UNIVERSITY OF LJUBLJANA
SCHOOL OF ECONOMICS AND BUSINESS

MASTER'S THESIS

AN ANALYSIS OF MEDICAL BIOTECHNOLOGY SECTOR AND FACTORS THAT CONTRIBUTE TO SUCCESS OF START-UPS

Ljubljana, August 2021 LUCIJA REMIC

AUTHORSHIP STATEMENT

The undersigned Lucija Remic, a student at the University of Ljubljana, Faculty of Economics, (hereafter: FELU), declare that I am the author of the master's thesis entitled Analysis of medical biotechnology sector and factors that contribute to industry's start-ups success, written under supervision of, Tjaša Redek Ph.D

D E C L A R E

1. this written final work of studies to be based on the results of my own research;
2. the printed form of this written final work of studies to be identical to its electronic form;
3. the text of this written final work of studies to be language-edited and technically in adherence with the FELU's Technical Guidelines for Written Works, which means that I cited and / or quoted works and opinions of other authors in this written final work of studies in accordance with the FELU's Technical Guidelines for Written Works;
4. to be aware of the fact that plagiarism (in written or graphical form) is a criminal offence and can be prosecuted in accordance with the Criminal Code of the Republic of Slovenia;
5. to be aware of the consequences a proven plagiarism charge based on the this written final work could have for my status at the FELU in accordance with the relevant FELU Rules;
6. to have obtained all the necessary permits to use the data and works of other authors which are (in written or graphical form) referred to in this written final work of studies and to have clearly marked them;
7. to have acted in accordance with ethical principles during the preparation of this written final work of studies and to have, where necessary, obtained permission of the Ethics Committee;
8. my consent to use the electronic form of this written final work of studies for the detection of content similarity with other written works, using similarity detection software that is connected with the FELU Study Information System;
9. to transfer to the University of Ljubljana free of charge, non-exclusively, geographically and time-wise unlimited the right of saving this written final work of studies in the electronic form, the right of its reproduction, as well as the right of making this written final work of studies available to the public on the World Wide Web via the Repository of the University of Ljubljana;
10. my consent to publication of my personal data that are included in this written final work of studies and in this declaration, when this written final work of studies is published.

Ljubljana, 20th July 2021 Author's signature: Lucija Remic

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF APPENDICES

INTRODUCTION

Medical biotechnology has emerged as an important link between biotechnology, medicine and pharma industry. According to Srinibas (2015), it stands to be the most important area of improvement for human health and quality of life. In general, medical biotechnology includes companies applying technology to the life sciences. Some firms that were first characterized as biotechnology firms then matured and are now considered pharmaceutical companies, among them Millenium Pharmaceuticals, Genentech and Amgen (Gottinger & Umali, 2008). Originally, there was a distinction between pharmaceutical firms and biotechnology firms. Pharmaceutical firms initially developed and commercialized small molecule drugs and biotechnology firms produced biopharmaceuticals. This division is now disappearing. Today's big pharms companies, primarily through licensing partnerships and acquisitions, manufacture and sell a majority of the most profitable biotechnology therapeutics (Noonan, 2018).

Research shows that biotechnology industry has a large positive economic impact (Hevesi & Bleiwas, 2005). Biotechnology as a knowledge-based industry generates high-value added jobs, and in turn creates high value-added products/services (Erickson, Nelson & Winters, 2012). Furthermore, it enables and supports development of sustainable national economy. Slovenia is recognizing the importance of biotech sector, as SRIP Health - Medicine is one of the nine strategic areas in the country identified by Slovenian government to advance the social and economic transformation as one of the main strategically important developmental goals in Slovenia (TikhePharma d.o.o., 2020). Biotechnology is dependent on small firms and the smaller businesses tend to occur in clusters that are geographically close to the knowledge source, namely universities (Cook, 2001). In 2018, the Republic of Slovenia and EU co-invested 20 million euros in the new Biotechnological Hub (Presentation of the Investment Project). In 2017, there were 27 active biotech companies in Slovenia. These companies predominantly either sell their products and services to larger biopharma companies or conduct research in the scope of the governmental grants. There is a great diversity and variety of biotech products/services that Slovenian companies offer (TikhePharma d.o.o., 2020). In 2020, Slovenian medical biotech industry includes small companies such as Educel, Acies Bio, Biosistemika, Gene planet, Bia Separations, Cosylab, etc. and large companies such as Novartis and Krka.

In Slovenia, there are many skilled biotechnologists. Our knowledge and skills in area of medical biotechnology can be compared to the best countries worldwide, but Slovenia lacks biotech entrepreneurs (Bratanič, 2015). According to Global entrepreneurship monitor (Rebernik et al., 2020) one of biggest drawbacks is non-stimulative taxation for start-ups. Additionally, there is a huge shortage of venture capital and angel investors in Slovenia. Leading to seed capital being hard to obtain. The exploratory research showed that Slovenian environment is better developed than South and East Europe and less developed than Central and West Europe. The environment has many advantages: universities are creating a strong foundation for the industry; public funding is highly accessible and the global demand for

biotech solutions is growing. On the other hand, the country is struggling with a shortage of professional infrastructure such as centers of excellence or technology parks, bureaucratic laws and the lack of private funding.

The goal of the thesis is to contribute to understanding the ways and the challenges of building a company in the medical biotechnology industry worldwide and in Slovenia. More specifically, the goal of the thesis is three-fold: (1) analyze the dynamics of biotechnology globally and in Slovenia and (2) study the determinants of companies' success and (3) evaluate the development of the sector in Slovenia and potential of Slovenian companies with a (4) special attention to start-ups. The purpose of master's thesis is to discover potential methods and processes that make it possible for companies in medical biotechnology industry to succeed. The key research question is whether Slovenian medical biotech industry is underdeveloped in comparison to its potential due to suboptimal environment. Would Slovene medical biotechnology industry blossom, if methods and process, which stimulate entrepreneurship in the industry, existed?

Methodology. In order to achieve the objectives of master thesis three different research approaches are used: literature review, use of secondary data, existing statistical sources and collection of primary data to obtain further insight into the sector in Slovenia. Firstly, the descriptive approach, which is based on the methods of description, analysis and synthesis of secondary literature, is used to present the industry, the current market and industry trends in medical biotechnology. Furthermore, key factors contributing to the companies' success, with an emphasis on raising capital, partnerships and supporting policies are identified. In this part, where possible findings are additionally illustrated with a review of empirical literature in the field. In the presentation of the current market and industry trends in medical biotechnology, I also use different sources of official statistical data, international statistical sources, from Eurostat, Slovenian Statistical Office data, to Statista and other sources. Where available, I use in this part relevant industry expert reports. Secondly, the exploratory research approach is used to help me identify the present state of Slovene medical biotechnology ecosystem and the development path of those companies. This is achieved through in-depth interviews with .companies working in this arena.

The topic of this study is unexplored. The author's exploratory research is the first qualitative research investigating the Slovene medical biotechnology ecosystem. The qualitative research of Slovene ecosystem is compared to analysis of the dynamics of biotechnology globally.

Limitations. There is only a small numbers of medical biotech companies in Slovenia. Therefore, only a small number of interviews were conducted and analyzed. Nevertheless, the study provides a good first glance at the area studied and represents a good foundation for future research. Secondly, analyzing the interview data from open-ended questions pose greater problems in comparison to when closed-ended questions are used because varied responses from participants are more challenging to compare.

Structure of the thesis. The master thesis is split in three main parts. The first part focuses on the review of the existing secondary literature on the current market and industry trends in medical biotechnology. Furthermore, key factors contributing to the companies' success, with an emphasis on raising capital, partnerships and supporting policies are identified. Additionally, Slovene medical biotechnology ecosystem and companies' nature is analyzed and compared to world's best practices in order to find proposals for development of Slovenian medical biotechnology industry. In the second part, the methodology and results of empirical research are presented. I conducted four in-depth interviews with Slovene medical biotechnology companies. It needs to be emphasized that the number of those companies is very limited and small. The third part consist of presentation, analysis and discussion of results, followed by final conclusions of the master thesis, which could lead to important contribution to the understanding of key factors contributing to medical biotechnology company's success.

1 MEDICAL BIOTECHNOLOGY

Biotechnology is technology which employs biological systems, living organisms or their building blocks with the goal to develop new products (Amarakoon, Hamilton, Mitchell, Tennant & Roye 2017). Brewing or baking bread are both a process, which fits into the definition of biotechnology; when we bake bread, we use yeast (a living organism) to produce the chosen product (bread).

1.1 Definition and development of biotechnology

The first biotechnological product were rather simple. Many forms of agriculture of human origin correspond to the general definition of "employing a biotechnological system to make products". In fact, plant farming can be considered the first biotechnology business. Think of the earliest farmers selecting and breading crops that best adopted to their environment and had the highest yields, to generate a sufficient amount of food for an always-growing number of people. During the history of agriculture, the genetics of farmer's crops were unconsciously changed by introducing crops to unfamiliar environments and breeding them with different plants. Another popular biotechnological product which has been around for centuries is beer. Beer fermentation was popularized in early Mesopotamia, Egypt, China and India (Jennings et al., 2005). During the process of brewing, enzymes in malted grains convert starch from grains into sugar. After that, yeasts is added to make beer. Fermentation is how biotechnology was originally used to convert a food source into another form but they did not entirely understand it until the observation of Louis Pasteur in 1857. At the beginning of the 20th century, scientists learned more about microbiology and in 1917, a pure microbiological culture entered an industrial process. It was done by Chaim Weizmann, in the production of corn starch using Clostridium acetobutylicum to make acetone. It is important to understand that in the UK, they badly needed acetone to make explosives during

World War I. Next major step for biotechnology was the development of antibiotics. In 1928, the mold Penicillium was observed by Alexander Fleming. Next, they purified the antibiotic compound formed by the mold and developed a well-known penicillin. From 1940 onwards, penicillin is used in medicine, mainly for treatment of bacterial infections. The field of modern biotechnology developed after the Second World War with some major scientific discoveries. In 1953, JD Watson and FHC Crick presented the 'Double Helix Model of DNA'. In 1961, Jacob and Monad identified the concept of Operon and in 1971, the gene splicing experiment by Paul Berg paved the way for the invention of recombinant DNA technology (Verma, Agrahari, Rastogi & Singh, 2011). The 1984 Office of Technology Assessment Report, Commercial Biotechnology, had popularized the term "new biotechnology" (Tansey & Catterall, 1994).

The commercial viability of biotechnology considerably grew in 1980, when the United States Supreme Court rendered its decision that genetically modified organisms are patentable in the case of Diamond v. Chakrabarty. Chakrabarty, employed at General Electric, had found a solution for treating oil spills. He modified a bacterium so that it was able to break down crude oil. Initially, the application was rejected, because before 1980, patent law did not permit the patenting of living things. This case is of an extreme importance for the industry.

1.2 The role of medical biotechnology

By the same token, as the 20th century was named the era of electronics, the 21st century can be called the era of biotechnology. Among the fields in which biotechnology offers huge benefits are: Human Health, Animal Health, Medicine, Agriculture, Mining, Environment, Horticulture, Forestry Fisheries, Floriculture, Dairy, Food processing, Animal Husbandry, Renewable energy, Crime detection, parental dispute (confirming the biological father), Aquaculture etc. Biotechnology seeks to enhance the quality of human life and increase our longevity. Furthermore, it enables and supports development of sustainable national economy (TikhePharma d.o.o., 2020). It is one of the most important emerging technologies that can be used to expand the knowledge-based industry (Sadraei, Sadeghi & Sadraei, 2018). Research also shows that biotechnology industry has a large positive economic impact (Hevesi & Bleiwas, 2005). Biotechnology as a knowledge-based industry generates high-value added jobs, and in turn creates high value-added products/services (Erickson, Nelson & Winters, 2012).

Based on application, the five main branches of biotechnology are:

- animal Biotechnology;
- medical Biotechnology;
- industrial Biotechnology;
- environmental Biotechnology and
- plant Biotechnology.

Animal biotechnology focuses on genetically engineered animals. For example, genes are modified to increase milk or meat production or to improve or establish resistance to various diseases and then eggs are fertilized in-vitro with these genes. Next, they move the embryo to the womb of female animal and there it grows until the animal is born.

Industrial biotechnology is concerned with manufacturing for commercial use. It produces many different beneficial organic compounds, like citric acid, acetone, acetic acid, glycerine, etc., and antibiotics such as mitomycin, penicillin, streptomycin, etc., using the microorganisms most often bacteria or fungi.

Environmental Biotechnology is concerned with detoxifying waste and industrial emissions, cleaning sewage water, and eliminating plant diseases or insects by using biological agents, like bacteria, viruses, fungi etc.

Plant biotechnology is both tissue culture and genetic engineering. It is concerned with how to make genetically modified plants which will be resilient to biotic and abiotic stress by using clonal multiplication, haploids, embryo rescue, cryopreservation etc. (Jain, 2010). With the help of plant biotechnology humankind is able to generate enough food for the growing population. This evolution is known as agricultural revolution, the third agricultural revolution is also named green revolution. Today, more than ever, new biotechnological methods are helping us grow plants that are resilient, do not get infected, and have high yields. Furthermore, we are introducing inoffensive bio fertilizers as an alternative to offensive chemical fertilizers.

Medical biotechnology aims to manufacture pharmaceuticals for the treatment of terrible diseases in humans or animals. It is concerned with diagnosing different diseases, manufacturing different therapeutics and hormones like human insulin and making vaccines for infections like Covid. Medical biotechnology is a link between pharma industry, biotechnology and medicine. A new period of healthcare science was born from medical biotechnology and its branches: molecular medicine, personalized medicine and regenerative medicine. These advances have enabled medical biotechnology to become the most important field that improves human health and quality of life (Srinibas, 2015).

The first biotechnology companies pursued everything from animal health to industrial applications; many were in the business of human therapeutics since these products can reach high prices. The initial targets were human insulin and human growth hormone, because scientist knew exactly how to use them, there was already an existing market for these compounds, and because they are quite simple to reproduce (Greenwood, 2014).

1.3 Products of Medical Biotechnology

The most famous products in the field of medical biotechnology are antibiotics, which are used in treatments of bacterial infections. Another well-known and widely used product in

this field is human insulin, which we are nowadays able to make in fungi or bacteria. Key products groups of biotechnology are:

– antibiotics,
– vaccines,
– recombinant proteins,
– monoclonal antibodies,
– regenerative medicine,
– diagnostic.

Antibiotics may kill or suppress bacteria. While antibiotic normally attacks bacteria, certain antibiotics can kill fungi and protozoa. We, humans can also be targets. On the other hand, antibiotics cannot kill viruses.

A vaccine is a biological product. Its goal is to make a recipient immune to a specific virus. Typically, a vaccine encompasses the pathogen responsible for the disease in a form of a weakened or destroyed pathogen. It can also be made from toxins or surface proteins of this virus. This activates the host immune system, producing a defensive response to the virus.

Recombinant protein is a genetically changed protein. It can be modified in different ways to generate huge quantities of proteins, alter gene sequences, and produce valuable commercial products. Recombinant proteins provided important breakthroughs in biomedical biotechnology. First, they are used in treatment, as drugs. Second, they are often used in biomedical research. Recombinant human insulin was the first recombinant protein used for medical purposes, in 1982. The industry has been growing fast since then (European Pharmaceutical Review, 2014). In 2018, more than 130 recombinant proteins gained FDA approval and more than 170 recombinant proteins were made and used for medical treatments globally (Pham, 2018). At first, it was thought that recombinant proteins will be used in diseases where small amount of protein is needed. Meaning for enzyme, hormone, and coagulation factor deficiencies. Now, they are also used to treat inflammation, cancer and macular degeneration, which represents a huge increase in market value (Bartfai & Lees, 2013a). Moreover, nowadays, new small molecule drugs are invented with the help of recombinant protein technology. Recombinant protein manufacturing is now a mature discipline (European Pharmaceutical Review, 2014).

Recombinant proteins are drugs with high earning potential. In large pharma companies like Novartis, Pfizer, Roche, AstraZeneca, and Merck creation of new recombinant proteins was important for the growth of the company. In the past, these firms relied heavily on medicinal chemistry (small molecules). They have entered the recombinant protein industry through multiple acquisitions, of biotech companies. It is worth mentioning that several large pharmaceuticals, such as GlaxoSmithKline (GSK), Merck, Sanofi-Pasteur-Merieux, and Pfizer-Wyeth, were already in possession of biological production know-how through their vaccine production, but the vaccine production and development has always been an isolated

part of these conglomerates since vaccines are tested, distributed, and priced differently from other biologicals (Bartfai & Lees, 2013a).

Monoclonal Antibodies. Among important breakthroughs in medical biotechnology is our knowledge to use patient's own immune system to fight illnesses and monoclonal antibodies offer just that. Nowadays one third of new treatments globally are monoclonal antibodies. Including therapeutics for breast cancer, medicine for arthritis, psoriasis, leukemia and asthma, medicines preventing transplant rejection, and many more currently in the last phase of clinical trials (MRC Laboratory of Molecular Biology, 2020). Monoclonal antibodies are widely used to prevent, diagnose and treat the disease (MacroGenics, Inc., 2017).

The global monoclonal antibodies therapy market size was valued at USD 123.03 billion in 2019 and is estimated to reach USD 350.10 billion by the end of 2027. Monoclonal antibodies like Humira, Remicade, Rituxan and Herceptin are extremely profitable drugs also called blockbuster drugs. Furthermore, numerus biosimilars entered the market, which are also driving the monoclonal antibodies market growth. Some of the major firms providing monoclonal antibodies are Novartis AG, Johnson & Johnson Services, Amgen Inc. Merck & Co., Inc., AbbVie Inc., Inc., Daiichi Sankyo Company, Limited, Bristol-Myers Squibb Company, Alexion Pharmaceuticals, Inc. and F.Hoffmann-La Roche Ltd. (Insights, 2020).

Regenerative medicine is concerned with tissue engineering, production and usage of stem cells, and the making of artificial organs. It is able to cure or replace tissues and organs impaired by age, illness or injury and stabilize congenital defects (Mao & Mooney, 2015). The field of regenerative medicine can be segmented based on application into wound care, dental, oncology, musculoskeletal disorders, ocular disorders, and other. Based on products we divide the regenerative medicine field into cell therapies, gene therapies, tissue-engineered products, and stem cell therapies. The tissue-engineered products segment has the biggest market size of the segments. The chronic wounds treatments, musculoskeletal disorders and the rising funding for the research in the field of regenerative medicine are driving the growth of tissue engineering market. Moreover, the market for regenerative medicine is growing rapidly with evermore funding in regenerative medicine R&D and growing pipeline of regenerative medicine treatments for chronic diseases, melanoma, and genetic diseases. Experts project, the global regenerative medicine market to be USD 17.9 billion by 2025 from USD 8.5 billion in 2020, at a CAGR of 15.9% (MarketsandMarkets Research Private, 2020).

Regenerative medicine treatments change and progress the way illnesses are treated and increase chances of curing them all together. Injecting gene or cells in patients will sooner or later be possible and we will dodge countless drugs and several surgeries. These therapies are lifesaving and more effective in comparison with old-style treatments. Nevertheless, despite all this the demand for regenerative medicine treatments is smaller than experts anticipated. The demand is perhaps lower because these treatments are expensive and it is

challenging to obtain coverage and reimbursements for these treatments (MarketsandMarkets Research Private, 2020).

Diagnostic. When a patient is faced with a disease, a doctor wishes for diagnosis to be as specific as possible so he or she is able to decide on the best following treatment. This is becoming increasingly important with the usage of expensive focused therapies. If the wrong drug is prescribed treatment is completely ineffective. One example of diagnostics industry is Genomic Health. Genomic Health was founded in 2000 to develop differentiated cancer tests based on examining which mutated proteins are present in a tumor biopsy from a patient whose sample is sent to their laboratory.

Diagnostic industry is important also to pharma. As, when patients are diagnosed incorrectly there is more chance that a drug will fail during clinical trials. Famously, one of the most challenging obstacles of pharmaceutical firms is that 90% of the projects fail miserably. When the drug has progressed in clinical trials to phase 3 but was then unsuccessful to continue, the expenditures of several hundred million dollars are not recovered. One of main reasons for these failures is imperfect selection of patients for clinical trials. With the help of biomarkers, one can validate if the drug is effective or not and at which dosage the affects occur during clinical trials (Bartfai & Lees, 2013a, Chapter 9). Personalized medicine and diagnostics go hand in hand. The idea of companion diagnostics rose from intertwining genotyping and drug prescription by prescribing drugs based on specific genotypes. Currently, there are very few drugs approved only for patients with a genetically determined profile. Meaning they require genotyping of the patient before prescribing a drug. The breast cancer drug trastuzumab (Herceptin) is the first drug to require genotyping (Florko, 2017).

