RISK ANALYSIS OF THE SOUTH AFRICAN BIOTECHNOLOGY INDUSTRY

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DISSERTATION

Submitted in partial requirements for the degree

MAGISTER COMMERCII
in

Business Management
in the

FACULTY OF ECONOMIC AND MANAGEMENT SCIENCES

at the

RAND AFRIKAANS UNIVERSITY

JOHANNESBURG

Study Leader: Prof A.L Boessenkool

November 2004

Acknowledgements

I can do all things through Christ who gives me strength
(Philippians 4:13)

- **Almighty God**
- **My husband, Winston**

  For your love, prayers, patience and support

- **My study leader, Prof. Boessenkool**

  For your guidance and help.

- **Mrs R. Venter and Mrs van der Westhuizen**

Your handshake, your warmth, your friendliness could make the difference in someone's life (Max Lucado). Ladies thanks for making the difference in my life.

Family and Friends,

Your prayers and encouragement was definitely not in vain

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Chapter 1

Introduction and Research Background

CHAPTER 1

1.1 INTRODUCTION

Biotechnology as an industry has come to the fore in the last 2 decades. It is a fast developing industry that offers significant growth opportunities to financial investors with significant advances also being made in terms of the medical fields (blood disorders), agriculture (pest resistant plants), food (genetically modified food) and forensics (DNA fingerprinting).

1.1.1 Definitions

Bains (2000, pp 66) defines **Biotechnology** as the application of knowledge of living systems in order to use those systems or their components for industrial purposes.

Risk arises when the future is unclear and where a range of possible future outcomes exists (Atrill 2000).

Venture Capital is defined as money provided by professionals who invest alongside management in young, rapidly growing companies that have the potential to develop into significant economic contributors" (NVCA, 2002).

Although biotechnology is a relatively young field in South Africa, it can play an important role in the economic growth in the country. To be able to contribute to economic growth, biotechnology must be able to sustain a competitive advantage. In his *State of the Nation Address in Cape Town,* on 9 February 2001, Thabo Mbeki stated the following "We recognise the fact that competitiveness is driven by technological advances and innovation. In recognition of this, investment in research and development is one of the focal points of our integrated plan aimed at attaining a cutting edge in key areas such as biotechnology."

Biotechnology cannot, make profits on its own. According to Kristiansen (2000 pp 239), every emerging technology needs investments for society to reap benefits that technological developments promise. The industry will need large amounts of investments to be able to develop and market their new invention. This is because biotechnology companies are riskier, possess little or no debt and possess unique information concerning their research and development (R&D) projects they differ from other firms.

There are various sources of funding for biotech companies e.g. venture capitalists, banks, and private investors and governments. Venture capitalist are people who are willing to invest in risky propositions (Bains and Evans, 2000: pp270). It is this risk element that is important in both biotechnology and venture capital industry.

According to Atrill (2000) like any other emerging technology, biotechnology faces great technological and other uncertainties. The development of new products involves both market risks, which affect all companies in the industry and specific risks, which are more specific to the company and its projects.

To invest in biotech companies most venture capitalists like other investors would want to assess the business and evaluate the various risks against expected returns.

The balance of risk and return is an essential motif for the financier and needs to be balanced in terms of the type and length of period the investment is entered into. People will invest in riskier assets only if they expect to receive higher returns, as explained by Brigham & Houston (1998 pp 156). Conversely the lower the risk the lower the return. Given the correlation of risk and return, the authors have gone to the extent to classify risk as diversifiable and undiversifiable risk. The postulation being that risk can be diversified away through creating a portfolio of investments. The portion not diversifiable is often referred to as the

market risk. With relation to biotechnology it would make sense to invest in a portfolio of investment to balance risk and return.

1.2 PROBLEM STATEMENT

In the United States of America and in Europe the biotechnology industry has shown tremendous growth. In other parts of the world the main risk takers in the biotechnology industry have been the venture capital funders, but this is not the case in South Africa. Thus far Bioventure is the only biotechnology venture capitalist fund in South Africa (Business Day, 23 November 2003). This reluctance from venture capitalist to invest in biotechnology leads us to the problem statement:

The problem is that there is a perception that risks in the biotech industry are high and is difficult to determine and therefore funding from the Venture Capitalist is not forthcoming.

Flowing from the above problem statement the following questions can be asked:

- *What are the risks that are associated with the biotechnology industry?*
- *How does the venture capital industry measure risk before they decide to invest in biotechnology?*

1.3 OBJECTIVE

Accordingly, we will identify the risks associated with the biotechnology industry, and analyse the impact thereof to Venture Capital investors in relation to expected returns.

The primary objective is as follows:

To determine the risks associated with the Biotechnology industry and the identification of investment risks by Venture Capital funders, in order to further investment by Venture Capitalist in this industry.

To specifically identify the general and unique risks associated with the biotech industry to be used by venture capitalists for investment evaluation. Highlighting crucial risks that may impact specifically on the investment within the industry that in the end may promote investment from financiers.

The goal is to match up the risks within the biotech industry with the investment requirements by Venture Capitalists and find common ground between the risk categories in order to give a better view of the biotech industry from an investment point of view.

1.4 LIMITATIONS

This study will be limited to the following areas:

- The South African biotechnology market

- The biotechnology industry restricted to the pharmaceutical biotechnology industry.

1.5 RESEARCH METHODOLOGY

A literature study will be undertaken into the biotech industry that will highlight the risks in the industry. The research will be of such a nature as to establish a theoretical qualitative risk framework

Chapter Layout

- Chapter 2 Characteristics of biotechnology and the biotechnology industry
- Chapter 3 Characteristics of the Venture Capital Industry and Venture Capital firms criteria for investment in the Biotechnology industry
- Chapter 4 Development of risk framework to determine the interrelationship between risks in the pharmaceutical biotechnology industry for use by the venture capitalists
- Chapter 5 Conclusions and recommendations

Chapter 2

Biotechnology and Risks

CHAPTER 2

BIOTECHNOLOGY AND RISKS

2.1 INTRODUCTION

Biotechnology is a multifaceted technology that can be applied to a vast array of fields, e.g. health, agriculture, minerals and their processing, criminal justice and defense and environmental management.

South Africa has been involved with biotechnology research and development for over for 25 (Anon, Africa bio, 2000), it is therefore a relatively young field, which can play an important role in the economic growth of the country. It could provide answers to problems such as food safety, alleviate poverty, health care e.g. HIV/AIDS.

Biotechnology in South Africa has followed the traditional route i.e., brewing, creation of plant varieties, and in the manufacturing of dairy products and pharmaceutical. Most of the activities are focused at the Research and Development (R&D) level, and the application of biotechnologies within certain defined sectors. (Webster & Koch, 2002)

In June 2001 the government introduced its National Biotechnology Strategy for South Africa to make up for lost ground compared to the rest of the world. According to this Strategy, the country has failed to extract value from recent advances. There are few reasons for this i.e.

- lack of adequate skills,
- ethical issues relating to concerns about the release of GMO (Genetically Modified Organisms) into the environment,
- a lack of knowledge and understanding as to what biotechnology really is and how it can affect our daily lives.

Biotechnology can make an important contribution to our national priorities, particularly in the area of human health (including HIV/AIDS,

malaria and TB), food security and environmental sustainability (National Biotechnology Strategy for South Africa, 2001).

A public understanding of Biotechnology was launched to deal with the lack of understanding about this technology that's currently providing a vacuum for unbalanced and often, non-factual information to be disseminated, which has led to the confusion of the general public.

Another reason for the lack of growth in the biotech sector is the lack of adequate funding, especially from venture capitalists. According to the National Biotechnology Strategy of SA (2001), the South African venture capital industry (including private equity funds) consists of about 64 firms, but has shown little interest in investing in biotechnology sector.

South Africa is one of the top 5 developing countries, earmarked internationally for Biotechnology investment (SRI, representing the World Bank, 2001)

2.2 BIOTECHNOLOGY

2.2.1 What is Biotechnology

Biotechnology in essence is the "technology using modern forms of production utilizing organisms, especially microorganisms and their biological processes" as defined by The Oxford English dictionary). Manning (2000, 13) states that a useful working definition of biotechnology is "the technological use, through science and engineering, of living organisms or parts of living organisms in their natural or modified forms" which encompasses the interdisciplinary facets of this field.

The interdisciplinary field refers to the modern biotechnology project that uses expertise from numerous disciplines that include medicine, engineering, biology, chemistry, and agriculture and bio informatics.

(Manning, 2000, 14). Bains (2000) defines it as the application of knowledge of living systems in order to use those systems or their components for industrial purposes. The biotechnology industry, consists of firms established to develop this knowledge and to exploit it commercially (Cortright and Mayer, 2002).

Classical biotechnology makes use of knowledge and discoveries dating back as early as 5000 B.C., where in Mexico, hybridisation of corn first took place. It builds upon Austrian Monk Gregor Mendel's discovery of the laws of heredity, and the emergence of modern biotechnology from the landmark 1953 discovery of the double-helix model of DNA by James Watson and Francis Crick (Anon, 2004).

It is a complex, **knowledge-based industry** in which many companies emerge and fail, and where strategic alliances are very important. In general terms, biotech firms make use of biological processes to solve problems or make new products. Biotechnology is not just about recombinant DNA, of cloning and genetics; it is equally about producing more prosaic materials, like citric acid, beer, wine, bread, fermented foods such as cheese and yoghurts, antibiotics and the like. It is also about providing clean technology for a new millennium, of providing means of waste disposal, of dealing with environmental problems (Ratledge and Kristiansen, 2000, p1).

