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FACULTY OF ENGINEERING

Opportunity framing

Critical junctures and tough choices in the MedTech industry in Sweden

Master thesis

Faculty of Engineering LTH
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MIOM05 Degree Project in Production Management

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Acknowledgements

This master thesis makes out the final assignment of the author's 300 ECTS Master of Science degree in Engineering, Industrial Engineering and Management at Lund University, Faculty of Engineering LTH. This research project constitutes 30 ECTS and has been conducted at the Department of Industrial Management and Logistics, division of Production Management.

Firstly, I would like to thank my supervisor Carl-Johan Asplund for all his support, interesting discussions, relevant input and guidance throughout this master thesis. Asplund has been a source of inspiration for me and during the making of this master thesis, I have experienced his enthusiasm for the field and learnt a lot along the way.

Secondly, I would like to thank my external supervisor Jonas Åkeson for guiding me within the medical field. Without his medical knowledge and academic experience, this master thesis would have been much harder.

Thirdly, I would like to thank the people I had the fortunate to interview and who made this master thesis possible: Paan Hermansson, Michael Åkesson, the founder of MedTech AB, Simon Jegou, Christine Widstrand and Malin Sjöö. They have provided a great insight into both the start-up world and the MedTech industry and have shared both their time and knowledge generously.

Axel Åkeson
Lund, June 2022

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Abstract

Title

Opportunity framing – Critical junctures and tough choices in the MedTech industry in Sweden.

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Background

In today's competitive market, renewal through innovation is of utmost importance to stay relevant. Creating a start-up is associated with great uncertainty and doing so within the heavily regulated MedTech industry, puts even higher demands on a start-up.

Purpose

The purpose of this master thesis is to identify issues and challenges facing MedTech start-ups in the different phases of business-development, and formulate possible approaches to handle those obstacles.

Methodology

In this master thesis, a combination of explanatory and exploratory methods has been applied. An abductive research approach was chosen. The research data collection method is qualitative, and appropriate measures to mitigate the risk of bias have been taken. The research strategy was a multi-case study including three start-ups and three supporting organisations.

Limitations

This master thesis focuses on USOs and supporting organisations within the MedTech industry in Sweden, while international research and literature has be reviewed. A deep analysis of each company's innovations and competitors is outside of the scope of this master thesis, since it would require extensive medical knowledge beyond a civil engineering degree.

Conclusions

Creating a start-up in the heavily regulated MedTech industry puts high demands on founders and team concerning commitment and competence fields. Founders and team should have a solid and relevant medical background to be able to develop a competitive product and create credibility towards investors. If given the opportunity, they should at an early-stage approach one or several supporting organisations, whose advice and experience are of high value. Securing a strong IP protection and having a long-term perspective and commitment are vital prerequisites for launching a successful MedTech company.

Keywords

Critical junctures, Financing, Innovation, MedTech, Start-up, Technology strategies, University spinout.

Tables and figures

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Abbreviations and glossary

Abbreviations

AB	Aktiebolag (eng: Ltd (Limited Company))
ASU	Academic Spinout/spinoff company
BAE	Business Angels Europe
BioTech	Biology Technology
CE	Conformité Europëenne (eng: European Conformity)
COGS	Cost Of Goods Sold
DeepTech	Deep Technology
EBAN	European Trade Association for Business Angels, Seed Funds and Early Stage Market Players
EC	European Commission
EEA	European Economic Area
EPC	European Patent Office
EU	European Union
FDA	Food and Drug Administration
IP	Intellectual Property
ISO	International Organization for Standardization
LU	Lund University
LUAB	Lunds Universitets Utvecklingsbolag AB (eng: Lund University Development Ltd)
LUIS	Lund University Innovation System
MAS	Malmö Allmänna Sjukhus (eng: Malmö University Hospital)
MD	Medical Device
MDD	Medical Device Directive

MDR	Medical Devices Regulation
MedTech	Medical Technology
NABC	Need Approach Benefits Competition
NB	Notified Body
NTBF	New Technology-Based Firm
PCT	Patent Cooperation Treaty
PRV	Patent- och RegistreringsVerket (eng: Swedish Intellectual Property Office)
RD	Research and Development
TTO	Technology Transfer Office
UDI	Unique Device Identification
UN	United Nations
USO	University SpinOut/spinoff company
VC	Venture Capital
VFS	Verifiering För Samverkan (eng: Verification for cooperation)
VFT	Verifiering För Tillväxt (eng: Verification for growth)
WIPO	World Intellectual Property Organisation

Glossary

Business angel: A person with experience in entrepreneurship from their previous companies and who invests their gained capital and knowledge in a new company, usually in an early stage, compared to other investor types.

Hard money: Financial means where the investor receives a part of equity in the company, proportionate to the size of their investment. Examples of investors in this category can be business angels, VC (venture capital) companies, holding companies or private investors.

MedTech: Stands for Medical technology and is an umbrella concept for devices and technology used in modern medicine. Examples of this can be syringes, oxygen masks, joint implants and heart vaults.

Project: An invention or a business idea before the company has been created.

Soft money: Financial means applied for with no demands for equity or fee in return, usually from funds, development projects or organisations. Examples of this can be grants, subsidies and contributions.

Supporting organisation: An organisation who assists start-ups at different phases of their development through advice, investments and guidance. Examples of these organisations are TTO (Technical Transfer Office), University holding companies and incubators.

USO (University spinout): A company where the intellectual property has been developed either at a university or through an inventor with connections to a university.

Venture capital: Financing of start-ups or small companies believed to have long-term growth potential. Venture capital usually comes from investment banks, well-off investors or other financial institutions.

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Table of contents

1. Introduction

In this chapter, a description of the background of this master thesis is presented, along with its problem formulation, purpose, focus areas, research questions and limitations. An outline of the chapters along with shorter descriptions is found at the end.

1.1. Background

1.1.1. Innovation

Innovation can be defined as when an invention or idea turns into a service or good and thereby creates new value for the customer. An innovation often refers to new technology, but it doesn't actually have to involve any technology or a new invention. Both innovation and invention are words used to describe a new product, but there is a crucial difference between the two. An invention is not in itself marketable or useful on its own. An innovation uses an invention in combination with satisfying a customer or market need and thereby creates value. To exemplify: A solar panel is an invention which doesn't bring value on its own, but when applied on roofs of buildings it creates something the market values.

To be competitive, a patented innovation is preferred and a criterion for patentability is that an idea is innovative. This puts higher demands on an inventor wanting to turn entrepreneur, who then must find an appropriate market for their product, create a solid business case and handle critical junctures (see chapter 4.1.2). Coming from the academia, the specific product

knowledge is high but abilities in other areas needed for a successful company, such as business, economy, marketing and company structure are often limited. These knowledge areas, along with contact networks, need to be completed along the journey.

1.1.2. MedTech

The MedTech (medical technology) industry is a broad collective name for any technology used for saving lives or helping individuals suffering from a wide range of conditions. Taking many forms, MedTech is used for diagnosing, monitoring and treating medical conditions or diseases. Medical technology can be everyday objects which everybody is familiar with, such as latex gloves, plasters and syringes. It can also be wheelchairs, surgical thread, painkillers, pregnancy tests and blood pressure measurement equipment. In a hospital, or similar institution, more from the high end of the scale will be found, ranging from heart monitoring, defibrillators, life-supporting machines and MRI machines to implantable devices like pacemakers and heart vaults and replacement for joints in knees and hips. The MedTech industry in heavily regulated, which requires specific knowledge and following certain frameworks according to the EU regulations in MDR (Medical Device Regulations)

1.2. Problem formulation

There are certainly the common challenges which all start-ups must face, especially if there is a lack of previous entrepreneurial experience. Creating a company with e.g., the right business proposal, target group, securing proper IP protection and ensuring sufficient financing are fields which need to be addressed. When a start-up is going into an industry as heavily regulated as

the MedTech industry, there are several other aspects to consider as well. Understanding the regulations and the demands this puts on the company and its processes are challenging. Many start-ups unfortunately fail, according to the research presented in chapter 3. To ensure more regional growth and higher success rate, there are certain supporting organisations who assist start-ups during different stages of their development.

To avoid confusion concerning the chosen title for this master thesis: "Opportunity framing" refers to how a start-up should frame their product and business proposal and does not refer to the 2nd development phase "Opportunity framing" presented by Vohora et al (2004) in chapter 4.1.1.2.

1.3. Purpose and research questions

The purpose of this master thesis is to identify issues and challenges facing MedTech start-ups in the different phases of business-development, and formulate possible approaches to handle those obstacles. This master thesis is answering the following MRQ (main research question):

***MRQ**: What are the key success factors for a new innovation start-up company within the MedTech business?*

To be able to answer the MRQ, it has to be broken down into the following set of sub research questions which were answered:

***RQ1:** Which factors should a MedTech innovation company consider in order to increase their chances of success?*

***RQ2**: What role do supporting organisations play when it comes to the development of MedTech innovation companies?*

***RQ3**: Which phases of a company's development are critical junctures and how have these been handled in a successful or unsuccessful way?*

1.4. Focus and limitations

This master thesis focuses on USOs and supporting organisations within the MedTech industry in Sweden, while international research and literature was reviewed. A deep analysis of each company's innovations and competitors is outside of the scope of this master thesis, since it would require extensive medical knowledge beyond a civil engineering degree.

1.5. Conflict of interest

To clarify from the start of this master thesis: Jonas Åkeson, one of the founders of Stairway Medical AB, is my father and this fact could therefore create a risk of a conflict of interest. Stairway Medical AB has worked as an inspiration for this paper but has not been the focus of it. This master thesis was conducted in an objective and academic manner, thus mitigating this risk and ensuring scientific validity and reliability of the results found and conclusions made.