2 OVERVIEW OF MEDICAL BIOTECHNOLOGY INDUSTRY AND MARKET

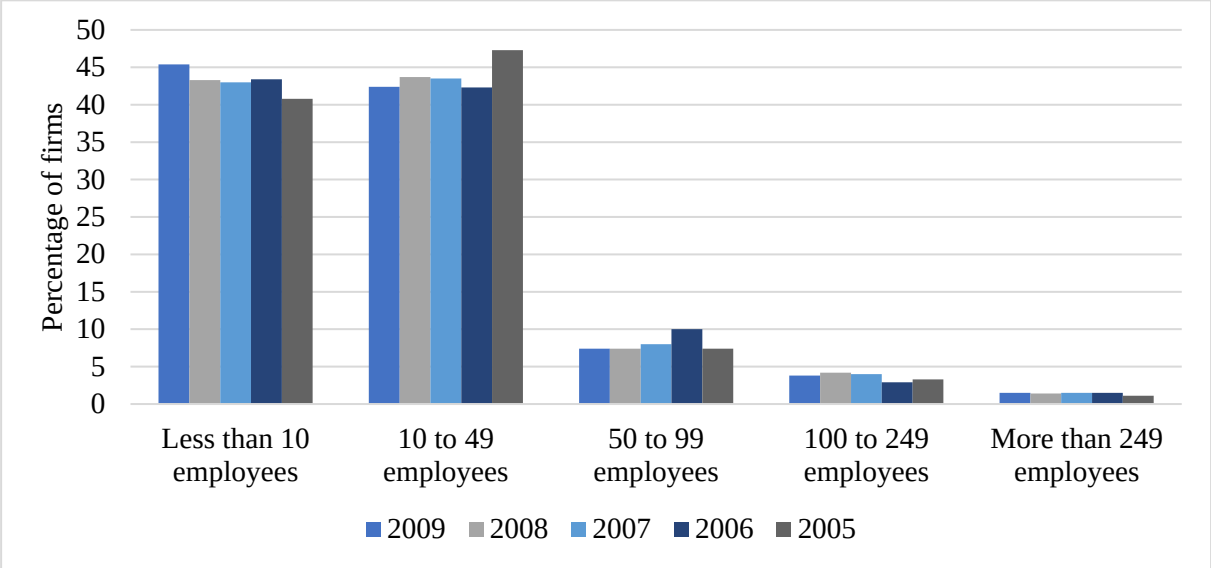
The birth of this industry was in the United States. In the late 1970 small biotech firms (New Biotechnology Firms or NBFs) emerged. They advanced knowledge with roots in genetic engineering and made "discoveries" that were later commercialized. Medical biotech firms are often small research firms providing specific services, manufacturing a particular protein or doing research, aiming to invent a new drug. They are typically incapable of completing the development by bringing the drug to market and therefore they collaborate with larger companies (big pharma companies) and source the drug they worked on to big pharma firms. The United States biotechnology industry is a true network of universities, privat and public research centers, small biotech businesses and big pharma firms. They seem to collaborate rather than compete (Sadraei, Sadeghi & Sadraei, 2018). In bio cluster areas such as Boston, London, San Diego, and San Francisco we can find pharma companies which have established links with academic centers located in the cluster (Noonan, 2018). Small biotech companies act as a bridge between the academia and the industry. New knowledge and discoveries are born in the scientific community and inside clusters various small firms

encourage applying research knowledge to marketable products (Sadraei, Sadeghi & Sadraei, 2018). In 1982, the first genetically engineered product was FDF approved. This product is recombinant human insulin and it came to life by joined efforts of Genentech and Lilly. Genentech provided the product and Lilly provided the funds and experiences. Lilly guided Genentech on how to progress the product development, maneuver the product through the regulatory review process, and how to set up the production process. The cooperation between Genentech and Lilly was a key model for the biotech industry. Genentech has continued to make several profitable therapeutics. They manufactured and commercialized these products and became fully integrated pharmaceutical company. However, this is not what most small biotechnology companies today aim for. Instead, they develop drugs to the proof of concept phase and they manage to do this with lower cost than pharma firms do. After successfully reaching this phase, they usually look for a pharmaceutical firm to partner with. Pharma firm licenses the product and is in charge of the product's development, getting FDA's approval, marketing, and product production (Greenwood, 2014). Pharma companies are seeking for disruptive technologies and to improve R&D efficiency. They seek for the early discoveries and innovation in small biotech companies and universities. According to J. Leslie Glick, Ph.D., "Successful biotech companies will continue to be acquired by big pharma, but those companies will be replaced by a new batch of up-and-comers, and new companies will continually be formed. It will be a long time before the biotech sector will have reached its maturity." (Glick, 2012).

2.1 The industry today

Biotechnology is a young, knowledge-based industry that is primarily represented by new startups and small businesses. According to Audretsch (2001), most biotechnology firms are relatively small. Majority of them have fewer than 50 employees. This is also illustrated by Figure 1 (Statista, 2010). The biotechnology industry has many entrepreneurs, but commercial successes are rare (Audretsch, 2001). The reason behind the small size of the average biotech firm might be the diseconomies of scale deep-rooted in the "bureaucratic process which inhibits both innovative activity and the speed with which new inventions move through the corporate system towards the market" (Link & Rees, 1990, p. 25). Furthermore, biotech companies are considered highly risky. Phosphagenics CEO Ross Murdoch said that big pharma companies were no longer able to cope with high risk of inventing so small biotech firms took the job (Noonan, 2018). Developing a new drug is generally a long and challenging process. Research projects can take more than ten years and less than one percent of them advance into a successful product launch (Swiss Biotech Association, 2019).

Figure 1: Biotechnological company size between years 2005 and 2009



Source: Statista (2010).

Originally, there was a clear line between a pharmaceutical business and biotechnology business. Pharmaceutical companies were in business of small molecule drugs, which they manufactured and marketed. On the other hand, biotech companies produced large molecule therapeutics by using recombinant technology. This division is now disappearing. Now, pharma companies are cooperating with biotech companies who do the research that is often fostered in universities and the distinction between biotech and pharma is oriented more toward: "who is doing the research and who is doing the development in the drug R&D process" (Noonan, 2018). Moreover, some small biotechnology companies are developing small molecule drugs and understanding molecular biology of the disease is their core strength. Nevertheless, biotech industry needs big pharma money to bring products to market. Big pharma companies today, mainly via licensing, partnership or acquisition, manufacture and sell much of the most profitable biotechnology products. These products are becoming increasingly important part of big pharma pipelines. Pharma is a high-tech, non-cyclical industry. Entry materials are expensive and add on value is enormous. Investors are aware of high risk and high return. By 2023, size of biologics pharmaceutical market is expected to reach USD 402 billion from USD 313 billion in 2020 (Statista, 2020b). At the beginning of 2013, United States biopharma firms were applying biotechnology to develop 907 drugs and vaccines aiming to heal more than 100 diseases, according to the Pharmaceutical Research and Manufacturers of America (PhRMA). Reportedly, 338 medicines from the pipeline (more than a third) had a cancer target. Most products were developed by using older technologies, like vaccines or were products for which market is already established like monoclonal antibodies. Nevertheless, there were also representatives of new biotechnologies including 69 cell therapies and 46 gene therapies which show the growing importance of these products (PhRMA, 2013).

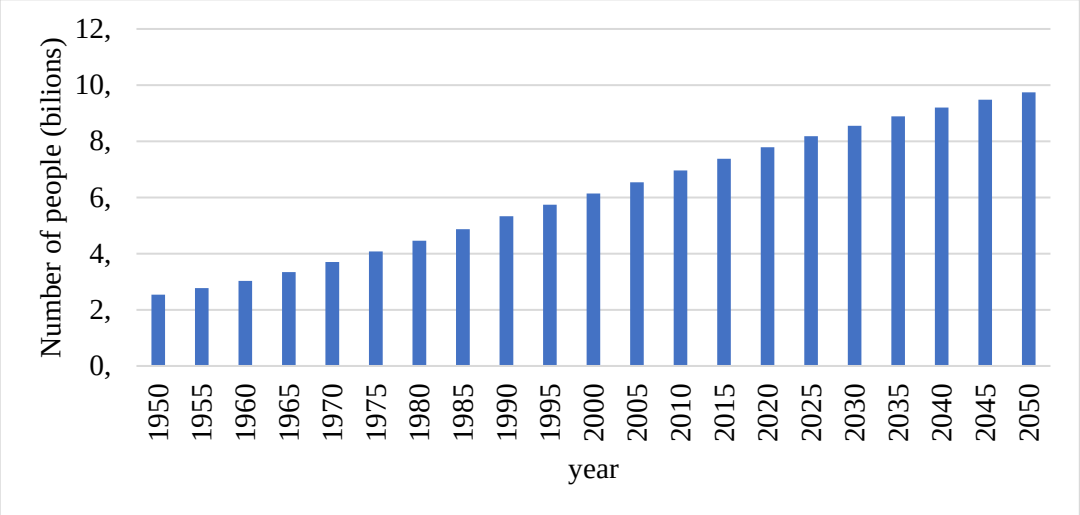
2.2 Trends in medical biotech industry and market

Global pharmaceutical revenue is growing and some of the factors behind the growth of pharmaceutical sales are:

– increasing global population,
– aging of population in developed markets,
– high prices of biological medicines,
– diagnostics market growth,
– developed countries are increasing assistance for health in the developing world (Kremer, 2002),
– growing obesity rates.

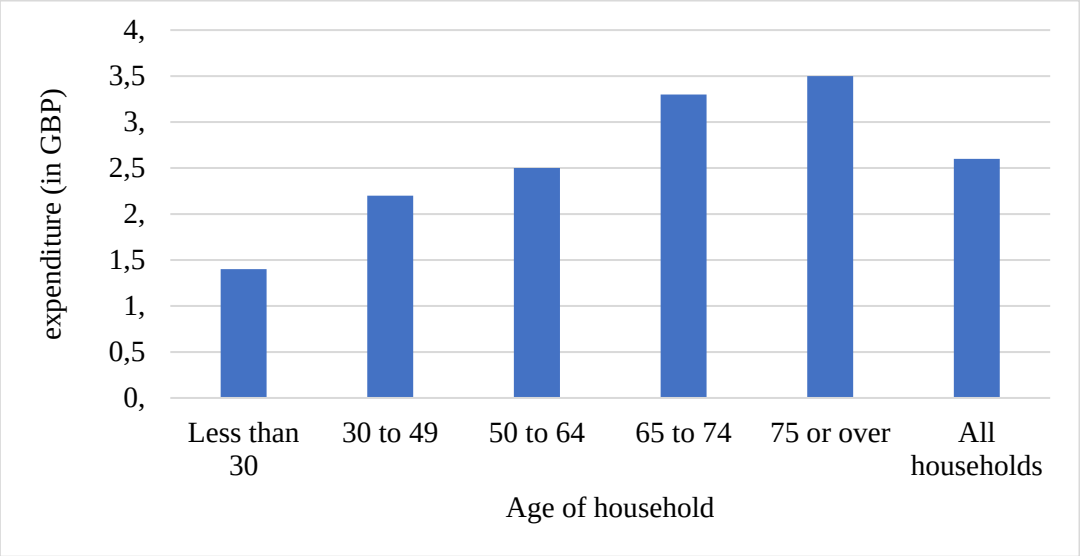
The global population will grow to almost 10 billion people in 2050 (see Figure 2). The aging of population in developed markets is problematic as expenditure on medicines greatly increases with age (Statista, 2020c). In Figure 3 the correlation between age and expenditure on medicines is shown. Furthermore, prices of biological medicines are very high. On average, daily dose of a biologic drug is 22 times more expensive than daily dose of a small molecule drug. In 2017, only two percent of American prescriptions consisted of biologics, but this small amount accounted for 37% of net drug spending (Makurvet, 2021). Additionally, diagnostic market grows even faster-five to eight percent per year (MarketsandMarkets Research Private 2020) than pharmaceutical market-three to four percent per year and new diagnostics detect new patients in the earlier stage of the disease. Consequently, doctors can prescribe different medications with greater effectiveness (Mordor Intelligence, 2020). Finally, obesity rates rose dramatically in the last 20 years, which leads to more obesity related diseases (see Figure 4).

Figure 2: Increasing global population between years 1950 and 2050



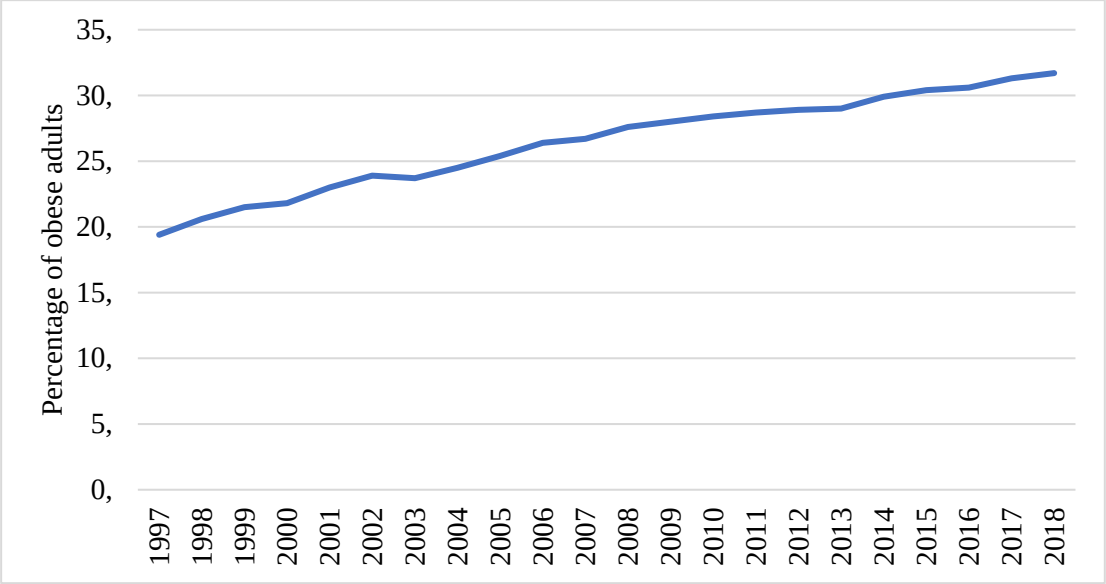
Source: Plecher (2020).

Figure 3: Weekly household expenditure on medicines in the United Kingdom (UK) 2019, by age



Source: Statista (2020c).

Figure 4: Obesity prevalence among U.S. adults aged 20 and over 1997-2018

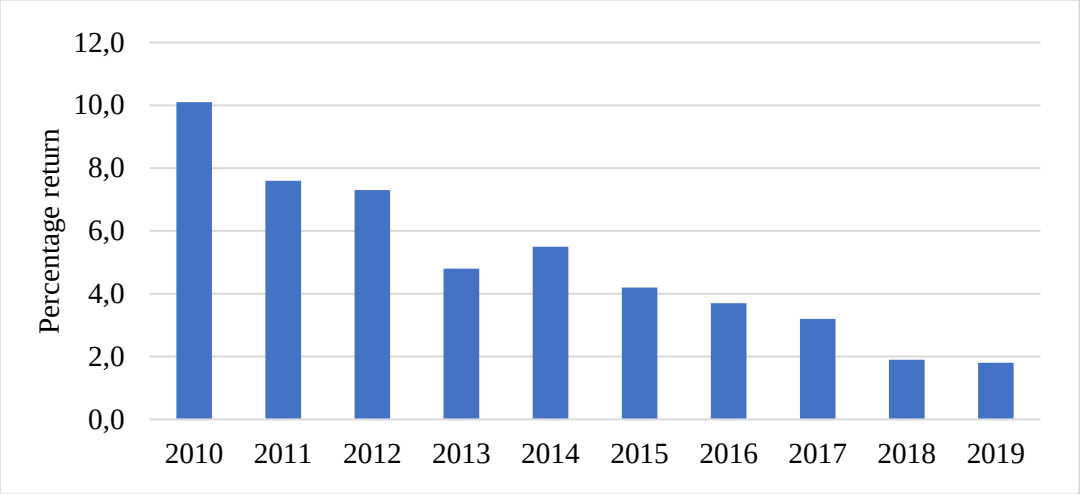


Source: Elflein (2020).

The pharmaceutical industry today is facing many patent expirations, regulatory challenges, and increasing pricing pressures from payers. A growing number of countries is calling for comparisons between drugs regarding their effectiveness so pricing and usage can be justified. The most important question is no longer "Will we be able to get this approved?" but rather "Can I get paid for this?". This leads to elimination of me-too drugs on the market and brings a desirable level of discipline to investors as well as pharma companies (Greenwood, 2014). According to Statista percentage return on investment on research and

development declined from 10.1 percent in 2010 to below two percent in 2018 (see Figure 5).

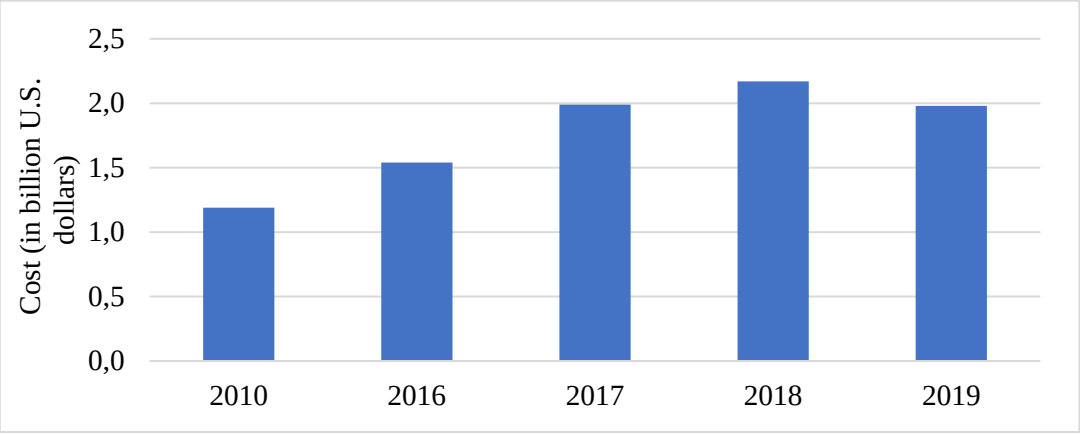
Figure 5: Projected return on biopharma R&D investments U.S. 2010-2019



Source: Statista (2021a).

Simultaneously, we can observe that big pharma firms are challenged by a large increase in average cost to bring a pharmaceutical asset to market. We can observe, that for pharma industry the cost to bring an asset to market was almost two billion U.S. dollars in 2019 (see Figure 6).

Figure 6: Cost to bring large cap biopharmaceutical assets to market 2010-2019



Source: Statista (2020a).

Large biotech and pharmaceutical firms are in dire need of creative and more predictable innovation. This has led the industry to depend on genetics when deciding to kill the project in early phases of the clinical or even preclinical trials and when designing studies in the most efficient way. Consequently, we are witnessing the shift to personalized medicine. It is ever more important to understand the genetic basis of illnesses before inventing a drug. The first drug, made especially for patients with a certain gene, was Herceptin. This marked the

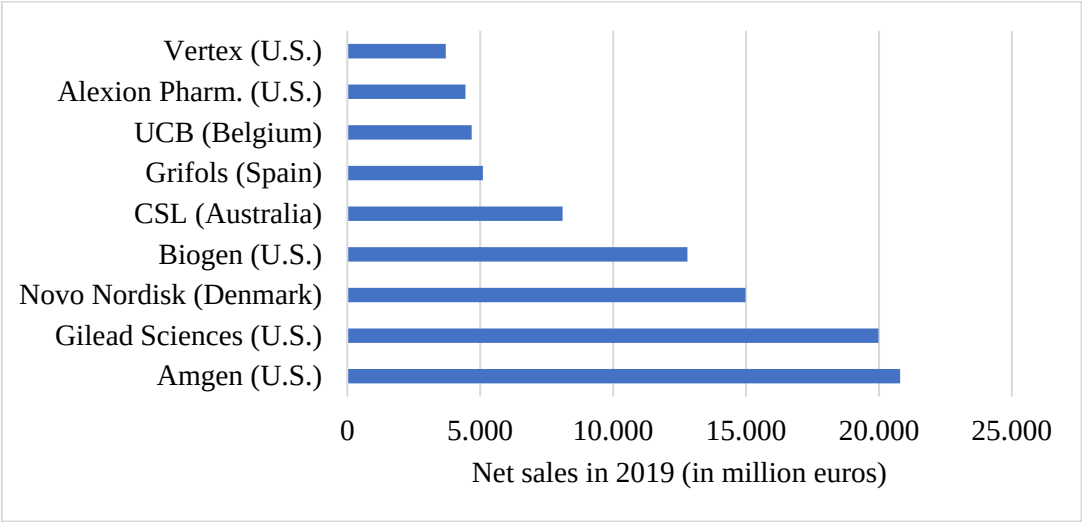
beginning of personalized medicine (Issa, 2007). In 2012, the United States pharmaceutical firm Amgen acquired deCODE for USD 415 million. deCODE's aim was to find the associations between genes and diseases. This was not the common practice for pharmaceutical business. The usually way would be to acquire a company with a promising product in phase two or phase of clinical trials. Nevertheless, this case exemplifies the importance big pharma is placing on disease genetics (Noonan, 2018).

2.3 Most important companies in biotechnology industry

Biotechnology industry nowadays consist of companies that make medical devices and diagnostics, as well as pollution controls, biofuels, biomaterials, and more. Yet, most biotech firms are in the business of pharmaceuticals. Globally the number of biotech companies grew from a few hundred in the 1980s to more than 4000 by the late 1990s. There were between three to four hundred publicly held American biotech companies in the 1990s. Including large companies like Amgen, Immunex, Genentech, Biogen Idec and Genzyme (Giovannetti & Morrison, 2000). In 2014, there were more than an estimated 10,000 businesses in the biotechnology industry worldwide (Greenwood, 2014).

According to Statista (2021b) the biggest Biotechnology company by net sales in 2019 was Amgen with 20,8 billion euros of revenue. Amgen, Inc. is a biotechnology firm that performs research and development, manufacturing and marketing of medicines.

Figure 7: Top global biotech companies' net sales in 2019



Source: Statista (2021b).