The biotechnology industry has potential applications in a wide variety of industries. It is already used in the following sectors (Corthright and Mayer, 2002):

- **Agriculture (**genetic engineering of plants and animals for food and fiber**)**
- **Forensic** e.g. DNA Fingerprinting
- **Food** e.g. Genetically Modified food
- **Fabrics and textiles** e.g. enzymes to treat textiles and leather

- **Pharmaceutical and medical:** The discovery and developments of new drugs

2.2.2 Characteristics of a biotechnology industry

The entire biotechnology industry is characterized by **rapid technological change and advancements**, which gathered momentum in the 1990's, with notable breakthroughs such as Human Genome Project (Wolf, 2001).

In South Africa R&D, in the main, characterizes the biotechnology industry. According to Koch and Webster (2000) the major biotechnology investment in the country is the African Explosives and Chemicals Industry (AECI) commercialized lysine plant aimed primarily at export and / or import replacement. Another major area of focus has been Aids research in Africa. Listed below are some of current Biotechnology R&D Activities in South Africa(Anon, Africa-Bio, 2000)

- Development of AIDS and TB treatments
- Development of recombinant horse sickness virus subunit vaccine
- Genetic enhancement of pearl millet for downy mildew resistance
- Molecular makers
- Production of marker-free transformed plants
- Identification and isolation of resistance and commercially important genes
- Molecular based pathogen detection methods
- Genetic Improvement of Plants Through Molecular Breeding
- Cereal crop transgenic, particularly maize, sorghum, millet and barley
- Functional genomic and gene mining of South African plant resources
- Molecular farming
- Industrial microbe and enzyme improvement strategies, namely transgenic and
- Directed evolution
- Plant tissue culture for agro-industry development

- Citrus, Mango and Banana research
- FMBC: The Forest Molecular Biology Co-operative programme
- TPCP: The Tree Pathology Cooperative Programme
- Tuberculosis Research and Development Coalition
- Genomic Research for Africa
- SANBI: South African National Bioinformatics Institute. University of the Western Cape.

The industry is **highly technological** with long intensive periods of research and does not have "quick turnaround times" in terms of product life cycles and profits**.** If the technology works, the payoffs can be huge. But it takes a long period of time and research to make a breakthrough. Though this is true for many business ventures, developing a biotech company is often more capital-intensive and time consuming. New medicine in the USA take around 7 to 12 years from concept to market sales and cost around $300million to develop (Thumm and Werner, in Russel & Vogler, 2000). Accordingly, it is a very risky industry in terms of length of time for product development and financial returns. The profit motive is however sometimes secondary in the minds of the researchers themselves but has to be married to some extent to the investment motives of financial backers.

The growth in the past decades in the US has reached rates of $353 billion and an annual turnover of $22 billion p.a. in terms of turnover (National Biotech strategy, 2000). In South Africa the industry has only taken off in the last 25 years with the medical and pharmaceutical sector attracting the most research funding while the plant sector attracting the second largest amount.

In South Africa, approximately 106 companies are involved in biotechnology and locally commercialised products are mostly in the plant and medical sectors. The number of field trials for genetically modified organisms (GMOs) has increased rapidly from 12 in 1995, to 45 in 1998(Anon, 2000) Established Biotechnology businesses operate within the areas of agricultural, medical

and industrial biotechnology, with long established industries in medical devices, wine, fruit, fishing, food processing, nutraceuticals, pharmaceuticals, industrial processing and environmental management in the Western Cape (Anon, 2000)

South Africa's new biotechnology developments include; the establishment of an Innovation Hub for modern technologies, a provincial Biotechnology Incubator, a Biotechnology Venture Capital Fund, and the draft Biotechnology Strategy (Gain report, 2002).

2.2.3 Pharmaceutical biotechnology

As mentioned earlier we will focus on the pharmaceutical biotechnology industry. The largest application of biotechnology is in health and medicine: diagnosing, treating, and in some cases preventing diseases (Corthright and Mayer, 2002). In the medical industry, biotechnology can lead to new vaccines to improve the prevention of illness; or new diagnostic tests to help detect hereditary infections; or new medicines that offer patients and doctors more effective treatments (Anon, 2004). According to Bains and Evans, (in Ratledge and Kristiansen, 2000, 256) the discovery or invention of a new drug is critical to the commercial strategy of many pharmaceutical companies. Depending on the substance involved, this process can take anywhere from a few years to 15 years to complete. (Menninger, 2001).

The development pathway of a new drug is as follows: (Bains, 2000, 136 – 137)

2.2.3.1 Preclinical research

It is all research that goes on before you try the compound out on other people, but is often taken to mean animal studies of the drug.

2.2.3.2 Phase I Trials

These are the first trials in which a drug candidate is given to people. Only permission needed here is from the local hospital ethical board or committee. After phase I the developer applies for an investigation new drug application. This is the regulatory hurdle necessary to go on to Phase II trials.

2.2.3.3 Phase II trials

This is the first time the drug is tried out on ill people. The drug is said to being developed for one “indication” i.e. one collection of symptoms or one disease. The object of this and subsequent trials is to show that the drug has an effect on this indication.

2.2.3.4 Phase III trials

During this phase huge amount of money is spent on drug development. The object of this phase is to see whether the drug is worth launching, because it is better than existing therapies does not have severe side effects, and so on.

At the end of phase III the drug is submitted for a new application or product license application.

2.2.3.5 Phase IV trials.

Phase IV trials, post- marketing surveillance, then takes over to look for rare adverse reaction (adverse drug reactions, ADR’s), to look for opportunities to decrease the dose, and to extend the range of indications for which the drug may be used.

2.2.4 BIOTECHNOLOGY COMPANY BUSINESS MODELS.

According to Bains and Evans (2000), the science in a biotechnology company falls into two categories, i.e.

Discovery – You have discovered something wonderful
Platform technology – you can do something wonderful

These categories form part of two business models that have been adopted by the biotechnology industry.

A business model is a description of how your company intends to create value in the marketplace. It includes that unique combinations of products, services image and distribution that you company carries forward, (Fisken, J & Rutherford, J., 2002).

2.2.4.1 Product business model

You discover or invent products, take them as far through development as your funding allows and then sell or license them to someone with experience in manufacture, distribution, etc. (Bains and Evans, 2000). This business model has its origins in the FIPCO (fully integrated Pharmaceutical company) business model and aims to generate value in progressing products along the drug development process and either licensing them out to pharmaceutical and top tier biotechnology companies or, when the company has reached maturity and there is free cash flow available, taking them straight through to commercialization). It is still a relatively high-risk model, although companies may partner initial products at an early stage of development to mitigate this risk. (Fisken, J & Rutherford, J., 2002).

2.2.4.2 Platform or tool business model

You develop tools or technologies that help other people develop products .(Bains and Evans, 2000).This is considered a relatively new business model in the biotechnology industry, dating back to the late 1980s, although it has been around for some time in other high-- technology industry sectors. It aims to generate value (predominantly from the front end of the industry value system) through licensing fees, subscriptions and service fees and can include the provision of new research tools, informatics and/or services and reagents. .The evolution of the platform/tool model was driven by the need to reduce the risks in drug development through applying technological advances to drug discovery. (Fisken, J & Rutherford, J (2002).

Fisken and Rutherford (2002) also identified two other models, i.e. the Hybrid model and the Fully Integrated Pharmaceutical Company (FIPCO) models.

2.2.4.3 Fully Integrated Pharmaceutical Company (FIPCO) models

The Fully Integrated Pharmaceutical Company (FIPCO) model is a vertically integrated model. The attraction of this model in terms of value generation was apparent: by managing and controlling the entire value chain, the companies hoped to maximise and sustain a superior financial return. However, in so doing the companies were also maximising the level of risk, with high levels of financing required to establish and maintain the FIPCO infrastructure and to fund drug development through to commercialization.

2.2.4.4 Hybrid model

Fisken and Rutherford (2002) describes this model a hybrid of the product and platform business models and generally constitutes a platform technology capable of generating a pipeline of products.

The biotechnology industry is characterized by unique risks, other than general risks affecting any business and these are highlighted below.

2.3 RISKS AND RISKS SPECIFIC TO THE BIOTECHNOLOGY INDUSTRY

2.3.1 Definition of Risk

Olsson (2002, 8) makes the following statement about risk “Risk is intangible and will be seen differently by different people not only in terms of what the risks are but also what the range of possible outcomes are and probabilities they attach to the outcomes”. The art of risk analysis is fundamentally about first identifying potential failures (categorizing events into “risk types”), then estimating the frequency of occurrence of these failures, and, finally determining the magnitude of the consequences. Malcolm et al (1999, 64)

2.3.2 BUSINESS RISKS

According to Gleason (2000) risk can be divided into financial and non-financial risks. Financial risks and non-financial risks defined below and the

main biotechnology risks are discussed thereafter. The financial risks and non-financial risks are defined as to provide a framework given that investors also take cognisance of these risk factors in making investment decisions.

2.3.2.1 FINANCIAL RISKS

The risk of loss from holding positions that is subject to change in value with changing market conditions. This risk include risk all changes in market conditions, such as, prices, volatility, liquidity and credit risk, the ability and willingness of counterparties to honor their contractual obligations (Gleason 2000,247). Pike & Neale, (1996, 222) defines it, as the risk, over and above business risk, which results from the use of debt or capital.

2.3.2.1.1 Financing risk

Blake (2003) indicates, “Biotech firms are by their very nature cash hungry operations. They have the potential to consume large quantities of development capital over a number of years, although the objective is to generate assets and increase asset value.” The risk of running out of cash is a significant risk factor to consider given the large R&D component of the biotech industry

2.3.2.1.2 Market risk

The risk that positions can lose value due to changing market conditions including prices, volatility and market liquidity (Gleason 2000:248). Olsson (2002, 43) defines it as the loss due to changes in market prices. Market risks exposes the company to uncertainty due to movements in the factors such as foreign exchange rates, commodity prices, equity prices, and volatilities related to options positions (Malcolm et al, 1999, 74).

2.3.2.1.3 Credit risk

This is the risk of loss from failure of counterparty to perform as agreed (contracted) (Gleason 2000, 250). Malcolm et al states (1999, 65) that it is the risk of defaults by counterparty.