1.6 Master thesis outline

The chapters of this master thesis are outlined below, with a short description of the content of each chapter.

Chapter 1 Introduction

In the first chapter, a short background for this master thesis is presented, along with the problem formulation, purpose, research question and focus and delimitations.

Chapter 2 Methodology

In the second chapter, the methodology used in this master thesis is presented. The methodological frameworks used are presented and the design, data collection methods and analysis are explained.

Chapter 3 Theoretical background

In this chapter, the necessary background for the master thesis is presented. To be able to understand what a start-up is and how it develops is crucial to further understand its development. MedTech is a regulated industry and the essential parts of regulations, patent processes and financial options need to be explained.

Chapter 4 Theoretical framework

After having built a theoretical background of the MedTech business, this chapter introduces certain models, theories and frameworks that were used to define and evaluate the interviewed companies' processes.

Chapter 5 Results

In this chapter, the result of the six interviews are reported. Three interviews were conducted with MedTech start-ups and three with supporting organisations, who assist start-ups at different stages of development. Some sections have been partly anonymised, to ensure that sensitive information and opinions cannot be tracked back to a certain start-up.

Chapter 6 Discussion

In this chapter, results of the interviews are combined with the theoretical background and the theoretical framework and analysed. The first subchapter presents each company's connection to the definitions and their usage of theories. The second subchapter presents three big challenge area the companies have had to face. The third subchapter describes the companies' placement into Vohora el al's model (2004) and connects them to the start-up methodologies. In the final subchapter, critical reflections on the chosen research approach and methodology are discussed.

Chapter 7 Conclusion

This chapter reports conclusions of the master thesis, and the main research question and the sub-research questions are answered. At the end of the chapter, contributions of the master thesis and suggestions for future research areas are presented.

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2. Methodology

In this chapter, this master thesis's research approach and chosen methods are presented. Chosen methods are explained to clarify their relevance and usefulness and the chapter ends with an explanation of the structure of the study and how it has been executed. The evaluation of this will be presented in Chapter 6.

2.1. Research methods

Before conducting a research project, it is of importance to have determined a methodology and strategy concerning how the research should be carried out. The choice of research method is based on how the research will be conducted. Höst et al (2006) argues that there are four different main research methodologies to characterize any research:

1. **Problem solving**: When coming across a clearly defined problem that needs to be analysed, the problem-solving methodology can be used.
2. **Explanatory**: This method's goal is to find connections and links between variables, explaining why a phenomenon appears or occurs.
3. **Exploratory**: In an area where there is little to no currently existing knowledge, this research method is preferably used. It answers the question "What is happening" and seeks to give new insights in a less defined subject, where the connection between cause and effect is unclear.

4. **Descriptive**: This type of study can be performed in an area where there is existing knowledge and research, with the goal of deepening the analysis concerning a certain problem or knowledge.

When conducting research, an important aspect is to perform the study or work ethically. Instead of approaching the research questions with preconceived opinions, the results have to lead to the conclusions made. Another important aspect is to not only rewrite existing knowledge but as well bring in some novelty into the field of research, since research is not only to gather information but also to explore, describe and explain something or solve a problem in a, if possible, new way. Simple research questions that guide the researcher to visualize a goal and construct the path to get there, usually are the best ones. The purpose of the study greatly determines and influences what kind of research should be performed. (Badke, 2017)

To answer the research questions, both exploratory and explanatory approaches have been applied. The exploratory approach has been used since there is little current literature answering this question and new information from different fields must be put together. The explanatory approach has been used to collect information and thereafter explain its connection to practice.

2.2. Research approach

When conducting research on an observed phenomenon, there are two main ways to approach it: an inductive approach, a deductive approach and an abductive approach.

The inductive approach starts with some type of observation or data and from there determines what logical conclusions can be drawn from that specific

data. Hypotheses that could explain the observations or the data are made and tested, and theories confirming the hypotheses are formed. (Young et al, 2020)

The deductive approach is just about the opposite of the inductive approach and starts with a predetermined hypothesis which is broken down into smaller and more specific hypotheses, which are tested. The observations or data collected are then used either to confirm or reject the hypothesis. Based on this, the original theory can either be approved or disapproved. (Young et al, 2020)

The abductive approach concerns an investigation of the relationship between everyday concepts and the language. An abductive reasoning can be seen as a combination of an inductive and a deductive approach and is useful when the purpose is to discover a connection between relationships and variables, which has not previously been described. (Dubois & Gadde, 2002)

When analysing complex phenomena comprising several factors that could affect them, the abductive approach can be beneficial. In this master thesis, the abductive approach has been applied, since the research area is complex, and many factors can have both direct and indirect effects on the companies.

On difference between universities in Sweden and internationally, is the fact that in Sweden, the researcher owns their research themselves, while the universities internationally own the researcher's discoveries. Due to the uniqueness of the MedTech industry, comparison to other specific high-tech industry research was not conducted. The specific field addressed in this master thesis, concerning start-ups within the MedTech industry in Sweden, in Lund, has not previously been addressed in the research reviewed.

2.3. Research data collection

When conducting this research, there are two main types of data that can be collected: quantitative and qualitative. Quantitative data is usually simpler to present as numbers, graphs or charts, due to its numerical information. On the other hand, qualitative data takes the form of words, language and concepts. Qualitative data could be how an entrepreneur describes his or her initial strategy when starting a company. This type of information is tough to quantify and demands a different approach when analysed.

2.3.1. Quantitative data

Quantitative data can be categorized into several types, such as ratio, interval, ordinal and nominal. When working with quantitative data, it can either be collected and analysed in its original form or derived from other sources of data and later analysed using mathematical statistics, models and formulas. An advantage of using qualitative data is that the analysis will give the same result, regardless of who performs it.

2.3.2. Qualitative data

Qualitative data collection is often harder to analyse compared with quantitative data but offers more flexibility. There are two activities involved concerning analysing qualitative data, referred to as the practicalities of qualitative data, according to Gibbs (2008). The first one being the creation of awareness of what kind of data could be collected and studied and how to both describe and explain this data. The second one being what kind of data should be analysed and through what practical activities.

Due to its nature, qualitative data is easier to draw bias conclusions from, and it is therefore necessary to take measures against them. Four common biases need to be considered, according to Moss (2016):

1. **Confirmatory**: Actively looking for research and information supporting the author's theories or beliefs.
2. **Holistic**: Interpreting a deeper connection between phenomena than there is and drawing inaccurate conclusions from this.
3. **Representative**: Misunderstanding the effect phenomena have on each other, as a result of not analysing how they occur by themselves.
4. **Elite**: Focusing too much on conclusions by well renowned researchers and in recognized scientific journals, and disregarding lesser-known literature and publications.

In this master thesis, a qualitative approach has been deemed the better choice, since the results are based on conducted interviews with subjective opinions and thoughts, which requires the author to analyse and interpret the information. There have, though, been a few elements of quantitative data in the theoretical background regarding statistics surrounding e.g., the success rate for start-ups and the financing options available.

2.3.3. Literature review

A literature review should serve the purpose of putting the research into context and find similarities between different research (Denscombe, 2017). To ensure good practice, Denscombe (2017) points to the importance of using guidelines to approach the gathered information systematically and thoroughly. Höst et al (2006) declare that a literature review should be an iterative

process, where the researcher can perform a more focused search when the nature of the research becomes clearer.

In this master thesis, a qualitative literature review was used to better understand the knowledge base and system that surrounds the MedTech industry, from foremost a Swedish perspective. The review covers innovation and start-ups, which is an important base to clarify before moving on further. The MedTech industry is heavily regulated, and to be able to analyse the companies further down the process, an intensive mapping out of the regulatory process had to be made. The financial options for a start-up are needed to understand as well, along with what kind of support there is to be found in surrounding organisations. Understanding the literature has improved the quality of the case study interviews and created possibilities to go deeper into certain topics. To be able to analyse how theory meets practice, there is a section covering different strategies and models for start-ups in chapter 4. The literature review has mainly been based on academic papers and research, found in scientific databases and on the Internet, along with published books and articles.

2.4. Research strategy

There are five major research strategies: Experiment, Survey, Archival analysis, History and Case study (Yin, 2014), reported in Table 1.

The appropriate strategy depends on what form of research questions one has, and if there is requirement of control of behavioural events, or if there is a focus on contemporary events.

Table 1: Research strategies (Yin, 2014).

Strategy	***Form of research question***	***Requires control over behavioural events***	***Focus on contemporary events***
Experiment	How, why	Yes	Yes
Survey	Who, what, where, how many, how much	No	Yes
Archival analysis	Who, what, where, how many, how much	No	Yes/No
History	How, why	No	No
Case study	How, why	No	Yes

In this master thesis, a case study strategy has been used on multiple start-ups in order to map out their development from idea towards a profitable company. To further understand the environment of these companies, surrounding and supporting organisations have also been interviewed. This is thought to add an outside perspective and complete the company interviews, resulting in a more complete analysis and conclusion.