According to annual research conducted by BioSpace.com (BioSpace, 2020) expected top life science startups in North America are Cerevel Therapeutics, Anthos Therapeutics and Century Therapeutics. Looking first at location, we can see that almost all of 21 top startups are located in biotechnology clusters and it is worth mentioning that governments can contribute greatly toward development of biotechnology clusters. Second, the top three

companies all have partnership between investment firm and big pharmaceutical company. This supports the believe that big pharma is the one who can successfully bring the product to market (Pharmaceutical Technology, 2018; Bayer, 2019). The analysis of the top three companies on the list can be seen in Table 1.

Table 1: Top three Life Sciences Startups to Watch in 2020 and their attributes

Company	Location	Founders	Phartnership	Contribution	Focus
Cerevel Therapeutics	Boston, MA	Bain Capital and Pfizer	Bain Capital Private Equity and Bain Capital Life Sciences	Investment of $350 million with the ability to invest more if necessary.	Develop drugs for central nervous system (CNS) disorders.
			Pfizer	Contributed a portfolio of pre- commercial neuroscience assets, which included three clinical-stage compounds and several preclinical compounds. Pfizer will retain a 25 percent equity position in Cerevel.	
Anthos Therapeutics	Cambridge, MA	Blackstone Life Sciences and Novartis	Blackstone Life Sciences	Provided the $250 million.	Next generation of targeted therapies for high-risk cardiovascular patients.
			Novartis	Anthos licensed MAA868 antibody from Novartis.	
Century Therapeutics	Philadelphia, PA	Versant Ventures	Bayer	Financing commitments and an integral partner in Century's investor syndicate.	iPSC-derived adaptive and innate immune effector cell therapies.
			Versant	Healthcare investment firm.	
			Fujifilm Cellular Dynamics Inc.	Under the terms of the iPSC platform license agreement, FCDI will serve as the primary manufacturer of Century's cellular products.	

Source: BioSpace (2020), Pharmaceutical Technology (2018) and Bayer (2019).

3 THE ROLE OF ENTREPRENEURSHIP IN MEDICAL BIOTECHNOLOGY

It is generally accepted that a lively SME (small and medium-sized enterprises) sector drives the progress of a market economy and is an important part of a successful economy (Nafukho & Helen Muyia, 2010). According to Joseph A. Schumpeter (2000) the entrepreneur is the source of all economic change. Entrepreneurs are able to "invent" (discover innovative technical knowledge and how to practically apply it to the industry) and "innovate"

(introduce original technical methods, forms of industrial organization, sources of supply, and products). Entrepreneurs create new opportunities and make new technologies progress. When commercializing new technologies, entrepreneurs make decisions to produce on basis of: Courts and government agencies ruling judgments and defining if the technology is appropriate, financial markets placing value on technologies before products realize, researchers confirming product is viable, and companies understanding the technology and its commercial applications. When looking at the first biotech entrepreneurs, we observe they were not just seeking opportunities. Rather, they dynamically constructed and reconstructed rationalizations for the value of their companies. Inside their companies, they realized economic aspects of biotechnology, and consequently they were able to obtain millions of dollars of private and public capital (Link & Rees, 1990; Kaplan & Murray, 2010).

The phrase “creative destruction," describes the process that sees new, entrepreneurial innovations replacing existing leaders that are rendered obsolete over time. As noted by J. Leslie Glick, Ph.D. in the January 15, 2011, issue of GEN (Xavier, Kelley, Kew & Herrington, 2011): “When one considers the vibrant pattern of financings, internal growth, acquisitions, and yes, closings in the biotech industry, it clearly fits Schumpeter’s model of creative destruction.” In biotechnology, there are numerous product development opportunities. For example, many untreatable hereditary diseases could be effectively treated with biotech products. Similarly, personalized medicine offers a chance for better treatments for conditions that are at this time handled poorly (Glick, 2012). Yet, the term creative destruction does not adequately describe biotech industry. It is better describe as creative acquisition. There is no rule that a successful company should drive the existing leader into failure but instead the small company can be acquired by the leaders. Creative acquisition is a function of the intensifying growth potential of the biotechnology industry (Glick, 2012).

3.1 Factors of success of entrepreneurs

There are many studies describing environmental factors, which influence the success of small companies. Amongst them are: long-term capital availability, government efforts and incentives, infrastructure facilities, bureaucratic difficulties faced by entrepreneurs in the pursuit of starting a business, technology and information, personal and political hostility between political rivals, frequency of strikes and more (Chowdhury, Zahurul & Arif, 2013). GEM (Global Entrepreneurship Monitor) is used for evaluating the environment for enterprise by using many distinct entrepreneurship framework conditions (see Table 2). These conditions affect the ease or difficulty of establishing a new start-up.

Table 2: GEM's Entrepreneurship Framework Conditions

	Entrepreneurship Framework Condition	Question
1	**Access to entrepreneurial finance**	Are there sufficient funds available to new startups, from informal investment and bank loans to government grants and venture capital?
2	**Government policy: support and relevance**	Do government policies promote entrepreneurship and support those starting a new business venture?
	Government policy: taxes and bureaucracy	Are business taxes and fees affordable for the new enterprise? Are rules and regulations easy to manage, or an undue burden on the new business?
3	**Government entrepreneurship programmes**	Are quality support programs available to the new entrepreneur at local, regional and national levels?
4	**Entrepreneurship education at school**	Are schools introducing ideas of entrepreneurship, and instilling students with entrepreneurial values such as enquiry, opportunity recognition and creativity?
	Entrepreneurship education post-school	Do colleges, universities and business schools offer effective courses in entrepreneurial subjects, alongside practical training in how to start a business?
5	**Research and development transfers**	To what extent can research findings, including from universities and research centers, be translated into commercial ventures?
6	**Commercial and professional infrastructure**	Does access to affordable professional services such as lawyers and accountants support the new venture, within a framework of property rights?
7	**Ease of entry: market dynamics**	Are there free, open and growing markets where no large businesses control entry or prices?
	Ease of entry: market burdens and regulations	Do regulations facilitate, rather than restrict, entry?
8	**Physical infrastructure**	To what extent are physical infrastructures, such as roads, Internet access and speed, the cost and availability of physical spaces and such like, adequate and accessible to entrepreneurs?
9	**Social and cultural norms**	Does national culture stifle or encourage and celebrate entrepreneurship, including through the provision of role models and mentors, as well as social support for risk-taking?

Source: Bosma et al. (2020).

Results of GEM 2020 demonstrate that physical infrastructure is generally seen as supporting entrepreneurship, followed by market dynamics, cultural norms, and availability of professional services. The framework conditions that most countries require to improve are education on entrepreneurship, research and development transfers, and government policies regarding bureaucracy and taxation (Bosma et al., 2020).

Perhaps, the most important factor in development of biotech industry is the presence of scientific talent in a region. Scientific talent should be present, at either universities, public research laboratories, or private companies. The consequence of scientific talent existing in geographical proximity is that the biotechnology industry is also prevailing in clusters (Audretsch & Stephan, 1996).

An entrepreneur is able combine already existing resources in creative ways. An entrepreneur is someone who takes agency and initiatives. Some of the attitudes associated with entrepreneurs are: the motivation to achieve, being accountable, open-minded, able to tolerate ambiguity and uncertainty, creative thinking, problem solving, persistent, able to formulate a vison, the capacity to make an impact and so on (Johnson, 2001). According to Langer (2014) the typical biotechnology entrepreneur normally originates from one of four backgrounds:

- the physician, bioengineer or scientist with former career in an academic institution (university, research foundation, nonprofit research institute);
- the physician, bioengineer or scientist with former career in a life science industry for example biotech firm or pharma firm;
- the business men or women, with former career as executives of the pharma, life science, or venture capital company;
- a core group of people from a different life science company or institution within the industry.

In an interview (Kaučič, 2002), Slovene medical biotechnology entrepreneur, dr. Knežević shared his opinion of what makes for a great biotech entrepreneur. He said: “One must have great network and think about interests of all stakeholders. You must not peruse everything from the ground up but rather find other people working in the specific field and collaborate with them. That being said you still have to think outside the box. If you just follow the recipe you are already too late”.

3.2 Business models in medical biotechnology

The way an organization captures, generates, and delivers value is defined by different business models (Segers, 2018). Entrepreneur must develop the business model early on, as it is essential for value proposition of the company. I will describe various business models a biotech company can chose. Starting with describing the one business model that virtually all biotech firms operate under for some time at the beginning of their journey.

The virtual company business model. This is only a temporary business model and many times the only model a start-up can afford. The majority of activities are outsourced and the company owns little to no equipment and physical space. Typically, the company’s founder already worked in a laboratory beforehand and this lab is then used for company’s early research. Personnel is payed money wages accompanied by either stock options or stocks,

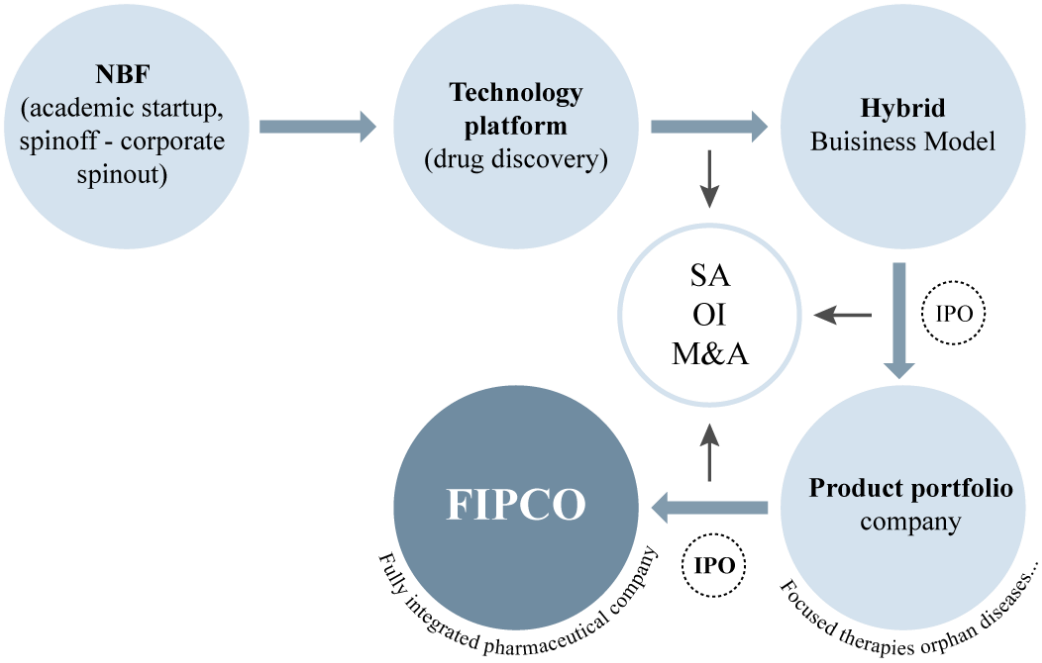
sometimes also restricted stock for professional services (Shimasaki, 2014b, p. 12).

Pharma companies in the era of blockbuster drugs chose the “vertically integrated” model. The second generation of biotechnology startups focused on early stage research and worked in partnership with big pharma companies to develop and market the products. The third generation of biotechnology startups innovated in selling access to technology platforms, rather than specific therapeutic applications (Segers, 2018; Thong, 2015).

Other business models for medical biotech company are:

1. Product-based model. This is the vertically integrated model including: Fully Integrated Pharmaceutical or Biotechnology Company (FIPCO or FIBCO) business model, Fully Integrated Pharmaceutical or Biotechnology Network (FIPNET or FIBNET) business model. This models require major capital investment and that makes the models unattractive and unattainable for young biotech companies (Segers, 2018).
2. Technology Platform-based. This business model delivers value by the early drug development phases (molecule development) and licensing the technologies to downstream firms (Segers, 2018).
3. Hybrid business model. This is the preferred business model, where the company initiates proprietary projects of its own (Thong, 2015). Typical evolution of platform companies leads them to evolve into hybrid companies. Technology platforms are combined with services and generation of pipeline of products. Ideally an attempt to develop downstream integration would be financed from existing platform-based revenue stream (Thong, 2015; Fisken & Rutherford, 2002). Picture below offers a clear representation of biotech company evolution (Segers, 2018).

Figure 8: Key stages of biotech companies



Source: Segers (2018).

3.3 Raising capital

The investors finance the biotechnology start-up so it can remain productive on its way to the market. The entrepreneur cannot be certain that funding will be available in all later stages. Expenses such as recruitment of the best researchers and plentiful funding to progress research trough very long timeliness are inducing needs for large investments. Consequently, drug development projects typically depend upon many sequential investment rounds. Therefore, a biotechnology firm must persuade investors to invest hundreds of millions of US dollars and sometimes more than one billion dollars in order to develop medical products (Swiss Biotech Association, 2019). A company must demonstrate progress and proof of concept, to proceed to the next phase of financing (Tscherning, Frank & Schönharting, 1999). To emphasize the importance of capital in this industry we can look at the development of Covid 19 vaccine. One of the reasons why the development of vaccines usually takes 10 years or more but it only took half a year for Covid is the financing. Firms didn't have to wait for another round of financing to enter into the next stage of clinical trials (Lurie, Saville, Hatchett & Halton, 2020).

Some of the ways biotechnology startups can raise capital are:

Public funding. Usually, the business idea originates in academic research, which is financed by government programs or local grants. In Scandinavia, it is a common practice to include provisions for "pay-back" funding or "forced patenting". Academic institutions and funding agencies, who initiated this practice, require that research scientist take appropriate steps to

ensure intellectual property rights for patentable matters coming from publicly funded research. Scientists are motivated to patent their work because they obtain extra USD 30,000 to USD 40,000 added financing and around 30 percent of any upcoming patent royalties in return for filing for a patent (Tscherning, Frank & Schönharting, 1999). In USA, the Small Business Administration provides government grant funding through Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. Federal agencies provide SBIR and STTR programs. To take part in the STTR or SBIR program, a for profit company must be no less than 51 percent individually owned, must not have more than 500 employees and it must be controlled in the United States (USA Angel Investment Network, 2009).

Incubators. Another increasingly important source of starting capital in Scandinavia comes from incubators. In incubators, a combination of public and private capital, offers funding for early basic research and support to get to the proof of concept stage, which is crucial when entrepreneur seeks further funding from venture capitalists. They also, enable an entrepreneur access to laboratory space and equipment at an affordable price (Tscherning, Frank & Schönharting, 1999).

Angel Capital. The wealthy who invest in high-risk, start-up businesses are angel investors. Usually, they also offer their time, which brings knowledge, networks and expertise. They tend to invest in sectors they know well. In biotech industry investors are attracted by high returns and positive impact on society. This form of investment is particularly relevant to businesses operating in diagnostics, medical technology and digital health. Angel capitalists usually invest in the pre-series of phase 1 or seed phase and the amount invested is normally less than two million euros. London's Angels is a program that links life science start-ups with angel investors in MedCity. Joana Neves dos Reis, who manages London's Angels told: "Life sciences can be more challenging than other sectors for angel investing. One of the main reasons being that a return on investment will typically take longer, 8 to 10 years compared to 5 to 7 years for other sectors such as artificial intelligence or automation." (Rodríguez Fernández, 2021).

Venture capital (VC). In its early years, the biotechnology industry progressed by obtaining financing mainly from venture capitalists. Venture capitalists typically finance biotech firms in late phase 2 and early phase 3 clinical trials. They take a percentage of firm's ownership but beside the money, they also provide expertise and guidance to the company. However, majority of venture capitalists operating in life science industries need to make a return on investment in five to maximum seven years. An IPO or selling the company is typically their point of exit and this can hurt the company in the long run (Rodríguez Fernández, 2021), (USA Angel Investment Network, 2009). Finding a VC investor in this industry can be important because VCs are able to support the next round of financing for growing biotech company, whereas angel investors do not typically have the funding capacity (SPIRIT Slovenija, 2019b; Shimasaki, 2014c).

Strategic investors. Strategic investors has a strategic motive to why he or she invested in a company. The main concern of a strategic investor is not a financial return. In biotechnology industry, a strategic investor is usually a pharmaceutical company that is interested in the technology of the small company because it either provides opportunities for synergies or sees the start-up as competition. It is possible that strategic investor would be more patient regarding the company's growth. (Martin, 2019).

Royalty financing. A company that has a product it needs to market can consider royalty financing. This allows the owner to maintain full control but when the discovery begins to yield revenue, investor gets royalty payments from revenue stream (Oliver Wyman, 2015).

Licensing and partnering agreements. There are quite a few models of licensing deals. In an original licensing arrangement an owner (biotech company) of intellectual property allows its technology to be used by another firm (usually pharma company). In exchange, the owner is payed and receives royalties from sales of product(s) developed from the intellectual property. Usually, biotech company gets an upfront payment and additional payments that are bound to milestones of product's development (Research and Markets, 2019). These agreements can result in hundreds of millions in payments but on the other hand, the drug can fail in early stage and there is no more payments made to biotech firm. Biotech firms have been inclined toward inflating the value of deals closer to future promise than actual upfront cash payment. To describe the exaggerated value of partnership deals the term "biobucks" was coined. More exactly, biobucks is the difference between the upfront cash payment and the value stated in the headlines after the press release (Abate, 2012).

Initial public offering (IPO). For biotech firm, IPO is not necessarily an exit point but rather a new source of money needed to finance expensive research and development and clinical trials. Therefore, it is normal that a firm, which is backed by venture capital, goes public quite some time before having a revenue stream. IPOs were not the best option for biotech companies in the early 2000's. However, since then, biotech companies' valuations considerably increased. In the 2000s, the median post-money valuation was USD 213 million. The number increased by 50 percent (to USD 323 million) in the 2010s. Nowadays this number for biotech companies is more than USD 600 million. Demand for biotech IPOs has been growing since 2000's (Booth, 2020).

In biotechnology industry, upfront cash payments for partnership deals are increasing, and partnerships are now entered in very early stages of the company, before proof of concept is shown. This is a very recent development. For instance, Merck & Co. agreed to a USD 20 million upfront payment, additional milestone payments and tiered royalties last year for a preclinical program for cancer drug from Harvard. (Timmerman, 2016). Another example is Bristol-Myers Squibb that bought Flexus Biosciences in immuno-oncology to get full rights to Flexus' lead pre-clinical small molecule. The deal could be worth up to USD 1.25 billion, with an USD 800 million upfront payment (Adams, 2015). In 2019, pharma companies spent USD 217 billion on M&A deals, while biotech IPOs raised an average of USD 88 million.

Venture capital investments in biopharma total USD 13.9 billion across 396 rounds. The term “mega rounds” has been coined for rounds that amassed USD 100 milion or more. Additionally, capital is being increasingly concentrated into shrinking number of start-ups (see Table 3). The focusing of capital reflects a shift in investment strategy, which allows start-ups to be properly funded and given the best chance of success (Evaluate, 2020).

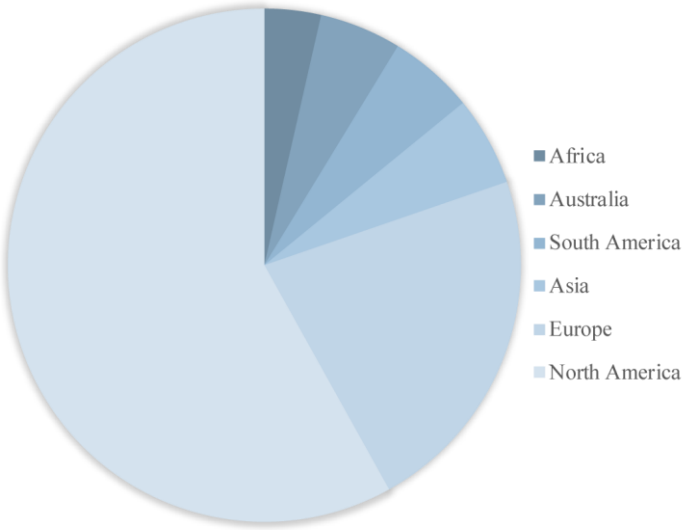
Table 3: Biopharma and venture capital financing between years 2015 and 2019

Year	Total investment ($b)	Financing count	Avg per financing ($m)	No. Of rounds ≥$50m	No. Of rounds ≥$100m
2019	13,9	396	36,7	110	32
2018	17,9	467	40,2	130	39
2017	13,2	518	37,8	76	19
2016	10,5	484	23	52	15
2015	11,5	533	22,4	59	15

Source: Evaluate (2020).

America is spending more than Europe on health-related research and development. This includes private and public funding (Janssen health policy center, 2015). In Figure 9, we can observe the destination of venture capital flows in relation to health care (value of investments, Q1 2009–Q3 2017). On the picture, the size of the surface represents the investment volume. When looking at how venture capital is geographically concentrated, companies from North America, get more than 50 percent of total funds, valued at USD 500 billion (Karpa & Grginović, 2020).

Figure 9: Destination of V.C. flows in relation to health care between years 2009 and 2017

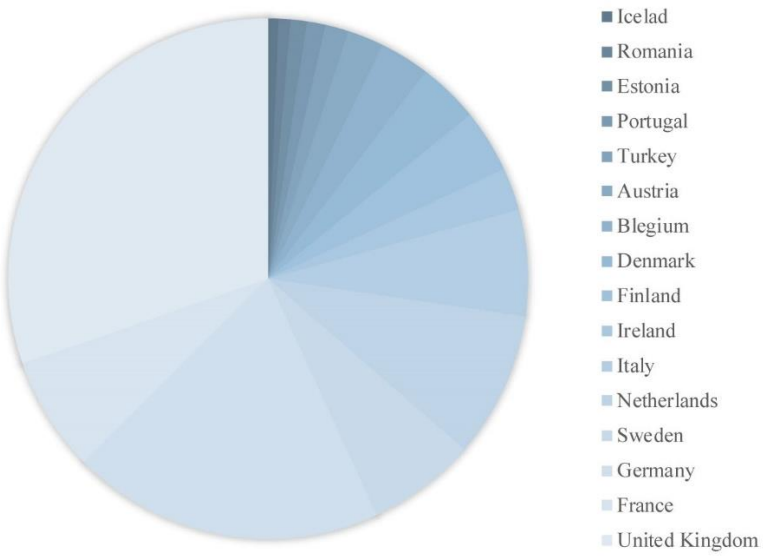


Source: Karpa, Waldemar & Antonio Grginović (2020).