2.3.2.1.4 Liquidity risk

The risk that amounts due for payment cannot be paid due to a lack of available funds (Olsson, 2002, 45). Olsson also states that, meeting liabilities when they fall due is important to maintain credibility and customer confidence, as this will ensure that your credit standing will remain.

2.3.2.2 NON- FINANCIAL RISK

2.3.2.2.1 Operational risks

This is the risk of loss arising due to the procedure errors, omissions or failure of internal control systems. (Gleason 2000,247) Olsson (2002, 46) defines it as the risk due to actions on or by people, processes, infrastructure or technology or similar which have an operational impact, including fraudulent activities. Operational risks is everywhere within an organisation (Malcolm et al, 1999, 88).

2.3.2.2.2 Regulatory risk

The risks of non- compliance with legal or regulatory requirements (Olsson, 2002, 35).

There are two types of regulatory risk, one is compliance risk (incorporating approval process risk) and the other unregulated goods/services approval risk

Blake (2003). Compliance risk is the more and this risk pertains to the ability of a company's facilities or products to meet prescribed regulatory standards of operation, manufacture, marketing or labelling. Compliance risk furthermore pertains to the regulatory process encountered by a company with the approving authority when it seeks approval for a pharmaceutical or medical product or service.

"Approval related risk can be hugely significant for a biotech company, and a failure to achieve approval in a key market can potentially cause the failure of a small biotech. There is no viable, reasonable method of predicting approval for therapeutic goods, and past product approval successes are not reliable indicators of future success." Blake (2003)

The second type of regulatory risk relates to unregulated goods and services whereby new technologies are unknown to regulatory authorities and the necessary processes have not be defined and documented for approval of products and services. It may be that the new technology emerges in a regulatory vacuum. It would therefore take time for regulators to develop methods of analysis for new technologies and it takes time for guidelines to be established to govern and aid the development of the emerging technology in an appropriate manner.

2.3.2.2.3 Legal risk

Intellectual property risk transforms could lead into "a new form of investment risk when rivals are unequally matched according to financial and human resources" Blake (2003). Legal challenges of small biotech firms but larger more established and more resourced biotech firms may bankrupt the smaller firm or provide significant set backs to product and market development.

2.3.2.2.4 Business risk (specific risk):

The risk of failing to achieve business targets due to inappropriate strategies, inadequate resources or changes in the economic or competitive environment (Olsson, 2002, 34). Malcolm et al, (1999, 66) defines it as the risk that one transaction or a small group of transactions, causing losses, exposes the firm to the risk of failure. A firm's business risk depends, in large measure, on the underlying economic environment within which it operates. (Pike & Neale, 1996, 221)

2.3.2.2.5 Political risk

It is the risk that includes tax, trade, regulation, education and social policies (Malcolm et al, 1999, 66).. A government's attitude towards capital and business sets the stage for either success or failure of its economy. Olsson (2002, 35) defines it as the risk that there will be a change in the political framework of the country.

2.3.2.2.6 Industry risk

The risk associated with operating in a particular industry (Olsson, 2002, 35). A few key dimensions to consider with this risk are: -

The stages in the life cycle – is the industry growing or is it in the declining phase

Volatility -a volatile industry is one where growth can change rapidly, up or down.

2.3.2.2.7 Environmental risks

The risk that an organization may suffer loss as a result of environmental damage caused by themselves or others which impacts on their business (Olsson, 2002, 35). What is of concern is both the direct impact a business has on the environment but also the indirect ones it has through it interactions

with its customers and suppliers. It may not be the production processes that cause environmental damage but the products themselves

2.3.3 RISKS IN THE BIOTECHNOLOGY INDUSTRY

The following are specific risks that are associated with the biotechnology industry, and may be in addition to those mentioned in the previous section and would have to be considered by potential investors.

2.3.3.1 Technical Risk / Product Risk

Blake, (2003) asserts, “This category of risk encompasses the biotechnology in development from a scientific or medical point of view. It allows for the possibility that a pharmaceutical product or medical device may not work in a safe, efficacious and desired manner. This is the risk category most often considered when drugs are being progressed through human clinical trials, although it is a risk feature of earlier development stages as well.”

2.3.3.2 Product Failure risk

Product failure: the possibility that a company’s product may not work in a safe and effective manner. This risk usually arises when products are being tested in clinical trials. (Anon, 2004).

2.3.3.3 Information risks

The data used to make strategic decisions or manage processes are inaccurate, irrelevant or incomplete. Information risks affect the company at all stages of decision-making and process information. (Moon and Piper, 2001).

2.3.3.4 Risk of business interruption

This risk relates to an interruption in business resulting from a physical event- a fire, explosion, or lab contamination-or from a natural disaster such as an earthquake or hurricane. Given the large investment in R &D by biotech firms this risk can be significant for the product development of the firm (Fiscus, P.W, 2002).

2.3.3.5 Lack of a commercial market

This is the risk that there will not be a demand for the product. This could occur for a number of reasons - There could be a negative reaction to the product from industry professionals such as doctors, or there simply may not be enough market interest. (Anon, 2004)

2.3.3.6 Obsolescence risk

Obsolescence risk pertains to the products of a company being superceded and therefore rendered obsolete by another company's product that may turn out to be more effective, easier to administer, or have fewer side effects. Anon,(2004)

2.3.3.7 Product liability risk

Unexpected off-label use may result in unintended or less manageable product liability risk. Product liability coverage for bodily injury and property damage caused by a pharmaceutical or biologic agent is essential protection for biotech companies and can help defray the staggering costs of a lawsuit. Product withdrawal insurance pays for costs incurred to facilitate a drug recall,

helping companies act quickly when they discover unexpected problems or defects (Fiscus, P.W, 2002).

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2.3.3.8 Intellectual property risks

The discovery of new technologies often leads to the registration of patents for the technology. In biotech it is no different and it is often “the number one investment plank in biotech”. This includes intellectual property rights, including patents and trade secrets. Patents in general serve as a barrier to entry to a particular market. However this is surmountable over time or through inventive advances or through the legal challenge to patent validity. Blake (2003)

2.3.3.9 Partnering risk

This risk relates to agreements whereby a smaller biotech company may partner with another larger firms in order to develop new discoveries. The risk for the smaller firm is that its partner may not have the same commitment toward the success of the product or technology to the market. Blake (2003)

2.3.3.11 Reputational risk

It is the risk that the reputation of an organisation will be adversely affected (Olsson, 2002, 35). Moon and Piper, 2002 state “Reputation risk is the risk that a representative of the organisation will make a decision that or behave in a way that is inconsistent with the organisation’s values or shareholder expectations. An example of this risk on biotechnology would be Improper messaging of clinical trial data that lead to over hyping the potential of specific products by either not adopting good clinical practices or by misrepresenting clinical data.

2.4 SUMMARY

Biotechnology is a multifaceted technology that can be applied to a vast array of fields, e.g. health, agriculture, minerals and their processing, criminal justice and defense and environmental management.

South Africa has been involved in biotechnology for the past 25 years and it is mostly involve in the Research and Development. A national Biotechnology Strategy and Public understanding of Biotechnology has been launched to make up for lost ground compared to the rest of the world and deal with lack of understanding the technology in the country.

Biotechnology can be applied to a wide variety of industries, i.e. Agriculture, Forensics, Pharmaceutical and Medical, Food and fabrics and textiles. The industry is characterized by rapid technological changes and improvements, is highly technological and knowledge based.

The pharmaceutical biotech industry is mainly involved in drug development. This development process is involves the following steps, i.e. preclinical trials, Phase I, Phase II, Phase III and Phase IV. There are risks involve in each of these phases. Science in biotechnology falls into two categories, Platform technology and discovery. These two categories can form part of two biotech business models, i.e. Platform or tool business model or product business models. Two further models are the Fully Integrated Pharmaceutical Company (FIPCO) and the hybrid model.

Like in any other industry the Biotechnology industry also involves a lot of risks. Risks can be divided into business risks, financial risks and non-financial risks. Furthermore there are risks specific to the biotechnology industry are, among other, technical risk / product risk, product failure risk information risks, risk of business interruption, lack of a commercial market,

obsolescence risk, product liability risk, intellectual property risk, partnering risk, and reputational risk.

Chapter 3

The Venture Capital Industry

CHAPTER 3

THE VENTURE CAPITAL INDUSTRY

3.1 INTRODUCTION

The marrying of research and finance is risky at best and involves a significant commitment from financiers. To convert a biotechnology discovery into a commercial product significant amount of capital is required fat every phase of product development Angel investors and venture capital firms are two common sources of funding for growing biotechnology and pharmaceutical firms (Silverstein and Osborne, 2002).

3.2 THE NATURE OF VENTURE CAPITAL

Venture capital (VC), is defined as 'independent, professionally managed, dedicated pools of capital that focus on equity or equity-linked investments in privately held, high growth companies' (Gompers and Lerner, 2001, p. 146).

Venture Capital (VC) is a form of financing for a company in which the business gives up some level of ownership and control of the business in exchange for capital over a limited time frame, usually 3-5 years.

According to Coyle (2000) venture capital has two features

- it is provided by one or more external investors
- it is risk capital.

