product is also relevant for several multi-billion dollar markets. Each applicable market is briefly outlined and includes for each market the limitation of current solutions and the market potential.

The outline of the target market potential is preceded by an outline of the general trend in the e-Healthcare industry, including a brief outline of Internet use development. The business plan continues to outline the addressable medical market, which is, in turn, used as a basis for calculating different user groups.

With regard to outlining their competitive advantage, all companies took a one-to-one comparison approach, presented in a table format, to highlight the superiority of the various product features. The competitive advantage of the company's product/service was also reemphasised in the product description section. Cost savings were a prominent advantage to each individual target customer base, i.e. all products were said to be more cost-efficient for the client compared to competitive products. In addition, all start-ups were refraining to open up new markets, but intended to gain market share by responding to existing market deficiency.

### **Business strategy**

Three business plans portrayed the individual business strategies in a separate section, which included issues such as the marketing and sales, revenue generation, intellectual property, value proposition and/or alliance partners.

A mission statement was included in both business strategy sections of C1's business plan:

*"In regards to its X based products, Company 1's mission is to develop ... delivery solutions to enable the absorption of ..."*

*"The Company's core objective is to serve its target customer base, the ..., by providing versatile and unique delivery systems to meet their ... requirements."*

After this, a concise account of the current status and intended focus is provided:

*“The Company is currently focusing on developing a dedicated delivery system for ... based on its proprietary ... Company 1 aims to establish the ... as the gold standard in the over \$X billion ... market, replacing traditional ... products with a real ...solution. Once the ... in-vivo trials have been successfully completed (Phase I/II), the Company will seek strong alliances in the ... industry for marketing their...product.”*

*“In addition to its R&D focus on ..., Company 1 intends to capture short term revenues based on the commercialisation of its developed line of .... The Company is actively seeking and negotiating with strong alliance partners for these ... products. These ... products will provide Company 1 with initial top-line growth.”*

*“The company is well positioned for growth with several product candidates including ....The Company is creating a specialized line to enhance the product offering of ...companies that have an active focus of creating premium products .... Company 1 is addressing the so far ignored market needs of the growing population of ...*

*The Company’s specialised products for the ... will enable ... that facilitate public compliance and provide ... companies with a sound and easy penetration into this growing niche market.”*

Other issues included are the alliance, intellectual property (i.e. patent) and revenue generator strategy.

The business strategy section of C3’s business plan states at the beginning:

*“Company 3’s business model has been devised to capitalize on ...first mover advantage in establishing a new paradigm in turnkey ... solution”*

The value proposition of C3’s product is provided for each target market:

*“In some of the Company’s targeted industries ... is a significant portion of the total cost of the product and en essential marketing feature for product differentiation...will be a key to promoting cost-containment on non-R&D expenditure.”*

*“... product differentiation tool for competitive markets ...”*

An outline of the commercialisation and launch strategy, which includes positioning, current status, strategic target policy, product development policy, revenue model, advertisement and promotion strategy is also included.

*“Company 3 strongly believes that the introduction of its proprietary system in markets where ... is an essential requirement, will aid in establishing new ... standards...”*

The final subsection, the so-called business model, details the different modes of co-operations the company is able to offer, including both clients and alliance partners.

C4’s strategy section opens with the statement:

*“... has been devised to capture a dominant position in the provision of online services geared towards the ...”*

This is followed by an outline of C4’s objectives and solutions, including capturing a dominant market share, establishing a brand name, adding value through additional services, and continuously identifying new growth markets where

*“...its knowledge base and market dominance can be applied.”*

Furthermore, the marketing and launch strategy, the anticipated penetration rate of the various target user groups, and an extensive list of strategic alliance partners (see above) are provided.

C2, on the other hand, has structured its business plan differently, splitting it into three broad components:

- The description<sup>198</sup> part includes a company profile, an outline of the concept and the market need.
- The planning section entails a detailed description of the product<sup>199</sup>, marketing, general and administration, and financing issues for each.

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<sup>198</sup> which has been analysed above

<sup>199</sup> which has been analysed above

- The revenue projection, cost structure and financial statements are included in the financing discussion.

The marketing section opens with an outline of the marketing strategy:

*“ Company 2’s marketing mission is to establish ... products as a standard ... in the field of .... Thus, the Company bases its strategy on several crucial market drivers including ...”*

*“ ... believes that the introduction of the proprietary ... products in markets where the elements of ... are crucial to all parties involved, will help to forge new standards in the market of ....”*

The plan continues with a discussion of several marketing-related issues, such as the most suitable target customer base, marketing communication, an account of the marketing human resource base, the marketing budget, and the launch strategy (including milestones).

*“The Company will hire a leading local PR firm to lead the market campaign. Furthermore, the Company will generate localized marketing material, including an information website and brochures for ...*

*The Company’s MARCOM efforts will initially focus on ... This endeavour will be undertaken by executing a direct mail campaign of promotional material, approaching ..., advertising in respected medical newspapers and magazines, attending relevant industry conventions and programs and offering workshops, seminars and courses. The Company will organize various road shows that will provide specialized workshops in key/relevant locations ....”*

The last subsections of part two focus on general and administrative and financing issues:

*“ Company 2 intends to finance its ... costs through equity placements, while raising the required working capital investment through short-term bank loans. In terms of short term financing, the Company will cover all necessary financing activities (i.e. 100% of its working capital) via short-term bank loans...”*

## **Finance**

The financial statements and analysis section, which is the final part of all four business plans, is seen as a crucial part of the business plan, as both VCs and the entrepreneur determine the start-ups value on the basis of the figures exhibited in this section. The finance part includes:

- any historical funding and expenditure,
- funding requirements and use,
- a list of assumptions on which the financial analysis is based, i.e. the anticipated penetration rate, the revenue model, cost of revenues/goods sold, R&D, marketing and sales, and general and administrative expenditure levels. An explanation of the most important items must also be incorporated.
- projected financial statements, i.e. profit and loss statement and a cash flow analysis
- a ratio analysis (against gross profit)

The review of the individual financial statements revealed the following points:

- All companies foresaw a break-even during the third year after the investment placement, i.e. 2003, with the exception of C4, which broke even the following year.
- Only C1 assumed a constant ratio between income revenue and cost of goods sold, all others assumed a decreasing trend.
- Although C2 included a projected balance sheet, it did not include a ratio analysis.
- All firms foresaw operating profit margins of at least 40% during 2005.
- Both C1 and C4 assumed very unrealistic penetration rates. For one market application, C1 assumed a 55% penetration rate and a 60% penetration rate for its second platform technology. For one of its target groups, C4 assumed a 100% market share and 50% each for two different groups.
- All companies are experiencing rapidly decreasing marketing and sales, and general and administration margins. With the exception of C4, which does not have any R&D expenditure, all firms are also experiencing a very steep decrease in their R&D margins.

The aforementioned problem of estimating an appropriate value for an early-stage company<sup>200</sup> may become apparent when summarising the above information. It was also mentioned in Chapter 1.4 that there are some extreme cases where the start-up's main assets are its

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<sup>200</sup> see chapter 1.4.1

intellectual property, (pending) patents, the team's experience and an idea, which is the case for Company 1. All other companies have obtained some other form of asset, mainly technology-based.

All four business plans demonstrate a negative cash-flow<sup>201</sup> at the early stages of their development and do not provide historical data which reflects the previous allusion to the general financial disadvantages of Venture Capital projects. However, all companies should be able to account for the expenditure of previous investment placements, in particular Company 2.

6.4.

6.5. Evaluation and interpretation of evidence

In the following section, the business plans are first evaluated separately, and then compared to each other in order to draw conclusions from this analysis.

6.5.1 Evaluating each company's business plan

As shown below, the individual factors highlighted above will be grouped together:

- Management-related issues, i.e. management team, level of education, industrial knowledge and new venture skills
- Patent strategy and the product pipeline
- Alliances and cooperation
- Other factors, e.g. target markets or financial analysis

The management-related issues are grouped together because it seems unreasonable to differentiate them. The product pipeline and the patent strategy/situation are also grouped together because, as discussed in the literature review section, a correlation is likely to exist between the product pipeline and the patent strategy/situation, a belief supported by the author.

**Company 1:** The Company has developed two promising platform technologies, has minimised the risk of competition through patents and has identified a multitude of

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<sup>201</sup> The cash flow refers to retained profits plus depreciation for a period

applications for both technologies. However, the company has not advanced much since 2000. First, it has not only failed to forge an alliance with an established player in any of its target industries, it has also been unable to acquire a client. C1 therefore has not produced any revenue flow thus far. Secondly, the management team has been unable to expand its key personnel. The analysis exposed several reasons for these shortcomings.

**Management team, level of education, industry knowledge and new venture skills:** The management-related issue sections revealed several shortcomings. First, the business plan did not clearly spell out the number of top managers, nor did it actually disclose who the team members were; the latter information was revealed in the recruitment strategy. These ambiguities inhibited an identification of both the skills and the background of the management team.

Further, the management team is by no means complete, and the recruitment strategy provided seems to be unrealistic, especially in the light of the product development strategy. C1 has assumed an average annual human resource growth rate of 108% over a 6-year period. Even if these anticipated growth rates were implemented, C1 might not be able to face the challenges associated with rapidly expanding companies.

With regard to the level of education, both team members attained relevant University degrees. Furthermore, both founders had previously been involved in setting up a successful start-up, though their exact involvement remains unclear. In addition, both entrepreneurs had obtained extensive industrial knowledge, particularly founder 1.

When comparing these results with the literature review section, no clear answer may be deduced. On the one hand, the management team acquired previous industrial experience, new venture skills and education. On the other hand, the management team clearly lacked several important factors, such as communication skills.

**Product Pipeline and patents:** The Company has a well-filled product pipeline, including ready-to-market products. However, the product's diversities, both in application and target markets, do not permit a channelled focus; C1 lacks the capacity required for this. This diversity may also confuse alliance partners who may suspect the company of being unsure of the direction it wants to pursue for each product platform. In fact, this diffuse focus supports

the claim of Stuart/Abetti's (1987) that a negative correlation exists between initial success and R&D intensity.

With regard to the company's patent strategy, the company signalled that it understood the importance of protecting its intellectual properties, which VCs consider a risk reduction tactic.

**Alliances and co-operations:** The management team of C1 stated that it was negotiating with several potential marketing and sales partners for its ready-to-market line of products. They also spelled out their strategy in terms of future alliance partners. In addition, C1 had a clear understanding of their offering to alliance partners and of which services they were seeking in return. However, although C1 designed a timetable for the R&D development of the product platform's clinical applications, it failed to mention the potential alliance partner it required to do so. The clinical approval process is, as elucidated in Chapter 3, a long, difficult and costly process, for which Company 1, like most start-ups, clearly lacks the necessary capacities.

**Other factors:** As mentioned above, Company 1 is focusing on a wide variety of existing markets, each of which either already is or has been forecast to develop into a multi-billion dollar market. Therefore, with regard to market potential, C1 shows that it is neither aiming to service unattractive markets in terms of low market potential, nor is it trying to create a new market. Both strategies are usually preferred by VCs, who consider them to reduce the level of risk of company failure. However, as mentioned before, VCs and other potential alliance partners may feel wary about the lack of focus. Another risk factor is that the company's main asset is patents and an idea. This deficit may be compensated by the fact that a line of ready-to-market products has already been designed.

The product superiority, the company's business and marketing strategy, including outlining potential revenue streams, and the status, are structured well and cover all issues. Nevertheless, the range of target markets is also reflected in these sections.

The financial analysis section, which at the outset looks well thought-through, also betrays a clear lack of business understanding and focus. The penetration rate seems quite unrealistic, with 55% and 60% assumed for two separate markets, especially in view of the target market's size and existing brand loyalty. It also assumes a constant cost-of-goods-sold ratio, which again is unrealistic, as both theory and practice have demonstrated that this is not the case, especially with increasing revenue streams. The assumption of falling R&D and

marketing and sales margins should not occur, especially in view of the company's focus on R&D and marketing.

**Company 2:** C2 has achieved a nationally and internationally renowned status in its target market. Although the firm has failed to include several details in its business plan, it has shown a clear and well thought-through overall strategy. The company has successfully acquired several rounds of VC funding and has also understood how to utilise the skills and knowledge of the team members of its board of directors.

**Management team, level of education, industrial knowledge and new venture skills:** With regard to the top management, Company 2 has successfully assembled a complete team whose members have obtained several years of relevant business experience but have also developed a thorough understanding of the target industry. Further, all team members have acquired the necessary academic education. C2 has also been able to bring together a very high-profile team for the board of directors, with a multitude of experience in all areas needed for this kind of venture. By leveraging the help of these professionals, the company was able to obtain the skills needed to successfully master any problems associated with the formation of a start-up. The only information omitted is details of any scientific advisors. Furthermore, an aggressive human resource strategy is assumed, anticipating an average annual growth rate of over 60%.

When making a forecast based on a comparison of the literature review and the above information, the success rate would be high.

**Product Pipeline and patents:** C2 has described the products which were in the developing phase or on the "drawing board". It has also included details of each product's development stage. Despite the lack of a specific patent strategy, it would be very surprising to find that the company has not taken the necessary measures to protect its intellectual properties.

**Alliances and co-operations:** As mentioned above, C2 has included its international commercialisation strategy, consisting of local alliance partners only. From the information provided, it could be concluded that the company is not interested in forging an alliance with a multinational company. As the information on the reasons given<sup>202</sup> would reveal too much detailed information about the Company, which could in turn lead to identification of the firm, no examples can be provided.

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<sup>202</sup> They are not clearly spelled out, but are rather included in the text at various places.

**Other factors:** The different structure of the business plan enables C2 to differentiate itself from other businesses trying to secure equity financing. It has used the business plan to clearly outline the market potential, explain the needs of the target markets, the product superiority, its business and marketing strategy, potential revenue streams, as well as general and financing issues.

The financial analysis section is clearly structured and consists of the projected balance statement and profit and loss account as well as a cash flow analysis. However, no ratio analysis is provided, which means the VC is not able to review these ratios quickly. Like all other companies, it has assumed falling R&D and falling marketing and sales margins, which again is quite surprising, especially in the light of the fact that the company will have to allocate increasing levels of its resources to its R&D and marketing efforts.

**Company 3:** As indicated in Chapter 5, C3 was not able to survive the global recession of 2002. Although C3's target market focus was, like C1's, quite varied, it used the business plan to signal its understanding of business matters. However, C3 neglected to include certain information and showed ambivalence between managerial skills, business understanding and the actual implementation of these.

Similarly to C1, no further commercialisation partners or clients were acquired, even though the management team had already established alliances with national partners and had been negotiating with (multi)national companies.