2.5. Case studies

To be able to answer the main purpose of this master thesis, interviewing companies, who had developed a medical technology product and been active within the MedTech start-up industry, but still were not fully market ready seemed to be the best approach. The companies were chosen based on the following criteria:

- **The company has been created and received funding at multiple occasions** (having received funding at several point proves that there is interest among investors, who have evaluated and approved the company, their business case and their product)
- **The company has an innovative and patentable MedTech product** (without a strong IP-protection, competitors could copy or steal the product idea and the start-up would lose their competitive edge)
- **The company has been active for at least 4 years** (after 4 years, the company is deemed to have passed the initial struggles and have had a chance to develop)
- **The company has been started in collaboration with Lund University** (companies started without connection to Lund University would not be able to collaborate with the chosen supporting organisations focused on in this master thesis and start-ups without connection to any university would not be classified as a USO)
- **The company has not yet reached the market** (companies who have reached the market were considered to have left the start-up mindset and thereby their experiences from that time)
- Several companies were contacted, out of which three were selected (Suturion, MedVasc and MedTech AB). Three supporting organisations assisting start-ups and helping them to develop were identified. These supporting organisations (SmiLe Incubator, LU Innovation and LU Holding) were identified, contacted and interviewed. All interviews were semi-structured in their format to leave room for interviewees to elaborate their answers, with minor alteration depending on a company's or organisation's specific product focus (Höst et al, 2006). The aim was to perform all interviews face to face, but due to

sickness and travel arrangements, some interviews were conducted through video call via the video call application Zoom (see Table 2)

To ensure validity and reliability of the interview material, each interview has gone through the following three steps, before being presented among the results in chapter 5:

- Recorded and later transcribed in great detail, to provide both auditorial and written documentation of the interview
- Structured in Swedish and sent to each interviewed person for first validation, to ensure everything was perceived in the correct way
- Rewritten in English and sent to each interviewed person for second validation

Table 2: Interviews performed in this master thesis.

Name of company or organisation	***Product or role of organisation***	***Person interviewed***	***Date and format***
Suturion	SUTURE-TOOL	Paan Hermansson, CEO	**Time**: 09.00 – 11.00, 30th March, 2022. **Place**: Interview in person at the Suturion office, Lund
MedVasc	Solutio	Michael Åkesson, founder & CEO	**Time**: 16.30 – 17.30, 30th March, 2022 and 16.30 – 17.45, 5th April, 2022. **Place**: Interview via Zoom
MedTech AB (anonymised)	Product 1 & Product 2	Founder & CEO	**Time**: 09.00 – 11.30, 1st April, 2022. **Place**: Interview via Zoom
SmiLe Incubator	Incubator, Lund	Malin Sjöö, Business developer & Coach	**Time**: 12.00 – 13.30, 4th April, 2022. **Place**: Interview in person at the SmiLe Incubator office, Lund

LU Innovation	TTO, LU	Simon Jegou, former Head of Life Science department	**Time**: 12.00 – 12.15, 4th April, 2022 & 12.00 – 12.45, 29th April, 2022. **Place**: Interview via Zoom
LU Holding	Investor and guidance, LU	Christine Widstrand, CEO	**Time**: 13.00 – 14.00, 12th April, 2022. **Place**: Interview in person at the LU Holding office, Lund

2.6. Summary

In this master thesis, a combination of explanatory and exploratory methods was applied. An abductive research approach was chosen. The research data collection method was mainly qualitative, and appropriate measures to mitigate the risk of bias were taken. The research strategy was a multi-case study including three start-ups and three supporting organisations. By combining the experience from individual companies with the collected experience from the supporting organisations working with hundreds of companies and connecting it to the available theory in the field, a deeper analysis can be conducted (see Figure 1).

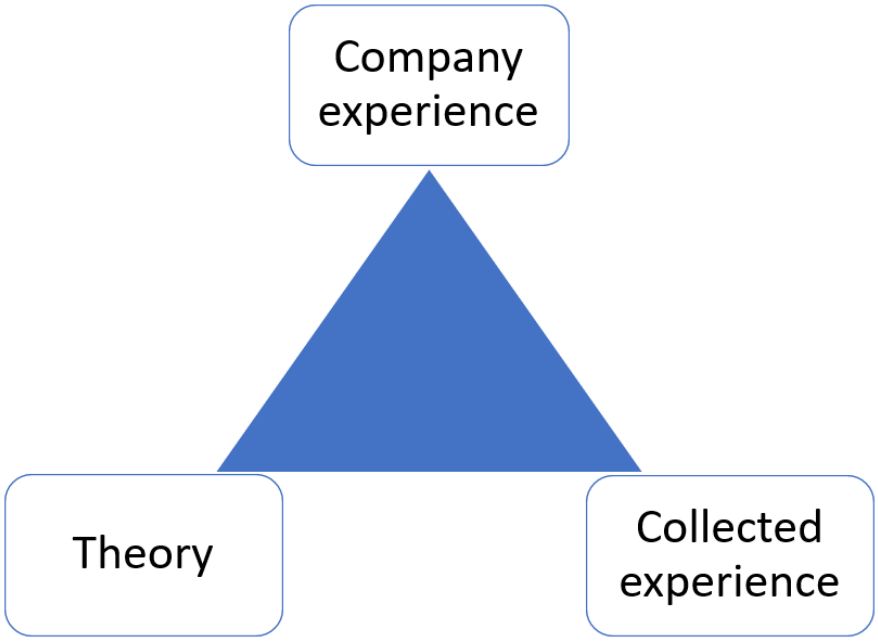

Figure 1: The combination of information sources in this master thesis

3. Theoretical background

In this chapter, the theoretical background needed for the understanding of the field is presented. An extensive literature review covering innovation, start-ups, the MedTech industry, different sources of funding and the supporting organisations was conducted.

3.1 Innovation and invention

The word innovation comes from the Latin word "*innovare*", translating to: to renew or change (Kalbach, 2012). Innovation can be defined as when an invention or idea turns into a service or good and thereby creates new value for the customer (Kotsch, 2017). Technological innovation can take many forms: radical and innovative in degree, some kind of modification of existing or new entities (can refer to products, services or processes), which can be oriented to a variety of customers such as governments, companies or consumers, based on one or more technologies (Roberts, 2007). An innovation often refers to new technology, but it doesn't actually have to involve any technology or a new invention. Both innovation and invention are words used to describe a new product, but there is a crucial difference between the two. An invention is not in itself marketable or useful on its own. An innovation uses an invention in combination with satisfying a customer or market need (exploitation) and thereby creates value. (Kotsch, 2017). In his article from 2007, Edward B. Robert sums this up by making the definition of innovation as: Innovation = Invention + Exploitation. To exemplify: A solar panel is an invention which doesn't bring value on its own, but when applied on roofs of buildings it creates something the market values (Kotsch, 2017).

3.1.1 Four zones of innovation

Different theories about how to look at innovations have been presented over the years: Bower & Christensen (1995) refer to differences between disruptive and sustaining innovations, Abernathy & Clark (1985) shine light on radical and conservative innovations, Porter (1985) elaborates about continuous and discontinuous technological changes, and Tushman & Anderson (1986) differentiates between breakthrough and incremental innovations. Viewing innovation from these angles helps differentiate different types of innovation, but due to looking at it along one dimension, the whole story cannot be analysed and told. Kalbach proposes (2012) another way of looking at innovation (inspired by previous models), by creating a two-dimensional model of innovation called "The four zones of innovation", which can be seen in Figure 2. The model is made up by the y-axis and the x-axis:

- **Y-axis**: Represents the degree of technological progress an innovation contributes with. Moving from low to high along this axis may indicate that a company has improved its services, capabilities and/or products.
- **X-axis**: Shows the amount of impact an innovation has on the market. Moving from low to high along this axis may indicate that a company has improved its target groups or business models.

Using these axis, four distinct zones for innovation are created:

- **Incremental**: Innovations in this zone are usually modest changes on existing services and products. Enhancements like these keep a business competitive on the market, by presenting service improvements or new product features, providing short-term revenue.

- **Breakthrough**: This applies when making a larger, technological advancement with the ability to propel an existing service or product ahead of competition. Often, this is a result of R&D labs, striving to achieve the next patentable device, formula or technology and can catapult the company ahead of competitors.
- **Disruptive**: An innovation is disruptive when it brings a very different value proposition to the market compared to what was previously available but result in worse product performance in the short-term. This is done by serving an underserved market with a product or service which is cheaper, easier to use or more convenient to access. Usually, this lead to a new business model, which makes implementation more challenging. To tackle this challenge, a strategy could be creating a separate affiliated company or brand, similar to a start-up.
- **Game-changer**: Innovations in this field have a radical impact on how people think, act and feel in some way, and can transform markets or even society on the whole. This new service or product could ensure long-term success for the company.

Kalbach recommends that a good innovation program should balance their attention in all the zones. The lines between the zones can sometimes be blurry, but by using the model, it can help companies to both explain and understand their innovation and apply the right strategy for them.