A venture capital firm raises money from wealthy individuals, pension funds, financial institutions, insurance companies and other sources that are

interested in investing in technology-based start-ups, but lack the ability to do so. These investors become limited partners in the VC fund, while the partners in the VC firm manage the money by investing in and advising entrepreneurial start-ups. Venture capitalists finance new firms with the potential for high growth in return for partial ownership. When the young company is sufficiently developed, the firm goes public through an initial public offering (IPO) or is acquired by another company. At this point, the VC cashes in its ownership stake, and reaps its rewards. Venture capital obviates the need to grow slowly via self-financing, and fuels growth that is more rapid. (Smith and Doerr, 2002)

The role of venture capitalists is not only to provide financial capital, usually equity, but also the opportunity to guide these young companies by offering managerial advice and controls. In the life sciences and other technology-based fields, venture firms provide more than money. Because many of the founders of biotech firms are research scientists, venture capitalists often do much more than monitor or advise; they may even play a hands-on role in the running of the young company (Smith and Doerr, 2002), in other words they become active not passive investors. They provide value-added services, help professionalise the companies they finance, and help their companies establish them in the marketplace and can use their extensive networks to provide essential competitive advantage for promising new enterprises. In return for this medium- or long-term financing, the VC receives a share of the company's equity, usually 25–50%. Oftentimes, the VC will serve as a board member or financial and strategic advisor to the portfolio company (Frankle and Lisa, 2003). The venture capitalist also adds another advantage in the sense that they help to increase the rate of innovation and can also use their extensive networks. Venture capital represents one established solution to financing high-risk, high-reward ventures.

Venture capital financiers can either be generalists or specialists depending on their investment strategy (Cooke, 1996).

Generalists, invests in various industry sectors, or various geographic locations, or various stages of a company's life.

Specialists invest in one or two industry sectors, or may seek to invest in only a localized geographic area. Specialist healthcare or biotechnology funds are dedicated to specific market and can either be short-term or long term in investment outlook (Brooks, 2003).

3.3 VENTURE CAPITAL INVESTMENT REQUIREMENTS

VCs typically invest in businesses that meet their investment criteria and where they can add value with their own expertise and contacts (Anon, 2004). Before VC makes an investment they tend to conduct a very thorough due diligence on a company and demand professionalism to shine through in the business plan, the company strategy, the science and, above all else, the management team (Whitehead, 2003). Bains and Evans (cited in Ratledge and Kristiansen, 2001) states " the VC will carry out an external test of the science, by calling up experts, having any patents checked out by the lawyers, asking around at meetings and conferences and checking the perceived strength of the company's science and people

The investment evaluation process that a VC would follow for investments would also be applicable to Biotech investments but would need to carefully consider the biotech specific risk aspects as discussed in Chapter 4. For example Moon and Piper (2003) indicate that "biotechnology is an industry that is highly dependent on intangible assets" and Bøllingtøft,et al,(20030 indicate that complexity of technology increases risks and affects financing. Accordingly, the Biotech specific issues are highlighted with the VC investment requirements even though the detailed discussion on risks only follows in the next chapter. The idea being to provide the relationship of the

biotech risks to the VC requirements and therefore show the relevance to the VC of the biotech specific risks.

3.3.1 Due Diligence

In this environment rigorous and independent due diligence will pay handsome returns by minimizing 'asymmetry of information', and will allow companies to structure more successful deals, with risks and rewards more fully understood. The due diligence team should have the experience to cover all aspects of the operation, including:

- commercial;
- products;
- intellectual property;
- clinical development;
- regulatory issues;
- operations;
- management;
- financial;
- human factors;
- fundamental technology.

Venture Capitalist also looks for the following in potential investments candidates (Anon, 2004). According to Bains and Evans (2001, 271), the due diligence process in biotechnology would give the VC and estimate for how reliable the current science is and what the market might be

Due diligence for Biotech investments would need to cover more in depth the commercial market, products, intellectual property, clinical development and the fundamental technology being applied. These are areas of risk for the

biotech industry, see later, which have impact on potential returns for the investor.

3.3.2 A well thought out Business plan

A business plan is a written document that sets out the basic idea underlying a business and related startup considerations (Longenecker et al, 2000).
According to Silverstein and Osborne, (2002) a biotechnology business plan is a document that describes the major selling points of its idea, its business strategy and its management team. They also state that It must be persuasive, but at the same time realistic. It is intended to generate investor interest in the company's product or technology and encourage investors to discuss the company and its ideas further. It is a living document that will change and be revised as a business evolves. A formal business plan will consist of the following (Anon, 2003):

- Executive Summary -
- Industry Analysis -
- Market Analysis -
- Competitor Analysis
- Strategic Analysis - Strengths/Weaknesses/Opportunities/Threats (SWOT) Analysis,
- Strategic Action Plan
- Organization and Management -
- Financial Plan
- Loan Proposal

The business plan for a biotechnology company covers many subjects including the company, the product or technology, the product or technology development plan, the regulatory and safety and efficacy testing strategies, and the financial needs of the company. (Silverstein and Osborne, 2002). The business plan for the biotech company is important in that aspects that the VC would look at during the due

diligence investigation such as products, intellectual property, clinical development, technology and regulatory issues often impact directly on viability of the business. It may be perceived as a “weakness” of scientists not to be business minded but during the due diligence the VC would look at the management of the company. Part of management responsibility is to have a good business plan, for any business, but for the biotech company it is imperative as is indicated later the biotech industry requires large capital investment and impacts on the financing risk.

3.3.3 The management team

Venture capital firms feel strongly that the strength of the management team is the key decision criterion for venture capital investment (Silverstein and Osborne, 2002). Anon (2004) states, “Venture capitalists do not normally want to operate a business. They are value adding investors that usually want to provide management with access to their expertise and contacts as well as their investment capital. As a result, they look to invest in companies that have the strength and depth of management to achieve its targets.” According to Gompers and Lerner, (2001, 179) lack of experience among managers can constitute a red flag.

Strong management teams with proven track records are a very difficult area. Companies with management of enormous pharmaceutical experience can go to the wall. The key is whether the management team has the right experience for the job (Fazeli, 2003).

It is unlikely that a venture capital fund will make a significant investment in a company without an experienced CEO. However, most start-ups cannot afford to recruit an experienced CEO until the venture capitalist has made the investment. One way out of this dilemma is to line up a CEO who commits to

joining the company on completion of the investment round. An alternative solution that we have observed is for the venture capitalist to make the investment contingent on finding an acceptable CEO. (Rodgers, et al, 2002). In a biotech investment the VC would have to consider this route, especially for start ups, as the risks – unidentified and unmanaged – could lead to disastrous results for the biotech firm.

3.3.4 Market Analysis

Market Analysis is defined as an evaluation process that encompasses market segmentation, marketing research and sales forecasting (Longenecker, 2000) The market analysis includes the following Target Market, Pricing Strategy, Advertising Strategy, Distribution Strategy, External Influences, Government Regulations (Anon, 2003). Information about the value of the market terms of market growth rate, market size (domestic and international), market served and market potential and projected changes over the next several years, is provided in the market analysis (Silverstein and Osborne, 2002). For VC investment in biotechnology this market analysis may be difficult but is a real issue to consider during the due diligence process as the risk of a lack of a commercial market is a risk to dealt with in depth.

3.3.5 Exit route

A venture capital organization will require an exit route for its investments. An exit route is a means by which the investments eventually can be sold (Coyle, 2000). According to Frankle and Lisa (2003) the VC exit route or strategy may include the following:

- the sale of the portfolio company stock
- in an initial public offering (IPO);

- the exchange of the portfolio company stock to a publicly traded company or other private company in a tax-free reorganization;
- a sale of the portfolio company for cash or a combination of cash, stock, and debt instruments; or
- a sale of the VC's securities back to the portfolio company in a redemption transaction that may take the form of a put option.

For the VC the exit routes as noted above applies to all types of investments including biotechnology companies but may also include specifically a sale of the start up biotech company to a bigger biotech competitor would sees significant value in the start up's products or R&D.

3.4 FUNDING STAGES

Coyle (2000) states that venture capital investments can be categorized according to the stage of development they have reached when risk capital funding is required. These investments are accomplished through a broad range of vehicles ranging from the injection of seed capital for the development of new products to the acquisition of already established companies (Lefton, 1998).
Schilit (1991) divides Venture Capital into Early Stage Financing, Expansion financing and Late stage Financing. Early stage financing can be divided into three phases, i.e. seed capital, Start –up capital and First stage capital (Schilit)

3.4.1 Early stage financing

3.4.1.1 Seed Capital

Seed capital is provided during the research and development (R&D) development of a product before the product is commercialised (Coyle,

2000). According to Bains and Evans (sited in Ratledge and Kristiansen, 2001) Seed funding provides enough money to set the company up, acquire key patents, negotiate the graceful exit of founding scientists from their current job and create a corporate entity. Coyle (2000) states that investing seed capital is a very risky high-venture, because of the following reasons:

- A short product life cycle
- Lack of awareness of competition
- Launching the product too soon, before there is market acceptance
- Launching a product too late, after a competitor
- Inability to make the product work
- Poaching of key technical staff by a rival
- Lack of financial control

High interest returns are expected to attract the investors. (Coyle, 2000)

3.4.1.2 Start-up

Start up funding is provided to develop the company's products and fund their initial marketing. Companies may be in the process of being set up or may have been trading for a short time, but may not have sold their product commercially (BVCA, 2000). Given the associated high risk profile, many venture funds steer clear of this area (Cooke, 1996)). To achieve funding for early phase or start –up ventures, proposals must contain some of the following characteristics:

- Well balanced and experienced management team;
- A fully developed product
- A growing marketplace which is not dominated by a few firms
- Preferably a non-capital intensive industry
- Minimal continuing research and development costs;
- Asset backed companies as opposed to people assets only

According to Rodgers et al, 2002 Biotechnology start-ups will almost certainly require investment finance to support their development, investment finance for start-ups has been difficult to find, because such new ventures are considered to be too risky by most venture capital funds.

3.4.1.3 First stage financing

During this stage capital is provided to initiate commercial manufacturing sales (Schilit, 1991). According to Bains and Evans in (Ratledge and Kristiansen, 2000) this money will typically take a company engaged in drug discovery and development through to 1.5 to 3 years' work and take the science from some basic research to a proof of principle.

3.4.2 Expansion financing

This type of funding is to grow and expand an established company. For example, to finance increased production capacity, product development, marketing and to provide additional working capital (BVCA, 2000). . Expansion financing is usually low risk-venture capital, compared with early investments and turnarounds (Coyle, 2000)

According to Schilit (1991, 36), there are also three stages of expansion financing, which are as follows:

3.4.2.1 Second stage finance

In second stage financing the capital is used for initial expansion of the company that has already been producing and selling a product. The company might not be profitable at this time (Schilit, 1991, 36).