**Management team, level of education, industrial knowledge and new venture skills:** With regard to the top management, or key personnel, C3 successfully assembled a complete team of seasoned professionals with a wide range of managerial and business experience. All team members had also acquired the necessary academic and professional education. Further, the company's scientific advisors were in a position to test the suitability of the product for certain medical purposes. Another prominent factor was the company's very moderate recruitment strategy, which signalled an understanding for the need to grow at a moderate rate. This conservative growth would have enabled the team to design an expansion strategy appropriate to the individual projects, while being enabled to identify potential problems early on.

One shortcoming of the management team, however, was that only one member had previously acquired experience in a (relevant) manufacturing industry. Additionally, the reader is likely to assume that, given the available data, all but one key employee had gained new venture experience.

**Product Pipeline and patents:** C3 designed its product development strategy to suit the needs of its potential clients, while covering any initial R&D costs from its own resources. In addition, the management team identified an array of further R&D activities, which was expected to increase the number of target markets. The business plan also included the stage of development for each product.

With regard to its patent strategy, the team's understanding of the prerequisite for patent protection was justified by specifying that patents would be sought for new applications or designs based on their core technology. The number of patents was also listed.

**Alliances and co-operations:** As mentioned above, C3 forged alliances with various alliance partners. A detailed outline of the responsibilities of each party was also included. This again showed the well thought-through strategy and the entrepreneurial understanding of the management team.

**Other factors:** The firm outlined the initial target markets' potential in a transparent manner. The BP also outlined the specific needs of the main target markets, the product superiority, C3's business and marketing strategy, potential revenue streams, and a financial analysis.

With regard to the target markets, C3 had a rather wide focus, which may have hindered it from establishing itself in one particular market sector before venturing into a new industry. This was supported by the fact that the management team had shown that it already had a clear strategy for each target market, including the revenue model and marketing strategy.

The financial analysis section was clearly structured and included a projected profit loss account, a cash flow and ratio analysis. Such details enabled VCs to gain an understanding of the various business strategies from a financial perspective. Similarly to the other start-ups, C3 assumed declining R&D and marketing and sales margins, which, as previously mentioned, was incompatible with the stated R&D and marketing strategy.

**Company 4:** As previously discussed in Chapter 5, C4 was also unable to survive the turbulent times following the collapse of the internet/new economy hype. The business plan revealed a clear target market focus and demonstrated the firm's well-structured strategy plan, which indicated the management team's understanding of business matters. The company's weaknesses were mainly revealed in the financial analysis section.

**Management team, level of education, industrial knowledge and new venture skills:** The management team consisted of experienced professionals who had all acquired the necessary skills and, where appropriate, industrial knowledge, as well as academic and professional education. However, the founder and CEO of the company, although a renowned professional in his field, did not obtain previous business-related skills. In terms of new venture experience, only the company's CFO had gained previous experience.

The VC should in fact view the incompleteness of C4's management team positively as, at the current stage, a full management team would have produced unnecessary costs. In addition, the recruitment strategy revealed an understanding of the timely acquisition of appropriate personnel. However, the recruitment strategy plan foresaw a very aggressive recruitment strategy, with a growth rate of over 50% per annum on average until 2004. If the firm had implemented this strategy, it is very likely that the management team would have been faced with the challenges associated with rapidly growing firms.

**Product Pipeline and patents:** C4 outlined the anticipated timeframe for the geographical launch of its website. However, an equivalent for the services was not included, with the exception of one service targeting one customer group. Further, no indication of future services was included.

The issue of patent protection was not relevant to the firm. However, the management team took other measures to protect its intellectual property and business idea.

**Alliances and co-operations:** A detailed account of the current and potential alliance partners was revealed. The management team also specified their understanding of the significance of alliances for the success of this venture.

**Other factors:** C4 clearly outlined its target market and target customer groups, the product uniqueness, the marketing and revenue strategy, in addition to anticipated penetration rates for

each target group. These penetration rates are, however, unrealistic. The company assumed a 100% penetration rate for one group and 50% for two other target customer groups until the end of 2004, which was improbable considering the chosen medium used to approach and sell its services to its target groups. With regard to the ratio analysis, the company, like the other three companies, was experiencing decreasing marketing and sales ratios, which yet again should not have been the case when still aspiring to achieve the forecast penetration rates.

### 6.5.2 Interpretation

Prior to drawing any conclusions from the above analysis, tables (Table 6.1 to Table 6.3) were assembled allowing a quick and simple comparison of the investigated factors. The left hand side of the tables lists all factors analysed, while the remaining columns indicate whether a company had been rewarded a positive (+) or a negative (-) valuation for each one.

In Table 6.1 a positive indication was made for those factors which were mentioned, a negative one for those factors which were not included.

**Table 6.1: Summary of results**

<b>Factors</b>	<b>C 1</b>	<b>C 2</b>	<b>C 3</b>	<b>C 4</b>
<b><i>Management team</i></b>				
Complete Management team	-	+	+	-
Scientific Advisory board	+	-	+	+
Management Skills	-	+	+	-
Industrial Knowledge	+	+	-	+
New venture skills	+	-	-	-
Education	+	+	+	+
<b><i>Business Strategy</i></b>				
Product Pipeline	+	+	+	-
Patents	+	-	+	NA
Alliances	-	-	+	+
<b><i>Other Factors:</i></b>				
Target Markets	+	+	+	+
Recruitment Strategy	-	-	+	-
Main Asset – Technology based	-	+	+	-
<b><i>Financial Analysis</i></b>				
Historic Funding	+	+	+	+
R&D margin	-	-	-	NA
M&S margin	-	-	-	-
Penetration strategy	-	+	+	-

Source: Own

A negative sign was allocated in the management section for C4, since its management team was not complete and only one team member had acquired the necessary skills.

In Table 6.2 the positive and negative signs are assigned for factors which may be perceived as negative, such as too wide a market focus (both C1 and C3), or, as in the case of C4, other means of product protection than patents.

**Table 6.2: Other influences of these factors**

<b>Factors</b>	<b>C 1</b>	<b>C 2</b>	<b>C 3</b>	<b>C 4</b>
<b><i>Management team</i></b>				
Complete Management team				+
Management Skills				+
New venture skills				+
<b><i>Business Strategy</i></b>				
Patents				+
Alliances	+			
<b><i>Other Factors:</i></b>				
Target Markets	-		-	
<b><i>Financial Analysis</i></b>				
Historic Funding				-

Source: Own

In Table 6.2, it can be observed that C4 was allocated only positive signs where it had previously received a negative sign. This is because it had successfully acquired a high profile CFO for the management team with vast experience in managing health care-based start-ups, and it stated clearly that it understood the importance of recruiting suitable candidates for its management team.

In Table 6.3 the two tables above are merged.

**Table 6.3: Summary of results**

<b>Factors</b>	<b>C 1</b>	<b>C 2</b>	<b>C 3</b>	<b>C 4</b>
<b><i>Management team</i></b>				
Complete Management team	-	+	+	-/+
Scientific Advisory board	+	-	+	+
Management Skills	-	+	+	+/-
Industrial Knowledge	+	+	-	+
New venture skills	+	-	-	+/-
Education	+	+	+	+
<b><i>Business Strategy</i></b>				
Product Pipeline	+	+	+	-
Patents	+	-	+	NA
Alliances	-/+	-	+	+
<b><i>Other Factors:</i></b>				
Target Markets	+/-	+	+/-	+
Recruitment Strategy	-	-	+	-
Main Asset – Technology based	-	+	+	-
<b><i>Financial Analysis</i></b>				
Historic Funding	+	+	+	+/-
R&D margin	-	-	-	NA
M&S margin	-	-	-	-
Penetration strategy	-	+	+	-

Source: Own

The above summary reveals some unexpected issues worth reviewing in greater detail. First, the analysed data seems to suggest that the level of education of the management team may not be relevant for the success of a start-up working in one of the health care industries<sup>203</sup>. Although this contradicts Bates/Bradford (1992), it supports Sandberg/Hofer (1987), who claimed that the biographical background of the entrepreneur is irrelevant to the survival rate of a new venture. Additionally, the projected financial analysis and, hence, the corresponding financial margins appear to be extraneous to the success of a company. As shown above, all companies have assumed decreasing R&D and M&S margins. These assumptions are, however, not congruent with the overall business strategy set out in the business plans. One justification for this finding is the general practice of showing decreasing rates of margins<sup>204</sup>. If this unsuitability is manifested with further research, questions arise concerning the usefulness of such information and what data would provide a suitable alternative.

<sup>203</sup> One plausible reason for this may be the fact that, unlike in many other industries, a thorough technological and scientific knowledge of the underlying processes and technologies is a necessity for working (and establishing a new venture) in this arena.

<sup>204</sup> This practice was perceived by the author during her professional work.

The review of the two surviving firms exposed several interesting details. First, it seems that 75% of the information included in a business plan (and therefore analysed here) is either meaningless (such as the financial forecasts) or does not reveal information about the potential success of a health care-related start-up<sup>205</sup>.

Two seemingly critical management-related factors emerged: management skills, which has been proposed by previous academic research (see Chapter 4), and a complete management team appear, supporting the findings by Weber/Dierkes (2002). A clear and well-defined target market also seems to enhance the probability of sustainable success. In addition, the above analysis seems to suggest that start-ups are better positioned if the main asset is technology-based, i.e. if at least a working prototype exists. Finally, the success potential appears to be positively influenced by a conservative market penetration forecast, which could, in turn, signal a general understanding of business concepts. Conversely, prior experience with new ventures does not seem to be an associated factor for developing into a profitable firm.

A comparison of differences between Company 1 and 3 also produced a number of unexpected findings. First, the data seems to suggest that, although experience with new ventures is important, overall management skills and a complete management team are not. This, however, contradicts the findings discussed in the previous paragraphs. In addition to the conclusions drawn regarding the factors discussed above, it seems that neither the forecast penetration rates and human resource recruitment strategy nor the type of the organisation's main asset are correlated to the survival prospect.

Contrasting Company 2 with the other companies revealed that for this test statistic neither a scientific advisory board, patents – or, to be more exact, a discussion of the organisation's intellectual property protection strategy – nor the inclusion of the proposed alliance strategy are imperative for either the endurance or profitability of a new venture.

Table 7.1 clearly shows that, in comparison to Company 2, Company 3's survival and profitability prospects should be superior, as it received a better overall valuation. In fact, the latter start-up achieved either the same, if not better, valuation scores for each but two factors. Consequently, it may be construed that the factors "industrial knowledge" and "focused target

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<sup>205</sup> i.e. whether a company, in addition to being able to survive, is also successful in terms of generating enough income to facilitate self-sufficiency.

market” are imperative for the successes of a start-up and may even outweigh other factors, such as a sound recruitment strategy.

In effect, when comparing both Company 1 and 2 with Company 3, the only (positively valued) factor which the latter organisation lacks is previous industrial knowledge. Another interesting finding is that, while Company 3 has assumed a conservative recruitment strategy, neither Company 1 nor 2 have. Therefore, it may be assumed that a conservative recruitment strategy is not significant, or even counterproductive, to a company’s ability to survive. It may also be assumed that the lack of industrial knowledge cannot be compensated for by any other factor.

A comparison of both C1 and 2 with C4 revealed that its two disadvantages are linked to prior funding and the product pipeline. As stated in Chapter 6, all companies received previous funding. However, although C4 received a sufficient investment placement to cover all related expenditure,<sup>206</sup> it failed to do so. This ineptitude to manage its own funds, which is crucial for the prospect of survival, may have led to the failure of this venture, especially during the global recession during the early 21<sup>st</sup> century where (further) investment placements were scarce. This inability to manage its resources efficiently may be the result of a lack of management and new venture skills from the CEO. In addition, both the available and planned product pipeline seem to be essential, which again is supported by other research - see Chapter 5.2.

Examining the individual evaluation, the results of the above analysis seem to suggest that, in order to be particularly successful, the firm should portray a conservative penetration forecast while its main asset should be technology-based. However, the data indicates that these factors may be insignificant for the mere survival of a start-up. Finally, the analysis did not reveal any specific factor which would enable a start-up to subsist.

### **Limitations of the interpretation of the data**

Several important and intriguing questions were not addressed in this work, mainly due to data limitations. For instance, the size of the test sample impedes the performance of any meaningful quantitative analysis. In addition, due to the small sample group, both the above

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<sup>206</sup> As indicated, the actual sum cannot be divulged. However, the above statement is made in the light of a comparison of similar Internet-based start-ups, whose focus is, however, not the health care sector.

analysis and the resulting interpretation prevent any generalisation. Further, both the differences in company types and the dissimilar target markets renders a one-to-one comparison virtually impossible, as each industry has its own rules and challenges. These criticisms aside, however, some results did seem to confirm previous studies.

Moreover, the failure of both Company 3 and 4 may not have been due to any fault of the management team and/or the proposed strategies. For example, C4 may have fallen victim to the general collapse of the Internet hype. Although this supposition seems quite plausible, the information provided and the fact that it was the only Internet-based start-up in the sample group prevents closer examination.

Company 3, on the other hand, may have suffered from the general economic downturn experienced by most industries and consequently the changing market structures. The different economic and modified environmental setting caused companies to reduce their non-essential expenditure levels. However, similarly to Company 4, the plausibility of this reasoning cannot be tested, either by qualitative or quantitative methods.

If, however, further research confirms the above analysis, the question arises of whether the BP, in its current form, is a suitable tool for initial business valuation, or whether the VC should focus on other factors, to make a more informed and prudent investment decision. The results of such an analysis would in fact be very useful for both investors and companies seeking investment placement.

## 7. Summary and Recommendation

On the basis of practical work experience, it became apparent to the author that the currently available evaluation tools used when focusing on medical-related start-ups were suboptimal. The goal of this thesis was to provide VCs with tools which could be used during the initial screening process and beyond. To do this, the thesis focused on analysing various factors which a health care-based start-up might use as competitive advantages. These factors can thus be used as tools in risk minimisation.

Although a universal consensus exists that VCs are experts in the new venture-funding realm, it seems that there is room for improvement in their decisionmaking process. As stated in Chapter 1, Müller (2002) claims that only 20% of all Venture Capital-backed start-ups which have received Venture Capital funding make an IPO or are acquired by a large, revenue-making company, while 60% will “toddle along.” The remaining 20% face bankruptcy<sup>207</sup>.

Start-ups have, by definition, no or only a limited financial history, which impedes the usage of traditional valuation methods. Furthermore, due to a lack of securities which established companies can demonstrate, VCs have to revert to methods using predictions about the development of the firm and the target market.

The only information source available to VCs during the screening phase is the BP. In view of the question set, the BP is therefore the only data collection instrument which is analysed. The approach of this study was to first review all established factors - as provided in the BP; this was carried out in Chapter 1.4. In subchapter 1.4.2, there was a summary discussion of the factors which the author felt needed to be included in the initial screening process, namely various issues regarding the management team, the patents, the firm's product pipeline and any existing alliances.