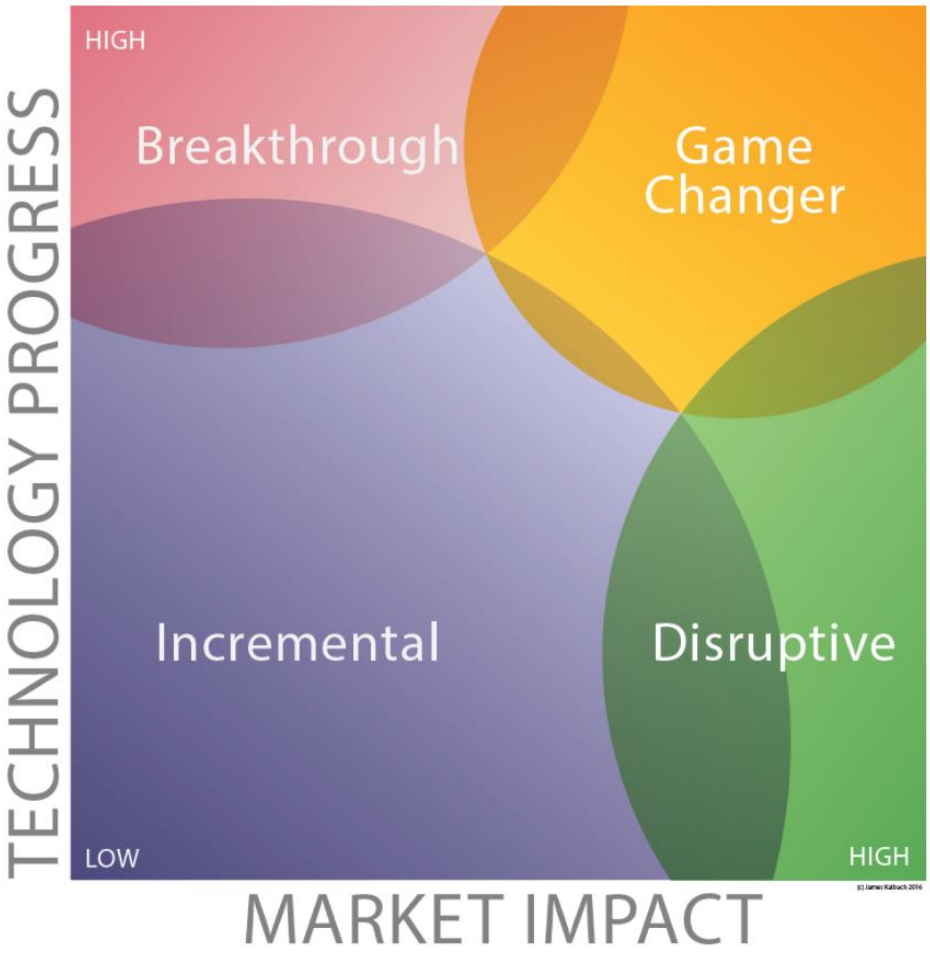

Figure 2: The four zones of innovation (Kalbach, 2012).

3.1.2. Intellectual property and patent

When coming up with a new invention, an important step is to secure your idea or technology (PRV, 2021a). An important difference between Sweden and other countries concerns the right to the IP (intellectual property). In other

countries, the university own the right to their employees' IP to a large extent, while in Sweden, the employee has the right to their IP themselves (Swedish Agency for Growth Policy Analysis, 2016). Securing your invention is done by sending in an application regarding the IP to the patent office on the intended market (PRV, 2021a). An application for IP includes copyright, patent right, design rights and trademark rights, and gives the holder the exclusive right to their assets for a certain amount of time, which varies depending on the right (PRV, 2020a). The right to a patent is a negative right, meaning that the patent holder can prohibit others from the use of the invention in particular ways (PRV, 2021b). A Swedish patent is only valid in Sweden, so if there is an export market for your inventions, applications for the other markets has to be sent in and granted. This means that by only being in possession of a Swedish patent, others have the right to manufacture and sell your invention abroad. To ensure a wider spread patent, one can choose to either make separate patent applications for each market or a European application (EPC application) or an international application (PCT application) (PRV, 2019a). An EPC application (European Patent Convention) is handled by the EPO (European Patent Office) and can lead to protection in over 30 countries in Europe (PRV, 2019b). PCT (Patent Cooperation Treaty) is administrated by the UN agency WIPO (World Intellectual Property Organisation) and an application there can lead to protection in around 140 countries around the world (PRV, 2019c). It is recommended to consult an expert concerning which application or applications to send in and analyse the total cost of the separate or combined applications (PRV, 2019a). The application process for a patent is often a both time consuming and complex process (Colyvas et al, 2002).

The inventor has the right to apply for a patent of their innovation but the right to apply and hold the patent can be agreed upon (PRV, 2021b). However, the right to be mentioned as the inventor cannot be transferred to another person. If an employee comes up with an invention which falls within the employer's operational area, certain limitations exist for the inventor's right to claim the right to the invention, depending on how strong the connection between the invention and the employee's work tasks is. (PRV, 2021c)

3.1.3. Criteria for patentability

There are three certain criteria to be met for an invention, in order to be patentable:

- **Novelty**: The invention must not be known prior to you patent application. An invention counts as known regardless of where in the world and by whom it has been made known. This includes getting known through a lecture, a publication, an interview, being sold, a film or video, even through your own publication. Your invention must also not have been discussed among your acquaintances, colleagues or friends. (PRV, 2020b)
- **Inventive step**: The invention has to differ significantly from other known products and the solution must not be obvious for a trained person within that technical area. A combination of known objects or methods in a new way may not be patentable. (PRV, 2021a)
- **Industrial applicability**: The invention must be industrially applicable, meaning it can be utilized or produced in any kind of industry. The word "industry" in this context refers to the broader sense, not only concerning traditional industry but also different activities, e.g.,

agriculture, transport, public services, hunting and medical services. (PRV, 2021a)

A patent is valid for a maximum of 20 years and its validity can cease for one of the following reasons (PRV, 2021d):

- The patent term has expired
- The required annual fee has not been paid to the PRV
- By request from the patent holder
- The patent has been revoked after opposition
- The patent has been declared invalid by a public court

Exceptions from the patent law regarding what can be patented do exist, despite having fulfilled the three criteria previously presented. Other authorities have the possibility of preventing a patent from being used, even though a patent has been granted (PRV, 2021a). There are also exceptional cases where the patent could be granted on incorrect grounds and could thereby be taken in later (PRV, 2020c).

It is recommended to draw up a confidentiality agreement, to highlight the importance of confidentiality before discussing it with concerned parties (PRV, 2020b). TTOs' marketing activities are especially important for inventions within technological areas, where existing links between industry and academia is weak (Colyvas et al, 2002).

3.2. Understanding customer needs and wants

Never before have companies known more facts and have more information about their customers, partly thanks to the big data revolution. And although

companies label innovation as extremely important, most of them are dissatisfied with the innovation performance within their organization. The problem with this is that the customer data the companies create is structured to show correlation. Customers can be grouped and sorted according to many different traits, such as gender, education, nationality and zip codes, to name a few. While finding patterns is satisfying, it is not certain that the patterns are showing causality and basing decisions on correlation a company is likely to miss the main target. Using gathered data can be useful, along with e.g., ethnographic research, customer panels, focus groups competitive analysis and personas, and work as a good foundation. But, according to a new theory, companies are doomed to hit-or-miss innovation, if they cannot identify what job the customers want their purchased product (product in this case is a broad term covering all kind of products and services) to do, the "job to be done". (Christensen et al, 2016)

"People don't simply buy products or services, they 'hire' them to make progress in specific circumstances." (ChristensenInstitute, 2022)

To identify the job to be done, one has to put themselves in the shoes of their customer and ask the question: "When buying this product, what job is the product being hired to do?". If the product does a good job, the likelihood of a customer turning back to it increases. And if it does a crummy job, the product will be 'fired', and the customer will look for an alternative. To uncover what help one's customers need, these five questions should be considered: (Christensen et al, 2016)

1. **Do you have a job that needs to be done?** Look at the market and see if you notice a potential for something on the market, which is not there yet.

E.g., Mathem.se, a webpage where you can order food from home and have it delivered at your door.

2. **Where do you see nonconsumption?** One can learn just as much from non-consumers, who are not hiring any product, compared to those who are. The most fertile opportunities often lie among non-consumers.

   E.g., Everyone shops for food but might be limited to the closest store, often with limited supply. By shopping online, new brands and products can be discovered, and impulse purchases limited.

3. **What workarounds have people invented?** If you see a customer struggling to get a specific job done and are cobbling together workarounds to solve it, pay attention. These customers are usually unhappy with their current available solution and could therefore work as a good base of new business.

   E.g., Making shopping lists and bringing the list to the store, takes a great deal of planning, leading to big weekly purchases.

4. **What tasks do people want to avoid?** Some jobs are regarded as 'negative jobs', meaning that the customer want to get it done and get out of it as soon as possible. Solving these negative jobs could be a potential gold mine.

   E.g., Going to the supermarket for grocery shopping, driving there, finding a parking space, standing in long queues and carry home the grocery bags.

5. **What surprising uses have customers invented for existing products?** See if there are any examples on the market of customers using product A, intended to solve problem A, to instead solve problem B.

Could there then be a better way to create a new product, product B, which is more tailored for solving problem B and easier to use?
E.g., Getting in contact with a neighbour to co-shop on their account or planning weekly grocery shopping.

3.3. Start-up

A start-up could be defined as a temporary organization looking to find a more repeatable, scalable and profitable business model (Blank & Dorf, 2012). It is an organization with a dedication to create something new and unique while dealing with great uncertainty (Ries, 2011). If a start-up is successful, it is expected to experience fast growth (Kotsch, 2017). According to Bland and Dorf (2012), a core insight in the start-up world is that not every start-up is alike and faces different challenges. The relationship between a new product and its market is one key differentiator and generally the start-up fits one of the following categories:

- Presenting a new product into an already existing market
- Presenting a new product onto a new market
- Presenting a new product into an already existing market, to try to:
    - re-segment the existing market as a low-cost player
    - re-segment the existing market as a niche player
- Copying an existing business model which has been successful in another country

Launching a start-up company traditionally includes taking a big risk, due to the fact that success is far from certain (Blank, 2013). Blank brings the fact to light that 75% of all start-ups fail, according to new research. Another study found that 9 out of 10 start-up companies fail (Kotsch, 2017). But creating a successful start-up is not about luck, but instead a skill that could be learnt and taught as a process (Ries, 2011).