3.4.2.2 Third stage finance

During third stage financing capital is required to fund major expansion, for example, plant expansion, product improvement and marketing (Schilit, 1991, 36)

3.4.2.3 Mezzanine financing (or bridge)

Capital is provided for a company that expects to go public (Schilit, 1991, 36). Schilit (1991) also states that this type of finance is designed for companies in the intermediate sales range, which are considered intermediate low risk ventures. Notably, while valuations have skyrocketed for late-stage deals, they have plummeted for seed- and early-stage deals. For the past few years, there's been an early-stage funding drought, since VCs could invest in later-stage companies at prices that were 10% to 20% of their peak valuations, says Daphne Zohar, founder and managing general partner of PureTech Ventures, a Boston-based life sciences venture consulting company that helps turn promising technologies into companies

3.4.2.4 Management buyouts and Buy-Ins

Management buyout (MBO) the purchase of an existing company or a business unit by a group of its managers, with the support of external investors, typically from venture capital sources and bank loans (Coyle, 2000).

A management buy-in (MBI), is the purchase of an existing company or a business unit by an external management team, with financing from venture capitalist and banks (Coyle, 2000).

3.5 RISKS AND RETURN

Depending on the type of risk, high or low they undertake, the length of period they invest for (5 – 10 years) and the measure of returns they require, venture capital firms can be structured in partnerships; limited liability companies or even listed on the stock exchanges. (Coyle, 2000)

The balance of risk and return is an essential motif for the financier and needs to be balanced in terms of the type and length of period the investment is entered into. The higher the risk the higher the expected return as explained by Brigham & Houston (1998) Conversely the lower the risk the lower the expected return. Given the correlation of risk and return, Brigham & Houston has gone to the extent to classify risk as diversifiable and undiversifiable risk. The postulation being that risk can be diversified away through creating a portfolio of investments. The portion not diversifiable is often referred to as the market risk.

The other aspect of the risk return relationship is the expected return. This is the return expected by the investor according to the risk taken on. Coyle (2000) explains that the investment strategy of the venture capitalist should be aim towards a portfolio of investments that provide a suitable balance between risk and return. Return can be measured in various ways like the one period return, the return on investment, return on assets as explained by (Brigham & Houston, 1998)

The realisation of this return is typically either through initial public offerings (IPO's), mergers and acquisitions (M&A's), or through the sale of investment to other investors. Venture capitalists invest in equity in the form of common stock, or preferred stock, convertible debentures, or other financial instruments convertible into common stock when the small company is sold

through either a merger or a public equity offering. At this liquidity, event venture capitalists realize their profits in the form of capital gains. (Kenney)

Venture capitalists are a class of investors willing to take on the significant risks involved in the biotech industry due to its the high-risk high return relationship. This type of investment has fueled the industry to significant growth in the last few decades.

3.6THE SOUTH AFRICAN VENTURE CAPITAL INDUSTRY

In South Africa the private equity industry was only formalized with the constituting of the Southern African Venture Capital and Private Equity Association in 1999. (SAVCA KPMG Private Equity Survey 2003)

3..6.1 Sources of funds

Players in the South African Venture capital fund include the following:
Pension and endowment funds, Insurance companies, Institutions, Banks, Government and aid agencies. Private individuals, Corporate, private equity of funds and other or unspecified (SAVCA 2003).

SAVCA indicates that: “63% of all third party funds raised during 2003 were from governments and aid agencies. The most significant contributor to this was the UK Government. Governments and DFI’s were also the major source of funds raised during 2001 although pension and endowment funds contributed the most funds raised during 2002.”

The significant contributions by government has resulted in the government agencies being the most significant contributor over the 3 year period followed by pension and endowment funds with insurance companies third on the list of most significant contributors.

The source funding from year to year can differ significantly with no consistency in the funding sources.

3.6.2 Investments made by all funds by sector

The majority of the investments by Private Equity has gone to Information Technology, Services and Manufacturing in both 2002 and 2003. The notable difference in 2003 has been the 12% investment in Infrastructure. Biotechnology in the South African context is not a separate major category of investment and would probably fit under the Healthcare sector for classification purposes. The table however highlights the lack of fund investment in the life sciences areas given that 67% of the funding of investments has gone to the infrastructure, information technology, services and manufacturing sectors.

As indicated before in this chapter – there is a lack of investment in the biotechnology field in South Africa that may be attributed to a lack of understanding of the industry in general and the risks and return profile associated with the industry.

3.7 VENTURE CAPITAL REQUIREMENTS FOR INVESTING IN BIOTECHNOLOGY

Before investing in a company a due diligence analysis of the company is normally performed which gives the VC an idea of how reliable the science is and what the market might be. According to Bains (sited in Ratledge &

Kristiansen, 2000, 272) the Venture Capitalist looks for the following in a biotech company

- Strong patent position
- Experienced management, world-class management, proven track record (Rodgers et al, 2002)
- Business focus
- R&D partnership
- Corporate partnership
- Platform technologies
- Unique technologies
- Products in early clinical trials or a broad product pipeline

The issues identified above to which the VC looks are related to the biotech specific risks, as discussed in a later chapter, as follows:

- Strong patent position *(intellectual property risk; legal risk)*
- R&D partnership; corporate partnerships (partnering risk;
- Platform technologies; unique technologies *(product risk; information risk; commercial market risk)*
- Products in early clinical trials or a broad product pipeline *(clinical trial risk; regulatory risks; commercial market risk)*

In relation to the level of investment and development pathway of trial phases clearly, biotechnology companies that have had a maximum of £20m-50m ploughed into them by VCs should not be expected to have four products in Phase II with one about to enter Phase III. But it is not too much to expect to see at least one completed Phase II trial with two or three products in Phase I and II behind it (Fazeli, 2003)

Instead, the biggest winners of venture funding now tend to be firms with several drug candidates already well advanced in their development pipelines. This indicates the VCs focus on technologies, broad product pipeline and commercial market viability.

Such investments, dubbed by VCs as specialty pharmaceuticals makers, offer several advantages. They are generally lower risk; since the companies involved often have drug candidates already well along in human tests. In addition, because the potential products are more mature, VCs are in a position to cash out much more quickly (exit routes) if the companies they fund make public offerings or are acquired. (Regalado and Hamilton, 2002)

For the VC the products on the market offer a potential for high rate of return on investment (Silverstein and Osborne 2002) and also mitigates the risks of product viability, commercial market risk and intellectual property risks.

3.8 SUMMARY

To turn a biotechnology discovery into a commercial product substantial amount of capital is needed. Venture Capitalist can be seen as a source of funding because they share risk and rewards with the company. They are active investors who get involve in the running of the company.

Before they invest in a company the venture capitalist will conduct a thorough due diligence of the company. Potential investees must submit a business plan that includes the market analysis and the experience of the management tea as well as an exit route.

Venture Capitalist injects capital at various stages of development in the company, e.g. Seed capital, expansion capital, management buy-outs (MBO) or Management buy-Ins (MBI).

Players in the South African Venture capital fund include the following:
Pension and endowment funds, Insurance companies, Institutions, Banks, Government and aid agencies, Private individuals, Corporate, private equity of

funds and other or unspecified. The majority of the investments by Private Equity has gone to Information Technology, Services and Manufacturing in both 2002 and 2003.

Another aspect of Venture Capital investments are the risk and return relationship. The VC investment strategy should be aimed at a balance between risk and return

Before making an investment in a biotech company the VC will look at the various aspects that normal investments are evaluated against during the due diligence process. These include business plans, management teams, market analsysis and exit routes. The VC, however, will need to look in more detail at aspects which relate to biotech specific risks. Some of these aspects are patent position *(intellectual property risks)*, R&D and corporate partnerships *(partnership risks)*, platform and unique technologies *(product, information, commercial market risks)*. The VC will need to focus on these aspects in the biotech company as they have potential impact on investment returns.

Chapter 4

Biotechnology Risks & Theoretical Risk Framework

CHAPTER 4

4.1 Introduction

This chapter discusses in more detail risks in the Biotech Industry and seeks to develop a theoretical framework of Biotech industry associated risks for potential use by a Venture Capitalist for evaluating investment in the biotech industry. Definitions of the various risks from a prior chapter are repeated to provide context and are expanded upon to provide completeness which leads into the theoretical risk framework which is set out in tabular format.

4.2 DETAILED DESCRIPTION OF RISKS

A. Non Financial Risks

4.2.1 Operational risks

This is the risk of loss arising due to the procedure errors, omissions or failure of internal control systems. (Gleason 2000, 247) Olsson (2002, 46) defines it as the risk due to actions on or by people, processes, infrastructure or technology or similar which have an operational impact, including fraudulent activities. Operational risks is everywhere within an organisation (Malcolm et al, 1999, 88). This risk is applicable to all types of organisations but is of special interest to the biotech industry because it assists in managing the biotech specific risks as listed below. Organisations need good internal control systems in order to manage business processes to prevent or detect procedural errors, omissions or failures on internal controls.

4.2.2 Regulatory risk

There are two types of regulatory risk, one is compliance risk (incorporating approval process risk) and the other unregulated goods/services approval risk Blake (2003). Compliance risk is the more common risk and pertains to the ability of a company's facilities or products to meet prescribed regulatory standards of operation, manufacture, marketing or labelling. Compliance risk

furthermore pertains to the regulatory process encountered by a company with the approving authority when it seeks approval for a pharmaceutical or medical product or service.