The theoretical background of each factor was discussed in the second part of the thesis. These factors were evaluated empirically in Chapter 6. The initial aim of this study was to perform a quantitative analysis; however, due to the limitations associated with the data sample, a qualitative methodology was chosen instead. The four available business plans were analysed by means of explicated content analysis. The results were summarised in Table 6.1.

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<sup>207</sup> Müller (2002)

The interpretation of these results revealed that several factors currently regarded as decision-making criteria may not be relevant to the success of a start-up.

### **Findings**

A solid basis for a well-positioned biotech firm is a team of highly qualified scientists. The above analysis revealed that all entrepreneurs had indeed obtained the appropriate education. This finding may, however, indicate that only entrepreneurs with such a level of education will establish companies in these. A further result with regards to the management team was the existence of industrial knowledge. In addition, the results suggest that other management team-related factors currently perceived by VCs as important may not be so: a scientific advisory board and previously obtained new venture skills. Finally, an examination of the business plans also revealed that the proposed recruitment strategy might not influence a company's value. This may be due to the fact that this strategy is based on a prediction for a period of 5 years, which is not feasible.

Furthermore, when basing a valuation of the management and scientists' team purely on the information available from the business plan, VCs are faced with the problem of information asymmetry. Thus, existing partnerships with other companies, preferably with well recognised ones such as Johnson & Johnson, Bayer, Merck, Aventis, Schering or Siemens, are convincing competitive advantages which signal a positive attitude to understanding the importance of risk minimisation. First of all, these corporate, and well-established, pharmaceutical or medical technology companies have the resources required to help the start-up in their R&D, or marketing, sales and distribution efforts. Secondly, such alliances indicate that at least one expert entity has carried out a due diligence and believes that both the technology and the management team are worth the time and money invested in them. However, the results of the empirical analysis seem to suggest that such alliances are not a crucial success factor.

Another essential factor is the number of pending and previously granted patents. The latter are important as they create a barrier to entry for potential competitors. In fact, although the results seem to suggest that this may not be the case, as one company did not include their patenting strategy it is not significant, as all firms had previously obtained patents.

It was suggested that a product pipeline is a further key factor as it indicates how many products the company is developing. This information may subsequently be used to gain an understanding of the target markets. In fact, although the analysis illustrated the importance of a product pipeline, the analysis of the target market did not lead to any significant result.

No meaningful statement could be drawn with respect to the other factors observed. All companies had previously obtained funding and their financial analysis appears to be rather irrelevant, as all exhibited the same trend, such as decreasing rates of margins.

### **Scope for further research**

Since this thesis is only a first approach to the subject at hand, no clear or statistically meaningful answer to the importance of the individual factors evaluated can be given. By contrast, several important and intriguing questions were not addressed in this work, mainly due to the limitation of the sample data. Firstly, the very small sample group of four start-ups did not permit any meaningful quantitative analysis. Secondly, all firms are based in different medical-related industries, rendering a direct comparison between the individual business plans difficult. Thirdly, since all firms are based in one national market, Israel, no statements may be concluded about international standards. Finally, due to the make-up of the empirical analysis, the actual decision-making part of the screening process was not observed.

Nevertheless, this situation implies a need for studies to be made in greater detail. Such studies should involve much larger test samples, which in turn could be subdivided into the various medical-related industries, e.g. medical devices, therapeutics or diagnostics, or even similar markets, such as finding a cure for a certain illness or minimally invasive diagnostics. These results could subsequently be compared in order to offer sound advice to VCs on the importance of such factors. An international study would in turn be useful, as each national market provides different conditions for start-ups, and hence certain success factors may indeed vary from country to country.

The study of the influence of risk-minimising strategies on a start-up's value is still in its early stages. The research findings should therefore be viewed as tentative. In addition, the nature of competition (both among VCs and between start-ups) implies that successful approaches will be imitated and that such imitation may tend to change the relationships reported here.

In summary, it may be said that much remains to be learned about the factors influencing a start-up's value. Nonetheless, if further research supports the claim that the proposed risk-minimising strategies are in fact to be considered as risk management tools for both the entrepreneur as well as the VC, while other factors currently focused upon by investors are less so, the question arises as to whether the business plan in its current form is a suitable tool for an initial business valuation.

## 8. Appendices

### 8.1. Structure and single components of a Business Plan

A business plan has a dual purpose. On the one hand, it should demonstrate the potential of the business and stimulate the interest of investors to seriously consider the opportunity and must, therefore, be viewed as a marketing tool or sales document<sup>208</sup>.

On the other hand, once the company has convinced the investor that the plan is achievable it serves as a guide to assess the performance of the management. As a result, the document also serves as a blueprint for the implementation of the business's strategy.

There is no precise road map for preparing a business plan. The length of the plan and areas of its focus will depend on the industry, the stage of the company's development, the complexity of its business, and the intended audience. Business plans are never perennial. They are subject to constant amendments and evolution depending on the identification of new market opportunities, technical breakthroughs, and the forces of the competitive landscape. Despite the variations between businesses, a type of industrial standard has developed over the years and it is generally expected to reflect the following items<sup>209</sup>:

- Executive Summary
- Business History
- Product and/or Service
- Market landscape
- Competition
- Marketing and Sales
- Significant Risks
- Exit Alternatives
- Financial Projections
- Any necessary appendices

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<sup>208</sup> Eberhardt (2000), Schlecht & Zinner (2000), Rochart & Arundale

<sup>209</sup> Wipfli (2001), Sahlman (1997), Venture Investors, Sontheimer & Matzen (2001), Weitnauer (2001), McKinsey & Company (1999), Peisel & Hanny (2002), Rochart & Arundale, Schefczyk and Pankotsch (2001)

The plan should cover the intended investment horizon of the investor, which is usually five to seven years. The investor is interested in knowing how the value of the company will be built, and how an opportunity for eventual liquidation can be created, either through the sale of the company or through an initial public offering of the company's stock.

### **Executive Summary**

The executive summary is often viewed as the most important section<sup>210</sup>. It should provide a compelling story about the large market opportunity of the product or service provided by the company, why the market is currently not being served adequately, the company's unique capabilities and any competitive advantages that will enable it to generate superior growth and margins. This includes a thorough explanation of how the customer will be reached through a marketing and sales programme. In addition, there should be an illustration of the management skills required to implement the business plan as well as the current qualifications of the existing key managers. Finally, the capital needed and a summary of the financial analysis should be detailed.

### **The Business**

Naturally, the investor is interested in the business's background. Thus a short section on the history of the business should be included, including the type of organisation, any important milestones reached, and any equity already invested. The current breakdown of the ownership should be provided. In addition, the business history should also document why the company came into being – this should include what the chance discovery, the unique perspective, or the ideal combination of experiences which enabled the company to identify the superior solutions to the market problem was. The business history should provide insight into why the founders were in the right place at the right time with the right skill sets to seize the opportunities.

### **The Product / Service**

This section provides a detailed description of current products (or services) and products which are currently under development (and maybe even planned products). Most investors consider a broad range of opportunities and many may not have a (relevant) technical background. These factors may prevent them from having an intimate understanding of the

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<sup>210</sup> Wipfli (2001), Sahlman (1997), Schefczyk and Pankotsch (2001), Venture Investors, Weitnauer (2001)

status of technical developments in single industries. As a result, it is often recommended to avoid highly technical descriptions filled with undefined industrial jargon, especially if the company is operating in a niche market which is not widely known or understood. At the initial screening phase, the investor is mainly interested in the following points:

- The proprietary features of the product
- The economic and other benefits to the customer
- The importance of these benefits compared to other important purchase criteria
- The availability of patents and other intellectual property protection required for the uniqueness of the product and enabling a sustainable competitive advantage
- Any regulatory approval process needed; the current situation of the company with regards to this process; the milestones left to completion; as well as the cost involved and the degree of uncertainty in the process.

### **Business Opportunity/ Market**

This section provides a broad overview of the market sector and the specific niche being targeted. The overall market size and growth, significant industrial trends, major opportunities and constraints presently facing the industry should be discussed. This information should be supported by references to trade journal articles, industrial studies, industry experts, and government sources publishing the supporting historical data and industrial forecasts. Further, a more detailed description of the company's specific niche is also required. It should cover factors such as:

- Target customers – e.g. industry, government, consumers or even geographical target – and the characteristics of the primary targets
- Historic and forecast sales and growth rates
- Purchase decision-maker of customers and who influences the decision
- Process and product loyalty; discussing whether a sale is a separate decision or involves a long-term commitment
- Critical product characteristics – such as performance, reliability, durability, availability, price, service, conformance to industry standards; buyers' preference between making optimal choice or avoiding the wrong selection
- Seasonal or cyclical industry
- Switching costs, involvement of new process or education of customer to utilise the company's product

### **Competition**

All too often business plans fail to acknowledge the presence and potential of all forms of competition. Identifying the existing competitor in the market, including a discussion of their particular strength and weaknesses, signals a deep understanding of the marketplace to the investor. Estimations of the competitors' market share and information about their financial performance and resources may also be available. Discussions about the relative price, performance and other characteristics of these products from a customer's perspective are viewed favourably as well, as investors may interpret this as an ability to understand the market forces.

This section should not only discuss the key rivals, but also the competitive responses to the product offerings, both in terms of those that have already occurred and those that are anticipated. A rationale should be provided for the expected responses from the competitors, both current and long-term. In addition to existing competitors, this section should also include a discussion of potential new competitors – thus including a short description of barriers to entry - as well as potential substitutes.

### **Business Strategy**

Venture Capital investors typically expect to be shareholders in a company for three to seven years. They can be viewed as patient, long-term investors, but eventually need liquidity to return capital to their investors. Thus, a brief discussion of the exit strategy which will create liquidity for the investor should be included. The usual exit strategy includes either:

- a buy back of the shares by the portfolio company,
- a trade sales, i.e. an acquisition of the company by an outsider, which is often a large company interested in venturing into this market segment or a competitor,
- a secondary purchase, i.e. the sale of shares to a different investor
- an IPO
- or in the worst case scenario the liquidation of a company. However, in this case some equity could be recovered through the sale of patents and other assets.

A section on the critical success factors should be included, as well as a description of how the management is going to obtain these. A SWOT analysis should be provided, i.e. a

discussion of how the company aims to maintain its strength and how it is going to exploit its opportunities. However, a good business plan should also include the risks the company has to face, be it internal risks (i.e. weaknesses) or external risks (threats). A section on how the company will try to reduce these risks signals to the investor that the management understand the fact that they are not alone in the marketplace.

### **Marketing and Sales**

A business plan is a strategic document; it provides a broad overview of the market opportunity and the competitive niche targeted by a company. The marketing section should not only describe the strategy, it must also go beyond strategy and into the tactical details. It is not sufficient to say what a company is going to do, but more importantly, how they are going to do it. The key components of a comprehensive marketing plan include:

- **Promotion:** What is the advertising, promotional and public relations plan? This should include a detailed breakdown of the selected media that will be used to communicate with the company's customer and why this is the optimal medium. Any costs involved should be included, as well as the time needed to reach targets, repetitions needed and the quota that is expected to be reached.
- **Sales:** What are the sales strategy and the sales cycle? This should include the sales organisation (employees, exclusive distributors, manufacturer reps, etc) and reasons for this choice. The compensation structure in place for the sales organisation, as well as required qualifications.
- **Distribution:** What are the distribution channels? Whether they are intensive, selective, or exclusive, as well as the compensation structure.
- **Price:** The pricing strategy, including premium, cream skimming, or sacrificing market share should be discussed. Questions about the willingness of customers to pay a premium or, in case of undercutting the competitor's price, the ability to withstand competitive responses, typical industry terms and the individual terms should be discussed.
- **Service:** Any service and support systems required should be discussed and whether these could be used as a source of revenue or are an added expense.

### **Management and Organisation**

Investors are known to have a rule of thumb that they would rather invest in a Grade A manager with a grade B product, than a Grade B manager with a grade A product. It is the

single most important criterion in the selection of an investment opportunity<sup>211</sup>. Thus, a complete résumé of each senior manager's relevant work experience, education, patents and technical publications, and professional certifications should be provided, as well as an organisation chart.

Early-stage companies typically have incomplete teams. In these cases, investors want to understand the particular strength of the current team. Equally important are recognition and an understanding of the qualifications required to complete the team. A description of the expected evolution of the present team and a provision of a recruitment schedule to fill key positions as the company grows and the team is completed signals to the investor a business understanding and a long-term view of the management.

Background information on board members, shareholders, or advisors who give added expertise and credibility to a company should also be included. A description of how active they are within the organisation and any expected changes in their role should be included as well.

### **Financial Analysis**

Historical and projected financial information is required to enable an investor to understand the use of capital, assess the current and potential value of the company, and to evaluate the trade-off between risk and return for the investment. The business plan authors have to find a balance between an optimistic outlook which conveys the potential of the opportunity and a conservative forecast which makes the numbers achievable, so that an investor's expectations can be met, and to enable the company to have continued access to financing.

At a minimum, this section should include:

- Annual income statement and balance sheet for the last five years (or since inception if the company is less than five years old), year-to-date income statement and a current balance sheet.
- Projected income statement, balance sheet and cash flow on an accrual basis for the next five years. The first year projection should provide a monthly breakdown (and annual totals) with enough detail to provide investors with information on head counts

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<sup>211</sup> see e.g. Venture Investors

and compensation levels. Year two should also provide monthly, or at least quarterly, details. Years three to five only require annual projections and do not require the same level of line item detail.

- Unit sales, product margins, terms, etc. should be provided.
- A summary of all critical assumptions used in developing the forecast.
- A detailed breakdown of how the invested monies will be used.
- A discussion of the company's ability to accept staged funding.
- Key milestones which will be achieved with the funding and how they will translate into growth in investor value.