3.3.1. University spinout companies

There are a variety of words used to describe the roughly same phenomena: *University spinout, university spinoff, academic spinout* and *academic spin-off*. A definition of a USO (university spinout) is, according to Djokovic & Souitaris (2006), a company which commercializes and transfers intellectual property from the university, developed from research within the academic institution. The research must therefore originate and have been developed from the university. Another definition of USO is, in the authors' own words: "the company founder or founders must come from the university; the activity of the company must be based on technical ideas generated in the university environment; and the transfer from university to company must be direct and not via intermediate employment of the technology" (Gübeli & Doloreux, 2005, p.270). This definition differs from the previous one, proposed by Djokovic & Souitaris (2006), concerning that the specific technique must not be developed at the university but instead have been generated in the university environment. Cantner & Goethner (2011), describes an academic spin-off company which has been set up by the faculty of the university, research employees or students, who had still connection to or had quit the parent organization to commercialize their research knowledge. Throughout this master thesis, for simplicity, the name university spinout will be mainly, but not exclusively, used, in its broad meaning. This choice of expression is supported by Fryges & Wright (2014), who in their article declare that there are different names to the same phenomena and that there is no difference between them. A company which evolves from a university is known as a university spinout (hereinafter USO) and makes up a complex phenomenon in the research field concerning entrepreneurship (Djokovic & Souitaris, 2006).

Spinout companies can be categorized depending on what organization they derive from and the origin of the entrepreneur's experience. A spinout company can come from different types of organizations, such as the R&D laboratory, private companies or institutions conducting research. A split can be made, into the two subdivisions, corporate spinouts and university spinouts. These subdivisions have a great deal in common, but university spinouts are considered more active in technology transfer while company spinouts keep more of their technological discoveries within the firm. (Gübeli & Doloreux, 2005)

In the medium to long perspective, competitiveness on the global market is dependent on technological and innovative achievements. These achievements include skill to develop innovative products, successful adaptation to new markets, ability to use and apply new technology, develop skill sets across the whole labour spectrum and incorporate the best management practices, all being elements that universities can contribute to (Jones-Evans, 1998). Scientific inventions from spinouts of universities, creating separate companies, presents an under-utilized but important option for creating wealth from commercialization of research ideas (Vohora & Lockett, 2002). These companies evolve intellectual property from the university and academic institutions into commercialisation (Djokovic & Souitaris, 2006). The technology being transferred from the university environment could be either formalized intellectual property such as a patent being transferred via technology licensing, but it could also concern non-formalized technology and results from research (Fryges & Wright, 2014). In their development, USOs repackage their offer and can be regarded as experiments to test whether a technology or product is promising or to test the size of certain markets (Cooper, 2001). Despite the potential importance for innovation, contribution

to the economy concerning wealth and job creation, this field has become more studied more recently (Djokovic & Souitaris, 2006).

USOs are at risk, due to lack of experience in the entrepreneur and novelty to the market, increases the risk to "liability of newness" (Vohora et al, 2004). These factors could, according to the authors, be a barrier preventing an early USO to earn sufficient profit and become an established company on the market.

In the 1960s, spinouts from different academic and university institutions started to establish their role as a bigger channel for the transfer of technology and commercialization of research results. Researchers who had left the university not-for-profit scientific community to start and set up firms for-profit, were initially seen with scepticism, since working for a firm making profit was not in accordance with the traditional scientific norms (Stuart & Ding, 2006). According to Fryges and Wright (2014), the literature discusses which factors could work as motivators for researchers to leave the academia and start a new firm. On one hand, the reasons for wanting to leave the academia could be classified as "push factors" and includes dissatisfaction with bureaucracy and objection towards the low risk orientation perceived in the university environment. On the other hand, the reasons for wanting to start one's own company, a spinout company, are classified as "pull factors" which includes a desire for independence, the wish to commercialize an idea and achieving fulfilment, after identifying a market opportunity. Another factor which should be considered is the monetary possibilities coming from a spinout success, but this is not the primary objective. (Fryges & Wright, 2014)

3.4. MedTech

The medical technology (hereinafter MedTech) industry is a broad collective name for any technology used for saving lives or helping individuals suffering from a wide range of conditions. The common denominator for this industry is the positive impact it has on people's health, quality of their lives and on society as a whole. The R&D connected to MedTech involves a wide range of actors, everything from medical professionals and doctors, engineers and mechanics to government authorities and agencies, universities and academic institutions, large, multinational corporations to smaller family firms and start-ups (Donzé & Imer, 2020). Taking many forms, MedTech is used for diagnostics, monitoring and treating every condition or disease humans may suffer from (MedTech Europe, 2021). Medical technology can be everyday objects which everybody is familiar with, such as latex gloves, plasters and syringes. It can also be wheelchairs, surgical thread, painkillers, pregnancy tests and blood pressure measurement equipment. In a hospital, or similar institution, more from the high end of the scale will be found, ranging from heart monitoring, defibrillators, life-supporting machines and MRI machines to implantable devices like pacemakers and heart vaults and replacement for joints in knees and hips. (MedTech Europe, 2021)

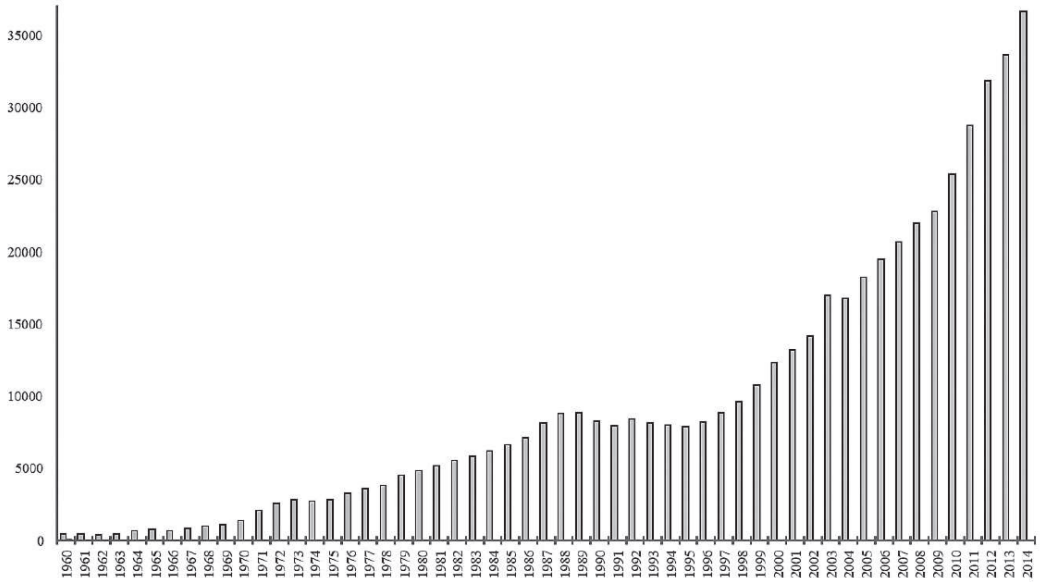

Figure 3: Patent applications in the medtech industry globally 1960-2014. (Donzé & Imer, 2020)

The MedTech industry is a fast-growing business category, all around the world and the number of patent applications has increased since 1960, which can be seen in Figure 3 (Donzé & Imer, 2020). In the European Union, MedTech is a tightly regulated field, with laws concerning the product's performance and safety during its lifetime, pre- and post-market (MedTech Europe, 2021). The MedTech industry is on the rise and has gone from 169 billion USD in the year 2000, to reaching 370 billion USD in 2017 (Donzé & Imer, 2020).

3.4.1. Classification of MedTech products

Due to the wide range of MedTech products and application areas, it is not practical or feasible to subject all medical technology to the same rigorous

tests and assessments (European Commission, 2015). Since 26th of May 2021, the European Union has a new classification system which has been developed for the MD (medical device) sector (MedTech, 2021). The MD sector is regulated by EU Regulation 2017/745 and the new classification system is called MDR (Medical Devices Regulation), having replaced the MDD (Medical Device Directive) and the Directives 93/42/EC and 90/385/EEC. Through this change in 2021, no MDs can be certified under the old Directives.

The level of control for each type of product is therefore corresponding to the level of hazardous risk of concern that the device poses (European Commission, 2015). The classification for MedTech products within EU ranges from Class I (low risk) up to Class III (high risk) and is classified under the MDR (MedTech, 2021) and can be seen in Figure 4. In the US, the market is following a similar classification system and is being controlled by FDA (Food and Drug Administration). Some countries accept European or US regulations, with some local adaptability regulations. Others have their own regulatory process, e.g., China, Japan, Russia and Brazil. (Piester & Rosager, 2017)

The classifications explained are the following:

- **Class I**: This is the lowest classification of MedTech and includes such as wheelchairs, simple bandages, oxygen masks, powered toothbrushes and scalpels. These devices and products can be classified as sterile or non-sterile.
- **Class IIA**: This classification indicated moderate risk and has low-risk and sterile appliances, such as laryngeal masks, syringes and ET-tubes.
- **Class IIB**: This classification indicates moderate risk and applies to low-risk implants such as knee implants.

- **Class III**: This represents the highest classification of MedTech and includes high-risk implants such as heart valves and stents.