Looking only at Europe, U.K. draws the most venture capital (USD 74.7 billion), next are

Germany and France (see Figure 4). On the other hand, there is little to no venture capital funding in Central and Eastern Europe (Karpa & Grginović, 2020).

Figure 10: Recipients of V.C. funds in Europe (in value, 2008–2017)



Source: Karpa, Waldemar & Antonio Grginović (2020).

3.4 Development of Biotechnology clusters

More often than not, the biotechnology industry develops within an international network including research institutions, universities, incubators, biotech startups and big pharma companies (Pisano, 2006). Clusters are important for entrepreneurship. More new firms are established and start-up employment is higher in industries that are situated in areas with strong clusters. Moreover, diversity is also important for development of cross-industry industrial activities as breakthrough innovations often spin from unusual encounters (Lämmer-Gamp, Gerd, Köhler, Kai & Kinscö, 2016).

Biotech industry relies on small companies and small companies rely on government research funding, VC or royalties and milestone payments from partnership agreements with large pharmaceutical companies. Another typical thing for biotech industry is that small companies are usually located in clusters and close to the life science research laboratories and universities (Cook, 2001). Regional system of innovation (RSI) is a network of organizations that collaborate and are geographically concentrated. The goal of organizations in RSIs is to advance a certain technology. RSIs include innovative companies, government laboratories, research universities and venture capital firms. VC pools and universities attract companies and a cluster is formed. RSIs in biotech industry were mostly formed in the United States. Namely on the West Coast (San Francisco, Los Angeles and San Diego) and on the East Coast (Boston, Washington, DC, Philadelphia and New York) (Niosi & Banik, 2005).

For example, the Life Science cluster Medicon Valley, located at the gateway to Denmark and Sweden shows the advantages of a strong cluster for entrepreneurship. The advantages are: high density of firms along different life science value chains, presence of private venture capital firms, national public seed investors and various incubator facilities, presence of big pharma firms that are collaborating with SMEs, universities that bring new talents, research entities, science parks and other entities to support commercialization of academic research (Lämmer-Gamp, Gerd, Köhler, Kai & Kinscö, 2016; Algieri, Aquino & Succurro, 2013).

The fact that biotechnology thrives inside clusters creates a likely challenge for countries that invest little in biotechnology research and biotechnology companies. The problem is brain drain, meaning that the country's most talented people move abroad and never come back. Additionally, the destination countries typically have many talented people of their own, which then even enhances the appeal of the destination country. Consequently the national research and development gap between these countries grows (Timmis, et al., 2017).

3.5 Regulations and supporting policies

At first, it was anticipated that biotechnology with biological drugs would enable drug makers to develop new products and commercialize them quicker and with less financial resources than small molecule products. However, they soon tackled similar regulatory timespans, lengthy processes and development expenditures as developers of small molecule drugs. While the regulatory requirements needed to register a biosimilar are not as strict as the requirements for innovative biopharmaceuticals, they are still harsher than the regulatory requirements needed to register a generic drug (Kesik-Brodacka, 2018). Amgen even had problems in producing and reproducing EPO in the United States as well as Germany in its own factories using its own experts. At firs there were many debates regarding the safety and ethics of the new technology, how would laws apply to them and what regulations are needed. Numerous important policy advances in the early years of the biotech industry lead the way for the following progress and growth of biotech industry (Bartfai & Lees, 2013b; Greenwood, 2014).

One of the most vibrant systems for life-sciences innovation is in the United States. For instance, the majority (more than 50 percent) of intellectual property associated to new pharmaceutical drugs between 1997 and 2012 originated in the United States. Additionally, in the 2000s, biopharmaceutical firms in in the United States invented more new small molecule drugs than companies from the next five countries combined. After the United States, Switzerland has the biggest number of new small molecule drugs created between years 2001 and 2010. This shows that the most innovative life science sectors are found in countries that have effective policies, which encourage innovation in these sectors. (Wu & Ezell, 2016). In United States, a vibrant and prosperous biotech industry developed because

of many innovative laws and foundational public policies.

National Institutes of Health (NIH) is the main agency in the United States government that is in charge of public health and biomedical research. Together with different federal labs they provide private sector entities with non-dilutive financing through the SBIR (Small Business Innovation Research) and STTR (Small Business Technology Transfer Research) programs (Beckett, 2014).

Bayh-Dole Act. This law, passed in 1980 allows universities and nonprofit institutions exclusive rights to the intellectual property resulting from research which was financed with federal resources. From the time when Bayh-Dole Act was passed, many new firms were established aiming to practically apply university research to the industry. The number of these firms is exceeding 6000. Research financed by NIH and technology transfer under Bayh-Dole stimulated the advancement of research universities, which are now at the heart and center of biotech clusters.

Food and Drug Administration (FDA). Prior to entering the marketplace, the FDA has to approve new drugs and medical devices for safety and efficacy.

Hatch-Waxman Act. Since generics are less expensive to develop this law helps to keep investors interested in more expensive development of biopharmaceutical medicines by still keeping generics low-cost (Boehm, Yao, Han & Zheng, 2013).

Orphan Drug Act. From the time when this law was passed, in 1983, it motivates investors by offering seven years of market exclusivity and tax credits of up to 50 percent to cover R&D costs for an orphan drug development (Swann, 2019).

Patent protection. Drug development is a very long process therefore, strong patents attract investors and regroup the costs of research and development (KISSPatent Europe, 2018). In 1980, the commercial viability of biotechnology expanded considerably because genetically modified organisms became patentable in the case of Diamond v. Chakrabarty. In this famous case, the United States Patent and Trademark Office first insisted that one cannot patent a living organism. Nevertheless, at the end, the court stated that the fact that something is living is irrelevant to the question of patentability (Wikipedia, 2020).

Technology Transfer Offices (TTOs). TTOs aim to practically apply university's and public institutions' research, to the industry (Ustundag, Uğurlu & Kilinc, 2011). Investment in research and promoting innovation in universities results to higher economic growth of particular regions. Additionally, a robust connection between universities and production companies promotes the process of technology transfer and increase chances that the result of research will be commercialized (Algieri, Aquino & Succurro 2013).

The 21st Century Cures Act. This new law signed in 2016, has been passed to progress research in regenerative medicine and innovation in the area of medicine. In the following

years this act is expected to progress the development and regulatory approval of various medical products (MarketsandMarkets Research Private Ltd., 2020).

Regulation is an important factor contributing to development of biotechnology industry. When looking for investors each completed stage of regulatory process is value-enhancing event for the company. Firms must be certain that their drug development is not delayed by unreliable applications of regulations (Audretsch, 2001). In the United States, the FDA regulates drugs. Likewise, other nations have their own regulatory bodies. A pharmaceutical product is market ready (approved for marketing) after it underwent numerous tests and safety and efficacy were demonstrated. Including preclinical tests that can take three to six years. In this stage, a drug is tested in the lab and in animals before used on human subjects. Investigational New Drug application must be submitted to the FDA for a drug to enter human clinical trials. After a compound enters human clinical trials it undergoes ever more costly human clinical trials, requiring more and more patients to participate in those studies. The goal is to ensure the safety, dosing, and efficacy of a specific compound for treatment of its target condition. Human clinical trials have three phases. A normal duration for the first phase of human clinical trials is around six months. It requires up to 100 participants. While, the phase 3 human clinical trials can take up to four years (Shimasaki, 2014a).

Cellular & Gene Therapies (CGT) are regulated by FDA under general drug, biologic and medical device laws and regulations in addition to particular laws and regulations for human cells, tissues and cellular and tissue-based products (HCT/Ps). Moreover, the FDA normally creates documents that guide CGT processes (Mendicino, Fan, Griffin & Nichols, 2019).

Recently, diagnostics have been facing harder and harder regulation. Serious diagnostic tests from larger companies obtain FDA approval for clinical laboratory improvement amendments (CLIAs). These are completed after rigorous clinical trials. When a CLIA test is finally approved, it represents a huge competitive advantage that permits running trials and asking higher prices (Bartfai & Lees 2013b).

4 OVERVIEW OF MEDICAL BIOTECHNOLOGY INDUSTRY IN SLOVENIA

According to dr. Branka Javornik we have a lot of skilled biotechnological knowledge workers in Slovenia. Our industry knowledge can be compared to best countries worldwide but Slovenia lacks biotech entrepreneurs (Bratanič, 2015). Slovenia has two large pharmaceutical companies that produce biopharmaceuticals - Lek and Krka. Another larger Slovenian company in medical biotechnology sector is Bia Separations, located in Ajdovščina that was acquired for EUR 360 million by Sartorius in October 2020. There are also some smaller but fast-growing companies. Among them are Acies Bio, GenePlanet and Educell (Bratanič 2015). When it comes to genetically modified organisms (GMOs), EU has taken a more precautionary approach. This could lead to EU's biotech industry lag in

comparison to China and United States (Dovjak, 2019).

4.1 The supportive environment for entrepreneurship in medical biotechnology

4.1.1 Environment and legislation

According to GEM (Bosma et al., 2020) in comparison to EU, Slovenia is less productive. Concerning skillset for rapid technological change, the country's education system needs improvement. Overall, people in Slovenia are slightly less likely to take part in starting their own or co-owned company in comparison to people from other countries in EU (OECD, 2020). Furthermore, the country's entrepreneurs are faced with excessive bureaucracy and unpredictable legislation. Transferring research from universities to private sector is weak in Slovenia. Burdensome permits and licenses process alongside heavy taxes and bureaucracy are contributing to country's lag in entrepreneurial activity. What's more, experts say that entrepreneurial values are not encouraged in Slovenia. Supposedly, our culture discourages taking risks, creativeness, innovation or individual responsibility (Rebernik et al., 2020).

In EU, industry environment varies among its member countries. According to Dr. Hrvoje Petković, industry collaboration with universities in Slovenia is less flexible then in Germany and UK. Researchers in universities are not provided with assistance when it comes to administrative work, contract preparation and handling intellectual property rights. Researcher thus finds it hard to devote his time to his core activities. Slovenian legislation is unresolved when it comes to spin-offs. Furthermore, universities have limits when collaborating with industry. Therefore, Dr. Petković decided to establish an independent company (AciesBio) rather than a spin-off. In UK, the university can own equity of a private company. This enables a simple way for researcher to establish a spin-off company building of off research work done at the University. Regarding patents Slovenian university has a dedicated service for patent applications, but it is rather new and therefore has limited capabilities (Dovjak, 2019). On the other hand, the director of AciesBio dr. Enej Kuščer believes Slovenia is a good place for a development of a biotechnological company. Contributing positively to Slovenian biotech environment are the large, pharma companies Krka and Lek, good universities and institutes. Moreover, there are many research niches where entrepreneur can find his or hers opportunity. This would be harder in countries such as UK as there would be more competition (Kontler Salamon, 2015). Additionally, The NIB (National Institute of Biology) has emphasized the importance of supporting environment for Slovenian biotech startups. They have initiated an investment project, worth 20 million euros: Biotechnological Hub of the NIB (BTH-NIB) for the construction of high-quality research infrastructure. The goal of the BTH-NIB is to assure suitable infrastructure for carrying out research and development projects in the areas where NIB operates.

4.1.2 Supportive policies

According to SPIRIT Slovenija (2019a), the initiatives to support entrepreneurs in Slovenia are:

- SPIRIT supports entrepreneurship in most broad sense. It is an entrepreneur-friendly institution for both potential and existing investors, which provides adequate support to companies in their start-up, growth and development phases. The activities for potential entrepreneurs and companies are carried out indirectly through two support networks. The SPOT offices (state support services for business entities) are intended for all potential entrepreneurs and companies. This system offers entrepreneurs consulting, educational courses and services. Whereas, the SIO services (Innovative Environment Entities) are primarily intended for new innovative companies (OECD, 2020);
- Slovene enterprise fund (SEF). The main function of SEF is to offer financial support but from 2019 on it also offers mentorship, paid courses abroad for high tech companies and networking (Slovenski Podjetniški Sklad, n.d.);
- Entrepreneurial incubators, universities incubators and business accelerators. The two Slovenia-based startup programs (ABC Accelerator and EIT Digital Venture Program) support and boost start-ups with several assistances such as financing, providing mentors and offices and of course networking (Incubator List, n.d.);
- Technologic parks and Co-working spaces. Technologic parks link technology with those who provide knowledge in mutual network, enabling collaboration on projects and providing support. TP in Ljubljana is a link between SMEs, research and big companies by promoting direct transfer of knowledge in the areas of green technologies, smart cities and digital health (Start-up AA, n.d.);
- Start: up Slovenia initiative. This is an independent, open platform of the Slovene startup ecosystem that supports innovative entrepreneurship;
- The Chamber of Commerce and Industry of Slovenia (CCIS) is responsible for critical services for Slovenia-based companies;
- Erasmus program for young entrepreneurs. This is an exchange program. The goal is to enable the would-be entrepreneurs to gain knowledge from people in other nations with entrepreneurial experiences (European Business Exchange Programme – Erasmus for Young Entrepreneurs, n.d.);
- The Internationalization, Entrepreneurship and Technology Directorate under the Ministry of Economic Development and Technology (MEDT): aims to increase companies' growth stimulate access to finance, and create an effective business support environment. Implementation is carried out by organizations like the Public Agency for Entrepreneurship, Internationalization, Foreign Investments and Technology, the Public Scholarship, Development, Disability and Maintenance Fund, the Slovene Enterprise Fund and SID Bank (SPIRIT Slovenja, 2019b).

4.1.3 Financing opportunities

According to GEM (Bosma et al., 2020), the government programs for entrepreneurship in Slovenia are improving. Nevertheless, one of biggest drawbacks is non-stimulative taxation for start-ups. When it comes to financing, there are many possibilities for entrepreneurs to get government subsidiaries. There are cheap loans available for small companies and start-ups. The Slovene enterprise fund and SID bank provide those loans. However, there is a huge shortage of venture capital and angel investors in Slovenia, leading to seed capital being hard to obtain. It is worth mentioning that venture capital is increasing in Slovenia according to GEM 2019 report (Rebernik et al., 2020). The co-founder of Educell, dr. Knežević said in an interview (Kaučič, 2002) that for them the obstacle in Slovenia was the unwillingness of Slovenian banks to finance the growing company, which was not generating any profit yet. The co-founder also believes that biotech sector offers high profits if you are willing to wait for at least ten years. He believes that, he will get return on investment from his company only when the company is sold or goes through IPO. He plans to use the money to start a new company. Nevertheless, he hopes to again collaborate with venture capital firm as VC does not only offer money but also brings knowledge and network to the table. Furthermore, he believes, his company would have progresed faster if the management would have more appetite for risk and they would peruse more aggressive growth strategies earlier on. Now, competition caught up and market penetration will be more difficult.

Financing for Slovenian entrepreneurs is provided by:

- Business Angels of Slovenia. Business Angels of Slovenia were formed in 2007. This is the largest and first group of angel investors in the country (Business Angels of Slovenia, 2021);
- Slovene enterprise fund (SEF) provides money to innovative start-up companies operating on global markets that are likely to achieve high growth or/and generate high added value products/processes/services;
- SID Bank (SID – Slovenska izvozna in razvojna banka, d.d., Ljubljana) this is a promotional development and export bank. The Republic of Slovenia is the sole owner of SID;
- The Public Agency for Entrepreneurship, Internationalization, Foreign Investments and Technology (SPIRIT). SPIRIT is publishing tenders; documents formally called ‘Invitation to Tender’ or ‘ITT’ (SPIRIT Slovenia, 2019a);
- EUREKA. Offers funding for R&D projects (Eureka, n.d.).

In the past venture capital in Slovenia was close to non-existing. In 2008, we were among the countries with the smallest amount of VC investment. In 2008, VC investment were equal to 0.054 percent of Europe’s GDP. The country with the largest VC investment in relation to GDP (0.15 percent of GDP) was Sweden. The runner-up is the UK (0.090 percent of GDP), and the country with the third largest VC investment in relation to GDP was Ireland (0.084 percent of GDP). On the other hand, Serbia (0.004 percent of GDP), Croatia (0.008

percent of GDP), and Slovenia (0.010 percent of GDP) attracted the lowest volumes of VC in relation to GDP (Bosma & Levie, 2010). In 2017, in Slovenia, VC investments as a percentage of GDP was 0,007 percent (OECD Statistics, n.d.). The reason for VC capital not being available in Slovenia is the high taxation of venture capital firms (Kupec, 2016). High taxation repulses international investors and therefore it is nearly impossible to get financing in capital intensive industry such as medical biotechnology. In the years following 2012, on Europe level, the amount of VC investment increased annually. In 2019, the total amount of VC funds collected was 14.8 billion euros (Statista, n.d.).

According to OECD reports, the growth of biotech companies in last decade was significant all over Europe and globally. In Slovenia, there were 27 active biotech companies in 2017. Mostly, they sell and market their products and services to either larger domestic and foreign biopharma or medical technologies companies or conduct research financed by governmental grants, EU supported grants and/or publicly funded institutions. Furthermore, the companies offer a great diversity and variety of biotech products/services (TikhePharma d.o.o., 2020).

AciesBio is a biotech contract research organization providing research and development services to biotechnology, pharma, chemical, and food industries. The company was established in 2006, as independent company, financed by private investor, a business angel who was willing to invest for a longer period of time (Dovjak 2019). Five scientists from University of Ljubljana Biotechnical Faculty founded the company. After initial seed capital from the business angel, the company was able to gel bank loans. Today, they provide assistance from idea generation through research until product is developed. They offer DSP (downstream processing) development, strain development, assessment in transfer to industrial manufacturing facility, and fermentation process development. AciesBio is successfully collaborating with biotechnical faculty on its research projects (Kontler Salamon, 2015). Furthermore, this company attributes its business success to long-term partnerships with Global F500 pharma, chemical and AgBio companies. In 2019, one of the projects was development of a new antibiotic. The product was in preclinical phase and one of the co-founders Hrvoje Petković is reported to say: “We have had conversations with some big companies regarding cooperation, not with Slovenian companies of course. In Slovenia, there is no appropriate institutions. The development of this kind of active substance brings enormous costs. Lek, for example, is strong enough financially, but is highly involved in development of generic drugs” (Dovjak, 2019).

AciesBio has a goal to become a long-term research partner this is why they believe in risk sharing with their client and thus going beyond the pay-for-service model. They divide R&D project into a number of stages and work bundles, and establish a clear timeline with milestones. They charge two different fees. A fixed fee, covering basic research and development expenses is always charged. Success fee is charged when (and if) milestone targets are reached. This is how AciesBio shares risk and motivation with its clients. In addition to maintaining a strong commitment to R&D partnerships in different areas of

microbial biotechnology, Acies is accelerating development in specific end-markets through its own initial investments in disruptive microbial products. In line with the EU Green New Deal incentive, Acies is building a pipeline of proprietary products: New biologicals for sustainable agriculture, Third-generation technologies for industrial chemicals and High-value natural food ingredients. Another business model practiced by this company are joined ventures. This includes teamwork with research partners inside universities as well as from other companies. In joint ventures, AciesBio contributes knowledge, experiences and collaborates in following R&D. If applicable, they also contribute IP rights and help with designing of production facilities. The partner is then responsible for product manufacturing, supply, and marketing (AciesBio, n.d.).

GenePlanet provides various a large variety of DNA test. They are grouped into categories:

- lifestyle DNA tests (sequencing and interpretation of genes connected to metabolism, sport performance,...);
- clinical DNA tests (NIPT, Cancer screen);
- blood Tests.

Their most popular product is NIPT- a non-invasive prenatal test. From week ten of pregnancy, it screens for the most common trisomies present at birth and some of other genetic irregularities. The company was founded in 2008 and it was amongst the finalist of the Slovenian start-up competition (Slovenski Start:up leta) (Gene Planet, n.d.). In 2019, it was named one of the fastest growing companies in Europe. It grew from eight employees in 2014 to 140 employees in 2020. In 2018, the company got a large investment from investment fund- JF investments. The money will be used for development of new products namely an intelligent digital platform called Health Intelligence, internationalization of products and entrance to African and Asian market. The new platform will be the customer's personal trainer and nutritionists. The company already has a similar product NutriFit that is available in many languages and countries (Slovenska tiskovna agencija, 2018).

BioSistemika builds software for laboratory instrument manufacturers, laboratories and software providers. They offer products in more than 100 countries. They are rapidly growing 20%-30% per year and are 95% export oriented (Pintar, 2018).

Their main three products are:

- custom software development (software and software integrations for laboratory instruments, standalone laboratory and medical software applications, solutions for data management and data analysis in laboratories);
- digitalization services (setting up a digital transformation strategy);
- laboratory software products.

This is a spin-off company established in 2010. Its ruts lay in national institute for biology. In 2015, they presented their product-sciNote on Kickstarter and gained necessary support

to grow. They then partnered with Gilson Inc. Together they established a company and launched the Sicknote in 2016.