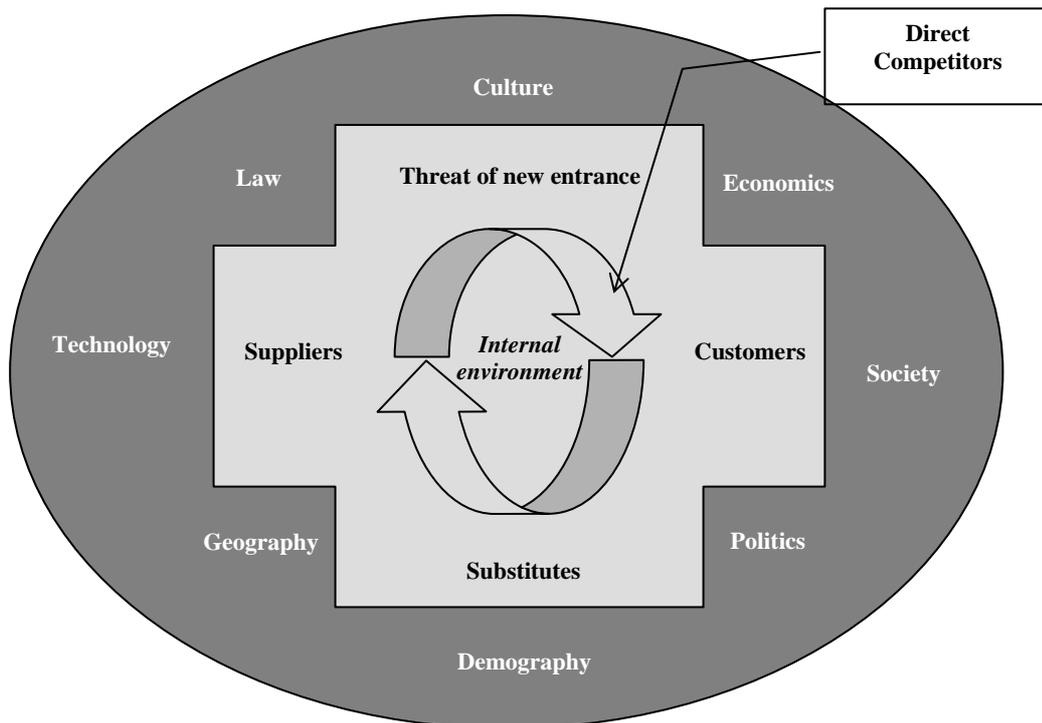
### **Appendices**

Any product brochures and trade industry articles which discuss the market opportunity or provide a description or review of the company's product should be included in the appendix. If appropriate, any other supporting material which provides further detail for any of the earlier sections and which aids the reader in understanding the product or market opportunity.

8.2. SWOT Analysis and Strategies in the health care-based industries

As Czinkota/Kotabe (2001) indicate, the environment surrounding the firm is like the layers of an onion. For the purpose of this work, these layers are differentiated between two layers: the macro and micro level. These different “layers” of the company’s environment are portrayed in Diagram 8.1.

**Diagram 8.1: The overall environment**



Source: Based on Czinkota/Kotabe (2001), Johnson/Scholes (1999)

This Chapter will focus on some of the micro and macro environmental factors which may influence the biotech arena. Readers interested in a comprehensive explanation of the SWOT analysis should turn to the abundant available literature, such as Johnson/Scholes (1999) or Czinkota/Kotabe (2001). However, prior to addressing the issues involved, it is worth remembering that Porter (1990, 1998) has argued that knowledge of the underlying sources of competitive pressure provides a sound groundwork for a strategic agenda of action. This is because a SWOT analysis highlights the critical strengths and weaknesses of the company, elucidates the positioning of the company in its industry, clarifies the areas where strategic changes may yield the greatest payoff, and highlights the places where industrial trends

promise to hold the greatest significance as either opportunities or threats. Understanding these sources therefore also proves to be useful in considering areas for diversification.

### **Macro environment**

All industrial players are dependent on the macro environment which is often referred to as PEST<sup>212</sup>. However, the author believes that this list is rather incomplete, as it does not take factors such as natural and cultural forces into account. This subsection will briefly investigate the factors which may influence the biotechnology and life science arena:

- **Demographic forces:** The demographic environment is of considerable interest to players in the biotechnology industries, as it includes factors such as population size or growth trends. For example, a changing age structure has implications on healthcare issues which will become of greater importance in years to come (e.g. cancer or arthritis). Another important aspect is changing lifestyles, which again affects healthcare, issues these people face. For example, in westernised countries it is not very likely that people will die of cholera. However, due to an increased number of smokers, various types of cancers are on the rise. Increasing consumption of so-called fast and junk food, linked with other factors, is another factor which has led to an increased level of obesity or diabetes.
- **Economic environment:** The consumption patterns are of great interest to marketers. For example, there has been a global trend towards herbal or natural medication which consumers are willing to pay for. An outstanding example is that of products claiming to help customers combat weight problems. In fact, research has shown that spending on so-called “light” products has increased exponentially over the last few years.
- **Natural environment:** Factors involved are the natural resources needed for the production of products. Indeed, as pointed out by Kotler et al. (1996), environmental concerns have grown steadily over the past two decades, and the protection of the natural environment will remain a crucial worldwide issue. Factors which are included are the shortage of raw materials, an increase in the cost of energy and an increase in pollution, which in turn influences the development of the green and grey biotechnology markets.
- **Technological forces:** The technological environment is perhaps one of the main dramatic forces shaping the industries. Issues involved are the fast pace of

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<sup>212</sup> Political/Legal, Economic, Sociocultural and Technological

technological change, high R&D budgets, and concentration on minor improvements and increased regulations. For example, as products become more complex, people need to know that they are safe. Government agencies are thus investigating and banning potentially unsafe products. One well-established example is the very strict FDA and EUMEA drug approval processes. However, understanding that companies may be able to help terminally ill or chronic patients, the FDA has changed the pace for companies which have developed innovative drugs targeting those groups, thus enabling those companies to bring the product more quickly to market.

- **Political forces:** Any strategic decision is strongly affected by developments in the political environment. The political environment consists of legislation, government agencies and pressure groups which influence and limit various organisations and individuals in any given society. Examples are given under both technological forces and publics.
- **Cultural forces:** The cultural environment comprises institutions and other forces which affect society's basic values, perceptions, preferences, and behaviours. Factors which influence the cultural forces include the persistence of primary and secondary cultural values (e.g. how to make business), but also the individual's view of themselves, others, organisations, society, nature and the universe (e.g. religion).

### **Micro environment**

As stated above, the company's micro environment consists of various internal and external factors. Usually, Porter's so-called 5-force model is used when investigating these factors; although, as the name suggests, only five factors are included<sup>213</sup>. It does not, however, take various other factors, such as marketing intermediaries and publics, into account. As the five-force model is a well-established methodology for dissecting and understanding an industry, only the latter two are discussed below.

- **Marketing Intermediaries:** Marketing intermediaries are firms which help the company to promote, sell and distribute its goods to final buyers. One example of such a practice is carried out daily in Israel, where it is common practice for foreign pharmaceutical companies to align with marketing intermediaries for the distribution of their products.

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<sup>213</sup> For a detailed discussion of the 5-force model, see for example Porter (1990 and 1998), Broda (2002), Johnson/Scholes (1999)

- **Publics:** A public is any group with an actual or potential interest in or impact on an organisation's ability to achieve its objectives. An example is the financial publics – usually banks, VCs, business angels, investment houses and stockholders – which influence the company's ability to obtain funds. Another example is the public, as the image of the company (or the issue the company is dealing with, e.g. gene therapy) will affect their decision to buy the company's product or venture into cooperation with it. Other publics include government, media, and citizen-action, local and internal publics.

In fact, the pharmaceutical industry is a popular example cited when explaining the impact of these factors. For example, this industry has enjoyed quite high barriers to entry, due to the need for immense fixed research and development costs and economies of scale in selling to physicians. However, the latter in particular is changing, as the sales department, including the sales consultants, can be outsourced for a low cost factor. Substitutes for an effective drug are slow to develop, and historically buyers have not been price-sensitive. Again, the latter has changed dramatically and more changes are very likely to happen. These changes are mainly connected with changes to the reimbursement system of both physicians and patients<sup>214</sup>. Suppliers, who provide mostly commodities, have little business acumen. Finally, rivalry has been moderate and focused not on price-cutting, which erodes industrial profits, but on other variables, such as R&D, which tend to expand the overall industrial volume. The existence of patents has slowed competitive imitation. The industry structure in pharmaceuticals has been highly favourable to profitability, supporting sustained returns on investment which are among the highest of any major industry.

In Datamonitor's methodology report (2003), the company summarized market events which could influence both the macro and micro environment of healthcare companies (Diagram 8.2):

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<sup>214</sup> This is not only occurring in Germany but in other countries as well. However, in other countries, such as Israel or the UK, this price sensitivity has been in place for quite some time, as the patients have to pay for a large chunk of their medical bill.

**Diagram 8.2: Market events affecting baseline product forecasts**

<u>Switching away from brand</u>	<u>Line extension</u>	<u>Sales &amp; Marketing</u>	<u>Treatment practice</u>
Patent expiry	New indications	Co-marketing	Treatment guidelines
Rx-to-OTC switching	Off-label use	Co-promoting	Treatment setting (in-/ out-patient)
Withdrawal of brand/competitors	New patient subsets	Licensing activity	Combination polytherapy
Negative publicity	New dosage strength	Sales force size	Scheduling
Drug resistance	New countries	Detailing	Surgery
		DTC advertising	Changes in dosage, units/Rx, treatment length
		M&A	
		Phase IV trials	
<u>Regulatory issues</u>	<u>Epidemiology</u>	<u>New Drug Launch</u>	
Healthcare policy	New diagnostic tool	New patients vs. switching	
Company/government subsidies	Aging population	Inter-/intra-class competition	
Patient advocacy	Demographics	Reformulations	
Reimbursement	Prevention	Combination monotherapy	
Formulary inclusion	Co-morbidities	First year market share	
Cost-containment	Screening		
Price cuts/ increases	Awareness		
NICE			
Approval process			

Source: Datamonitor (2003)

From the diagram above, it is apparent that any life science company, be it (bio)pharmaceutical or other, has to continuously conduct a thorough investigation of the various environmental factors in order to understand the market and hence have a better chance of survival. It also shows the diversity of environmental factors which could/should be taken into account when evaluating the potential of a new health care-based life science product/firm. Some of these factors should, when relevant, be discussed in the business plan, especially with regards to the epidemiology and regulatory issues, but treatment guidelines and line extension (such as new indications) are also crucial factors which could influence the competitive advantage, and hence the potential, of a start-up/project.

### 8.3. Types of Alliances

There are five basic types of alliances<sup>215</sup>, which will briefly be discussed while focusing on their relevance to the biotechnology arena. They are specifically:

- Sales alliances
- Solution-specific
- Geographical-specific
- Investment alliances
- Joint venture alliance

#### **Sales alliances**

A sales alliance occurs when two companies agree to go to market together to sell complementary products. Its focus is very simple: to create sales. Usually this resolves around joint selling activities with certain clients or industry. However, exclusivity is not a requirement. The trust factor, which is a crucial success factor for alliances, comes into play when both companies deal with that particular clientèle or industry.

#### **Solution-specific alliances**

A solution-specific alliance evolves when two companies agree to jointly develop and sell a specific marketplace solution. One practice which has become industry standard is when companies which have developed a platform technology adapt it to the specific need of their clients.

In this form of alliance, exclusivity may or may not be implemented. In many cases, one alliance partner will own the evolution developed, whereas the other alliance partner will have a “preferred partner” designation because of the joint development work. At times, the end customer may like the solution but not wish to do business with one of the partners. The nature of solution-specific alliance may provide for similar scenarios. It is important to note that, as long as there is a register for what clients are joint clients and what clients are “open”, there exists a mutual understanding and expectation of how each company will behave in the

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<sup>215</sup> Kuglin (2002) and Hooley/Saunders/Piercy (1998)

marketplace<sup>216</sup>. In turn, this will build a foundation of trust on which both companies can operate.

Summing up, the solution-specific alliance not only binds two companies to sell a specific product, but also to develop the solution. Usually, this category of alliance has detailed parameters and incentives to maximise the return to both parties for their part in joint development effort, regardless of other competitors potentially participating at a client's requests.

### **Geographical-specific alliances**

A geographical-specific alliance is developed when two companies agree to jointly market or co-brand their products and services in a specific region. One prominent example is the alliance between Pfizer and Medico, an Israeli-based company. Pfizer and Medico's geographical-specific alliance calls for Medico to market and distribute Pfizer's products in Israel, while Pfizer provides Medico with all the information and material needed.

Often, this type of alliance involves some sort of investment in plants and equipment, if the specified product to be co-manufactured involves different manufacturing processes which are already in place. In this case, the geographical-specific alliance involves an investment alliance as well.

### **Investment alliances**

An investment alliance occurs when one company makes an investment in another company while at the same time developing an agreement to jointly market their products and services. This type of alliance is a well-established practice in the pharmaceutical industry. For example, Johnson & Johnson's Corporate VC not only offers its investees monetary investments, but also the chance to utilise Johnson & Johnson's network and knowledge to go to market.

An investment alliance therefore not only involves a capital investment, but often investments of resources and some sort of joint effort to co-market and/or co-develop the product.

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<sup>216</sup> Kuglin (2002)

### **Joint venture alliance**

In a joint venture alliance, two or more companies come together to form a third company to specifically market and/or develop specific products and services. This type of alliance usually involves setting up a separate organisation and financial structure, with ownership interests and incentives specified when the joint venture is established. The positive aspect of this is that, as in a marriage, there is a legal and financial commitment between the involved companies. On the downside, just as with marriages, a failure can be very painful and “messy.” With sales, solution- and geographical-specific alliances, the partners can simply cancel the alliance agreements. When dealing with a joint venture, there is the responsibility of a separate company and the financial implications which are tied to the performance of both companies.

### **Networks**

Networks are a “special” form of alliance. Networks are arrangements in which two or more organisations work in collaboration, often without formal relationships, via a mechanism of mutual advantages and trust. Such networks can be enduring and provide considerable mutual benefit to the organisations involved.

According to Jarillo (1988), who researched the area of strategic networks, networks become a tool enabling managers to position their company in a stronger competitive stance. He argues that the relationships enjoyed by the firms in the network are essential to their competitive position, and therefore the care of the relationships becomes a priority for the management. Jarillo (1988) also explains that the value chain concept is a useful tool when trying to distinguish between the different activities. According to the author, the relationship between internal and external (i.e. subcontracting) costs is important for the networking activities of a company, as it allows a firm to specialise in activities in the value chain which are essential to its competitive advantage. In addition, this strategy enables the firm to reap all the benefits of specialisation, focus and maybe even size. All other activities are therefore outsourced to members of the network which carry them out more efficiently. At the same time, all network members enjoy greater flexibility by evading fixed commitments to “non-essential” activities.

#### 8.4. The Israeli Biotechnology Market

The Israeli market, although limited in its size with a population of 6.5 million, is a very unique market. Israel is home to a successful high-technology industry and, following the successes of its science-based industry in electronics, software and communications, Israel has great potential for taking a leading place in the world of biotechnology as well as making an impact on interdisciplinary technologies such as bio-informatics<sup>217</sup> and proteomics<sup>218</sup>. Furthermore, the country has already assumed a world-leading role in research to find treatments for cancer and diseases of both the autoimmune and central nervous system. In the area of agricultural biotechnology (green biotechnology), Israel has long been an international leader<sup>219</sup>.