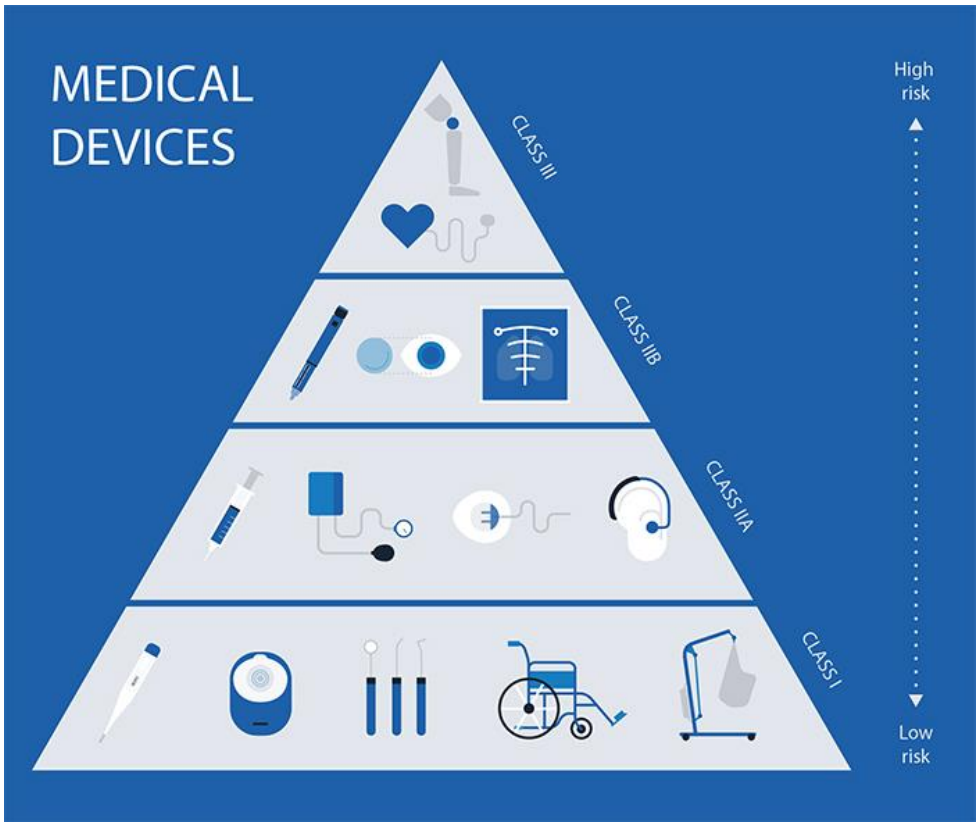

Figure 4: Classification of MDs under MDR (Laegemiddelstyrelsen, 2020)

3.4.2. Legislations and regulations

Legislations is the function and power of governments to create laws and rules. Then regulations are created, to help implement the laws. To ensure that MedTech products are safe for use, for both the patients and the medical personnel, the MDR is used in the EU. Companies who want to operate on

the European market must therefore comply with these regulations. As a minimum for market access ISO certification, Regulatory approval and Country registration planning is required. Depending on if one wants to sell directly or indirectly, or be a licensed provider, the level you have to comply with these demands differ. (Piester & Rosager, 2017)

3.4.2.1. ISO certification

The ISO (International Organization for Standardization) standards is used in the EU and around the world as a tool for adding credibility to a product or service (ISO, 2022). Within medical certification, the global standard being used is the ISO13485, but depending on the innovation, additional specific ISO standards might have to be met. By ensuring compliance with ISO13485 standard, that allows for the quality assurance management system of the company to examine how the medical device can be brought into compliance. Depending on the business, one might have certification for either a product or a quality management system. Having a ISO certification allows you to manufacture your MedTech product. Meeting the requirements of the ISO13485 standard is a crucial step towards acquiring a CE marking. (Piester & Rosager, 2017)

3.4.2.2. CE marking

Products sold in the EEA (European Economic Area) are often marked with the letters “CE” (Conformitè Europëenne), which signify that that product has been analysed and evaluated to meet high health, safety and environmental protection requirements and the symbol can be seen in Figure 5. The benefit for business to have a product with CE marking is that the product can be

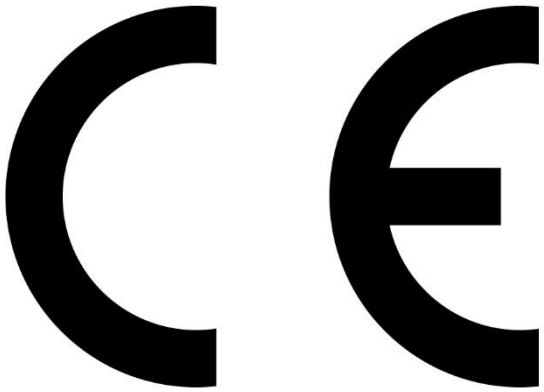

Figure 5: The symbol for CE marking (EC, 2022b).

traded freely without restrictions in the EEA (EC, 2022a). For each CE approval, certain documents and activities need to be included. There are also additional regulations which need to be complied with (Piester & Rosager, 2017):

- Complaint-filing system and quality-assurances
- UDI (Unique Device Identification)
- Risk management (the ISO14971 standard is used for this)

In the EU, MedTech products in class I require the company to report to health authorities. For other MedTech products of higher risk classification, especially for a class IIB and class III, clinical activities must be included. When a company gets a CE approval, they receive an identification number, which along with the CE mark must appear on the usage instructions and the product itself or the packaging of a sterile product. As Piester expresses it: "*The CE*

mark is a blue stamp – it is for us a clear milestone". (Piester & Rosager, 2017, p.163)

3.4.2.3. Notified bodies

Certification and control of MDs is made by a third-party, known as an NB (notified body), and is driven by the many pre- and post-market requirements before being placed on the market (MedTech, 2021). An NB is an organisation that has been designated by an EU country for assessment of the conformity of certain products, prior their placement on the market. The tightened control on the part of the NBs and higher demands on clinical documentation for new and existing products, are expected to lead to safer products in the future. MedTech products within class IIA, class IIB and class III must be approved by an NB. In cases with MDs within class I, the company itself is responsible for securing proper compliance and reporting to governmental systems. When an MD receives a certification from an NB, is has gotten a CE mark certification. The national healthcare authorities can also be advised when trying to find the right classification level for the product (Piester & Rosager, 2017). Manufacturers are allowed to choose any NB as long as that NB has been legally designated to complete the conformity assessment procedure (EC, 2022b). If there is a bottleneck for NBs, their prices are expected to go up, leading to higher cost for the company (Piester & Rosager, 2017).

3.5. Funding and investor types

The acquisition of financial resources is crucial for a company to ensure its survival. It is common for small and medium-sized businesses to face difficulties in accessing funding (Swedish Agency for Growth Policy Analysis, 2015). When a company is in a development phase and therefore have more costs than revenue, some kind of external funding is fundamental to keep the company alive. Funding can take different forms: soft money, being grants which are applied for or hard money, meaning the investor acquires a part of the company ownership, in relation to the company's value and the size of the investment. When talking about hard money, there are different kind of investors, e.g., holding companies, business angels and VC (Venture Capital) companies.

Getting a new company to where they are successful and can produce a commercial product is a difficult task, which usually involves going through the "cash flow valley of death", see Figure 6. When looking at the cash flow curve, three broad development stages are found where investments are necessary to keep the venture afloat: (Murphy & Edwards, 2003)

1. **Technology creation stage**: In this stage, investments are typically found in public funding.
2. **Market Focused Biz and Product Development stage**: When entrepreneurs enter this stage, they enter the "cash flow valley of death" and there face the dangerous conjunction of high cash demands and low ability to raise funding. Public funding decrease, while the need for investment in this stage is severely larger compared to the others.

3. **Early commercialization stage**: It is typically in this stage that the interest and investments from the private sector comes in. Venture capitalists prefer to finance the venture when solid initial sales have been recognised.

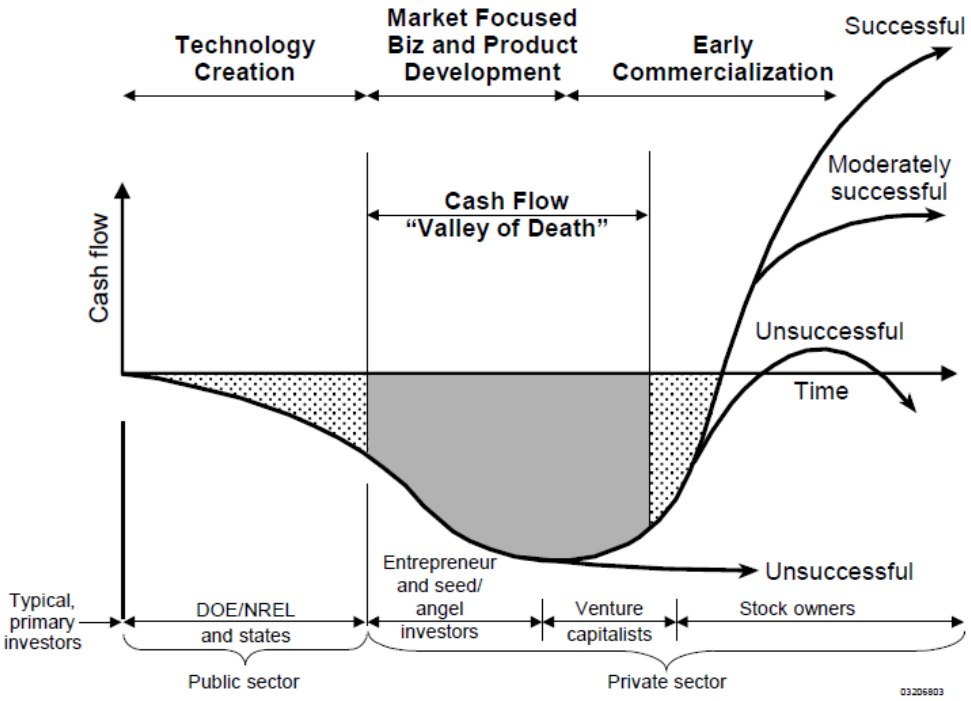

Figure 6: The Cash flow "valley of death" as a function of development stage (time), with typical investors shown at different stages (Murphy & Edwards, 2003).