“Approval related risk can be hugely significant for a biotech company, and a failure to achieve approval in a key market can potentially cause the failure of a small biotech. There is no viable, reasonable method of predicting approval for therapeutic goods, and past product approval successes are not reliable indicators of future success.” Blake (2003)

The second type of regulatory risk relates to unregulated goods and services whereby new technologies are unknown to regulatory authorities and the necessary processes have not be defined and documented for approval of products and services. It may be that the new technology emerges in a regulatory vacuum. It would therefore take time for regulators to develop methods of analysis for new technologies and it takes time for guidelines to be established to govern and aid the development of the emerging technology in an appropriate manner.

4.2.3 Business specific risk

The risk of failing to achieve business targets due to inappropriate strategies, inadequate resources or changes in the economic or competitive environment (Olsson, 2002, 34). Malcolm et al, (1999, 66) defines it as the risk that one transaction or a small group of transactions, causing losses, exposes the firm to the risk of failure (). A firm’s business risk depends, in large measure, on the underlying economic environment within which it operates. (Pike & Neale, 1996, 221)

The complexity of the biotech industry may lead to pressure on biotech businesses to perform and meet shareholder expectations in terms of returns and could lead to the organisations adopting inappropriate strategies or the

organisation may face competitive pressures from rivals investing in the same type of products and / or R&D.

4.2.4 Political risk

The risk that includes tax, trade, regulation, education and social policies (Malcolm et al 1999, 66). A government's attitude towards capital and business sets the stage for either success or failure of its economy. Olsson (2002, 35) defines it as the risk that there will be a change in the political framework of the country. This risk may come under specific scrutiny for example the production of genetically modified foods that is a product of biotech procedures and processes or the R&D and deployment of anti-retroviral drugs for HIV / AIDS treatments.

4.2.5 Industry risk

The risk associated with operating in a particular industry (Olsson, 2002, 35). The Biotech industry is perceived by its participants as being more technologically complex than other industries, including Information Technology (Bøllingtøft, et al 2003). The Biotech industry is seen as being more risky as a result of its technology complexity and affects investment risk preferences of investors in terms of the perceived length of time that returns are expected as well as the magnitude of the investment required to realise the potential returns.

4.2.6 Accounting risk

The risk that financial records do not accurately reflect the financial position of the organisation (Olsson, 2002, 49). It is generally accepted that investors require that organisation properly account for funds provided and invested by shareholders and financiers and to give good accountability of operations.

These transactions, with definite monetary values often manifests in the balance sheets of the company financial statements.

The complexity of the biotech industry and the fact that the assets invested in can often be intangible, aside from tangible assets like laboratory equipment, presents issues around accounting risk. Moon and Piper,(2001) suggests that the accounting framework as previously developed performs well for tangible and financial assets and has stood the test of time but fails to properly account for intangible assets which is the primary source of company value. According to the authors, it is a factor which gains prominence in the biotech industry in that "biotechnology is an industry that is highly dependent on intangible assets". The market values on the stock markets reflect values of intangible assets that are not accounted for in the balance sheet according to the traditional accounting frameworks. It is these assets, "principally intellectual property assets", that drive the market values of biotechnology firms.

B. Biotech Specific Types of Risks

4.2.7 Technical Risk / Product Risk

Blake, (2003) asserts, "This category of risk encompasses the biotechnology in development from a scientific or medical point of view. It allows for the possibility that a pharmaceutical product or medical device may not work in a safe, efficacious and desired manner. This is the risk category most often considered when drugs are being progressed through human clinical trials, although it is a risk feature of earlier development stages as well."

4.2.8 Financing risk

Blake (2003) indicates, “Biotech firms are by their very nature cash hungry operations. They have the potential to consume large quantities of development capital over a number of years, although the objective is to generate assets and increase asset value.” The risk of running out of cash is a significant risk factor to consider given the large R&D component of the biotech industry.

An indication of the cash investment required for R&D is given by an article Anon, 2004 which indicates through an “audit, funded by the Department of Science and Technology and the Egoli BIO Life Sciences Incubator, that South Africa has a ‘pipeline of potential new products and processes in the research and development stage’. It identifies 106 companies participating in biotechnology activities, 47 of which are classified as "core" biotechnology companies solely involved in biotech enterprises.”

“The audit found that total spending on biotechnology research and development exceeded R290-million during 2002, while revenues for 48% of products and services in the local biotechnology industry came to R368-million during the same period.”

From the above an indication is provided of the amount of R&D that is required in the industry relative to the revenues generated. It may also take a long time for a product to come to market in the Biotech field due to extensive R&D activities. It is therefore imperative that sufficient cash resources be available for the biotech venture and that the financing risk be appropriately managed.

Bøllingtøft,et al (2003) indicates that complexity of technology affects a firms financing practices and capital structures. Firms with more complex technology are more likely to report facing financial constraints. The more complex the technology the more complex the risk assessment would likely be for potential investors. Investors would also prove to be more risk averse the more complex the technology in that less risky investments require less

funding which in turn reduces the risk of the loss of investment. Complex technologies also then require substantial investment before an acceptable prototype for commercialization is obtained. Stated differently the less complex the technology the quicker to market and the earlier returns on investment can be realized, hence the less complex technology would attract more capital investment.

Bøllingtøft et al (2003) goes further to show that biotech firms do not spend significantly more time searching out sources of finance than say Information Technology companies given that the biotechnology is seen as more complex. The authors however indicate that external sources of financing dominates in the Biotech field versus the sources of financing for the Information Technology industry which is more reliant on internal sources of financing. The authors further state that the more complex the technology and the higher investment requirements it would also require that the entrepreneur understand this relationship, the technology risk perception and trust in raising the requisite financing.

The authors indicate that Financial Capital is a key strategic asset needed for the realization, the survival and growth of any new venture. Financing risk is a risk that should be carefully evaluated for Biotech firms and it is important that it be managed throughout the firm's life cycle to ensure long-term success.

4.2.9 Clinical trial risk

Clinical trial failure: the possibility that a company's product may not work in a safe and effective manner. This risk usually arises when products are being tested in clinical trials. (Anon, 2004)

According to Bratic, et al, (2000) product pipeline play an important role in product failure risk. A company with only a single product in clinical trials are more at risk than a company that which is developing several products. Wolf (2001) states the following" clearly a company that experiences the failure of a

drug undergoing clinical trials will suffer less from the loss of one candidate if it has many others in the pipeline".

4.2.10 Information risks

The data used to make strategic decisions or manage processes are inaccurate, irrelevant or incomplete. Information risks affect the company at all stages of decision-making and process information. (Moon and Piper, 2001). This may be especially so in the R&D phase of the product development in that the information gained from research should be reliable as it affects the key processes further down the line of commercialization of the product. Information risk also affects the clinical trial risk in that information could either be misinterpreted, falsified or contain errors that could affect the technical or product risk which in turn may increase risk of litigation.

4.2.11 Risk of business interruption

This risk relates to an interruption in business resulting from a physical event-a fire, explosion, or lab contamination-or from a natural disaster such as an earthquake or hurricane. Given the large investment in R &D by biotech firms this risk can be significant for the product development of the firm (Fiscus, P.W, 2002)

4.2.12 Lack of a commercial market

The risk that there will not be a demand for the product. This could occur for a number of reasons - There could be a negative reaction to the product from industry professionals such as doctors, or there simply may not be enough market interest Anon (2004). Rieder (2002) states, "A big market is when several people are suffering from a

certain ailment. A large market means significant revenue when the drug candidate is finally approved for market sale

4.2.13 Obsolescence risk

Obsolescence risk pertains to the products of a company being superceded and therefore rendered obsolete by another company's product that may turn out to be more effective, easier to administer, or have fewer side effects. Anon,(2004)

4.2.14 Product liability risk

Unexpected off-label use may result in unintended or less manageable product liability risk. Product liability coverage for bodily injury and property damage caused by a pharmaceutical or biologic agent is essential protection for biotech companies and can help defray the staggering costs of a lawsuit. Product withdrawal insurance pays for costs incurred to facilitate a drug recall, helping companies act quickly when they discover unexpected problems or defects (Fiscus, 2002)

4.2.15 Intellectual property risks

The discovery of new technologies often leads to the registration of patents for the technology. In biotech it is no different and it is often "the number one investment plank in biotech". This includes intellectual property rights, including patents and trade secrets. Patents in general serve as a barrier to entry to a particular market. However this is surmountable over time or through inventive advances or through the legal challenge to patent validity. Blake (2003) Patents are crucial to almost all areas of biotechnology. They

are the keys to translating inventions into concrete products and disseminating these new products widely. Patents provide the means to establish the necessary cycle of investment, research, innovation, and reinvestment that maximises the public benefits derived from biotechnology. Moreover, a patent related to the role of a gene does not confer ownership of the gene or invention to a company or university. The patent only protects the invention from theft by another economic actor, whether from the private or public sector. (Anon, 2004) According to Bains and Evans (cited in Ratledge and Kristiansen, 2001, 278), patents are critical when you make and invention and does not patent it, anyone with suitable resources can come along and copy it. A patent must fulfil three criteria:

- Novelty: none has done it before

Utility: it must be useful for something

- Enablement: you must describe how someone else could do it.

They also state that the critical part of the patent is the exact wording of the claims. The claims are the set of statements, usually at the end of the patent, which define exactly what it is you are patenting.

The management of the intellectual property risk is one that is of great importance given the rapid development that takes place in the Biotech field. Campbell (2003) indicates, “Such rapid technological progress presents enormous challenges not only to the patent laws but to the patent practitioners as well. While the patent system by definition confronts new technologies, perhaps in no other field have the challenges to existing patent law been greater than in biotechnology. Many of the defining inventions in biotechnology and the proprietary protection available are qualitatively different from those in other technical fields. These differences reflect the fact that much of the valuable technology emerging from biotechnology involves methods and materials for designing or identifying new and useful compositions, rather than the novel compositions themselves. While the primary value of these biotechnology "research tools" lies in the commercial

products they may generate, new intellectual property strategies are required to exploit the proprietary value of the research tools themselves."