Israel has an enviable pool of human talent and research facilities, with more than 1,700 students a year graduating in the life sciences. Over half of all scientists work in the life sciences arena<sup>220</sup> and an additional 40,000-60,000 technically trained immigrants from the former Soviet Union have been able to contribute to this field<sup>221</sup>. This consortium of scientists will help Israel to make an impact on interdisciplinary technologies, thanks to the education in mathematics, physics and computer science fostered by all universities and the country's specialized military units. Life sciences represent about 35% of all civilian research activities<sup>222</sup>, mainly at Israel's internationally renowned seven universities<sup>223</sup>, four medical schools<sup>224</sup> and two agricultural research institutes<sup>225</sup>, who all staff R&D commercialisation offices to support research and technology transfer. These efforts are also promoted by government structures, including at all major universities. Furthermore, all major hospitals are involved in advanced biochemical research. This close relationship between academia and

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<sup>217</sup> The creation of sophisticated machinery capable of sifting through the vast amounts of molecular information accumulated by the Human Genome Project

<sup>218</sup> The identification of proteins using human tissue analysis

<sup>219</sup> Goldman Barash (2002)

<sup>220</sup> Biospace (2000)

<sup>221</sup> Golan (2004), Bio2004 (2004)

<sup>222</sup> Golan (2004), Bio2004 (2004)

<sup>223</sup> Ben-Gurion University, Haifa University, Tel Aviv University, The Technion-Israel Institute of Technology, The Weizmann Institute, Bar-Ilan University and the Hebrew University of Jerusalem

<sup>224</sup> Ben-Gurion University, The Technion, Tel Aviv University and the Hebrew University

<sup>225</sup> The Volcani Institute and the Hebrew University's Faculty of Agriculture

industry may be one reason why many scientists from academic institutions have taken positions in biotech industries<sup>226</sup>.

Funds for life science research equal half of the total research funding in Israel<sup>227</sup>, while 40% of all R&D funds in academia are channelled towards the life sciences<sup>228</sup>. In 2004, approximately four percent of the national expenditure was spent on R&D<sup>229</sup>.

Israel is among the top 10<sup>th</sup> percentile in the world for biotech patents in relation to its population. Israel has taken the lead in the number of scientific publications per capita<sup>230</sup>; various fields of biology, biotechnology, biomedical<sup>231</sup>, clinical research, related medical areas and (bio)agriculture account for almost 60% of its scientific publications<sup>232</sup>. In fact, Israel is now one of the three leading countries worldwide for the number of biotech publications it produces<sup>233</sup>.

In recent years, both Israeli and multi-national Israeli-based pharmaceutical companies have obtained significant achievements, particularly in the fields of generics and biotechnology. Moreover, in view of the fact that the country has developed into an important pharmaceutical research centre, the majority of the leading pharmaceutical corporations, e.g. Johnson & Johnson, Roche Pharmaceuticals or Bayer, have intensified their direct involvement in Israeli-based projects. This development has generated an investment placement of \$80 million per annum in clinical trials conducted by Israeli medical institutions and physicians<sup>234</sup>.

The Southern California-Israeli Chamber of Commerce claims that Israel is third in the world in the number of start-ups in the field of biotechnology<sup>235</sup>. Golan (2004) asserts that the

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<sup>226</sup> Morgenstern (2002)

<sup>227</sup> Biospace (2000)

<sup>228</sup> Barash (2002)

<sup>229</sup> Israel High-Tech & Investment report (May 2004)

<sup>230</sup> Berry, O. Dr. (chief scientist at the Ministry of Trade and Industry), in Biospace 2000

<sup>231</sup> The area of neurology accounts for 23% of all Israeli biomedical projects in academia, followed by infectious disease (16%), autoimmune disorders and cancer (each 10%). Cardiovascular and endocrinology account for 7% and 4% respectively. An additional 30% of all academic research projects focus on a multitude of other related fields.

<sup>232</sup> Golan (2004), Molcho (2003)

<sup>233</sup> Berry, O. Dr. (chief scientist at the Ministry of Trade and Industry), in Biospace 2000

<sup>234</sup> Healthcareinformation.com

<sup>235</sup> Golan (2004)

country's biotechnology sector ranked fifth in comparison to European countries, after Germany, Great Britain, France and Sweden.

A firm foundation for the country's success in all technology, biotechnology and related medical industries is laid by its 23 technology-orientated incubators, which have successfully obtained more than \$626 million in private investment placements<sup>236</sup>. By 2002, 500 projects had been launched projects, over 243 biotechnology and other medical-related projects had successfully completed the incubator programs and had become operating companies<sup>237</sup>. Of these, 51% had become self-sufficient<sup>238</sup>. In addition, over 20% of them were involved in biotechnology-related projects<sup>239</sup>.

Nowadays Israeli start-ups are quite well capitalised and are gradually becoming profitable. In 2000, approximately 20% of the 160 biotechnology firms turned profitable while another 25% were expected to do so over the following few years<sup>240</sup>. Although the number of biotech companies decreased to 149 by 2003, the majority were generating revenue<sup>241</sup>. During 2004, however, the number of biotechnology companies had increased to 175 (start-ups, small and medium-sized firms only)<sup>242</sup>. With close to \$1 billion in sales and fewer than 4,000 workers, their value added and total factor productivity are enormous. According to Ilanot Batucha, a brokerage firm, there are currently 300 drugs in the FDA-mandated clinical Phase 3 trials. These will join the current pool of over 100 drugs which have obtained FDA approval and are being commercialised.

The developments in biotechnology and other medical-related industries are also contributing significantly to the growth of the Israeli economy. The whole medical industry, including medical equipment and generic drugs, achieved sales revenue of \$1.1 billion in 1998 from exports; this entailed over 5% of total Israeli exports<sup>243</sup>. A survey conducted by Israel's Ministry of Science suggested that sales from the biotech sectors would generate US\$1.8 -2.3

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<sup>236</sup> Golan (2004)

<sup>237</sup> Israeli Government

<sup>238</sup> Golan (2004)

<sup>239</sup> Meyer (2004)

<sup>240</sup> Meyer (2004)

<sup>241</sup> Israel High-Tech & Investment report (May 2004)

<sup>242</sup> Bio2004 (2004)

<sup>243</sup> Golan (2004)

billion by 2003-2004<sup>244</sup>. Currently, Israel's share of global biotechnology sales totals about 2.5%.

The information presented in the next sub-sections presents a brief outline of the unique country-specific factors which support the development of the Israeli life sciences industries. The first sub-chapter will provide a review of the Israeli biotechnology market's development, followed by a précis of the various life science markets and their relevant sales revenue. An account of various government intervention programmes is included in the third subsection.

### 8.4.1 The Development of the Israeli Biotechnology Market

The Israeli biotech industry was born in 1981 when Biotechnology General (BTG) and Interpharm – a subsidiary of the Swiss pharmaceutical company Ares-Serono<sup>245</sup> – were founded. Despite the vast amount of research carried out within Israel's hospitals and universities, these two companies were virtually the only players in the biotech sector for over a decade<sup>246</sup>. The main areas of research in the mid-1980s included genetic engineering, human and animal diagnostics, agricultural bio-fertilisation and aquatic biotechnology.

The situation changed in the early 1990s when dozens of start-ups began to emerge, aided by R&D grants (some providing up to half the research costs) from the Office of the Chief Scientist at the Ministry of Industry and Trade<sup>247</sup>. The Israeli government tried to further the growth of the biotechnology sector by creating a national steering committee whose task was to answer biotech's special needs. The government also created "Magnet"— a framework assembling university-based scientists and companies wishing to jointly perform research efforts in order to develop products suitable for commercialisation. Magnet also provides an incubator programme (see section 8.4.3 "Government Intervention").

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<sup>244</sup> Golan (2004), Meyer (2004)

<sup>245</sup> biotech.about.com, Barash (2002), Meyer (2004)

<sup>246</sup> biotech.about.com, Barash (2002), Morgenstern (2002)

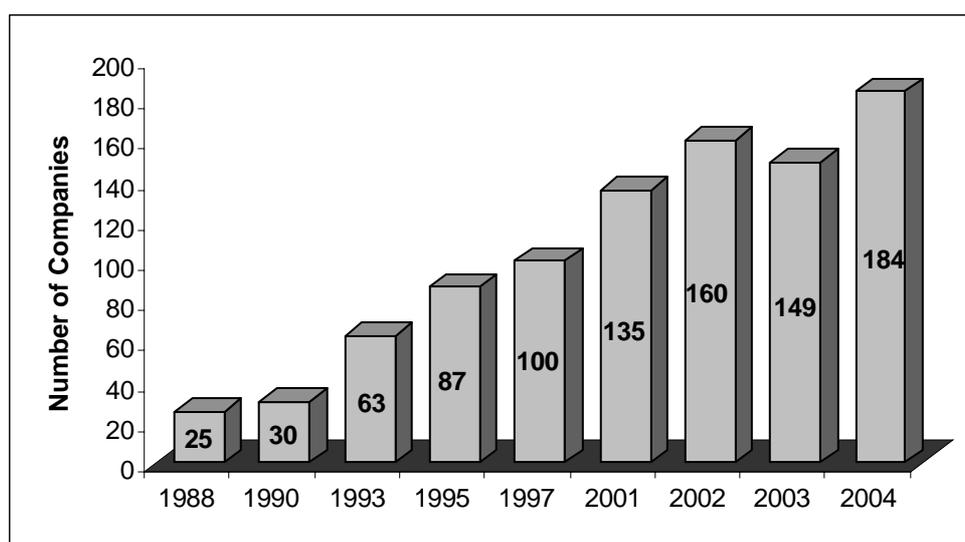
<sup>247</sup> biotech.about.com, Barash (2002),

By 1996, 90 biotech companies had been established. However, government funding was only available as seed capital. Due to difficult market conditions and a lack of funds, many biotechnology start-ups were unable to survive the latter half of the decade<sup>248</sup>.

These conditions also affected high growth companies operating in other medical-related industries, such as drug delivery and medical diagnostics. Innovative firms struggled to raise the necessary second or third rounds of financing and consequently failed to commercialise their products.

Despite these challenges, the number of registered biotechnology start-ups grew steadily, reaching 149 companies in 2003<sup>249</sup>. Diagram 8.3 shows the growth of the Israeli biotech and pharmaceutical industry<sup>250</sup>. In fact, by the turn of the century, the playing field was rich with companies performing the required Phase I and II clinical trials, advancing on the path to commercialisation of their products.

**Diagram 8.3: Number of Israeli biotech Companies - 1988 -2004<sup>251</sup>**



Source: Israel National Biotechnology Committee, Central Bureau of Statistics in Israel High-Tech & Investment report (May 2004), Uktradeinvest.com, Barash (2002), Morgenstern (2002), Bio2004 (2004)

<sup>248</sup> As elsewhere in the world for local Venture Capital during the second half of the 1990s, the market turned hostile to biotech and began ravenously devouring Internet and telecom stocks, which had fast and impressive rates of return. It therefore became suddenly extremely difficult for early- and middle-stage companies to secure funding.

<sup>249</sup> Barash (2002), Morgenstern (2002), Israel High-Tech & Investment report (May 2004), Meyer (2004)<sup>249</sup>

<sup>250</sup> The data for the very early stages of biotechnology is usually integrated with the data on the pharmaceutical industry.

<sup>251</sup> Prior to 1990 any data relating to the biotechnology sector was usually included in the pharmaceutical industry statistics.

As stated above, Israel's biotech companies are operating in the various market sectors of therapeutic pharmaceuticals, diagnostics, bio-informatics and agricultural biotechnology, including plant and farm animal products<sup>252</sup>. The focus of these 184 companies' work in 2004 is depicted in Table 8.1.

**Table 8.1: The Israeli Life Science Arena in 2004**  
 – Number of Companies according to market segment

Segment	Companies
Agro-Bio	60
Cell Biology	20
Biosensors	17
Cell/Gene Therapy	15
Drug Discovery	15
Fundamental Cancer Research	15
Infectious Disease Mechanisms	15
Genetic Engineering	13
Proteomics	8
Bioinformatics	3
Telemedicine	3
<i>Total</i>	<i>160</i>

Source: Bio2004 (2004)

In 2003, 118 of the biotechnology companies were either start-ups or R&D institutes. The remaining 31 (established) companies were involved in the development and manufacture of drugs for human and veterinary use<sup>253</sup>.

Further, half of the companies involved in biotechnology in 2002 were active in the field of human medicine; 20% of the companies were involved in agricultural and marine biotechnology; 19% worked in the field of environmental biotechnology, while 7% focused on cosmetics. The remaining companies were involved in the production of functional foods<sup>254</sup>.

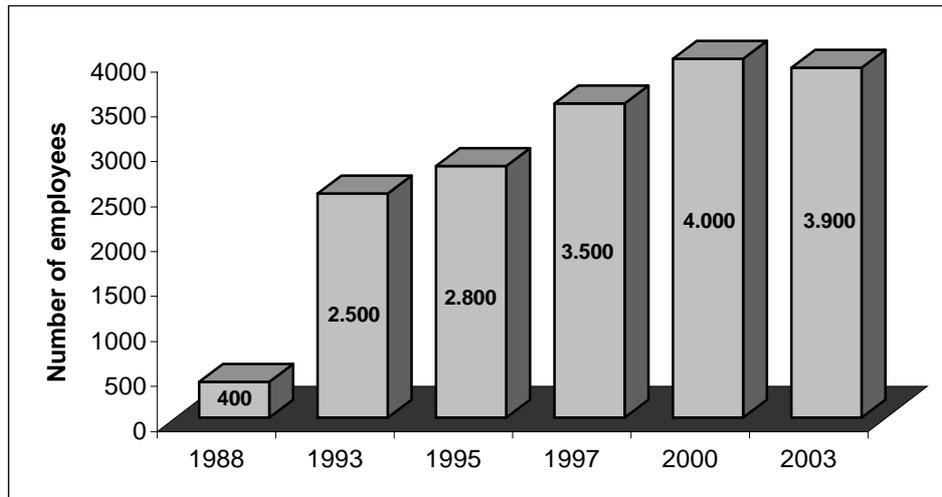
<sup>252</sup> Goldman Barash (2002), Morgenstern (2002), Uktradeinvest.com,

<sup>253</sup> Israel High-Tech & Investment report (May 2004)

<sup>254</sup> Israel High-Tech & Investment report (May 2004)

Additionally, as indicated above, Israel’s strong science-based workforce has been one of the founding pillars of the industry’s potential. In fact, the number of employees in the biotechnology sector alone has grown considerably (Diagram 8.4):

**Diagram 8.4: Biotech workforce in numbers – 1988 to 2002**



Source: Uktradeinvest.com, Morgenstern (2002), Barash (2002), Biospace (2002), Meyer (2004), Israel High-Tech & Investment report (May 2004)

In 2003, some 46% of the biotechnology workers were employed in R&D, 34% were involved in production and 20% worked in marketing and administration<sup>255</sup>.

Moreover, according to statistics provided by the Israeli government, Israel holds the highest ratio of scientists and technicians per capita – the latest statistics claim that this ratio is 135 scientists and technicians per 100,000 workers.