Attracting the right investors is an important issue for companies and in his article, Bashee (2004) treats this question. In an ideal world, managers should attract longsighted investors, focusing on the long-term benefit and performance of the company. Having these kinds of investors would in these cases act as insulation towards short-term performance and stock price volatility, making it possible for management to act on a long-term strategy. It seems,

though, that there currently is no clear consensus on which investors are more "patient". Bushee presents a categorisation of three types of institutional investors:

- **"Transient" institutions**: These investors own small stakes in portfolio companies and exhibit high portfolio turnover.
- **"Dedicated" institutions**: These investors take large positions in individual firms and provide stable ownership.
- **"Quasi-indexers"**: These investors own small stakes (comparable to an index strategy) but trade infrequently.

According to Bashee's research, transient investors are attracted to companies who have investor relations activities geared toward "news event", such as management forecasts and forward-looking information. A disproportionate presence of transient investors, within a company's investor base, seems to intensify pressure on achieving short-term performance, while resulting in a higher volatility in stock price. By focusing their disclosure activities on historical activities will help investors to look at corporate performance, rather than earnings forecasts which seem to attract transient investors and increase speculative trading, quasi-indexers will be attracted. This change in investor base will work as encouragement for managers to make long-term favourable decisions and thereby maximizing long-run value, and less focus being put on short-term consequences. (Bashee, 2004)

3.5.1. Soft money

Grants and other type of contributions are examples of what is considered as "soft money". These contributions differ from hard money since they do not involve giving up partial ownership of the company. Soft money is applied

for from different companies or innovation agencies and can work as pre-seed funding and for development within the company. Some big agencies giving out grants in Sweden are Tillväxtverket (the Swedish Agency for Economic and Regional Growth's), Vinnova and Almi (Almi, 2019). These money can also be distributed to different university connected agencies, with the mandate to distribute the grants themselves in the seemingly best way fit. According to the Swedish Agency for Growth Policy Analysis (2015), indirect (fund of funds) investments is a better way to invest public funds, compared to direct investments.

3.5.1.1. Tillväxtverket

The Swedish Agency for Economic and Regional Growth (swe: Tillväxtverket) is a Swedish authority, which belongs to the Ministry of Trade and Industry (swe: Näringsdepartementet) and works with entrepreneurship and regional growth. By working together with the regions in Sweden and both private and public organisations, networks are built and connected. (Tillväxtverket, 2021)

The main singular mission for Tillväxtverket is ensuring that EU funding is invested in regional growth and employment. Most of Tillväxtverket's funding takes the form of project funds and is managed by public actors. (Tillväxtverket, 2021)

3.5.1.2. Vinnova

Vinnova is the innovation agency of Sweden, with the mission to help Sweden innovation capacity and contributing to sustainable growth. The Swedish state is governing the agency's work and their work is based on the global

sustainability development goals of the 2030 Agenda, adopted by the UN (United Nations). Vinnova invests approximately SEK 3 billion in innovation and research, to give organizations and companies an opportunity to experiment and test new ideas, prior of becoming profitable. (Vinnova, 2021)

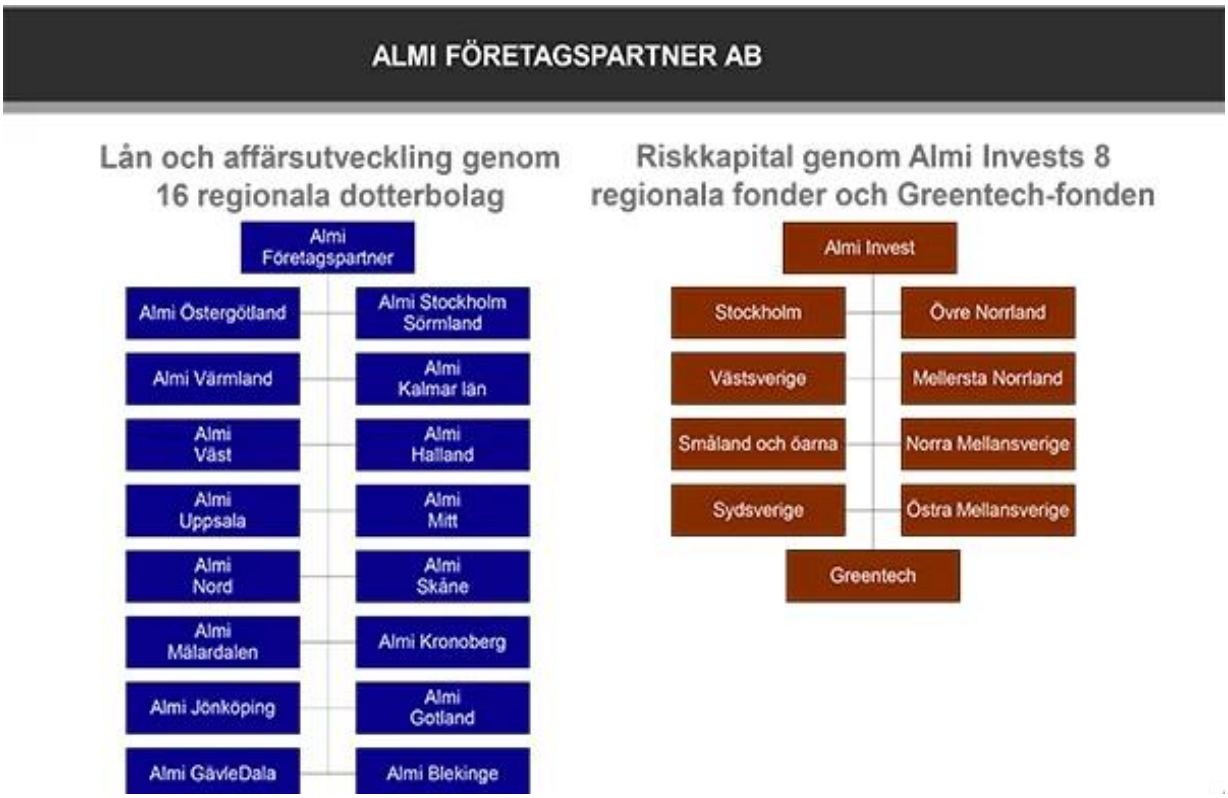

Figure 7: Organisationsschema för Almi Företagspartner AB (Almi, 2022)

3.5.1.3. Almi

Almi Företagspartner AB is own solely by the Swedish government and consists of Almi Företagspartner and Almi Invest, which are divided into different subsidiaries, which can be seen in Figure 7 (Almi, 2022a).

Almi assists companies in their pursuit for growth and development, by offering loans and business development, after an initial analysis of the company. Through Almi Invest, investments of both hard and soft money are made in early stages of a company with great growth potential (Almi, 2022b). Almi Invest have more than 350 companies in their portfolio and can be divided into the categories Tech, Life Science, Industry and Cleantech (Almi, 2022c). The different types of investments offered by Almi are: Growth financing, export financing, innovation financing, start financing and venture capital, along with financial guidance (Almi, 2022b). By working with Almi Invest, the company also get access to a large investor network, for future follow-up investments and sales. Today, Almi Invest manages SEK 3.5 billion. (Almi, 2022d)

3.5.2. Hard money

3.5.2.1. Holding companies

A holding company can be explained as a corporation that owns enough voting stock in one or multiple companies to be able to exercise control over them (Britannica, 2022). Other names for a holding company are financial holding company, parent company and management company (KVK, 2022). A corporation which exclusively exists for this reason is called a pure holding company, while a corporation which engages in its own business along with exercising control like a pure holding company is called a holding-operative company. With a minimum amount of investments, a holding company can exercise control of several companies and is both legally simpler and economically less expensive, compared to other means to gain control of a company, e.g., consolidation or merger. Typically, a holding company owns a

majority of stocks in their subsidiaries, but if the rest of the shares are widely diffused, a minority of ownership in a company might suffice in order to give the holding company control. (Britannica, 2022).

3.5.2.2. Business angels

A business angel is a private individual, often with a substantial net worth, who invests in companies. Business angels usually have business experience and use this along their capital to make direct investments in new or growing ventures. They invest either on their own or in syndicate with others, in which case one business angel often takes a leading role. Using their previous experience along with contacts and skills can prove valuable for the entrepreneur. (EC, 2022c)

In many countries, business angels are the second largest source of external funding in new enterprises, after friends and family. They play an important role in the economy and provide venture capital needed for technological advancement and economic growth. Business angel networks and groups can be both local, national and international. Within the EU, two large networks are The European Trade Association for Business Angels, Seed Funds and Early Stage Market Players (EBAN) and Business Angels Europe (BAE). (EC, 2022c)

3.5.2.3. Venture capital

Venture capital is used to grow faster, break into new markets and expand. Innovative small companies, with growth orientation, are in need of acquiring capital and equity investments from external sources, due to difficulties raising the capital on its own or getting approved loans. Venture capital funds

raise their capital from their investors, largely institutional ones. Although wanting to invest in rapid growth companies, many venture capital funds are reluctant to invest in innovative companies and start-ups, since the risk is for the investment in greater and does not match the potential expected returns. (EC, 2022d)

3.6. Supporting organisations

When a start-up is in its cradle, its future is unsure. Securing financing to pursue the invented idea is presents a challenge for most of them. And usually the management is small, sometimes only the entrepreneur, and the management's competence areas thereby insufficient. Having previous experience of entrepreneurship is favourable, but if the entrepreneur is unexperienced the challenges become greater and the chance for success slimmer. In order to help and assist start-ups, there are supporting networks and structures put in place by different actors, such as universities, governments, private companies and non-profit organizations. The structures focused on in this master thesis are: Technology transfer offices, University holding companies and incubators, all contributing at different stages with various assistance.