She further indicates the increased difficulty in patent protection where the patent is expected to cover research tools and methods. "Challenges to obtaining meaningful patent protection are amplified when the invention is a research tool so as to require particular attention and skill from practitioners seeking to protect such intellectual property. Included among these challenges are describing the invention sufficiently to satisfy the enablement and written description requirements, and establishing acceptable utility in order to support claims of sufficient breadth to prevent competitors from 'designing around'."

"In a field that is advancing as fast as biotechnology, today's methods may be obsolete tomorrow. It is therefore important to structure the claims to research tools in such a way as to cover modifications to the basic methodology. Separate claims should be drawn to different aspects of the invention so as to cover competitors who modify one aspect while keeping others the same
The author states, "Numerous examples are available which demonstrate that strategically-planned and well- managed patent portfolios can be financially profitable." And further more "A well considered strategy must take into consideration the types of claims that can and should be obtained to maximize protection without unnecessarily surrendering proprietary information. The use to be made of the portfolio whether to license or enjoin others should be determined in advance. Finally, licensing and litigation require skilled professionals able to understand the technology and accurately assess the value of the portfolio."

Proper management of the intellectual property risk is crucial to the biotech firm around

- Strategic planning;

- Correct wording of the patent around issues of novelty, utility and enablement of the technology

4.2.16 Legal risk

Intellectual property risk transforms could lead into “a new form of investment risk when rivals are unequally matched according to financial and human resources.” Blake (2003) Legal challenges of small biotech firms but larger more established and more resourced biotech firms may bankrupt the smaller firm or provide significant set backs to product and market development.

4.2.17 Partnering risk

This risk relates to agreements whereby a smaller biotech company may partner with another larger firms in order to develop new discoveries. The risk for the smaller firm is that its partner may not have the same commitment toward the success of the product or technology to the market. Blake (2003)

4.2.18 Reputation risk

The risk that the reputation of an organisation will be adversely affected (Olsson, 2002, 35).
Olsson goes further and states that “Reputational risks occurs principally as a result of failure to manage the other types of risk e.g. legal action to comply with the law or protests by green activists in relation to environmental damage caused…”

Moon and Piper, 2002 state “Reputation risk is the risk that a representative of the organisation will make a decision that or behave in a way that is inconsistent with the organisation’s values or shareholder expectations. Representatives include employees, subcontractors, partners, agents. Values

refer to minimum standards of behaviour i.e. they are universal and compulsory. Stakeholders include those individuals or groups that impact or are impacted by the actions of the organisation. Failure to manage reputation risk can lead to litigation, fines or penalties, increased scrutiny, long term damage to the good name of the company or even inability to operate."

Media coverage and pressure groups have contributed to a dramatic slide in the share prices of companies they target (Moon and Piper, 2002). Reputation can take a long time to build up, but a short time to destroy, so reputational risk is something that must be taken seriously at all levels in an organisation. Moon and Pipers (2002) states that damage to reputation leads to a fall in the overall value of the firm.

Reputation risk examples given by Moon & Piper include:

- Improper messaging of clinical trial data that lead to overhyping the potential of specific products by either not adopting good clinical practices or by misrepresenting clinical data
- Damage through critical media reports of through protests and demonstrations by pressure groups with resultant slides in share prices of affected companies. In this case the market is discounting negative news and reducing share market valuations of the companies concerned.

The authors recommend that this risk be managed through appropriate enterprise risk management procedures given that it is a real risk that potentially has direct impact on firm market value.

4.2.19 Environmental risks

The risk that an organization may suffer loss as a result of environmental damage caused by themselves or others which impacts on their business (Olsson, 2002, 35). What is of concern is both the direct impact a business has on the environment but also the indirect ones it has through it interactions

with its customers and suppliers. It may not be the production processes that cause environmental damage but the products themselves. Releasing genetically modified organisms (GMOs) into the environment is one of the risks that green activists are protesting about. (Anon, 2004), indicates that "The biotechnology industry combines the principles of chemistry and biological sciences with engineering and computer sciences to produce goods and services." They accordingly list the various types of contamination that can take place in the biotech industry.

Potential Environmental Exposures:

- Poor environmental management practices
- Chemical and radioactive materials handling and waste disposal
- Poorly written emergency plans in the event of a chemical spill or release
- Poor training or supervision of staff who handle chemicals and hazardous wastes
- Improper storage of chemicals and hazardous materials in containers and cabinets
- Loading and unloading of hazardous chemicals

Bio-hazardous Wastes: Biotechnology laboratories may generate waste cell cultures, bacteria colonies and tissue cultures that require disposal as a bio-hazardous waste.

Medical Waste: Medical laboratories performing biotechnological research or medicine may generate waste that must be disposed of as medical or infectious "red bag" waste.

Bioremediation-Related Waste: Some bio remedial techniques generate by products that are easier to treat or manage than the contaminants being remediated, but which must nevertheless be treated on-site or disposed of as hazardous waste.

Phytoremediation-Related Waste: Plants that remove contaminants from the environment by absorbing them through their roots may themselves become sufficiently contaminated to require disposal as hazardous waste.

Environmental Contaminants:

Solvents, metals, acids and caustics include;

- Hydrogen bromide
- Carbon tetrachloride
- Fluorine (used in dry etching)
- Acids and caustics (used in wet etching)
- Hydrofluoric acid
- Trichloroethane
- Perchloroethane (used in wafer fabrication)
- Antimony, arsenic, phosphorus, boron, gallium, germanium, beryllium and tellurium (used as dopants)
- Ammonia, phosphine and tungsten hexafluoride gases (used in vapor deposition)
- Aluminum, platinum, chromium, nickel, silver and copper (used in metallization)
- Organic solvents such as acetone, xylene, and isopropyl alcohol (used to clean wires and surfaces)

Wastes typically generated by these types of establishments include:

- Halogenated and non-halogenated spent solvents
- Spent acids and caustics
- Metal-bearing waste waters
- Metal-bearing residues and sludges
- D007 (chromium-contaminated) waste

The risk of environmental contamination has far reaching impact on the Biotech organisation and leads to increased reputation, legal, financing,

business failure risk. This risk of environmental contamination or damage is far reaching and may occur during the R&D phases of product development or during the manufacturing process of products which are ready for commercialisation.

Furthermore the improper management of environmental risk may lead to an increased regulatory risk with resultant increased regulatory monitoring and regulations for the organisation in the long run. Ultimately an escalation of these risks for a small biotech firm may lead to bankruptcy and the eventual demise of the firm.

4.3 THEORETICAL RISK FRAMEWORK

The various risks have been identified and described above and are tabulated below with key questions associated to each risk, the reason for the question and the potential impact on returns. Each risk is not meant to be evaluated in isolation but is meant to evaluated in context of the whole even though there are some risks that may have a larger impact on the Biotech organisation than on non-Biotech organisation.

The risk evaluation, of “High”, “Medium” and “Low” under the “Potential Impact on Returns” is provided with the intention of highlighting more those risks directly related to the Biotech industry. Whilst the other risks, like the non-financial risks are not meant to be reduced to non-important status the focus of the framework is to identify those risks that VC would specifically have to identify for the Biotech Industry. It is an assumption that the other non-Biotech risks a VC would evaluate in the normal course of business.

The meanings applied to the risk for its potential impact on returns are as follows:

High = means the risk has significant impact on the organisation and may also increase the risk exposure of other risks

Medium = means the risk has lower than significant impact on the organisation but does not directly increase the other risk exposures

Low = means the risk factor does not have any significant impact on the organisation and can be managed in isolation without increasing other risk exposures

The risk evaluation is subjective and is primarily driven by the definition and explanations of the risks as discussed above.

The risk framework below encapsulates specifically the biotech specific risks that affect the potential returns of a biotech organisation.

Table1: **Risk Framework**

NO.	KEY RISKS QUESTION	WHY THE QUESTION	POTENTIAL IMPACT ON RETURNS
1.	**Technical Risk / Product Risk** What is the likelihood of the product working in a safe, efficacious and desired manner?	Products from the biotechnology industry are at the forefront of new developments and are often ground breaking. Many products fail to pass clinical trail phase and pass through the regulatory process to market. The risk may increase should the biotech company only have one product on which it depends.	**High**
2.	**Financing risk** What is the company's cash position?	Biotechnology is complex and requires large amounts of investment over a long period of time. Time for product development and complexity of products adds additional risk to the investment. Investment in R&D is often extensive and is no guarantee of success but	**High**

NO.	KEY RISKS QUESTION	WHY THE QUESTION	POTENTIAL IMPACT ON
		requires large cash investment upfront.	
3.	**Clinical trial risk** What is the likelihood of success for the product in clinical trials?	Well defined processes, protocols, standards, well trained clinical trial research staff and properly run clinical trials add to the potential for success. Failure to adhere to proper processes in this area may lead to litigation further down the line including the commercialisation process.	**High**
4.	**Information risks** What processes does the organisation have to ensure the quality of information throughout its processes?	The entire product development life cycle is impacted by information control, sharing, evaluation and review. At each stage of the process information integrity is important and the quality impacts on investment and product launch decisions.	**Medium**
5.	**Risk of business**		

NO.	KEY RISKS QUESTION	WHY THE QUESTION	POTENTIAL IMPACT ON
	interruption What procedures and processes does the company have to ensure that R&D and other tangible investments are safeguarded?	Time is money is the adage and in the biotechnology industry it is particularly pertinent. Large capital investments are required and assets either damaged or standing idle presents a significant cost to investors. Business risk managing procedures will mitigate against this risk.	**Medium**
6.	**Lack of a commercial market** Is there significant market opportunity for the drugs being developed by the company?	Biotechnology products are often new and the market for the product is often undeveloped. The major issue however is whether the patients are sick which would imply that the market is clearly defined. Where the product affects the general health care market it could be impact on the product viability. The more clear the focus of the product the easier the market and market	**HIGH**