Yet, despite the industry's growth over the past few years, the country's combined sales of biotechnology-derived products were just a small fraction of Israel's gross domestic product (\$93 billion). Furthermore, Israel has an extensive pool of biotechnology intellectual property, which is frequently licensed out and less often commercialised on its own soil; this is a situation the nation is trying to change. A number of factors may be responsible for these two situations. First of all, the majority of biotechnology companies are still at an early stage of development, which may result in a paucity of commercially viable technologies. Secondly,

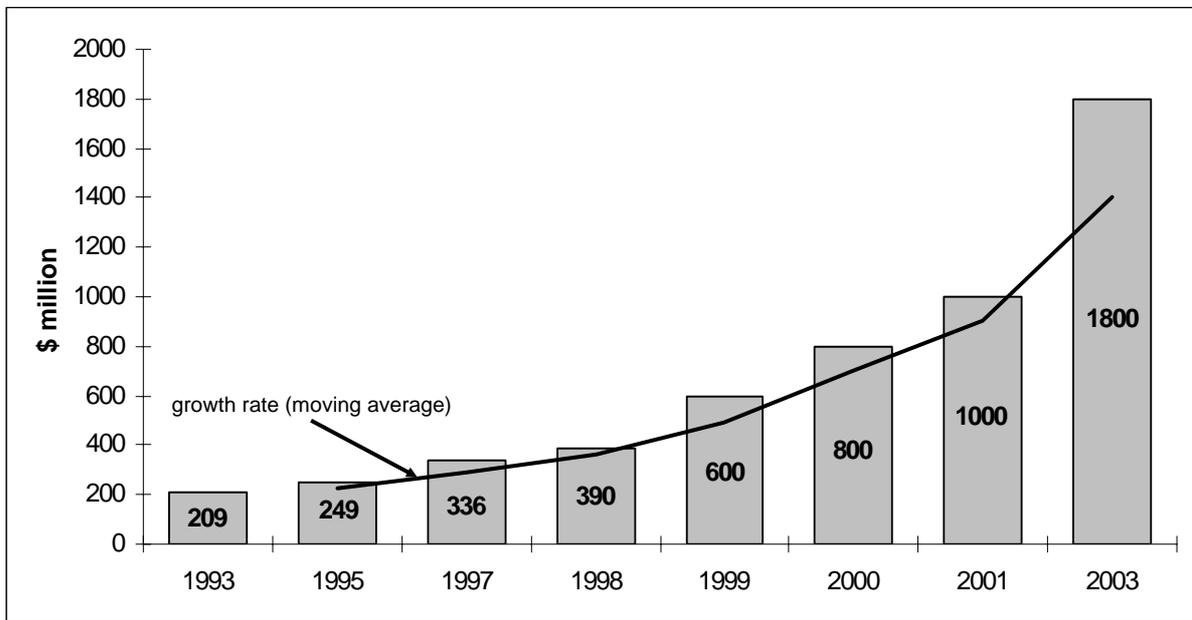
<sup>255</sup> Israel High-Tech & Investment report (May 2004)

despite all efforts by the government and great interest from external (and internal) investors, many companies are still suffering from a lack of adequate funding<sup>256</sup>.

#### 8.4.2 Sectors and Sales

Sales revenues generated by Israeli biotechnology products proliferated from a mere \$15 million in 1988 to \$800 million in 2000, while exceeding \$1 billion in 2001<sup>257</sup>, approximately 80% of which was generated from exports<sup>258</sup>. By 2003, biotechnology sales had increased by a further 80%, reaching \$1.8 billion. This trend is depicted in Diagram 8.5.

**Diagram 8.5: Biotechnology Sales (\$ million) – 1993 to 2003**



Source: The ministry of industry & Trade, Office of Chief Scientist, in Giza Venture Capital (2002) & Molcho (2003), Barash (2002), Morgenstern (2002), Meyer (2004), Uktradeinvest.com

Some 50% of biotechnology revenue in 2002 came from firms operating in the field of drugs for human and veterinary use; 22% stemmed from research companies; and 29% came from companies involved in agriculture and functional foods<sup>259</sup>.

<sup>256</sup> Barash (2002)

<sup>257</sup> Barash (2002), Morgenstern (2002), Meyer (2004)

<sup>258</sup> Barash (2002), Morgenstern (2002), Meyer (2004)

<sup>259</sup> Israel High-Tech & Investment report (May 2004)

Israel contributes to about 2.5% of the world's biotechnology sales<sup>260</sup>. Furthermore, sales revenue generated from medical equipment and electronics and generic drugs reached \$ 1.1 billion in 1998, representing over 5% of Israel's exports<sup>261</sup>. Yet, despite the industry's growth over the past few years, the country's combined sales of biotechnology-derived products and other medical-related industries was just a small fraction of Israel's gross domestic product (\$93 billion)<sup>262</sup>.

### **Therapeutics & bio-therapeutics**

Local scientists have developed methods for producing a human growth hormone and interferon, a group of proteins effective against viral infections. Copaxone, a medicine effective in the treatment of multiple sclerosis, has been developed in Israel - from basic research to industrial production. Genetic engineering, including cloning, has resulted in a wide range of diagnostic kits based on monoclonal antibodies, along with other microbiological products.

The world market of therapeutic gene products, many of which will derive from the human genome project, is very high. For example, Interferon for Multiple Sclerosis reached \$1.2 billion in 1999 with 170,000 patients treated<sup>263</sup>. Furthermore, bio-therapeutics<sup>264</sup> is emerging as the country's leading biotechnology sector; 48 companies are generating around 70% of the country's aggregate biotech sales<sup>265</sup>.

### **Medical Technology & Diagnostics**

As early as the 1970s, novel medical devices were being developed in this country<sup>266</sup>. Some of them, such as the CO<sub>2</sub> surgical laser and the computer tomography (CT) scanners, were at the forefront of medical technology. In the 1990s, Israel attracted the attention of the global

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<sup>260</sup> Morgenstern (2002), Meyer (2004)

<sup>261</sup> Morgenstern (2002), Meyer (2004)

<sup>262</sup> Morgenstern (2002), Meyer (2004)

<sup>263</sup> Biospace (2004)

<sup>264</sup> Biotherapeutic products are derived from human proteins, antibodies, enzymes, or carbohydrates. These products are believed to be more effective and safer as their number and the severity of their side effects are lower than conventional drugs. Furthermore, compared to traditional drug development the costs are approximately \$100 million and the time to clinical trials is often significantly less than the conventional 8 to 12 years (see Chapter 3.X).

<sup>265</sup> Morgenstern (2002), Molcho (2003)

<sup>266</sup> Israel High-Tech & Investment report (October 2002)

medical industry with its development of medical cardiac stents<sup>267</sup>. Other medical equipment developed and marketed worldwide includes magnetic resonance imaging (MRI) systems, ultrasound scanners and nuclear medical cameras. The industry is also seeing an influx of second-generation entrepreneurs from the software and telecommunication industries looking to apply their skills in other places. One very prominent example is that of *Given Imaging*<sup>268</sup>.

Although development costs in both the medical technology and diagnostic industries are less financially demanding, the markets are also more limited. In Israel, biotechnology-based diagnostics amount to nearly 5% of all biotechnology sales<sup>269</sup>. These are generated mainly from genetic and immunological assays for viruses and other pathogens; however, genetic diagnostics promises to become a major future activity. The success of the medical and medical instrument industry segments in terms of start-ups has secured Israel a place among the three international leaders<sup>270</sup>.

### **Agricultural R&D**

The agricultural sector is based almost entirely on R&D, implemented by cooperation between farmers and researchers. Research results are quickly transmitted to the field for trial via an extensive service system, and problems are brought directly to the scientists for solutions. The Ministry of Agriculture's Agricultural Research Organisation primarily carries out agricultural R&D. Most agricultural research institutes in Israel maintain close relations with the Food and Agriculture Organisation of the United Nations, ensuring a continuous exchange of information with other countries.

Israel has taken a lead position in various areas of (bio)agriculture. For instance, Israel's dairy cows are, on average, the world champions in milk production, having increased the average yield per cow from 6,300 litres in 1970 to over 10,000 litres today thanks to scientific breeding and genetic testing carried out by the Volcani Institute. Agriculture has also benefited from general scientific research and R&D, including automated plant tissue culture,

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<sup>267</sup> Israel High-Tech & Investment report (October 2002)

<sup>268</sup> The Company has developed an encapsulated miniature camera which is swallowed by the patient. The capsule, which travels down the small bowel, sends images to a screen from which doctors may accurately diagnose gastrointestinal disorders and diseases, without the need for invasive exploratory surgery.

<sup>269</sup> Morgenstern (2002), Moloch (2003)

<sup>270</sup> Horesh et al (1999)

biological insecticides, disease-resistant seeds and biological fertilisation<sup>271</sup>. Algae and fish cultures are other examples of Israel's diverse food and bio-nutraceutical sector<sup>272</sup>.

Agro-Bio and veterinary products amount to 23% of sales<sup>273</sup>. The majority were derived from the sale of genetically developed hybrid seeds for vegetables, crops, fruits and cotton, with resistance to pathogens, herbicide and adaptation to environments, poultry and farm animal vaccines.

### 8.4.3 Government Intervention<sup>274</sup>

The Israeli government has long recognized the importance of biotechnology and continues to promote its rapid development with financial support and other incentives for R&D activities, via the Office of Chief Scientist for the Ministry of Trade and Industry (OCS) and the Ministry of Science and Technology. Government support actions have included the creation of various national infrastructure centres for advanced biotech technologies, enabling scientists and industry to have access to equipment and methods essential to basic and applied technology projects. The following subsection briefly outlines some of these interventions:

#### **Government planning in Biotechnology**

At the beginning of the year 2000, the Ministry of Industry and Commerce pledged to invest more R&D funds in the various biotechnology-based industries. The government offered the biotechnology industry a variety of programmes for financial and technological support. The Office of the Chief Scientist (OCS) is responsible for supporting and encouraging industrial research and development, including biotechnology. Companies can apply to the OCS for funding to cover their R&D expenses, but are only liable to repay the loan if the projects have developed into a commercially successful product. This method has helped to reduce the risk of engaging in cutting-edge research.

In 1990, under the aegis of the OCS, the national Biotechnology Committee was founded to promote biotechnology research and entrepreneurial activities and to advise the government

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<sup>271</sup> Israeli Government, Barash (2002)

<sup>272</sup> Israeli Government, Barash (2002)

<sup>273</sup> Morgenstern (2002)

<sup>274</sup> All information included has been taken from information distributed by the Israeli Government

on the industry's development. The committee is made up of industrial executives and academics in equal numbers.

The largest and most important of the OCS's ventures is "Magnet", a programme which sponsors companies and universities to jointly develop novel, generic technologies, underwriting up to 65% of their budgets.

The OCS also sponsors high-technology incubators which provide a supportive environment for scientists who lack the entrepreneurial skills to interest investors. Until recently, biotechnology projects operated in general technology incubators, and were therefore subjected to the same demands as software and communications start-ups. However, the unique qualities of biotechnology, with its longer and more expensive development cycle, have compelled the OCS to set up two specialised biotechnology incubators which will host biotech projects for longer periods, and provide up to \$1.8 million in financing.

Outside the framework of the OCS, the Ministry of Trade and Industry also gives grants and tax incentives for capital spending on plants and equipment through its Investment Centre. In addition, the Ministry of Science, Culture and Sports has recognised biotechnology as a "national project" for 2002-2007, enabling at least 10 different research groups to train manpower, strengthen research infrastructure and allocate funds for academic biotechnology and medical research. The Ministry also sponsors national centres for intermediate strategic research which requires advanced instrumentation and skilled scientists, such as protein purification and micro-sequencing, transgenic plant and animal technologies, genomic technologies, gene therapy and high-throughput screening technologies.

An infrastructure program, Tashtit, has also been set up by the Science Ministry to expand scientific research on selected biotechnology topics. A national steering committee advises the ministries on the choice of topics to be included.

### **Intellectual Property Protection**

Israel's regulatory system, which was formerly considered to be very conservative and somewhat anachronistic, has undergone various dramatic and controversial reforms. Some of these changes may market global trends, so their significance may exceed the immediate Israeli context.

In 1998, the Government of Israel amended the patent law to allow local companies which are not patent owners or licensees to manufacture patented material prior to expiration in order to submit registration data to health authorities in Israel, and other countries which allow similar pre-expiration activities for marketing approval. The implementation of this law enables Israeli manufacturers without any rights to the patent to conduct large-scale manufacturing in Israel during the life of the originator's patent. Although the law is designed to permit the manufacture and export of patented medications for the limited purpose of applying for marketing approval, since the Israeli government has not established any effective enforcement mechanisms to prevent abuse of this provision, companies may manufacture and export large quantities of pharmaceutical products during the period of patent protection.

The law has, in effect, significantly shortened the period of patent protection for pharmaceutical products (which discriminates between technologies and so may violate TRIPS), and so reduces patent protection in Israel. The effective period of patent protection in Israel is now approximately five years, the shortest patent terms in any developed country except Canada. Notably, the EU has launched a WTO complaint against the Canadian system.

In early 1999, the Government of Israel passed into law amendments to the Pharmacists' Act allowing importation by non-right holders of patented pharmaceutical products registered in Israel. The goal of the legislation was to permit parallel import of generic products while ensuring that patent protection in Israel would not be weakened.

## 8.5. The Israeli Venture Capital Market

The Israeli Venture Capital market has been growing considerably and includes both private and corporate Venture Capital institutions. Although Israeli biotech companies had little access to Venture Capital or foreign partners during the mid to late 1990s, this situation has greatly improved in recent years. Today there are over 65 VC funds in Israel, about 20 of which are actively involved in biotechnological and other medical-related projects. Each of these funds holds \$10 million to over \$500 million in capital<sup>275</sup>. Foreign investors, such as Johnson & Johnson, Bayer or Baxter, have also taken an increasing interest in Israel's life science<sup>276</sup> industries. For instance, Johnson & Johnson has established a large Venture Capital fund and research centre, aiding its portfolio companies in issues such as managerial, research and development, and clinical trial efforts.

### 8.5.1 Industry growth

Prior to 1996, figures raised by the Venture Capital industry did not exceed \$400 million p.a.<sup>277</sup>. Since then, capital raised has increased significantly. During 2000, funds were able to obtain nearly \$3.3 billion<sup>278</sup>, almost twice as much as in 1999. However, during 2001, when the repercussions of the high-tech industry's breakdown were starting to emerge, the level of obtained funds plunged to nearly \$1.4 billion<sup>279</sup>. The development of available funds is depicted in Table 8.2, where the various types of funds, including investment companies, are classified.

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<sup>275</sup> Mordechai (2001)

<sup>276</sup> As the analyses of IVC and PricewaterhouseCoopers are used for this section, biotechnology, the health information system and medical devices are classed under life sciences.