BIA Separations produces leading products for purifying and analyzing large molecules, for example viruses, mRNA, and plasmids. Their products are an essential part in the making of cell, gene and other similar therapies. The company's core activity is making products for production of biological medicines, vaccines and viral vectors (BIA Separations, 2015).

Main products:

- PATfix. software which offers toolbox for the automated analysis of chromatographic data sets;
- monolithic columns (CIM). Monolith chromatography products purify biomolecules in the nanometer range (viruses, virus-like particles (VLP), exosomes, plasmid DNA (pDNA), nanoparticles, phages, antibodies, large proteins, plasma fractions, etc.).

Sartorius, a global pharmaceutical and laboratory equipment supplier acquired BIA Separations for 360 million euros (BIA Separations, 2020).

Labena d.o.o. is providing solutions for process and laboratory analytics. In South Eastern Europe, the firm is considered an important player in its area of expertise. Labena was established in 1992. Since its earliest days, Labena's target clients were pharma, medical and food industry and even academia. The company has representative offices in Croatia, Bosnia, Macedonia, and Serbia. In 2004, Labena invested into a service department. The CEO has pivoted the company's focus from selling equipment to a service company who does research project for large pharmaceutical and biotechnology companies. The Slovenian Chamber of Commerce titled Labena Slovenia "the most promising small enterprise of the year 2004". In 2008 the company introduced a research and development department in collaboration with Faculty of Chemistry (BIA Separations, n.d.). According to the CEO Borut Čeh the long-term goal for Labena is to become a technological intersection for research of pharma and biotech in Slovenia and broader. Furthermore, he is also considering selling the company to a strategic global partner who would provide funding and other benefits and help the company grow further (Združenje Manager, 2019).

In 2015 the company Labena entered a long-term partnership with BIA Separations. According to Ales Strancar "The gene therapy market started to grow exponentially within the last year and the demand for our services greatly increased, so we have decided to put all our efforts here". The partnership will enable distribution of BIA Separations products in the area of South Eastern Europe. Moreover, the contract research organization (CRO) laboratory that provides services for pharma businesses, which manufacture generics and small molecule drugs, will remain operating within Labena group of companies (BIA Separations, 2015).

Educell is a medical biotechnology firm established in 1997. According to its website, the

company earns more than 95 % of its market's income. They are operating and pioneering a niche market in the field of tissue engineering. Educell, through its robust clinical networks, has invented an array of medical devices and cell products that demonstrated effectiveness in clinical use. They offer: Medical services-support to clinicians for (performing) autologous cell therapies, research and development laboratory services, Advanced Therapy Medicinal Products (ATMP) and supply human allografts. They have partnerships with several public (University Medical Centre Ljubljana) and private clinics (Fabjan, Artros,...), (Educell, n.d.).

A group of independent researchers working for blood transfusion center of Slovenia, started a company because, they were unable to obtain funds for research from ministry of science and educations. They then turned to venture capital found-Horizonte and together they started a company. Horizonte even became the major owner, which was unusual for venture capital fund to do. Five years later, they built a production facility in Austria. They kept research and development facilities, marketing and finances in Slovenia. The reason why they moved production abroad was easier access to foreign markets and broad availability of subsidies and loans (Kaučič, 2002).

4.2 An exploratory research on the medical biotechnology industry in Slovenia

In this part of the master thesis, I present the scope of empirical research and the methodology behind the study. Furthermore, results and the main findings of empirical research, based on in-depth interviews with Slovenian biotech sector entrepreneurs and representatives of Slovene biotech sector are presented.

4.2.1 Research design

The main purpose of this exploratory study is to discover potential methods and processes that make it possible for companies in medical biotechnology industry to succeed. The author's main objectives are:

- to identify key characteristics of Slovenian Biotechnology sector, compare it to other EU countries and identify key external factors that influenced the development of medical biotechnology;
- to identify main activities and key players of Slovenian medical biotech sector;
- to comprehend the institutional and legal environment in Slovenia, from the perspective of entrepreneurship in general and also the medical biotechnology sector;
- to identify a typical way of starting a medical biotech company in Slovenia;
- to identify key internal and external elements for success and the most important internal and external stakeholders for the medical biotech start-up;
- to identify markets where most Slovenian medical biotechnology companies operate and reasons behind it;

– to comprehend the importance of innovation and human capital from the perspective of development and growth of the medical biotech company.

The two main research questions are:

Q1: Is Slovenian medical biotech industry underdeveloped in comparison to its potential due to suboptimal environment?

Q2: Would Slovene medical biotechnology industry blossom, If methods and process, which would stimulate entrepreneurship in the industry, existed?

Exploratory research approach is used to help identify the present state of Slovene medical biotechnology ecosystem and the development path of those companies. This is achieved through in-depth interviews with companies working in this arena. The exploratory research is based on the review of literature in previous chapters. I present the industry, the current market and industry trends in medical biotechnology and the role of entrepreneurship in medical biotechnology. Furthermore, key factors contributing to the companies' success, with an emphasis on raising capital, partnerships and supporting policies are identified. I collected the data used in this research through in-depth semi-structured interviews, which were held in Slovene. To follow the essence of this research, questions were prepared in advance. I asked sub-questions when there was an opportunity for deeper understanding of the main topic or where clarification was needed. The questioner structure is such that in the first part, the questions about the industry in general were asked. The second part of the interview is focused on a typical way of building and running a company in this sector. Interviewees were asked to answer from their own experiences or from their knowledge of biotechnology sector in general. In the first part, the interviewees were asked about the state of Slovenian medical biotech sector and comparison to EU and other world countries. Next, they were asked about the main activities, companies and the institutional and legal environment in Slovenia. In the second part, I asked about a typical way of starting a medical biotech company in Slovenia. Then the interviewees were asked to name key internal and external elements for success of medical biotech company and the most important internal and external stakeholders for the medical biotech start-up. Additionally, they were asked about the importance of innovation and human capital from the perspective of development and growth of the medical biotech company. Finally, they were asked to identify markets where most Slovenian medical biotechnology companies operate. The answers to this questions enabled me to analyze and understand Slovene medical biotechnology sector and identify factors that make it possible for Slovenian companies in medical biotechnology industry to succeed.

I carried out the interviews between 5th of March and 15th of April 2021 via online communication tool - Zoom, and in person. The average duration of an interview was 45 minutes. I conducted four in-depth interviews with Slovenian biotech sector entrepreneurs and representatives of Slovene biotech sector. The interview transcripts are archived and

available upon request from the author. A number from one to four was assigned to each interviewee (e.g. interviewee 1) in order to use it when specifying interviewee's responses under the results and findings section. The interviewee's company roll and age group is presented in the Table 4.

Table 4: The interviewees in exploratory research

	Company Roll	**Age Group (in years)**
Interviewee 1	Chief Executive Officer and Co-founder	60-70
Interviewee 2	Chief Operating Officer	40-50
Interviewee 3	Sales Director	40-50
Interviewee 4	Head of Business Development	50-60

There is only a small numbers of medical biotech companies in Slovenia. Therefore, only a small number of interviews were conducted and analyzed. Nevertheless, the study provides a good first look into investigated field and represents a good foundation for future research. Secondly, analyzing the interview data from open questions is more challenging than if closed questions are asked because varied responses from participants are harder to be compared.

4.2.2 Results

In order to understand the ways and the challenges of building a company in the medical biotechnology industry worldwide and in Slovenia, we first need to understand characteristics of biotechnology sector globally and in Slovenia. Biotechnology has been historically present in Slovenia; we have two pharma giants Lek and Krka. Interviewees agree that Slovenia has a strong tradition in biotechnology. Consequently, there is an abundance of biotechnology workers. On the other hand, there is not many medical biotechnology SMEs in Slovenia.

> *"Slovenia has a long tradition in pharma and pharmaceutical biotechnology industry." (Interviewee 1)*
>
> *"In Slovenia there is a lot of biotech knowledge, also as a consequence of history, we have Lek and Krka. […] We have so many skilled workers here; I think it is a tradition that Slovenia is strong in the area of biotechnology." (Interviewee 4)*
>
> Furthermore, SMEs in Slovenia have very narrow focus, are highly innovative, and interdisciplinary.
>
> *"[…] the reason why Slovenian medical biotechnology industry is growing is the new possibilities arising from merging biotechnology with IT and new*

microbiologic tests. Here, capital requirements are smaller." (Interviewee 1)

"Slovenian medical biotechnology companies are small and niche. Biotechnology became very interdisciplinary therefore; it is hard to say which company should be considered biotechnological" (Interviewee 2)

"In this industry, you have to have something new, something niche." (Interviewee 3)

In comparison to EU countries, our medical biotechnology industry is not on extreme ends when it comes to stage of development:

"In general we could say medical biotechnology industry is better developed in Slovenia than in South-East Europe and less developed than in North-West Europe. This is somehow logical and connected to capital availability." (Interviewee 1)

In comparison to Slovenia, other EU countries and especially the US have better access to private capital. As shown in previous chapters, spending on health-related R&D in Europe is lagging behind the financing levels of the United States (Janssen health policy center, 2015). When observing the destination of V.C. flows in relation to health care (value of investments, Q1 2009–Q3 2017), companies from North America, get more than 50 percent of total funds, valued at USD 500 billion (Karpa & Grginović, 2020). This can motivate biotechnology entrepreneurs to go abroad. The interviewees agree that access to capital is a highly problematic topic in Slovenia. They all believe that it is easier to raise capital if you are a US based company.

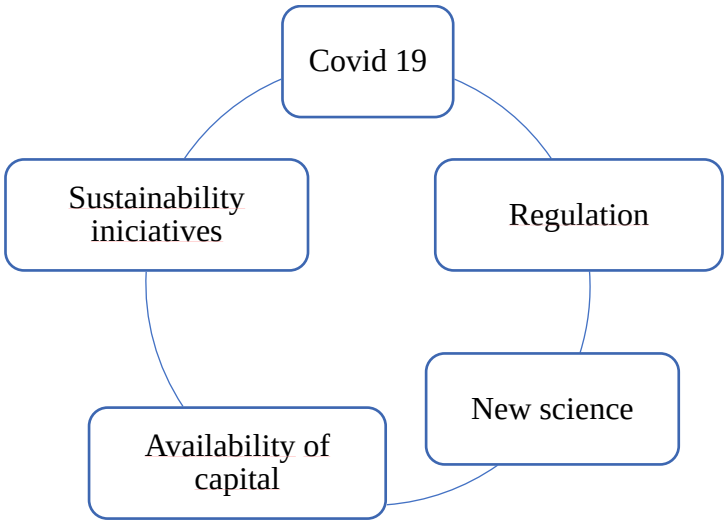
"Product oriented companies are highly capital intensive. Companies find it easier to obtain the capital abroad and consequently move the company in the country of capital origin. […] In Slovenia, investment funds are scared of biotech industry. They have no idea how to financially evaluate a biotech company. […] We Europeans, do great when it comes to science but then we let all the knowledge slip to US because that is where the capital is available." (Interviewee 1)

"Access to capital is harder than for companies operating in big capital markets. […] When visiting investments conferences each deal with investor was clear; you get the money, if you go abroad. In essence, you move where the money is, and it is not in Slovenia. […] The amount of money in Slovenian business founds is very small, insufficient for biotech industry. As far as I know, the players who succeeded globally, all got foreign investments." (Interviewee 2)

"In US, they have retirement funds which have written in their rules; they have to invest a small percentage of their money in risky investments. Biotechnology is very modern and popular choice and this brings big money to the industry." (Interviewee 4)

From analyzing the interviews, one can observe five major factors influencing biotechnology industry. They are shown in Figure 11.

Figure 11: Key external factors that influenced and will influence the development of medical biotechnology



Source: Own work.

The regulations are tightening and consequently the industry is getting more expensive. I described this in previous chapters; on global level, we can observe a decrease in percentage return on R&D investments (Statista, 2021a) and an increase what it costs on average to get a pharma asset to market (Statista, 2020a). Initially, biotechnology with biological drugs was expected to allow faster and more economical product development than small molecule products. However, they soon tackled similar development costs, long development and long regulatory timeframes as small molecule drugs (Kesik-Brodacka, 2018). Recently, also diagnostics have been facing harder and harder regulation (Bartfai & Lees, 2013b). The interviewees reported that stricter regulation will have big impact on the medical biotechnology in Slovenia.

> *"The regulations are getting stricter, which leads to initial investments getting higher. Moreover, new knowledge has to be acquired faster." (Interviewee 2)*

> *"The market demand for crops is flat or even increasing, while the enabling tools to satisfy this demand are being hampered due to stricter regulations." (Interviewee 4)*

Covid 19 will have various consequences on this industry. Interviewee 1 reported that demand grew and profits rose because they offer Covid related treatments. On the other hand, Interviewee 3 reported, sales and distribution channels are clogged. Additionally, Interviewee 2 observed that regulations softened.

> *"Recently, Covid had a big impact. Profits in our two firms significantly grew."*

(Interviewee 1)

"From current standpoint, I can see Covid will influence us the most. Our sales channels are doctors and this was crippled during pandemic. Another area, where Covid hit us and is preventing us from growth is logistics." (Interviewee 3)

"[…] Personally, I am very worried how regulations are getting softer because of Covid pandemic. For the sake of speed, regulatory guidelines are not respected. This is something we will have to correct for in the future." (Interviewee 2)

In general, medical biotechnology includes firms that apply technologies to the life sciences and stands to be the most important area of improvement for human health and quality of life (Srinibas, 2015). Also, Interviewee 1 and Interviewee 4 believe science advancements are an important factor influencing the industry progress: *"Science achievements of course, the ones that sell. Cell therapies and molecular biology are on the rise." (Interviewee 1).* Old technologies are making way for the new ones. For example, nowadays one third of all new treatments are monoclonal antibodies (MRC Laboratory of Molecular Biology, 2020). Furthermore, we expect, the global regenerative medicine market to grow to USD 17.9 billion by 2025 (today is USD 8.5 billion in 2020) at a CAGR of 15.9% (MarketsandMarkets Research Private Ltd., 2020). Interviewee 4 agrees with this view: *"Biotechnology in pharmaceutics is increasingly focusing on large molecules, for example monoclonal antibodies. […] Development of old technologies such as new generics (small molecules) has somehow stopped." (Interviewee 4)*

Interviewees believe that, since the industry requires high initial investments, access to public and private financing is a crucial factor. In general, access to entrepreneurial finance is important for start-up companies in every industry. New start-up needs enough funds, such us private capital, bank loans, venture capital, and government grants (Bosma et al., 2020). Additionally, the pressure to attract capital is growing, since it is being increasingly concentrated into shrinking number of start-ups. The focusing of capital reflects a shift in investment strategy, which allows start-ups to be properly funded and get the best chance to succeed (Evaluate, 2020).

"Very, very much is the industry's progress dependent on availability of capital. Both private and public investments are important." (Interviewee 2)

"The problem of the industry is that it is very capital intensive. This leads to importance of capital availability, which is weak in Slovenia." (Interviewee 1)

Environmental biotechnology is seen by interviewees to have a big impact on the future landscape of the industry.

"Green biotechnology will have a big impact in the future." (Interviewee 1)

"[…] one big part is the development of meet alternatives, […] then there is agro biotechnology where synthetic pesticides are retiring due to stricter regulations. […] We work on new areas such as alternative pesticides and bio stimulants. […] projects for alternative, airplanes' fuel made with biotechnology. This is going to be huge in the future..." (Interviewee 4)

Medical biotechnology includes companies applying technologies to the life sciences. Therefore, it is no surprise that interviewees told, Slovenian biotechnology companies are very interdisciplinary and it is often hard to define a company as a biotechnology company. Additionally there is not many medical biotechnology companies in Slovenia. Interviewees reported that there are only a few biotechnology SMEs in Slovenia, each occupying its niche market. Also, mentioned by the interviewees, were the two big pharma companies: Lek and Krka. Originally, there was a clear line between a pharmaceutical business and biotechnology business. Pharmaceutical companies were in business of small molecule drugs, which they manufactured and marketed. On the other hand, biotech companies produced large molecule therapeutics by using recombinant technology. Nevertheless, this division is now disappearing (Noonan, 2018). According to OECD reports, in Slovenia, there were 27 active biotech companies in 2017. Mostly, they sell and market their products and services to either larger domestic and foreign biopharma or medical technologies companies or conduct research financed by governmental grants, EU supported grants and/or publicly funded institutions. Furthermore, the companies offer a great diversity and variety of biotech products/services (TikhePharma d.o.o., 2020).

"Biotechnology is very interdisciplinary and therefore hard to define. […] Some areas are: bioinformatics, genetics, laboratory equipment, research and development." (Interviewee 2)

"[…] the only big pharma company with Slovenian ownership is Krka and they do not like to be called a biotechnology company. Another big corporation also located in Slovenia is Lek. Lek has very innovative biotechnology products. One of the big ones is also Medis, which again is pharma company with only crumbs of biotechnology. […] When looking at SMEs in Slovenia, there are some environmental biotechnology companies and companies producing supplements, many connected to pharma industry. There are also some research companies- AciesBio for example, there are many representative offices for laboratory or medical equipment. […] When it comes to cell therapies treatments, Slovenia is the biggest practitioner. […] I would mention Celica as they are also doing clinical trials, their products are important for medicine. There are also some companies who got big foreign capital investments: GenePlanet and Bia separations." (Interviewee 1)

"There is not many big biotech companies in Slovenia. We have two giants- Lek and Krka. Others are mostly re-sellers." (Interviewee 3)

As mentioned in previous chapters, there are number of environmental factors, which influence the success of small companies. Amongst them are long-term capital availability, government efforts and incentives, bureaucratic difficulties faced by entrepreneurs in the pursuit of starting a business, infrastructure facilities, technology and information, etc. (Chowdhury et al., 2013). Interviewees see that Slovenian environment has many advantages. Particularly, they all agree our universities are creating a strong foundation for the industry. Additionally, the physical infrastructures, such as streets, fast and accessible internet, the cost and accessibility of office spaces are mostly available to Slovenian entrepreneurs. Interviewees also believe Slovenia is in general a great country to live in as it offers beautiful nature and good health care system and this alone could attract ambitious entrepreneurs.

> *"[…] we should make use of our well educated workers, high quality social environment, good health care system, clean nature and great geographical location." (Interviewee 1)*

> *"The environment for biotechnology in Slovenia is quite good at the end." (Interviewee 4)*

It was emphasized in the interviews that we lack centers of excellence or technology parks. According to Bosma et al. (2020), commercial and professional infrastructure such as access to professional services (accountants and lawyers) that are not too expensive, should be supporting start-ups, inside a framework of property rights. Additionally, results of GEM 2020 demonstrate that physical infrastructure is generally seen as supporting entrepreneurship (Bosma et al. 2020). Furthermore, the advantages of having strong industry clusters were described in previous chapters. In short, new firms are established and start-up employment is higher in industries that are situated in areas with strong clusters (Lämmer-Gamp et al., 2016). Looking at annual research conducted by BioSpace.com, we can observe that almost all of 21 top startups are located in biotechnology clusters (BioSpace, 2020).

> *"There is a lack of centers of excellence. Though, there are some centers in Universities but the connection with business is weak." (Interviewee 1)*

> *"[…] look at the technology park for example. We are one of the rare companies there with a laboratory. […]When going to technology park in Israel this is a very different story. Here the technology park is just a place to rent an office." (Interviewee 4)*

As I mentioned, interviewees agree that our universities are strong but they have different views when it comes to knowledge flow from business to universities. Notably, interviewees named "ties with university" as one of key elements that enable medical biotechnology startup to succeed. This is in line with one of GEM's entrepreneurship framework conditions named "Research and development transfers" which refers to the ability to commercialize research results.

"Though, there are some centers in universities but the connection with business is weak." (Interviewee 1)

"Knowledge flows from Slovenian science and research institutions to companies is very vibrant. The question is does the company get what it wants at a certain point in time as these institutions can be rather slow and less business oriented. […] I also need to stress that majority of people in Slovenian companies were educated in Slovenian universities, which is also an example of knowledge flow." (Interviewee 2)

Public funding is seen as an important element when starting a biotechnology company. This is also one of the GEM's entrepreneurship framework conditions named "Government policy: support and relevance" which looks at government policies and whether they encourage entrepreneurship. Interviewees reported that they were able to get public funding for their company. According to interviewees Slovenia has institutions in place which help the company grow, especially in its early stages. Similarly, in United States, the Small Business Administration provides government grant funding through Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs (USA Angel Investment Network, 2009).

"In Slovenia public funds are relatively cheap way for financing the early stages." (Interviewee 2)

"AciesBio for example, has traditionally done one quarter of its projects true public projects. […] Our China and US colleagues often envy our environment. We have many public projects that focus on science. This way we can get founding for projects and focus on science, without thinking how to sell the story to profit oriented investors." (Interviewee 4)

"In Slovenia we have institutions who help you grow. Our firm, in early stage, grew trough public development programs." (Interviewee 3)

"[…] First, companies get money from start-up accelerator programs, there is plenty of those in Slovenia, but then they get to the valley of death." (Interviewee 1)

Interviewees see that the Slovenian problems occur at stages when larger investments are necessary. Public money is equally distributed among industries regardless of the fact that biotechnology requires more money than other industries. Globally, in 2019, venture capital investments in biopharma total $13.9bn across 396 rounds. The term "mega rounds" has been coined for rounds that amassed $100m or more (Evaluate, 2020). The capital requirements in this industry are large and growing so interviewees believe, this should be properly acknowledged by those distributing public funding.