NO.	KEY RISKS QUESTION	WHY THE QUESTION	POTENTIAL IMPACT ON
		size is defined and potentially greater the returns.	
7.	**Obsolescence risk** What other products are in the pipeline (either in development or on the market) from other companies that may potentially render the company's products obsolete?	Competitors in similar type of developments as the company may produce similar or better products. The product may be made through a new process and may be either more cost effective or produce better results for the customer.	**High**
8.	**Product liability risk** Does the company have product liability risks insurance cover that will cover potential fallout from biological agents not otherwise detected during clinical trials and other tests?	Smaller biotech firms may not have this type of coverage as the available cash is invested in R&D. The flip side of the argument is that where the product liability risk is not covered its eventual realization may effectively cripple the company and render all its activities and investment meaningless.	**Medium**

NO.	KEY RISKS QUESTION	WHY THE QUESTION	POTENTIAL IMPACT ON
9.	**Intellectual property risks** What type of intellectual property protection does the company have for its products and is it comprehensive to provide legal protection for products and research methodologies?	Patents provide a barrier to entry for a limited time period to biotech firms and this window period may provide the opportunity to recover investments and realise returns. Good patent registration by knowledgeable practitioners will protect against potential litigation and infringement whilst protecting intellectual capital. The biotech firms' biggest value generators are its intangible assets and the market often values companies by its intangible assets by virtue of its potential to generate returns.	**HIGH**
10.	**Legal Risk** Has the company taken sufficient steps to cover itself against legal action from rivals and or the	Legal action whether as defendant or plaintiff is highly costly and the avoidance of legal action is highly desirable. Not only costly but	**Medium**

NO.	KEY RISKS QUESTION	WHY THE QUESTION	POTENTIAL IMPACT ON
	public or other pressure groups?	time consuming which could lead to bankruptcy.	
11.	**Partnering risk** Is the company partnered with any major company players and / or a respected academic institutions	Partnering with established firms provides security in the financial and intellectual property aspects of product development. It provides a positive message to the market that the big firms see potential in the product.	**High**
12.	**Reputation risk** Is the company aware of reputation risk and does it have sufficient processes in place to manage risk to its reputation?	Reputation risk addresses aspects of intangible assets and given that intangible assets actually impacts market value. Intangible assets impacts future prospects. It is therefore sensible to actually manage and protect reputation for long run success.	**High**
13.	**Environmental risk** Does the company	Environmental damage and	**High**

NO.	KEY RISKS QUESTION	WHY THE QUESTION	POTENTIAL IMPACT ON
	have sufficient processes and procedures in place to manage potential environmental damage as a result of its activities?	societal impacts has short term and long term impacts for the firm and often proves costly. It costs a lot of money, time to fix the environmental damage, and it could impact other risks like litigation risk. There could be significant impact on long-term returns.	
14.	**Regulatory risk** What is the likelihood of success in the regulatory process (compliance and unregulated products) and associated timing for the process?	This process often follows on the clinical trial process and it may be a challenging time through the government approval process. Should undue delays be experienced during this process either due to unknown processes, technology or other regulatory delays it may result in costs to the company.	**Medium**

4.4 SUMMARY

Various risks pertain to the biotechnology industry in addition to the “generic business risks” that any investor may face in making the investment decision. Risks for purposes of this analysis are divided into general and biotechnology industry specific risks.

The general risks include operational, regulatory, business specific, political, industry and accounting risks. These risks are provided for completeness of the discussion and are not analysed in detail but relate to biotechnology firms in that they impact on potential returns. These risks add a unique perspective for the investor in that issues specific to the biotechnology sector increase the risk to the investor. For example the complexity of the research and development and the products developed by the biotech sector adds to the regulatory burden and given the intellectual capital generated often leads to it not being properly accounted for leading to an increase in accounting risk. The genetic modification of foods is another example that impacts on the political risk as certain governments do not endorse this kind of technological change to foods.

The biotechnology specific risks are discussed in more detail and it is on this discussion that a theoretical risk framework is built. These risks may not be analysed in detail or properly understood by potential investors, which could in turn impact on investment returns. The biotech specific risks include, inter alia, technical, financing, clinical trial, product liability, intellectual property, legal and environmental risks.

The biotech specific risks should not be analysed in isolation and should be evaluated in conjunction with other risks as one risk often impacts on another risk. For example risks associated with the product can impact on clinical trial risks which in turn could lead to increased legal risk where the relevant clinical trials have been passed but the information risk associated with the R&D and

the product itself may not have been properly controlled. The key factor to take into account is that the risks are interrelated.

Given that biotech specific risks are interrelated the theoretical risk framework is constructed on the basis that the risks need to be evaluated as a whole and no risk is to be evaluated in isolation. The theoretical risk framework focuses on the biotech specific risks and does not include the general risks in order to highlight the biotech risks and their potential impact on returns. Each risk is given a subjective risk rating of high, medium and low depending on its impact on other biotech specific risks and its potential impact on potential returns.

Chapter 5

Conclusions & Recommendations

Chapter 5

5.1 Summary

Biotechnology is defined as the application of knowledge of living systems in order to use those systems or their components for industrial purposes. (Bains 2000, pp16)

The biotech industry is characterised by rapid technological change and advancements, is knowledge based and highly technological. The problem is that there is a perception that risks in the biotech industry are high and difficult to determine and therefore funding from Venture Capitalists (VC) is not forthcoming. Risk arises when the future is unclear and where a range of possible future outcomes exists (Atrill 2000). This short dissertation therefore seeks to inform VC on these risks and provide a theoretical risk framework to inform the investment decision.

The biotech industry can be divided into the following specific biotech types Agriculture, Forensics, Food, Fabrics and Textiles and Pharmaceutical and Medical , but the focus of this paper is more on the Pharmaceutical and Medical sections of Biotechnology.

The Pharmaceutical biotech development pathway follows a process through preclinical research and phase 1, 2, 3 and 4 trials which are clearly distinct from one another. In addition to this biotechnology business models include a product based model, platform or business tool models, fully integrated pharmaceutical company models and hybrid models.

The biotech firm is subject to business, financial, non-financial risks like any other business but also has risks specific to the industry. These risks include inter alia technical/product risk, product failure risk, information risks, intellectual property risks, partnering risks, legal risks and reputation risks.

The biotech organisation, like any other organisation, requires investment capital in order to develop and one particular source of funding is Venture Capital. Even though Venture Capitalists are, like other investors, risk averse they do invest in biotech firms by providing inter alia seed capital, start up funding, first stage and expansion funding.

Venture Capital is defined as money provided by professionals who invest alongside management in young, rapidly growing companies that have the potential to develop into significant economic contributors. This fits well with the biotech industry where new discoveries are made regularly and where there is potential to make significant economic contributions.

Venture Capitalists have specific investment requirements which are often evaluated during a due diligence process for investment evaluation. The investment evaluation involves looking at management calibre and experience, commercial markets and well thought out business plans. There are specific issues that Venture Capitalists look at during the due diligence process and includes commercial aspects, products, intellectual property, clinical development, regulatory issues and fundamental technologies.

These investment requirements can be specifically related to the biotech industry in the following aspects that are often evaluated: strong patent position, experienced management, world-class management, proven track record, business focus, R&D partnership, corporate partnership, platform technologies, unique technologies, products in early clinical trials or a broad product pipeline. These aspects are in turn related to the biotech specific risks in that it touches upon risks such as product risk, clinical trial risk, information risk, commercial market risk, intellectual property risk and partnering risk.

General non-financial risks are present in the biotech industry and are often affected by the unique aspects of the industry for example regulatory

risk can be divided into compliance and unregulated goods and services risks. Biotech specific risks on the other hand are unique to the industry and have significant impact on investment decisions. These specific risks should not be viewed in isolation but should be viewed as a whole in that they impact on one another and one risk not managed properly can often increase the other risks. The qualitative theoretical risk framework is accordingly developed with this in mind.

The theoretical risk framework focuses on the biotech specific risks not to the exclusion of other general financial and non-financial risks but for the purpose of highlighting biotech specific risk issues for use by the Venture Capitalist in evaluating the investment decision. The biotech specific risks discussed in detail and are then evaluated on a subjective scale of high, medium, low in terms of its impact on other risks and its impact on its potential impact on returns. Items of high risk include inter alia product risk, financing risk, information risk, commercial market risks and intellectual property risk. This analysis both highlights, informs and provides guidance to the biotech investor but also indicates that biotech is a high risk industry.

It is worthwhile emphasising again that these biotech specific risks should not be analysed and evaluated in isolation but should be evaluated as a whole as the risks are often interrelated. It is therefore to the Venture Capitalist's benefit to evaluate these risks carefully but more so to have biotech manage these risks as far as is possible to ensure that the potential returns are improved for investors and stakeholders.

5.2 Conclusions

The complexity of biotechnology R&D and products increases risks for investors but where a risk is not identified it cannot be mitigated or managed. Venture Capital investors prefer risks not to be too high and are

risk averse but may seek to strike a balance between acceptable risks versus the level of returns.

Accordingly the analysis of biotech specific risks may increase the VC awareness of the biotech industry and could lead to further investment. This is on the basis is that once a risk is identified and analysed it can be investigated and evaluated. This process of risk identification and evaluation of risks aids in meeting the Venture Capitalist investment requirements. This in turn means that the risk can be managed and its impact on returns properly evaluated.

The theoretical biotech risk framework developed should be used to inform the investment decision-making process. The Venture Capitalist can use the theoretical risk framework to start asking the appropriate questions concerning the biotech investment in addition to their usual investment requirement investigation. It is to be used in conjunction with the normal investment risk analysis and should add a better understanding of risks and which of the risks could impact investment returns in the long run

5.3 Recommendations and Implications for Future Research

- A more detailed investigation into biotech risks can be done for the future and these can be further developed in order to produce a quantitative biotech risk model. The qualitative theoretical risk framework can be used as a basis for further study.

- The quantitative risk model can then be tested with consultation with Venture Capital practitioners.

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