<sup>277</sup> Mordechai/Er-El (2001A)

<sup>278</sup> Mordechai/Er-El (2001A)

<sup>279</sup> Mordechai/Er-el (2001A)

**Table 8.2: Capital raised by investor type 1991 – 2000 (\$ millions)<sup>280</sup>**

	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
VC funds												
Private funds	49	27	162	112	145	264	609	468	1,575	3,155	1,344	63
Public & other funds	0	54	42	0	0	0	27	8	44	35	6	-
Other private equity funds	0	45	128	242	6	110	66	74	40	26	--	-
<i>All funds</i>	<i>49</i>	<i>126</i>	<i>332</i>	<i>354</i>	<i>151</i>	<i>374</i>	<i>702</i>	<i>550</i>	<i>1,659</i>	<i>3,216</i>	<i>1,350</i>	<i>63</i>
Investment Companies	9	34	40	20	5	23	25	125	93	72	-	-
<b>All Capital sources</b>	<b>58</b>	<b>160</b>	<b>372</b>	<b>374</b>	<b>156</b>	<b>397</b>	<b>727</b>	<b>675</b>	<b>1,752</b>	<b>3,288</b>	<b>1,350</b>	<b>63</b>

Source: Mordechai/Er-El (2001A) Zakai (2003A )

According to IVC's analysis of 2001, active Israeli VCs were managing approximately \$7.74 billion, \$4.07 billion of which was still available in 2001. Moreover, according to Mr. Holtzman<sup>281</sup>, Chairman of IVC Research and Giza Venture Capital, over 15 Venture Capital funds were acquiring new funds during 2004. Based on this development, he expects an increase in the pace of technology investments while anticipating that these new funds will ensure a rate of investment exceeding \$1 billion over the next few years<sup>282</sup>. In point of fact, according to the latest figures by IVC<sup>283</sup>, Israeli high-tech companies have been able to raise \$1.5 billion, thus nearly regaining 2001's investment levels (see Diagram 8.6).

Following the aftermath of the collapse of the "new economy" hype, the Israeli Venture Capital market suffered severely. It reached its lowest level since 1998 in 2003. Notwithstanding this recessionary trend, 2004 saw a growth rate of over 95% (see Diagram 8.6), thus exceeding the forecast levels of \$1.2 billion to \$1.3 billion<sup>284</sup>. As a consequence of this extraordinary growth, the monies obtained in 2004 almost levelled 2001's aggregate equity placements. Despite this, available financial assets are still nowhere near the 2000 peak, when Israel's high-tech companies were able to raise \$3.6 billion in VC funds. A recent examination of the Israeli Venture Capital province by IVC<sup>285</sup> evidenced that the share of the total amount invested in by national VCs was 45%, representing a modest propagation from the average share of 42% Israeli VCs held since 1999.

<sup>280</sup> Mordechai/Er-El (2001A),

<sup>281</sup> in Israel High-Tech & Investment report (2004A)

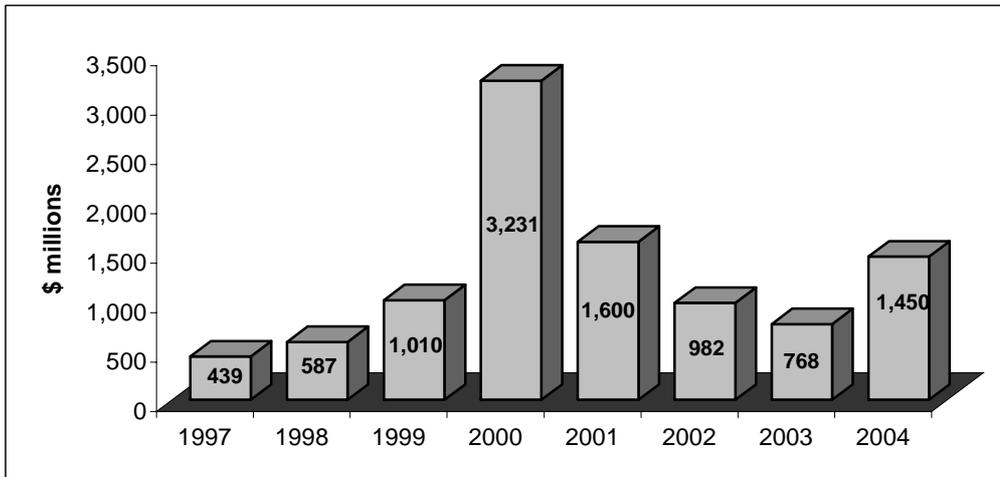
<sup>282</sup> Zakai (2004A)

<sup>283</sup> Zakai (2005)

<sup>284</sup> Red Herring (2004), Zaki (2004A)

<sup>285</sup> Zakai (2005)

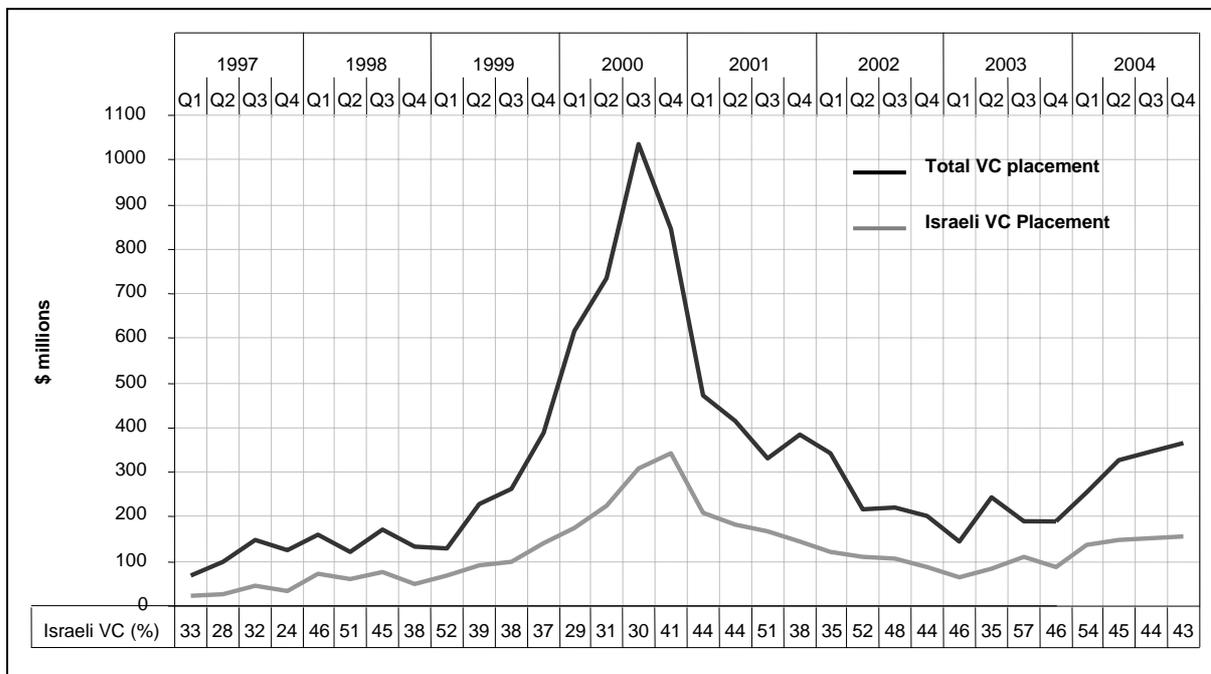
**Diagram 8.6: Total Venture Capital Placements – 1997 to 2004**



Source: Fellus (2000, 2001 & 2004), Fellus/ Bengal (200A through 2004), Fellus/Fried (2004A & 2004B), Zaki (2003A through 2005)

However, when presenting the data on a quarterly rather than annual basis, as in Diagram 8.7, a turnaround situation is revealed as early as Q1/2003. Over and above this, the lowest quarter during the period of diminishing pecuniary aid from private equity financiers was the previous quarter, i.e. Q4/2002.

**Diagram 8.7: Investment placement in Israel – 1997 to 2004**



Source: Fellus (2000, 2001 & 2004), Fellus/Bengal (2001A through 2004), Fellus/Fried (2004A & 2004B), Zakai (2003A through 2005)

The figures generated during 2004 reflect a continuous recovery of the overall high-tech sector and an inflation of liquid assets provided by VCs. Mr. Holtzman asserts that the amassed capital raised by Israeli high-tech firms in 2003 represented 50% of the total European Venture Capital investment placement level during the same year<sup>286</sup>. In addition to the above, the data presented in Diagram 8.7 reveals that the Israeli Venture Capital share of the cumulated financial resources granted to Israeli high-tech companies increased from 30% in 1997 to 45% in 2004<sup>287</sup>. Although the data suggests an evidently higher involvement of national-based resources, the cause for this intensification may be instigated in the behaviour of multinational risk capital providers. For example, the sharp expansion of the national share in Q1/1999 was not due to any abrupt changes in the pattern of national investors, but rather due to a substantial decrease in internationally available private equity.

Furthermore, although the average company financing round has fluctuated quite rapidly, it has, with few exceptions, mimicked the fluctuations of total investment raised.

One of the unique features of the Israeli VC market is that, until 2001, investors were focusing on companies which had not been in business for long; indeed, early-stage<sup>288</sup> companies received 50% plus of all available private equity until 2000 (see Diagram 8.8). Nevertheless, the proportion devoted to early stage continuously decreased. Actually, since 2002, expansion/latter stage companies received the bulk of all investment placements. Further, during 2004 seed/start-up investments increased to 8% of the total capital available. In fact, both the amount and relative share of seed investments reached a record level since 1998. Holtzman attributes this shift to seed funding to the fact that seasoned entrepreneurs are

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<sup>286</sup> Zaki (2003C)

<sup>287</sup> Fellus (2000, 2001 & 2004), Fellus/Bengal (2001A through 2004), Fellus/Fried (2004A & 2004B), Zaki (2003A through 2004B)

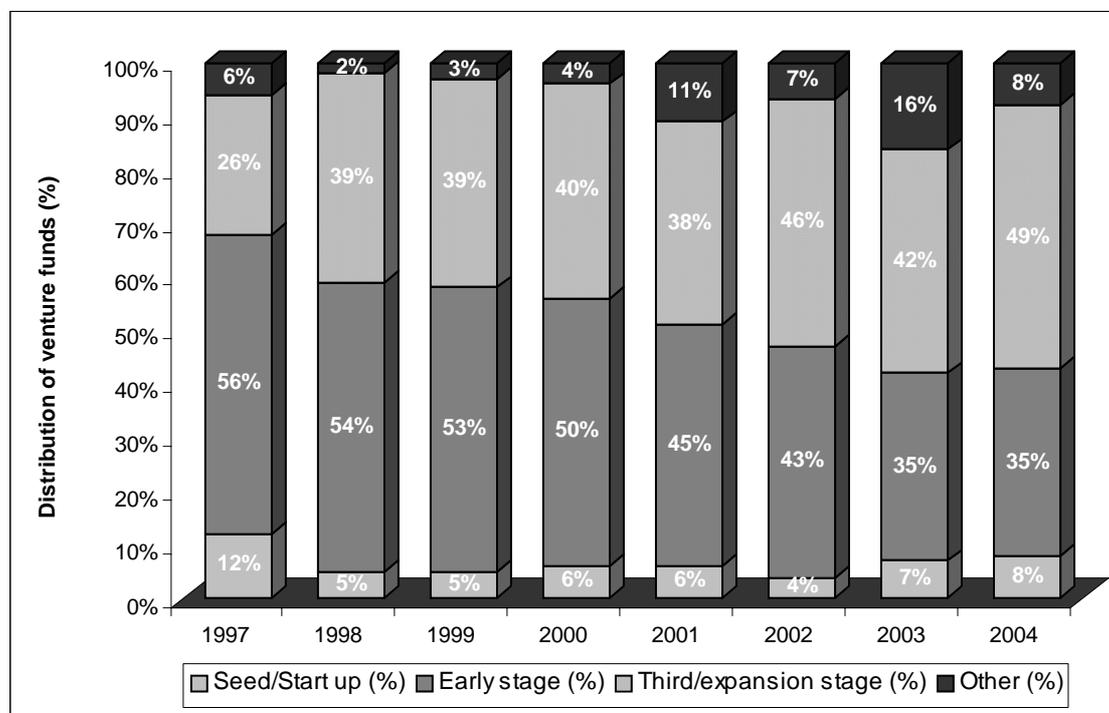
<sup>288</sup> Since the data used in this chapter is mainly based on analyses by PricewaterhouseCoopers and IVC, a common definition base had to be established. Hence, for the purpose of this chapter, PricewaterhouseCoopers definitions have been used, as the company differentiates the different development stages in more detail. The categories used are as follows:

- ◆ **Seed/Start-up stage:** The initial stage. The company has a concept or product under development, but is probably not fully operational.
- ◆ **Early stage:** The company has a product or service in testing or pilot production. In some cases that product may be commercially available. The company may not be generating revenues.
- ◆ **Expansion stage:** The product or service is commercially available. Further, the company is demonstrating significant revenue growth but may not be profitable.
- ◆ **Later stage:** The product or service is widely available and the company is generating ongoing revenue and may have a positive cash-flow. Further, the company is more likely to be, though not necessarily, profitable.
- ◆ **Others:** Includes bridge financing and all other financing rounds.

Please note that for the purpose of this thesis the expansion and late stage are viewed collectively.

increasingly more prone to return to the industry. In his opinion, 2005 should also have witnessed high levels of equity placements in seed companies.