"The problem is financial resources are distributed in eight areas and one of them is medicine and health. One of the other ones is for example informatics and we know that it is a lot easier to develop some products with $10m in informatics than in biotechnology. When looking at public funds with time limitations this is again problematic. The most comical mechanism in Slovenia is SID bank. I do not know anyone who got any serious money from them." (Interviewee 2)

There are many public tenders in Slovenia. Usually, they are financed from EU. This is a typical way to get public financing for the company. Many interviews mentioned that their firms make use of this tenders However, according to some interviewees, tenders are poorly written, with requirements that are hard to achieve by most biotechnology SMEs. As mentioned in previous chapters, the product development timelines in this industry are very long but once products are developed they often achieve high prices. Established players therefore inflate the average value added in the industry and this should be acknowledge by those who write public tender requirements.

"Government agencies are hostile to SMEs and can act in a bureaucratic way. The tenders are badly written and can not be changed afterwards." (Interviewee 1)

"The money for research projects is often coming from EU. People who write tenders often have poor knowledge of the industry. This results in unattainable requirements. For example, average value added in the industry is very high because of established big players. On the other hand, for small developing companies value added is catastrophically low in the first 10 to 15 years." (Interviewee 2)

Public tenders can also steer the company away from its business goals. They are a dangerous temptation for young, Slovenian medical biotech companies especially because, "staying focused on your goals and core activities" was identified by all interviewees as an important element of start-up success.

"[…] Some companies are overly dependent on public tenders which makes them drift away from business world." (Interviewee 1)

"When applying to public tenders you limit your freedom to choose your direction but this is normal." (Interviewee 3)

Interviewees reported that laws that regulate biotech industry are passed on EU level. Slovenia only makes subordinate legislations - statutory instruments.

"Main laws are decided on EU level. Slovenia then passes the statutory instruments. However, in our case, Slovenia has not made the needed subordinate legislation since the law had been passed in 2007. Meaning that the laws are not valid in Slovenia." (Interviewee 1)

"I would say guidelines come from EU to Slovenia." (Interviewee 3)

"The laws for biotechnology products are passed on EU level." (Interviewee 4)

Interviewees see the policies and legal environment to be unstable which makes the industry unattractive to private investors. Interviewee 2 expressed concern about government's fast changes regarding decisions on strategic investing. Biotech industry needs more than one political cycle to generate return on investment. Additionally, Interviewee 1 said that laws are left open to different ways of interpretation, which adds to uncertainty and scares away the capital. Furthermore, stability is not just about attracting capital. For example, Interviewee 3 said that when the laws suddenly change you have to change your established processes.

"If you are from a country who is not associated with Balkan's bad reputation of unstable political and business landscape it is easier. […] The access to capital is weak and so is the country itself. The politics are unstable, for example, they are willing to invest $20m of public funds into your company and then change their minds. […] There needs to be a stable strategic plan in place for biotechnology industry to work because the timelines are so long. However, in Slovenia the policy regarding the industry can change with each elections." (Interviewee 2)

"It should be an attractive choice for foreigners to open a biotech company in Slovenia but the legal environment is problematic. Not even so much the laws themselves but their interpretation, which can be unpredictable. This scares away the capital. […] we are far from becoming the next Switzerland." (Interviewee 1)

"[…] If we would know this laws are coming ten years ago we would incorporate them in our processes. It is harder to change existing processes." (Interviewee 3)

Interviewees see some laws and policies are adding layers of complexity. Importance of government policies has been recognized also by one of the GEM's entrepreneurship framework conditions named "Government policy: taxes and bureaucracy". This questions the fees and taxes and whether they are reasonably priced and if the regulations and rules are achievable, or are they troublesome for start-ups (Bosma et al., 2020). In this case, it was reported that Slovenia has many unnecessary levels of bureaucracy. This is costly to manage for the Slovene entrepreneurs. Suggested solution by the interviewees was establishment of incubators with entities that would help entrepreneurs maneuver bureaucratic laws and policies.

"The laws we deal most with are GDPRs (General Data Protection Regulations). […] this laws add complexity, you need more people, you have higher costs, it makes you slower." (Interviewee 3)

"[…] An entrepreneur has to deal with GDPRs and fire safety regulations which

takes time away from core business activities. This could be improved if we had appropriate technologic parks." (Interviewee 1)

The bureaucratic laws also make it impossible to establish a spin-off in Slovenia. This was also reported in an interview for RTVSLO where Dr. Hrvoje Petković said: "Slovenian legislation is unresolved when it comes to spin-offs. Furthermore, universities have limits when it comes to collaborating with industry." (Dovjak, 2019). Interviewee 1 further elaborated on the situation: "*There is no spin offs in Slovenia, there are only spin-outs. This is due to the bureaucratic barriers that complicate things. Government institution needs to have their member in the board. This leads to creation of spi-outs where the inventor becomes co-owner. This appears good at first glance, but maybe he does not want to be in the business world. […] consequently we get a bad entrepreneur from a great scientists." (Interviewee 1).*

In the second part of the interview, I asked about a typical way of starting a medical biotech company in Slovenia. According to (Langer, 2014) a typical biotechnology entrepreneur is often a scientist who previously worked in an academic institution or some other biotech company. Similarly, the interviewees reported that in Slovenia, scientists found a typical medical biotechnology company and the company often has origins in the university or an institute. Biotechnology is a knowledge-based industry, which is primarily represented by small companies and new start-ups. According to (Audretsch, 2001), most biotechnology firms are relatively small. Majority of them have fewer than 50 employees (Statista, 2010). Interviewees described how the new biotech startup is born in Slovenia:

"The idea originates in the University or institute. Then a spin-out is established." (Interviewee 1)

"Someone with deep understanding of the area, recognizes the business opportunity, surrounds himself with like-minded people and the start-up is established. This is a typical way. […] Biosistemika originates in National Institute of Biology (NIB)." (Interviewee 2)

"For our company it began with a few colleagues, doctoral students at a university who had an idea of doing something in a better way. They started by renting space at a university and found an angel investor. This enabled them to get started. Then they were applying to EU and Slovenian tenders a lot. This is how they got projects and financing." (Interviewee 4)

"The founder of our company is a biotechnologist. […] It all begins by having a very focused idea that you try to realize. If the idea comes to life you have to constantly improve it and grow it." (Interviewee 3)

Usually, the business idea originates in academic research, which is financed by government programs or local grants (Tscherning, Frank & Schönharting, 1999). Interviewees reported

that the typical Slovenian medical biotech company in its start-up phase also gets financing from public resources. *"In Slovenia public funds are relatively cheap way for financing the early stages." (Interviewee 2).* Public funds are seen as accessible. Furthermore, we have public development programs that help the company grow. "*In Slovenia we have institutions who help you grow. Our firm, in early stage, grew trough public development programs." (Interviewee 3).* What follows is the period that bridges early financers and strategic investors, which is called the valley of death. Interviewee 1 was describing this phenomenon: "*[…] First, companies get money from start-up accelerator programs, there is plenty of those in Slovenia, but then they get to the valley of death." (Interviewee 1).* According to Shimasaki (2014c), when the company is growing, capital requirements rise and thus it needs to find private investors.

Interviewees see below elements are important for company's success:

– Human capital. Having skilled and trust worthy people is seen by interviewees as an essential element. One of the biggest challenges of medical biotech industry are its high capital requirements. Having a strong leader that angel investors can trust is important according to Interviewee 3 and Interviewee 4. Usually, an angel investor also offers their time, which brings knowledge, networks and expertise to the company, which even further increases the company's human capital.

  "Always people and partnerships. Having excellent motivated people, experts in their field is crucial." (Interviewee 1)

  "The key thing in venture investments is that you trust the person." (Interviewee 3)

  "Angel investor saw the potential in this students, this is why he financed their start-up." (Interviewee 4)

– Interviewees see collaboration with universities is important from perspective of doing collaborative work as well as a pipeline to get new knowledge workers. Similarly, the United States biotechnology industry is a true network of universities, private and public research centers, small biotech businesses and big pharma firms. They seem to collaborate rather than compete (Sadraei, Sadeghi & Sadraei, 2018, 2018). As mentioned before, importance of collaborating with universities has also been recognized by GEM's entrepreneurship framework conditions (Bosma et al., 2020).

  "[…] Also, having connections with universities and public agencies. […] In the early phase it is important to collaborate with universities as they are able to conduct research your company might need." (Interviewee 1)

  "The connection to academia is important. We invite students to work for us so that they get to know us and vice versa. We also have research collaborations and our employees are guest lecturers at university." (Interviewee 4)

– Interviewees recognize that partnerships with other companies are helping the company grow faster by supporting its business operations, expanding its product portfolio and building sales channels. Small companies cannot afford to have all functions in house and gaining new customers can be achieved faster by partnering with other firms. According to the literature, medical biotech firms are often small research firms providing specific services, manufacturing a particular protein or doing research aiming to invent a new drug. They are typically incapable of completing the development by bringing the drug to market and therefore they collaborate with larger companies (big pharma companies) and source the drug they worked on to big pharma firms. (Sadraei, Sadeghi & Sadraei, 2018, 2018).

  "Always people and partnerships. […] Having partnership with another firm enables you to grow faster..." (Interviewee 1)

  "Since most biotechnology products are highly complex, it is very important that you are able to collaborate with other companies. Young company does not have its own IT department, test labs, etc. ..." (Interviewee 2)

  "In later stages when looking for investors, you have to make sure that money is not the only thing you gain by giving away a share of your company. An investor also has to bring you a partnership that supports your processes and increases your market share or introduces you to new markets or adds a new product to your portfolio." (Interviewee 3)

– All four interviewees mentioned staying focused on the company's goals and core activities is central for the company's success. This is important in general but since biotechnology is a highly capital intense industry, a company cannot afford any ill-thought-out projects. There is no surprise most Slovenian medical biotechnology SMEs are niche and all interviewees emphasized the importance of staying focused on your core activities.

  "[…] It is important not to lose focus on what you are trying to achieve...." (Interviewee 1)

  When we get an offer for a project it is important to evaluate whether we are able to achieve this goal. […], We know where we are going... […] Looking at BIA Separations, I can see that knowing what they want, having clearly defined direction was their advantage." (Interviewee 2)

  "In the early stage it is crucial that you prioritize because you have limited resources." (Interviewee 3)

  "We chose to work on projects that complement our internal development." (Interviewee 4)

– Interviewee 2 emphasized having high-quality products is important. Medical biotech industry has a very unforgiving regulation. For example, pharmaceutical product is market ready (approved for marketing) after it underwent numerous tests and safety and efficacy were demonstrated. Therefore, other interviewees might not mention this as it is almost impossible not to be high quality and simultaneously still live up to the industry's regulatory requirements.

  "The only way you can really break on the global markets is by having a niche, "wau" product. […] For BIA Separations, having flawless products is definitely a competitive advantage bigger than low prices. […] At least in the early stages of the company it is important to also have good value for money." (Interviewee 2)

– Broad, interdisciplinary knowledge. As mentioned before biotechnology is very interdisciplinary industry. Therefore, it does not come as a surprise that the interviewees stressed the importance of having broad knowledge, making knowledge connections and master the market complexity.

  "For biotechnology, to have interdisciplinary knowledge is even more important than in other industries. The leaders need to be able to make knowledge connections." (Interviewee 2)

  "Internal element that enables biotech company to succeed is to master the market complexity. If all you know is one small part, you become just a contractor for one service and you cannot get big profits out of that. […] We are competent to look at bigger picture." (Interviewee 4)

– Brain circulation. It was emphasized by interviewees that there are great benefits from people going abroad and bringing knowledge and experiences back to Slovenia. In fact, many Slovenian medical biotechnology company funders have been working or studying abroad. Interviewee 4 also mentioned that Slovenia lacks entrepreneurship spirit and going abroad can help eliminate this problem for an individual.

  "[…] You need to go abroad, this is the fact." (Interviewee 1)

  "[…] the founder studied genetics in Netherlands and then continued studying the business part in United States." (Interviewee 3)

  "I think in Slovenia, the main problem is we lack entrepreneurial spirit. It is interesting, how people who studied abroad are different in that aspect. […] They have a "drive" different from most people." (Interviewee 4)

Slovenian medical biotech companies all operate on global market. Therefore, the fact that Slovenian market is small is mostly not seen as an obstacle for Slovenian companies. Some pointed out that it is even an advantage as it offers a testing ground for products and learn in

the process. Furthermore, it can offer easier access to government agencies as one is able to know the majority of people working in the field.

> *"In biotechnology you need to operate on global markets […] Slovenia can offer a great testing ground for certain products. […] Furthermore, the fact that Slovenia is small offers a fast access to government agencies, as you probably know the people working there from the university days..." (Interviewee 1)*

> *"The fact that Slovenian market is small is not an obstacle. You can use Slovenian market as a testing ground and learn in the process. This is especially true when testing new processes; a small market enables you to act faster." (Interviewee 3)*

> *"The small size of Slovenian market is not at all an obstacle. Everything is global. Local clients or local contractors have no advantages over those on the other hemisphere." (Interviewee 4)*

Slovenian medical biotechnology companies are all very export oriented. They offer products or services on all major markets. Slovenia is typically not an important market for them. This makes sense as they are typically a niche company and can provide very unique products and services. Furthermore, it is very common for a company in this industry to file for patents, which makes this company the only provider of a certain product globally.

> *"I think our companies are present on most global markets. This is true especially for niche players since they offer something no other company has." (Interviewee 2)*

> *"Our company is extremely export oriented company. In Slovenia, we do little. […] We are the market leader in Central and East Europe. We are also present in Asian markets (South-East Asia), Africa (Nigeria) and Mexico. We are not present in US for two reasons. Firstly, other companies hold IP rights in US and secondly, there is too many competitors." (Interviewee 3)*

> *"Everything is global. We do little business in Slovenia." (Interviewee 4)*

All interviewees are convinced that without any doubt, both human capital and innovation are important success drivers. According to (Audretsch & Stephan, 1996) the most important factor in development of biotech industry is the presence of scientific talent in a region. Scientific talent should be present at either universities, public research laboratories, or private companies. Additionally, the consequence of scientific talent existing in geographical proximity is that the biotechnology industry is also prevailing in clusters. Science achievements were regarded previously as one of external success drivers, and a company needs skilled and knowledgeable biotechnologists who will successfully incorporate them into the company. The interviewees reported, they are thinking a lot about how to retain and attract talent. Furthermore, the role of innovation is of an extreme

importance. Nowadays, medical biotech companies are cooperating with pharma companies. The biotech company usually does the research and pharma company continues with the later and more expensive drug development stages (Noonan, 2018). In this set-up, innovating is a core activity for a medical biotech company. For example, Interviewee 3 mentioned that in his company, they are constantly introducing new technologies. If they would stop, their growth curve would soon plumped.

> *"Human capital is essential without a shadow of a doubt. Innovations are the result of human work." (Interviewee 1)*

> *"In a SME you need to be able to retain your people. If you lose one expert the effect could be devastating. We are thinking a lot on how to satisfy our employees." (Interviewee 2)*

> *"You have to grow, constantly introducing new technologies otherwise you are not able to compete. […] and behind all of this are of course people. Our approach is to motivate people […] we are careful that employees get what they expected out of working for us. If you do not have something new to offer, you do not stand a chance in a biotechnology industry. If you do not innovate, there are too many established big players you have to compete with. If you stop innovating, the competition will catch up and your growth curve will turn down. Innovation comes from people so this is connected. We are increasingly working on our human capital." (Interviewee 3)*

4.2.3 Discussion and implications

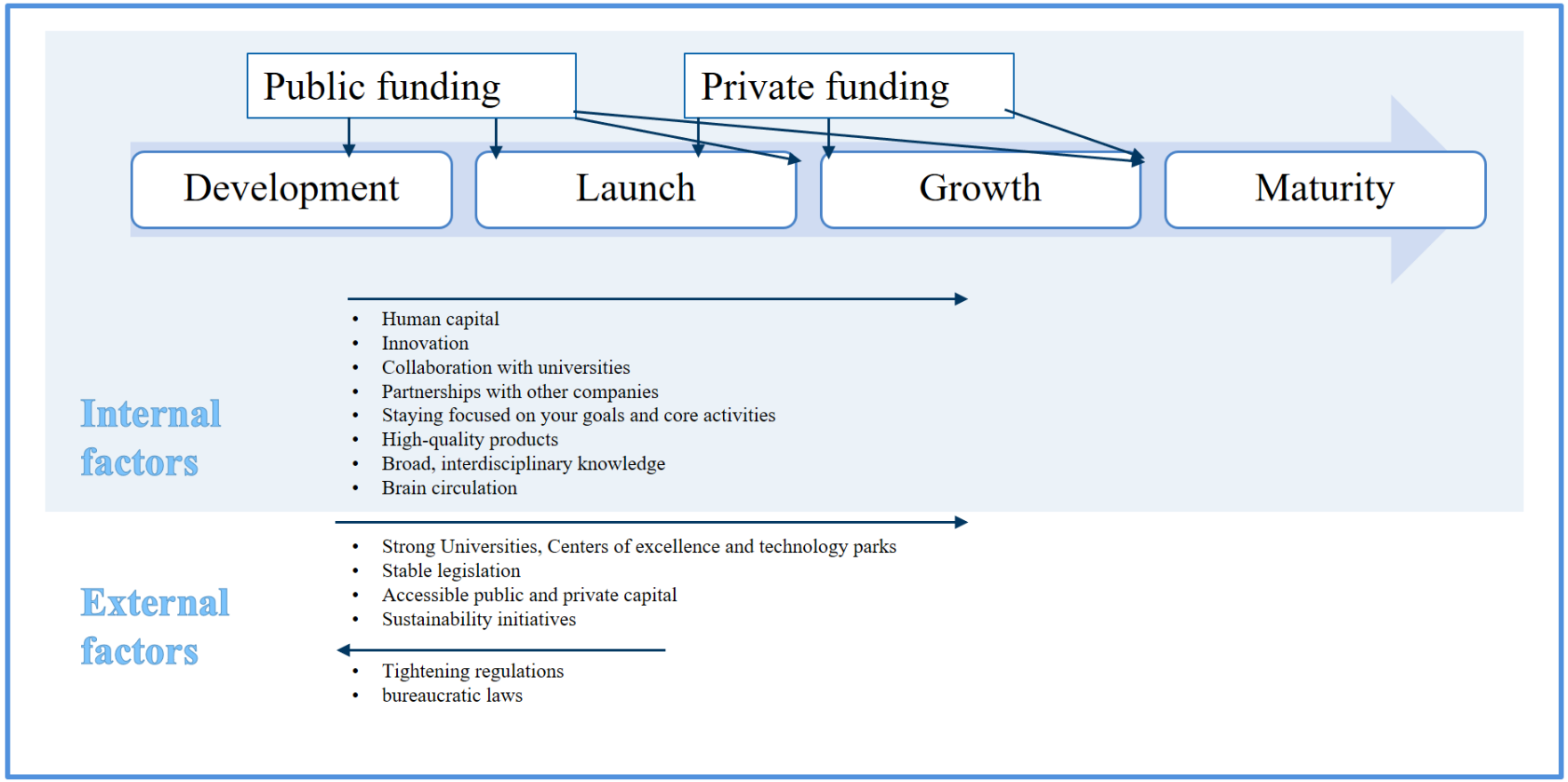
In Slovenia, the field of biotechnology is developing fast. As was recently evident from the COVID-19 vaccination development, this is an industry, where smaller players can be very successful, which includes also Slovenian companies. Slovene medical biotechnology ecosystem has a strong tradition and there are many skilled workers available but the number of SMEs in the industry is relatively small. The ones that do exist have very narrow focus, are highly innovative, and interdisciplinary. Their role and future strength of industry in Slovenia will go hand in hand with the development of the ecosystem. Currently, the sector in Slovenia is better developed than South and East Europe and less developed than Central and West Europe. Slovenian environment has many advantages. Universities are creating a strong foundation for the industry, public funding is highly accessible and the global demand for biotech solutions is growing. On the other hand, we have a shortage of professional infrastructure such as centers of excellence or technology parks, our laws are bureaucratic and we lack private funding. In Slovenia, a typical medical biotechnology company is founded by scientists, often has origins in the university or an institute and gets its initial financing from public resources. Factors that contribute most to the success of these companies are human capital, collaboration with universities, partnerships with other companies, staying focused on company's goals and core activities, high-quality products,

broad, interdisciplinary knowledge and brain circulation. In general, medical biotech companies usually operate on global market and Slovenian companies are no different. Therefore, the small size of Slovenian market is not an obstacle for the companies.

All interviewees are convinced that both human capital and innovation are important success drivers and since both of them often have roots in universities, this offers a competitive advantage for Slovenian medical biotechnology sector. We should though, work on developing centers of excellence, technology parks and further improve our connections between private companies and universities. This would improve collaboration, knowledge flow and more partnerships would get build. Additionally, supporting jobs to the SMEs would be available there so that company founders, who are usually scientist, would be able to concentrate on their core business instead of dealing with patent laws and data privacy laws. Another big advantage of Slovenian and even EU environment in comparison to US and China are public tenders, which give scientists time to innovate without pressure accompanied by private capital. Slovenian medical biotech industry however seriously lacks private funding. In comparison to some EU countries and especially US we have very low availability of venture capital, angel investors etc. This could be improved by improving Slovenian legal system, since it was recognized as an obstacle for private capital inflow. Slovene legislation is seen as bureaucratic and unstable, which makes the industry unattractive to private investors.

Based on described, and in order to understand factors that make it possible for Slovenian companies in medical biotechnology industry to succeed, I developed a comprehensive model, which shows external and internal factors that influence the success of Slovenian medical biotechnology company. Slovenia should work on further building and improving the success factors and eliminating the factors that have negative impact on industry's growth to enable the medical biotechnology industry to reach its potential.

Figure 12: Comprehensive model of external and internal factors that influence the success of Slovenian medical biotechnology company



Source: Own work.

Based on the exploratory research, results and findings I will describe initiatives and implications, which would enhance the development of Slovene medical biotechnology industry.

1. Public funding is crucial and only source of financing for the company in its early stage. Slovenia and EU should continue to offer public funding to companies as it gives them more space to do research without the pressure and short timelines accompanied by private capital. Additionally, we should make sure that public tenders are written by professionals who know the industry well and make sure it is possible for SMEs to satisfy tender's requirements.
2. In later stages, when capital requirements rise, the companies need private funding and this is one of Slovenia's weakest factors. Slovenia needs to work on more stable legislation in order to attract more private capital. Slovenia could also apply some good practices from the US, where private capital is widely available.
3. Bureaucratic laws make it harder for companies to focus on their core activities. Consequently, companies need to employ additional skilled professional to manure those laws. This can be very expensive for a small company. Moreover, bureaucratic laws are preventing academics from creating spin-offs and disturbing private capital inflow. I see the solution to this problem is two-fold. First, Slovenia should eliminate burdensome legislation and second, establish centers of excellence and technology parks where entrepreneurs would be provided with assistance when it comes to administrative work, contract preparation and handling intellectual property rights, GDPRs, etc..
4. Internal factors. There are many things that the company can do internally to assure its success. It is crucial for a company that it invests in people and innovation and creates high quality products. Ties with universities and other companies are also important growth drivers. US for example, improved commercialization of technologies and knowledge coming from universities and government research institutions with Technology Transfer Offices (TTOs). Slovenia could copy successful practices from US to improve the knowledge flow between companies and universities. Another internal factor where Slovenian institutions can contribute is helping companies to stay focused on their core activities by providing affordable professional services like accountants and lawyers. Broad, interdisciplinary knowledge is also regarded as important success factor. Enabling students to educate themselves on different areas is one way how we can assure human capital for our biotech companies. Finally, going abroad is an important experience for medical biotech entrepreneur. Slovenia should therefore enable students and aspired entrepreneurs to experience working, learning and leaving abroad.

The above, proposed initiatives and implications are based on the exploratory study. Thus, policymakers should identify feasibility of proposed measures by creating proper project plans accompanied by financial calculations. While the nature of this research project was exploratory, it is still a qualitative research and future research incorporating a larger sample would be necessary before the conclusions can be generally applied. Nevertheless, the

research gathers opinions of important members of Slovene biotech community. To conclude, the exploratory research determined, Slovenian environment for biotech SMEs already has some good established practices but could further benefit from copying US and Central and West EU countries regarding legislation and professional infrastructure.

CONCLUSION

This master thesis examinees the ways and the challenges of building a company in the medical biotechnology industry worldwide and in Slovenia. The term "new biotechnology" which marks the beginnings of medical biotechnology had been popularized by the 1984 Office of Technology Assessment Report. A new period of healthcare science was born from medical biotechnology and its branches: molecular medicine, personalized medicine and regenerative medicine. These advances have enabled medical biotechnology to become the most important field that improves human health and quality of life. It is a link between pharma industry, biotechnology, and medicine and offers numerous product development opportunities. For example, many untreatable hereditary diseases could be effectively treated with biotech products. Similarly, personalized medicine offers a chance for better treatments for conditions that are at this time handled poorly. Biotechnology is a new knowledge-based industry that is primarily represented by new startups and small businesses. New inventions in medical biotech industry relay on entrepreneurs, as they are the ones that can bear the industry's high-risk character.

In the paper, a wide range of internal and external factors that have an impact on the success of small business in medical biotechnology industry are described. Amongst them are long-term capital availability, government efforts and incentives, bureaucratic difficulties faced by entrepreneurs in the pursuit of starting a business, infrastructure facilities, technology and information, etc. The exploratory research is based on four in-depth interviews with representatives of Slovene medical biotechnology environment and it focuses on the characteristics of biotechnology in Slovenia, comparison to other countries, and its potential with the focus on start-ups. It was determined that Slovenian environment is better developed than South and East Europe and less developed than Central and West Europe. The environment has many advantages: universities are creating a strong foundation for the industry, public funding is highly accessible and the global demand for biotech solutions is growing. On the other hand, the country is struggling with a shortage of professional infrastructure such as centers of excellence or technology parks, bureaucratic laws and the lack of private funding. In order to understand factors that make it possible for Slovenian companies in medical biotechnology industry to succeed, I developed a comprehensive model, which shows external and internal factors that influence the success of Slovenian medical biotechnology company. Moreover, initiatives and implications, which would enhance the development of Slovene medical biotechnology industry, are described.

Both research questions were answered. The research revealed that Slovenian medical

biotech sector has great potential since we have strong tradition in medical biotechnology accompanied by skilled knowledge workers but certain external factors are holding back Slovene biotech entrepreneurs. If methods and process, which would stimulate entrepreneurship in the industry, exist, Slovene medical biotechnology industry would blossom. Slovenia should work on further building and improving the success factors and eliminating the factors that have negative impact on industry's growth to enable the medical biotechnology industry to reach its potential.

At the end it is important to note that a limited number of interviews were conducted and analyzed and although the nature of this research project was exploratory, there should be future research conducted incorporating a greater sample before the conclusions can be generally applied.

REFERENCE LIST

1. Abate, T. (2012, February 1). *Passing the `BioBucks'—Small Investors Aren't In on the Joke / Inflated deal values sometimes only way firms can raise funds*. Retrieved on 15 May 2021 from https://www.sfgate.com/business/article/Passing-the-BioBucks-Small-Investors-Aren-t-2925432.php
2. AciesBio. (n.d.). *Complete solutions in microbial biotech*. Retrieved on 23 June 2021 from https://www.aciesbio.com
3. Adams, B. (2015, February 26). *BMS buys immunotherapy specialist Flexus in $1.2bn deal (World) [Text]*. Retrieved on 23 June 2021 from http://www.pmlive.com/pharma_news/bms_buys_immunotherapy_specialist_flexus_in_$1.2bn_deal_661058
4. Algieri, B., Aquino, A. & Succurro, M. (2013a). Technology transfer offices and academic spin-off creation: The case of Italy. *The Journal of Technology Transfer, 38*(4), 382–400.
5. Amarakoon, I. I., Hamilton, C. L., Mitchell, S. A., Tennant, P. F. & Roye, M. E. (2017). Chapter 28—Biotechnology. In S. Badal & R. Delgoda (eds.), *Pharmacognosy* (pp. 549–563). Cambridge: Academic Press.
6. Audretsch, D. B. & Stephan, P. E. (1996). Company-Scientist Locational Links: The Case of Biotechnology. *The American Economic Review, 86*(3), 641–652.
7. Audretsch, D. B. (2001). The Role of Small Firms in U.S. Biotechnology Clusters. *Small Business Economics, 17*(1), 3–15.
8. Bartfai, T, & Lees, G. V. (2013a). *Personalized medicine.* In T. Bartfai & G. V. Lees (eds.), *The Future of Drug Discovery* (pp. 231–248). Cambridge: Academic Press.
9. Bartfai, T. & Lees, G. V. (2013b). *How much can drugs cost?* In T. Bartfai & G. V. Lees (eds.), *The Future of Drug Discovery* (pp. 249–263). Cambridge: Academic Press.
10. Bayer. (2019, July 1). *Century Therapeutics launches with USD 250M financing for induced pluripotent stem cell (iPSC) allogeneic cell therapy platform.* Retrieved on 23 June 2021 from http://media.bayer.com/baynews/baynews.nsf/id/Century-

Therapeutics-launches-USD-250M-financing-induced-pluripotent-iPSC-allogeneic-therapy
11. Beckett, R. D. (2014). National Institutes of Health. In P. Wexler (ed.), *Encyclopedia of Toxicology* (pp. 458–459). Cambridge: Academic Press.
12. BIA Separations. (2015). *BIA Separations and Labena Start Long Term Partnership*. Retrieved on 23 June 2021 from https://www.biaseparations.com/en/news-events/news/91/bia-separations-and-labena-start-long-term-partnership
13. BIA Separations. (2020). *Bia Separations bought by Sartorius for EUR 360 million—Slovenia Times.* Retrieved on 23 June 2021 from https://sloveniatimes.com/bia-separations-bought-by-sartorius-for-eur-360-million/
14. BIA Separations. (n.d.). *BIA Separations CRO – BIA Separations CRO.* Retrieved on 23 June 2021 from https://www.biaseparationscro.com/
15. BioSpace. (2020, June 1). *Top Life Sciences Startups to Watch in 2020.* Retrieved 16 May, 2021 from https://www.biospace.com/article/top-21-life-science-startups-to-watch-in-2020/
16. Boehm, G., Yao, L., Han, L. & Zheng, Q. (2013). Development of the generic drug industry in the US after the Hatch-Waxman Act of 1984. *Acta Pharmaceutica Sinica, 3*(5), 297–311.
17. Booth, B. (2020, September 21). Evolution Of The Biotech IPO Markets From Busted To Booming. *Forbes*. Retrieved on 23 June 2021 from https://www.forbes.com/sites/brucebooth/2020/09/21/evolution-of-the-biotech-ipo-markets-from-busted-to-booming/
18. Bosma, N. & Levie, J. (2010). *Global Entrepreneurship Monitor*. Retrieved on 23 June 2021 from https://www.coursehero.com/file//1313079015GEM_2009_Global_Report_Rev_140410.pdf
19. Bosma, N., Hill, S., Ionescu-Somers, A., Kelley, D., Levie, J. & Tarnawa, A. (2020). *GEM Global Report 2019/2020*. Retrieved on 23 June 2021 from https://www.babson.edu/media/babson/assets/global-entrepreneurship-monitor/2019-2020-GEM-Global-Report.pdf
20. Bratanič, J. (2015, July 5). Premalo poguma za vstop v elito biotehnološke industrije. *Dnevnik*. https://www.dnevnik.si/1042708821
21. Business Angels of Slovenia. (2021, February 11). *About us.* Retrieved on 15 May 2021 from https://poslovniangeli.si/en/about-us/
22. Chowdhury, M. S., Alam, Z. & Arif, M. I. (2013). Success factors of entrepreneurs of small and medium sized enterprises: Evidence from Bangladesh. *Business and Economic Research, 3*(2), 38.
23. Cook, P. (2001). *Clusters as Key Determinants of Economic Growth: The Example of Biotechnology*. Retrieved on 23 June 2021 from https://archive.nordregio.se/Global/Publications/Publications%202001/R2001_2/R0102_p23.pdf
24. Dovjak, R. (2019). Hrvoje Petković: V prihodnosti brez gensko spremenjenih organizmov ne bo šlo. *MMC RTV Slovenija.* Retrieved on 23 June 2021 from

https://www.rtvslo.si/univerza100/hrvoje-petkovic-v-prihodnosti-brez-gensko-spremenjenih-organizmov-ne-bo-slo/506094

25. Elflein, J. (2020, October 15). *Obesity Prevalence U.S. Adults 1997-2018*. Retrieved 16 May, 2021 from https://www.statista.com/statistics/244620/us-obesity-prevalence-among-adults-aged-20-and-over/
26. Erickson, B., Nelson, J. E. & Winters, P. (2012). Perspective on opportunities in industrial biotechnology in renewable chemicals. *Biotechnology Journal*, *7*(2), 176–185.
27. Eureka. (n.d.). *Eureka and Slovenia.* Retrieved on 23 June 2021 from https://www.eurekanetwork.org/countries/slovenia/
28. European Pharmaceutical Review. (2014). *Recombinant protein technology in small molecule drug discovery.* Retrieved 25 June, 2021 from https://www.europeanpharmaceuticalreview.com/article/27775/history-recombinant-protein-technology-small-molecule-drug-discovery/
29. Evaluate. (2020). *Evaluate Vantage Pharma, Biotech & Medtech 2019 in Review*. Retrieved 16 May, 2021 from https://www.evaluate.com/thought-leadership/vantage/evaluate-vantage-pharma-biotech-medtech-2019-review
30. Fisken, J. & Rutherford, J. (2002). Business models and investment trends in the biotechnology industry in Europe. *Journal of Commercial Biotechnology*, *8*(3), 142–148.
31. Florko, N. (2017). FDA Approves First Biosimilar To Genentech's Herceptin. Inside HealthPolicy. *Com's FDA Week, 23*(49), 7–8.
32. Giovannetti, G. T. & Morrison, S. W. (2000). *Convergence: The biotechnology industry report.* Palo Alto, CA: Ernst & Young.
33. Glick, J. L. (2012, December 1). Biotech: A Model of Creative Acquisition. *GEN – Genetic Engineering and Biotechnology News*. Retrieved 25 June, 2021 from https://www.genengnews.com/magazine/193/biotech-a-model-of-creative-acquisition
34. Gottinger, H. W. & Umali, C. L. (2008). The evolution of the pharmaceutical-biotechnology industry. *Business History*, *50*(5), 583–601.
35. Greenwood, J. C. (2014). Unleashing the Promise of Biotechnology to Help Heal, Fuel, and Feed the World. In C. Shimasaki (ed.), *Biotechnology Entrepreneurship* (pp. 3–13). Cambridge: Academic Press.
36. Hevesi, A. G. & Bleiwas, K. B. (2005). The Economic Impact of the Biotechnology and Pharmaceutical Industries in New York. New York: Office of the State Comptroller.
37. Incubator List. (n.d.). *Top Startup Accelerators, Incubators and VCs in Slovenia.* Retrieved 16 May, 2021 from https://incubatorlist.com/top-startup-accelerators-incubators-and-vcs-in-slovenia/
38. Insights, F. B. (2020, September 14). Monoclonal Antibody Therapy Market to Reach USD 350.10 Billion by 2027; Increasing Number of Regulatory Approvals Will Aid Growth, says Fortune Business InsightsTM. *GlobeNewswire News Room*. Retrieved 25 June, 2021 from http://www.globenewswire.com/news-release/2020/09/14/2092946/0/

en/Monoclonal-Antibody-Therapy-Market-to-Reach-USD-350-10-Billion-by-2027-Increasing-Number-of-Regulatory-Approvals-Will-Aid-Growth-says-Fortune-Business-Insights.html
39. Issa, A. M. (2007). Personalized Medicine and the Practice of Medicine in the 21st Century. *McGill Journal of Medicine, 10*(1), 53–57.
40. Jain, H. K. (2010). *Green revolution: History, impact and future*. Bonn: Studium Press.
41. Janssen health policy center. (2015, September 24). *Are levels of health R&D investment in Europe sufficient to cope with health challenges?* Retrieved 3 June, 2021 from https://www.politico.eu/sponsored-content/are-levels-of-health-rd-investment-in-europe-suffi-cient-to-cope-with-health-challenges/
42. Jennings, J., Antrobus, K. L., Atencio, S. J., Glavich, E., Johnson, R., Loffler, G. & Luu, C. (2005). "Drinking Beer in a Blissful Mood" Alcohol Production, Operational Chains, and Feasting in the Ancient World. *Current Anthropology, 46*(2), 275–303.
43. Johnson, D. (2001). What is innovation and entrepreneurship? Lessons for larger organisations. *Industrial and Commercial Training, 33*(4), 135–140.
44. Kaplan, S. & Murray, F. (2010). Entrepreneurship and the construction of value in biotechnology. In N. Phillips, D. Griffiths, & G. Sewell (eds.), *Technology and Organization: Essays in Honour of Joan Woodward* (pp. 107–147). Bingley: Emerald Group Publishing Limited.
45. Karpa, W. & Grginović, A. (2020). Long-term perspective on venture capital investments in early stage life-science projects related to health care. *Economic Research-Ekonomska Istraživanja, 33*(1), 2526–2540.
46. Kaučič, P. (2002, October 4). *Dr. Miodrag Knežević*. Retrieved 25 June, 2021 from http://www.podjetnik.si/clanek/dr-miodrag-kne%C5%BEevi%C4%87-20021004
47. Kesik-Brodacka, M. (2018). Progress in biopharmaceutical development. *Biotechnology and Applied Biochemistry, 65*(3), 306–322.
48. KISSPatent Europe (2018, March 1). *Patents in the Pharmaceutical Industry.* Retrieved 16 May, 2021 from https://kisspatent.com/resources/patents-in-the-pharmaceutical-industry-the-race-to-medical-innovation
49. Kontler Salamon, J. (2015, April 23). *Od biotehniške fakultete do uspešnega podjetja.* Retrieved 11 June, 2021 from https://www.ki.si/fileadmin/user_upload/datoteke-splosno/Objave/2015/1429788558761_email.pdf
50. Kremer, M. (2002). Pharmaceuticals and the Developing World. *Journal of Economic Perspectives, 16*(4), 67–90.
51. Kupec, B. (2016, July 11). Tvegani kapital v Sloveniji: Malo ga je, pa še država ga je dodatno obdavčila. *Finance*. Retrieved 11 June, 2021 from https://posel2030.finance.si/8850960
52. Lämmer-Gamp, T., Meier zu Köcker, G., Thomas, K., Pflanz, K. & Iszak, K. (2016, June). *Clusters and Entrepreneurship in Emerging Industries*. Retrieved 12 June, 2021 from http://www.sgg.si/wp-content/uploads/2016/06/2016-Clusters-and-Entrepreneurship-in-Emerging-Industries.pdf

53. Langer, L. J. (2014). *Characteristics of Successful Biotechnology Leaders*. In C. Shimasaki (ed.), *Biotechnology Entrepreneurship* (pp. 75–81). Cambridge: Academic Press.
54. Link, A. N. & Rees, J. (1990). Firm size, university based research, and the returns to R&D. *Small Business Economics, 2*(1), 25–31.
55. Lurie, N., Saville, M., Hatchett, R. & Halton, J. (2020). Developing Covid-19 Vaccines at Pandemic Speed. *New England Journal of Medicine*, *382*(21), 1969–1973.
56. MacroGenics, Inc. (2017). *Incyte and MacroGenics Announce Global Collaboration and Licensing Agreement for Anti-PD-1 Monoclonal Antibody MGA012*. Retrieved 16 May, 2021 from http://ir.macrogenics.com/static-files/bf9cd997-6cd4-4717-9e5e-4badf1ca0136
57. Makurvet, F. D. (2021). Biologics vs. small molecules: Drug costs and patient access. *Medicine in Drug Discovery*, *9,* 100075.
58. Mao, A. S. & Mooney, D. J. (2015). Regenerative medicine: Current therapies and future directions. *Proceedings of the National Academy of Sciences of the United States of America, 112*(47), 14452–14459.
59. MarketsandMarkets Research Private Ltd. (2020, September). *Regenerative Medicine Market—Global Forecast to 2025*. Retrieved 16 June, 2021 from https://www.marketsandmarkets.com/Market-Reports/regenerative-medicine-market-65442579.html
60. Martin, J. P. (2019, April 20). *Strategic Investors Vs. Financial Investors*. Retrieved 25 June, 2021 from https://jpmartin.com/strategic-financial-investors/
61. Mendicino, M., Fan, Y., Griffin, D., Gunter, K. C. & Nichols, K. (2019). Current state of U.S. Food and Drug Administration regulation for cellular and gene therapy products: Potential cures on the horizon. *Cytotherapy*, *21*(7), 699–724.
62. Mordor Intelligence. (2020). *Clinical Diagnostics Market - Growth, Trends, COVID-19 Impact, and Forecasts (2021-2026).* Retrieved 16 May, 2021 from https://www.mordorintelligence.com/industry-reports/clinical-diagnostic-market
63. MRC Laboratory of Molecular Biology. (2020*). Therapeutic Antibodies*. Retrieved 26 May, 2021 from https://www2.mrc-lmb.cam.ac.uk/research/technology-transfer/recent-technology-transfer-initiatives/therapeutic-antibodies
64. Nafukho, F. M. & Helen Muyia, M. A. (2010). Entrepreneurship and socioeconomic development in Africa: A reality or myth? *Journal of European Industrial Training, 34*(2), 96–109.
65. Niosi, J. & Banik, M. (2005). The evolution and performance of biotechnology regional systems of innovation. *Cambridge Journal of Economics, 29*(3), 343–357.
66. Noonan, K. (2018). *What's the difference between biotech and pharma?* Retrieved 16 May, 2021 from https://www.alacrita.com/blog/whats-difference-biotech-pharma
67. OECD Statistics. (n.d.). *Venture capital investments.* Retrieved 16 May, 2021 from https://stats.oecd.org/Index.aspx?DataSetCode=VC_INVEST