**Diagram 8.8: Investment placement by stage development (%) – 1997 to 2004**



Source: Fellus (2000, 2001 & 2004), Fellus/ Bengal (2000A through 2004), Fellus/Fried (2004A & 2004B), Zakai (2003A through 2005)

During 2000, all development stages experienced an annual growth of over 100%. Seed-stage companies exhibited the second highest rate of annual growth<sup>289</sup> (385%) after other stages (442%). The sum invested in early-stage companies proliferated by 308% while placement in third/expansion stage companies exhibited the slowest upsurge with 103% (Table 8.3)

**Table 8.3: Investment placement by stage development (\$millions) – 1997 to Q3/2004**

	1997	1998	1999	2000	2001	2002	2003	2004 <sup>290</sup>
Seed/Start-up	51	27	54	208	91	35	58	108
Early stage	248	315	527	1627	723	419	271	379
Third/expansion stage	115	229	394	404	606	453	320	819
Other	26.3	12	30	129	178	67	125	144

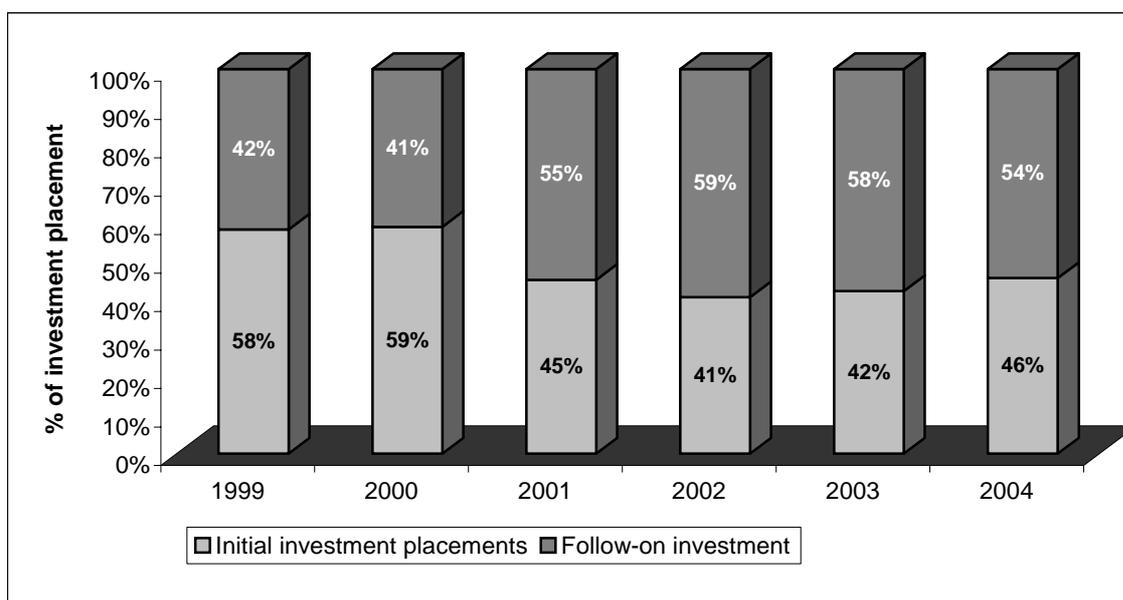
Source: Fellus (2000, 2001 & 2004), Fellus/ Bengal (2000A through 2004), Fellus/Fried (2004A & 2004B), Zakai (2003A through 2005)

<sup>289</sup> Fellus/ Bengal (2001D)

<sup>290</sup> Please note that no data was available for Q4/2004 for the early and other stage categories. Therefore, the remaining \$109 million was allocated evenly between the two categories.

Prior to the collapse of the new economy, the majority of funds invested in by Israeli-based VCs were first investment placements. However, since 2001 this has changed dramatically. During 2002 and 2003, nearly 60% of all Israeli Venture Capital investment placements were in follow-up investments (Diagram 8.9). This may be explained by the fact that VCs were channelling their resources more towards their portfolio companies, trying to support the more promising ones through the difficult economic times.

**Diagram 8.9: Israeli Funds Investments per investment type (%) - 1999 to Q3/2004**



Source: Mordechai/Er-el (2001B), Zaki (2003A to 2004B)

According to Mordechai/Er-el (2001B), the weight of initial and follow-on investments changes according to the current economic situation. This can be seen by the growth figures of these investments (see Table 8.4). During periods of economic confidence, national funds focused their assets on growth companies, while changing to follow-on investments during times of economic uncertainty.

**Table 8.4: Growth of Israeli Fund investment activity - 1999 to 2004<sup>291</sup>**

	2000	2001	2002	2003	204
Initial	324%	38%	55%	81%	131%
Follow-on	315%	66%	66%	76%	114%

Source: Zaki (2003A to 2004B)

<sup>291</sup> Mordechai/Er-el (2001B), Zaki (2003A to 2004B)

Furthermore, during 2000 the average deals size of first investment placements increased by 67% to \$2 million from \$1.2 million the previous year<sup>292</sup>. Although follow-on investments accounted for 53% of all placements made, the average investment size only reached \$1.2 million during the same year. Since Q3/03, the average first investment made by national VCs has been \$2.2 million, and \$0.8 million for follow-on<sup>293</sup>.

Israeli companies utilised a further source of obtaining equity, public offerings on the US and European stock exchanges. The amount of capital raised by all companies and venture-backed companies are presented in the two tables below:

**Table 8.5: Capital raised in public offerings of Israeli companies in the US – 1993 - 2000**

YEAR	All offerings		Venture-backed	
	Number of offerings	Capital raised (\$ millions)	Number of offerings	Capital raised (\$ millions)
1993	17	529	4	103
1994	10	336	2	35
1995	16	608	5	210
1996	31	982	13	535
1997	22	743	6	175
1998	12	505	5	144
1999	19	2,010	14	1,073
2000	27	2,469	20	1,530
<i>Total</i>	<i>154</i>	<i>8,182</i>	<i>69</i>	<i>3,805</i>

Source: Mordechai/Er-el (2001A)

**Table 8.6: Capital raised in public offerings of Israeli companies in Europe – 1995-2000**

YEAR	All offerings		Venture-backed	
	Number of offerings	Capital raised (\$ millions)	Number of offerings	Capital raised (\$ millions)
1995	1	6	-	-
1996	5	44	1	19
1997	3	28	-	-
1998	5	122	2	60
1999	12	446	4	129
2000	6	253	6	253
<i>Total</i>	<i>32</i>	<i>899</i>	<i>13</i>	<i>461</i>

Source: Mordechai/Er-el (2001A)

<sup>292</sup> Mordechai/Er-el (2001B)

<sup>293</sup> Zaki (2003A to 2004B)

In contrast to increased activity by Israeli companies on the US stock exchanges, companies on European stock exchanges saw only a few public offerings, around five per year. The only exception was 1999, which might be explained by the general high-tech bubble which existed on all markets. During this period, only six Venture Capital-backed life sciences companies used this resource – two in 1996, one in 1999 and three in 2000. The companies were able to raise \$344 million dollars, i.e. less than 4%. However, when viewing each transaction it becomes clear that these figures are distorted. The share of capital raised in 1996 on the NASDAQ was nearly 14.5% (two companies), with one company's share over 8.5%.

During 1999, one company raised \$57 on the SWX, representing 12.8%, and the company which obtained capital the following year on the LSE raised 20%. The two companies which attained capital on the NASDAQ during 2000 had a combined share of just over 4.5%. The three companies obtained \$146 million on foreign stock exchanges<sup>294</sup>.

Furthermore, a dramatic increase has taken place in recent years in the M&A activity involving Israeli firms. According to Mordechai/Er-el (2001A), approximately \$1.7 billion was raised during 1994-1997, and about \$5 billion during 1998-1999. M&A activity peaked during 2000, when transactions were valued at nearly \$11 billion. From a selected list of M&A involving Israeli technology companies and foreign strategic partners, four companies were listed, three of which were acquired<sup>295</sup>. The accumulated capital raised was just over \$1 billion. During 1997, one company was acquired (\$280) and one company merged with Johnson & Johnson (\$400). The two companies which were acquired in 1998 received a combined \$330 million (\$100 and \$230 million respectively).

### 8.5.2 Equity placements in the life sciences

Life science companies, like all start-ups, have two main sources of acquiring private equity. The most common one, like everywhere else in the world, is via Venture Capital funds. In Israel, companies also have access to a grant which is available from the Chief Scientist. In this section, the development of both sources will be summarised. Furthermore, the definition of life sciences used for this section will be that of PricewaterhouseCoopers and IVC, which both classify life sciences as the constitution of medical devices and biotechnology only.

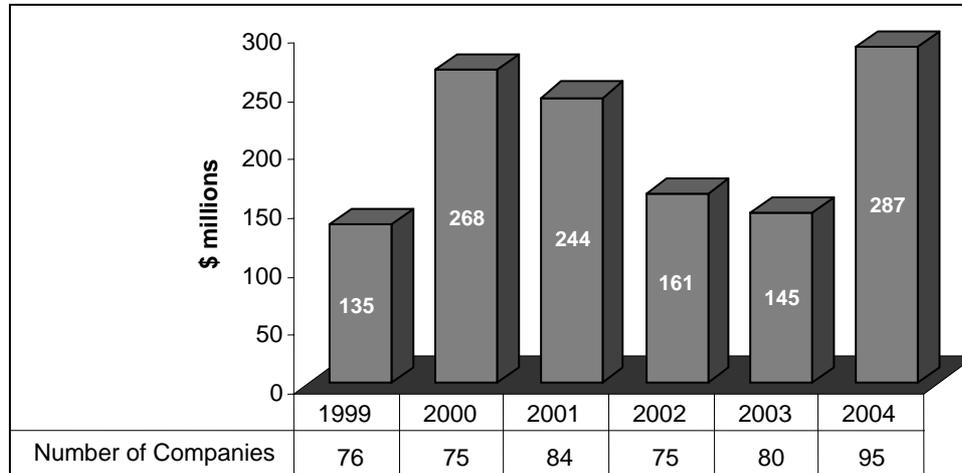
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<sup>294</sup> Mordechai/Er-el (2001A), Meyer (2003)

<sup>295</sup> Mordechai/Er-el (2001A)

Since 1999, the number of companies receiving VC funding has been stable, ranging from 75 to 84 (see Diagram 8.10). Furthermore, with the exception of 2000 and 2001, life science companies have been able to obtain about \$150 million.

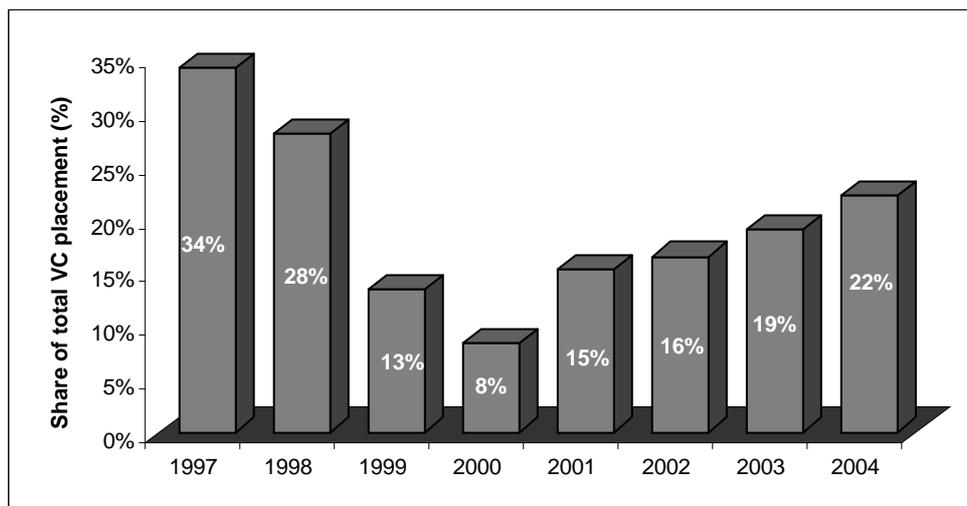
**Diagram 8.10: Total investment placements in life science start-ups – 1999 to 2004**



Source: Fellus (2000, 2001, 2004), Fellus/ Bengal (2000A through 2004), Fellus/Fried (2004A, 2004B), Zakai (2003A through 2005)

Although life science start-ups have experienced diminishing levels of available funds, their share of obtainable equity has increased. On the other hand, the total sum invested in life science companies increased between 1997 and 2000<sup>296</sup>, while its share of the invested assets decreased rapidly. The same pattern could be observed during the first three quarters of 2004. These trends are presented in Diagram 8.11.

**Diagram 8.11: Life sciences' share of total VC investments 1997 to 2004**

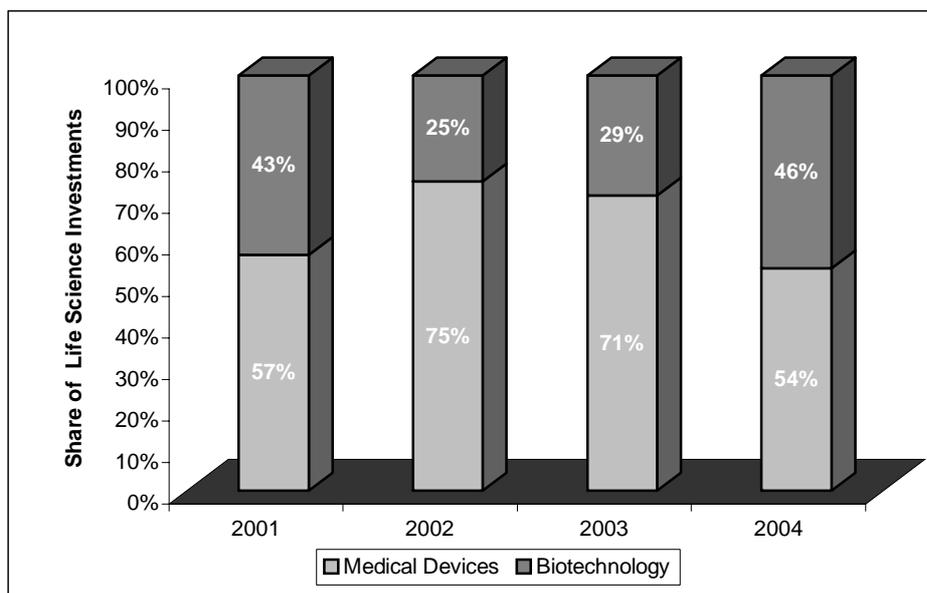


Source: Fellus (2000, 2001 & 2004), Fellus/ Bengal (2000A through 2004), Fellus/Fried (2004A & 2004B), Zakai (2003A through 2005)

<sup>296</sup> Investments in life sciences were \$149 million and \$164 million in 1997 and 1998 respectively. (Fellus/Bengal 2001D)

As indicated above, the definition of life sciences used in this chapter is that used by IVC and PricewaterhouseCoopers, i.e. life sciences only comprise medical device and biotechnology companies. Therefore, Diagram 8.12, which shows the life science investment placement by the share of its components, includes these two sectors only. The diagram reveals that the majority of life science equity placements are channelled towards medical devices. One possible reason for this may be Venture Capitalists' affinity for investing only in the development of medical products which are expected to be marketed within a short time.

**Diagram 8.12: Medical devices' and biotechnology's share of life science investments – 2001 to 2004**



Source: Fellus (2001 & 2004), Fellus/ Bengal (2001A through 2004), Fellus/Fried (2004A & 2004B), Zakai (2003A through 2005). Furthermore, during the past four years, the average investment placement has been almost equal for both categories – biotechnology companies received an average of just over \$2.2 million while the average sum invested in medical device companies was just under \$2.2 million.

A further source of equity available to Israeli high-tech start-ups is grants from the Chief Scientist. During 2003, 21% of all high-tech companies which received this grant were medical device companies, while biotechnology companies made up 14%. Thus, life science companies received the highest share. However, during the first three quarters of 2004, medical device companies only made up 14% and biotechnology companies 7%<sup>297</sup>.

<sup>297</sup> Fellus (2004), Fellus/ Bengal (2003A through 2004), Fellus/Fried (2004A & 2004B)

Although the amount of private equity available for life science companies is increasing, more capital must be made available to fully realise the potential of the various life science industries. The lack of finance may in fact endanger the success of promising projects which would have very good prospects if the necessary funds were available to them.

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