68. Oliver Wyman Inc. (2015). *Royalty Financing: Unlocking Value in the Life Sciences.* Retrieved 25 June, 2021 from https://www.oliverwyman.com/our-expertise/insights/2015/sep/royalty-financing--unlocking-value-.html
69. Organisation for Economic Co-operation and Development. (2020). *Inclusive Entrepreneurship Policies: Country Assessment Notes - Slovenia.* Retrieved 16 May, 2021 from https://www.oecd.org/cfe/smes/Inclusive-Entrepreneurship-Policies-Country-Assessment-Notes.htm
70. Pham, P. V. (2018). Medical Biotechnology: Techniques and Applications. In D. Barh & V. Azevedo (Eds.), *Omics Technologies and Bio-Engineering* (pp. 449–469). Cambridge: Academic Press.
71. Pharmaceutical Research and Manufacturers of America. (2013). *Medicines in Development for Biologics 2013 Report.* Retrieved 16 May, 2021 from https://www.phrma.org/Report/Medicines-in-Development-for-Biologics-2013-Report
72. Pharmaceutical Technology. (2018, October 24). *Pfizer partners with Bain Capital to launch Cerevel Therapeutics.* Retrieved 16 May, 2021 from https://www.pharmaceutical-technology.com/news/pfizer-cerevel-therapeutics/
73. Pintar, J. (2018). BioSistemika: Izvir mladosti ali dvig produktivnosti. *Dnevnik*. Retrieved 16 May, 2021 from https://www.dnevnik.si/1042836798
74. Pisano, G. P. (2006, October). Can Science Be a Business?: Lessons from Biotech. *Harvard Business Review*. Retrieved 16 May, 2021 from https://hbr.org/2006/10/can-science-be-a-business-lessons-from-biotech
75. Plecher, H. (2020, September 22). *Development of the World Population until 2050*. Retrieved 16 May, 2021 from https://www.statista.com/statistics/262875/development-of-the-world-population
76. Rebernik, M., Širec, K., Tominc, P., Crnogaj, K., Rus, M. & Hojnik, B. B. (2020). *Raznolikost podjetniških motivov*. Retrieved 16 May, 2021 from https://ipmmp.um.si/globalni-podjetniski-monitor/gem-slovenija-monografije/
77. Research and Markets. (2019, November 22). *Global Licensing Partnering Terms & Agreements in Pharma, Biotech & Diagnostics 2014-2019.* Retrieved 16 May, 2021 from https://www.prnewswire.com/news-releases/global-licensing-partnering-terms--agreements-in-pharma-biotech--diagnostics-2014-2019-300963724.html
78. Rodríguez Fernández, C. (2021, April 8). *Ditch the VC: Alternative Funding Options for Biotech Startups*. Retrieved 25 June, 2021 from https://www.labiotech.eu/in-depth/biotech-startups-alternative-funding/
79. Sadraei, R., Sadeghi, V. J. & Sadraei, M. (2018). Biotechnology revolution from academic entrepreneurship to industrial: Chemo-entrepreneurship. *Biometrics & Biostatistics International Journal, 7*(6), 546–550.
80. Schumpeter, J. A. (2000). *Entrepreneurship as Innovation (SSRN Scholarly Paper ID 1512266). Social Science Research Network.* Retrieved 16 May, 2021 from https://papers.ssrn.com/abstract=1512266

81. Segers, J. P. (2018). *Biotechnology Business Models: Catch-22 or best of both worlds?* Retrieved 16 May, 2021 from https://www.researchgate.net/publication/316275075_Biotechnology_Business_Models_Catch-22_or_best_of_both_worlds
82. Shimasaki, C. (2014a). *Biotechnology Entrepreneurship: Leading, Managing and Commercializing Innovative Technologies*. Camridge: Academic Press.
83. Shimasaki, C. (2014b). Understanding Biotechnology Business Models and Managing Risk. In C. Shimasaki (ed.), *Biotechnology Entrepreneurship* (pp. 161–174). Camridge: Academic Press.
84. Shimasaki, C. (2014c). Understanding and Securing Venture Capital. In C. Shimasaki (ed.), *Biotechnology Entrepreneurship* (pp. 293–302). Cambridge: Academic Press.
85. Slovenska tiskovna agencija. (2018, July 9). *JF Investments v Geneplanet vložil 10 milijonov evrov.* Retrieved 25 June, 2021 from https://krog.sta.si/2532926/jf-investments-v-geneplanet-vlozil-10-milijonov-evrov
86. Slovenski podjetniški sklad. (n.d.). *Vsebinska podpora.* Retrieved 16 May, 2021 from from https://podjetniskisklad.si/sl/produkti-sklada/sps-dvojcekdpora-pri-produktih
87. SPIRIT Slovenija. (2019a). *Priročnik za podjetnike začetnike.* Retrieved 16 May, 2021 from https://www.podjetniski-portal.si/programi/spot-poslovna-tocka/spletni-prirocnik-abc-podjetnistva
88. SPIRIT Slovenija. (2019b). *ABC Podjetništva.* Retrieved 16 May, 2021 from https://files.zotero.net/eyJleHBpcmVzIjoxNjI2MDA0NTQzLCJoYXNoIjoiZTU5YWU4ODA1Yjc2MWRiNTY1MDIwZDBiMzM4NTgwYjEiLCJjb250ZW50VHlwZSI6ImFwcGxpY2F0aW9uXC9wZGYiLCJjaGFyc2V0IjoiIiwiZmlsZW5hbWUiOiJwb2dsYXZqZV8xMV9wb2Rwb3JuZV9pbnN0aXR1Y2lqZS5wZGYifQ%3D%3D/433a374fe944159fb021704af1d7da6d7cbb128f9baaa3c0bc3af887f1335321/poglavje_11_podporne_institucije.pdf
89. Srinibas, K. (2015). *Biotechnology: Scope and Branches of Biotechnology*. Retrieved 16 May, 2021 from from https://www.biologydiscussion.com/biotechnology/branches-biotechnology/biotechnology-scope-and-branches-of-biotechnology/15653
90. Start-up AA. (n.d.). *Technology Park Ljubljana, d.o.o.* Retrieved 16 May, 2021 from https://www.startupalpeadria.eu/en-us/institution/75/technology-park-ljubljana-d-o-o-
91. Statista, M. (2021a, January 6). *Projected investment return on biopharmaceutical R&D 2010-2018*. Retrieved 16 May, 2021 from https://www.statista.com/statistics/886479/projected-randd-investment-returns-us-biopharma/
92. Statista, M. (2021b, February 2). *Top biotech companies by revenue 2018.* Retrieved 16 May, 2021 from https://www-statista-com.nukweb.nuk.uni-lj.si/statistics/262693/top-biotech-companies-based-on-revenue/
93. Statista. (2010, April 23). *Biotech companies: Size by number of employees Germany 2005-2009.* Retrieved 16 May, 2021 from https://www-statista-com.nukweb.nuk.uni-lj.si/statistics/580116/employees-size-biotechnology-companies-germany/
94. Statista. (2020a, July 1). *Cost to bring biopharmaceutical assets to market 2010-2019. Statista*. Retrieved 16 May, 2021 from https://www.statista.com/statistics/825698/cost-to-bring-large-cap-biopharmaceutical-assets-to-market/

95. Statista. (2020b). *Pharmaceutical market size by chemical drugs and biologics worldwide 2014-2023.* Retrieved 16 May, 2021 from https://www-statista-com.nukweb.nuk.uni-lj.si/statistics/1085563/revenue-chemical-drugs-and-biologics-global-pharmaceuticals/
96. Statista. (2020c, June 24). *Medicines and prescriptions: UK household expenditure 2019 by age.* Retrieved 16 May, 2021 from https://www-statista-com.nukweb.nuk.uni-lj.si/statistics/822499/medicines-prescriptions-weekly-household-expenditure-in-the-united-kingdom-uk-by-age/
97. Statista. (n.d.). *Venture capital funds raised in Europe 2019.* Retrieved 16 May, 2021 from https://www.statista.com/statistics/433418/total-funds-venture-capital-in-selected-european-countries/
98. Swann, J. (2019). *The Story Behind the Orphan Drug Act*. Retrieved 16 May, 2021 from https://www.fda.gov/industry/orphan-products-development-events/story-behind-orphan-drug-act
99. Swiss Biotech Association. (2019). *Swiss Biotech Report 2019*. Retrieved 16 May, 2021 from https://www.swissbiotech.org/wp-content/uploads/2019/05/Swiss-biotech-report-2019-1.pdf
100. Tansey, E. M. & Catterall, P. P. (1994). Monoclonal antibodies: A witness seminar in contemporary medical history. *Medical History, 38*(3), 322–327.
101. Thong, R. (2015). *Managing the Strategic Evolution of a Bioscience Platform Company*. Retrieved 16 May, 2021 from https://scitechstrategy.files.wordpress.com/2020/05/0c1be-platformco-paper-jan-15.pdf
102. TikhePharma d.o.o. (2020). *Technology and Knowledge Transfer: Promoting Innovation Capacity and Competitiveness Based on a New Cross-Border BioTech Station*. Retrieved 16 May, 2021 from https://www.ita-slo.eu/sites/default/files/progetti/BioTech%20station%20action%20plan_1.pdf
103. Timmerman, L. (2016, March 22). No More Peanuts: Merck Pays $20M For Harvard Cancer Drug. *Forbes*. Retrieved 16 May, 2021 from https://www.forbes.com/sites/luketimmerman/2016/03/22/no-more-peanuts-merck-pays-20m-for-harvard-cancer-drug/
104. Timmis, K., de Lorenzo, V., Verstraete, W., Ramos, J. L., Danchin, A., Brüssow, H., Singh, B. K. & Timmis, J. K. (2017). The contribution of microbial biotechnology to economic growth and employment creation. *Microbial Biotechnology, 10*(5), 1137–1144.
105. Tscherning, T., Frank, L. & Schönharting, F. (1999). Financing biotech ventures in Scandinavia. *Nature Biotechnology, 17*(3), 33–34.
106. USA Angel Investment Network. (2009). *Financial opportunities for early stage biotech companies*. Retrieved 16 May, 2021 from https://www.angelinvestmentnetwork.us/press-view/financial-opportunities-for-early-stage-biotech-companies/12

107. Ustundag, A., Uğurlum, S. & Kilinc, S. M. (2011). Evaluating the performance of technology transfer offices. *Journal of Enterprise Information Management*, *24*(4), 322–337.
108. Verma, A. S., Agrahari, S., Rastogi, S. & Singh, A. (2011). Biotechnology in the realm of history. *Journal of Pharmacy and Bioallied Sciences*, *3*(3), 321.
109. Wikipedia (2020). *Diamond v. Chakrabarty.* Retrieved on 23 June 2021 from https://en.wikipedia.org/w/index.php?title=Diamond_v._Chakrabarty&oldid=985323055
110. Wu, J. J. & Ezell, S. J. (2016). *How National Policies Impact Global Biopharma Innovation: A Worldwide Ranking*. Retrieved 16 May, 2021 from from https://itif.org/publications/2016/04/07/how-national-policies-impact-global-biopharma-innovation-worldwide-ranking
111. Xavier, S. R., Kelley, D., Kew, J. & Mike, H. (2011). *GEM Global Entrepreneurship Monitor*. Retrieved 16 May, 2021 from from https://www.gemconsortium.org/report
112. Združenje Manager. (2019, March 12). *Finalisti za priznanje Mladi manager 2019 so Borut Čeh, Lucija Sajevec in Marko Bitenc.* Retrieved 25 June, 2021 from https://www.zdruzenje-manager.si/sl/novice/finalisti-za-priznanje-mladi-manager-2019-so-borut-ceh-lucija-sajevec-in-marko-bitenc

APPENDICES

Appendix 1: Povzetek (Summary in Slovene language)

Magistrska naloga obravnava sektor medicinske biotehnologije. Biotehnologija je tehnologija, ki uporablja biološke sisteme, žive organizme ali njihove gradnike in ima cilj razviti nove produkte. Biotehnologija ni nova tehnologija. Med najstarejše oblike biotehnologije sodita peka kruha in varjenje piva. Moderna biotehnologija pa ima začetke v obdobju po drugi svetovni vojni. Takrat je bil predstavljen model dvojne vijačnice (DNK), kateremu so sledila še druga znanstvena odkritja na področju genetike.

Glede na uporabo, danes poznamo pet glavnih vej biotehnologije:

- živalska biotehnologija;
- medicinska biotehnologija;
- industrijska biotehnologija;
- okolijska biotehnologija;
- rastlinska biotehnologija.

V magistrskem delu je podrobneje predstavljena medicinska biotehnologija. Napovedujejo, da bo v prihajajočem obdobju prav medicinska biotehnologija najbolj prispevala k izboljšanju kvalitete življenja in boljšemu zdravju. Glavni produkti medicinske biotehnologije so: antibiotiki, cepiva, monoklonksa protitelesa, rekombinantni proteini, regenerativna medicina in diagnostika. Rojstvo biotehnološke industrije je v obdobju okrog leta 1970, v ZDA. Takrat so manjša podjetja razvijala znanje s področja genskega inženiringa in prišla do odkritij, ki so vodila do industrijskih aplikacij. Še danes, so medicinsko-biotehnološka podjetja pogosto majhna, raziskovalna podjetja, ki ponujajo specifične storitve, ki vodijo do razvoja novih farmacevtskih produktov. Farmacevtski trg vztrajno raste, industrija pa se kljub temo spopada s številnimi izzivi: zapadlost mnogih patentov, regulatorni izzivi in naraščajoči pritiski za znižanje cen. Biološka zdravila so sprva nudila upanje za cenejši in hitrejši razvoj. Sčasoma pa je regulativa postajala vse strožja kar je pripeljalo do vse višjih stroškov razvoja produktov.

Ker je farmacevtska industrija izjemno kapitalno intenzivna, mlada, majhna podjetja ne zmorejo sama dokončati razvoja produkta. Pogosto sodelujejo z večjimi farmacevtskimi podjetji. Biotehnološka industrija v ZDA je posledično celotna mreža deležnikov, ki sodelujejo med seboj in zajema univerze, privatne in javne raziskovalne centre, mala biotehnološka podjetja in velika konsolidirana podjetja. Posledično so vsi ti deležniki pogosto tudi locirani blizu drug drugega. K nastankom biotehnoloških skupkov pa prispeva tudi dejstvo, da je ustanovitelj pogosto znanstvenik, znanstveni talent pa se pogosto nahaja v geografski bližini. Biotehnološka podjetja so pogosto manjša ali srednje-velika podjetja, ta pa so glavna gonilna sila pri razvoju ekonomije in pomembna tudi za samo zdravje ekonomije. Biotehnološka industrija, do neke mere, ponazarja koncept kreativne destrukcije, ki opisuje kako nove iznajdbe zamenjajo stare velikane v določeni industriji. Specifično za to industrijo pa je, da uspešni inovatorji ne pahnejo starih velikanov v pozabo, ampak se

pogosto zgodi prevzem manjšega podjetja. V magistrskem delu sem raziskala tudi različne dejavnike, ki vplivajo na uspeh zagonskih in malih medicinsko-biotehnoloških podjetij. Med faktorji ki na splošno vplivajo na uspeh podjetij so: vladne iniciative, infrastruktura, birokratične ovire, dostopnost kapitala, tehnologija in informacije, politične okoliščine, pogostost stavk itd.

Eden izmed glavnih ciljev magistrskega dela je pregled in analiza medicinsko-biotehnološke industrije v Sloveniji. Pri pregledu literature sem ugotovila, da imamo v Sloveniji veliko znanstvenega talenta na tem področju, ki pa ga ne znamo dovolj dobro izkoristiti. Na splošno je izbira za podjetniško pot v Sloveniji manj pogosta kot EU povprečje. Podjetniki se morajo spopadati z birokracijo in nepredvidljivo zakonodajo, hkrati pa je izredno težko dobiti tvegani kapital. Strokovnjaki verjamejo, da Slovenska kultura ne spodbuja podjetniških vrednot kot na primer: tveganje, kreativnost, inovativnost in individualna odgovornost. Sodelovanje med podjetji in univerzami je včasih oteženo zaradi rigidne zakonodaje; npr. v Sloveniji je zaradi zakonodaje neprijazno ustanoviti spin-off. Stanje pa se izboljšuje. V Sloveniji imamo kar nekaj javnih iniciativ, ki spodbujajo podjetništvo: SPIRIT, Slovenski Podjetniški Sklad, tehnološke parke, Erasmus program za mlade podjetnike, SID banka, EUREKA... K napredku medicinske biotehnologije v Sloveniji pa bo v prihodnosti prispeval tudi projekt »Biotehnološko stičišče Nacionalnega inštituta za biologijo (BTS-NIB)«.

Empirična raziskava je vključevala štiri poglobljene intervjuje s predstavniki iz podjetij v panogi medicinske biotehnologije. Ugotovljeno je bilo, da ima ta sektor v Sloveniji velik potencial. Slovenija ima močno biotehnološko tradicijo in obilico izobraženega kadra na področju biotehnologije in farmacije. Vendar, določeni dejavniki zadržujejo vzpon biotehnoloških podjetnikov. Delo podrobneje predstavi notranje in zunanje dejavnike, ki vplivajo na uspešnost medicinsko-biotehnoloških podjetij s poudarkom na Slovenskih podjetjih. Dejavniki so ponazorjeni tudi preko celovitega modela. Na podlagi rezultatov raziskave so predlagana priporočila, ki bi v prihodnosti lahko pripomogle k nadaljnjemu razvoju medicinske biotehnologije v Sloveniji.

Empirična raziskava je temeljila na v naprej definiranem namenu in ciljih magistrskega dela, na podlagi katerih je avtor prišel do sledečih ključnih ugotovitev:

1. Področje medicinske biotehnologije je v Sloveniji bolj razvito kot v vzhodni in južni Evropi in manj razvito kot v severni in zahodni Evropi.
2. V začetni fazi so podjetju na voljo predvsem javna finančna sredstva. Slovenija in EU nudita podjetjem javna finančna sredstva in ta omogočajo podjetjem, da se osredotočijo na raziskave, brez pritiskov in kratkih časovnic, ki spremljajo privatna finančna sredstva. Izboljšati pa bi morali javne razpise. Avtorji razpisov bi morali prihajati iz stroke in dobro poznati panogo ter se zavedati katere zahteve malo biotehnološko podjetje realno lahko doseže.
3. V kasnejši fazi, ko so finančne potrebe podjetja večje, je finančni vir za podjetja tudi privatni kapital. Privatni kapital je v Sloveniji šibak. Slovenija bi morala zagotoviti

stabilno zakonodajo, da bi postala privlačnejša za privatni kapital.

4. Birokratski zakoni podjetjem otežujejo osredotočenost na ključne aktivnosti. Podjetja morajo zaposliti dodaten izobražen kader, ki se spopada z zapleteno zakonodajo, kar je za mala podjetja hudo finančno breme. Birokratska zakonodaja akademikom preprečuje ustanavljanje spin-off podjetij in na splošno odvrača privatni kapital. Rešitev tega problema je lahko dvoplastna. Slovenija mora eliminirati obremenjujočo zakonodajo in ustanoviti centre, stičišča ali tehnološke parke za biotehnološka podjetja. Tu bi podjetniki, ki so navadno znanstveniki lahko koristili podporne službe za administracijo, pripravo pogodb, manevriranje s patenti in splošni uredbi o varstvu podatkov (SUVP).
5. Med dejavniki uspešnosti so bili identificirani tudi številni notranji dejavniki, ki podjetjem omogočajo hitrejši razvoj in rast. Ključno je, da podjetje vlaga v svoj kader, inovira in nudi produkte ali storitve visoke kakovosti. V panogi medicinske biotehnologije, je zelo pomembna tudi povezava z univerzami in drugimi podjetji. Večkrat je bila kot izjemno pomembna izpostavljena tudi ciljna usmerjenost podjetij. Dostop do odvetnikov in računovodjih po ugodnih cenah, bi podjetnikom dal več časa in energije za ključne aktivnosti.
6. Medicinsko-biotehnološko podjetje v Sloveniji mora imeti široko in interdisciplinarno znanje. Podjetniki iz te panoge imajo pogosto tudi izkušnje v tujini. Slovenija bi morala omogočiti programe za pridobivanje interdisciplinarnega znanja in delo v tujini, namenjene študentom in bodočim podjetnikom. S tem Slovenskim medicinsko-biotehnološkim podjetjem zagotovimo kvaliteten kader in seveda nove biotehnološke podjetnike.

Z raziskavo sta bili odgovorjeni obe raziskovalni vprašanji. Obe vprašanji imata pritrdilen odgovor. V povezavi s prvim vprašanjem je bilo ugotovljeno, da ima panoga medicinske biotehnologije v Sloveniji velik potencial, a trenutno določeni dejavniki zavirajo njen vzpon. V povezavi z drugim vprašanjem pa je bilo ugotovljeno, da Slovenija s premišljenimi iniciativami lahko izboljša okolje za podjetja v tej panogi.

Za konec je pomembno izpostaviti, da je bila raziskava osnovana na poglobljenih intervjujih, ki sicer ponujajo dober prvi vpogled v raziskovalno področje, vendar bi za določitev natančnejšega stanja morali izvesti mnogo širšo raziskavo, ki bi temeljila na natančnejšem kvalitativnem in kvantitativnem vpogledu.

Appendix 2: Interview questions

PART 1:

1. In your opinion, what are some key characteristics of Slovenian Biotechnology sector? - Which activities inside this sector are developed the most in Slovenia and why?
2. Who are the key players on Slovenian medical biotech market and why?
3. Which key external factors influenced the development of Medical biotechnology in the past?
4. Today, what are the key positive factors that influence medical biotechnology?
5. Today, what are the key negative factors that influence medical biotechnology?
6. How would you rate the institutional and legal environment in Slovenia, from the perspective of entrepreneurship in general and the medical biotechnology sector?

PART 2:

7. Next questions are asking about a typical way of building and running a company in this sector. You can answer from your own experiences or from your knowledge of biotechnology sector in general.

7.1 What is a typical way of starting a medical biotech company in Slovenia?

7.2. In your experiences what are some key internal and external elements for success of biotechnology startup?

7.2. In your experiences what are some key internal and external elements for success of biotechnology startup? Can you discuss them in a detailed manner?

7.3 In which markets do most Slovenian medical biotechnology companies operate and why?

7.4 What is the role of supportive policies for entrepreneurs when building a medical biotechnology company?

7.5 Who are the most important internal and external stakeholders for the company?

7.6 How important are innovation and human capital from the perspective of development and growth of the medical biotech company?

7.5 Who are the most important internal and external stakeholders for the company?

7.6. How important are innovation and human capital from the perspective of development and growth of the medical biotech company?