3.6.1. Technology transfer offices

Due to the fact that, as previously mentioned, an employee of a university in Sweden owns their own IP, there is an increased incentive for a university to have an active TTO (Technology transfer office) and holding company. Having clear regulatory frameworks for distribute of revenue from sales, is regarded as an important success factor in this model (Swedish Agency for Growth Policy Analysis, 2016). The role of a TTO to manage the knowledge

transfer process, by protecting the research results, making technology and market assessments of the research results and by promoting and commercializing said results (TTO Circle, 2022).

3.6.1.1. LU Innovation

The TTO at Lund University is called LU Innovation and works as one unit together with LU Holding. The role of LU Innovation is to, together with scientists or students, develop ideas and research results into innovations. When a scientist approaches LU Innovation with their idea, LU Innovation contributes by assisting in performing a market analysis and creating a solid business case. LU Innovation also support in fields concerning IP law and other jurisprudence areas. Financially, LU Innovation has the ability to help, through e.g., Vinnova, through hand out soft money up to SEK 300,000 to a project, while other investments in projects are handled by LU Holding AB. By converting knowledge to useful innovations, society can develop, and sustainable growth can be achieved for the future. (LU Innovation, 2022a)

3.6.2. University holding companies

In Sweden, many universities have their own, though sometimes privately owned, holding company. One of the three main assignments for a university is to work with application and commercialization of research findings. If a holding company is active in many different fields, it poses the challenge of bringing a clear focus to their portfolios. Over the past decades, universities handling of commercialization and application of their findings have become more professionalised. This is an effect of relatively comprehensive political initiatives, by creating financial incentives for the activities and contributing

to competence improvement. (Swedish Agency for Growth Policy Analysis, 2016)

3.6.2.1. LU Holding AB

LU Holding, previously LUAB, is the investment function at Lund University which is owned by the Swedish state but managed by Lund University. It aims to, based on knowledge from Lund University contribute to job creation and growth in Sweden. LU Holding can support new companies both financially and operationally, provide representatives to the company's board and help with agreement templates. Lund University can, through their holding company, work operationally in bringing new innovations to the market, through becoming part-owners in research-based ventures or by helping to license research results into established companies. LU Holding and LU Innovation function as one unit with a common mission. The portfolio of LU Holding is mainly dominated by companies in the field of life science and technology. (LU Innovation, 2022b)

3.6.3. Incubators

An incubator offers a dynamic process for development of people, businesses and companies. Incubators assists the entrepreneur with active and suitable management support, technical, financial and commercial networks combined with a creative environment for growth along with office services. The incubator can work as a tool in creating new and healthy companies who develop new technologies and ideas. This can contribute to the creating of new jobs and work as a foundation for companies already established in the sectors

with high growth rate, leading to the generation of jobs and fresh ideas in the sectors. (SISP, 2022)

3.6.3.1. SmiLe Incubator

SmiLe Incubator in a non-profit business incubator located in Lund, with a focus on life science start-ups. By working on a non-profit and no-equity basis, they build a neutral platform from which health innovations can be launched into the world. With a vision to enable a future of better health by nurturing and supporting a community of life science innovators. (SmiLe, 2022a)

SmiLe Incubator offers a broad palette of services, including advanced coaching programs, a large international network of industry investors and partners, well-equipped labs with state-of-the art instruments and a community of top-class life science innovators (SmiLe, 2022a).

4. Theoretical framework

After having built a theoretical background of the MedTech business, this chapter introduces certain models, theories and frameworks that were used to define and evaluate the interviewed companies' processes.

4.1. Development phases and critical junctures

In a cased-based research method study about USOs (in this subchapter referred to as "the study"), made by Vohora et al (2004), three key conceptual findings were made from the data. Firstly, university spinout companies develop over five distinct phases in a non-linear manner. Secondly, when examining the gaps between the five phases, the results show four "critical junctures" that the USOs must overcome in the presented order to ensure a transition from one phase into the next one. It is crucial for a USO to identify these critical junctures, since they point out internal risks, within the university spinout company, which could be preventing further development. Thirdly, it was found that the USOs were qualitatively different when looking at their capabilities, resources and social capital, through examination of the USOs before and after each transition. According to the findings, it was recognized that a USO emerges rather through non-linear phases than through discrete steps. The crucial matter for the USO is how to overcome the critical junctures in order to reach the next phase, which requires focus and anticipation.

4.1.1. The phases of growth

In previous literature, the term “growth phase” is most commonly used, but in the opinion of Vohora et al (2004), the usage of the term “development phase” is preferred, to capture the essence of fluidity in the USO, which should be seen as ventures in transition. The study indicates that USOs move through five successive phases in an iterative, non-linear way. The five identified in the phases of growth are: (1) Research phase, (2) Opportunity framing phase, (3) Pre-organization phase, (4) Re-orientation phase and (5) Sustainable return phase, and can be seen in Figure 8.

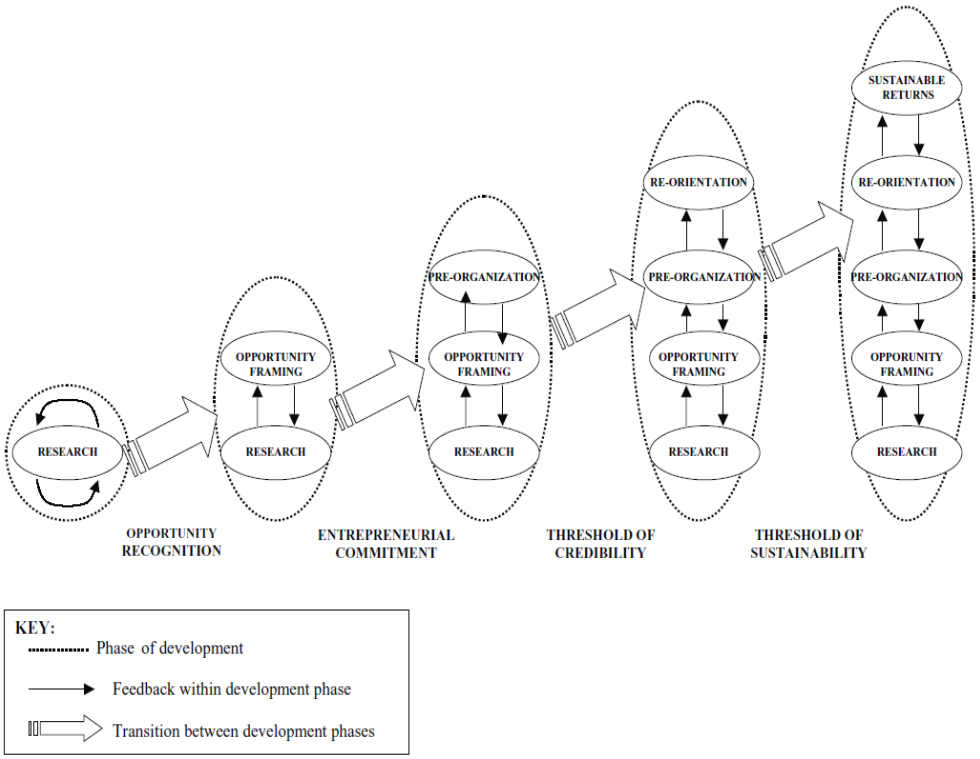

Figure 8: The development phases and critical junctures of a university spin-out company (Vohora et al, 2004)

4.1.1.1. Research phase

In the research phase, valuable intellectual information and property is gathered before the commercial opportunity has been recognized. The collection and performance of research is done with the goal to perfect the academic results and provide publications and research for the scientific community. With the academic support from conducted research, the research phase creates opportunities for commercialisation. The academic inventors studied were all at the front line of research within their field and had acquired valuable knowledge and technological assets. In accordance with existing research, according to Vohora et al (2004), this finding suggests that technology USOs are often driven by successful scientists, while inventors not highly accomplished within their field will encounter problems concerning obtaining necessary, strong intellectual property for protecting the spinout.

4.1.1.2. Opportunity framing phase

In this phase, the academic and TTO (technology transfer office) work either together or individually to examine whether the opportunity being recognized has a commercial opportunity or not. This is done through a screening process, where firstly an evaluation of the technology is conducted, to ensure there is enough evidence to support its functionality and make sure there is an application area outside the laboratory.

As a second step, after analyzing the technology's validity and performance, the work of framing the opportunity within commercialization begins. Both the TTOs and academic entrepreneurs try to identify alternative markets for

their technology innovation, what alterations would need to be done and create the best access strategy to target said market. Doing this proved to be hard initially, due to entrepreneurs lacking experience within framing scientific discoveries according to market attractiveness and commercial exploitation. This made them make imprecise, ambiguously targeted and impracticable assumptions concerning their commercialization plans. All entrepreneurs studied suffered from a lack of understanding how to best generate maximized profit. Not possessing or being able to access capabilities of how to frame their opportunity successfully so that a promise of value and generating profit is shown, they were likely to make little profit. According to an interview in the study with a VC, a USOs business plan was rejected on the basis that there was "*...little proof of concept, no proof of market and no commercial management*". The VC continues by pointing out that universities lack commercial expertise and resources to overcome these deficiencies in order to develop an opportunity which is fundable, a view echoed by several other VCs.

Evidence, found in the study, proposes that the initial opportunities recognized were not the best for exploiting the full commercial value of the technological resource. Where, how and when down the line complementary resources, such as human, physical, financial and technological, would be acquired were not defined precisely. The four out of nine companies in the study who thoroughly explored alternative commercial scenarios, for a variety of potential application areas of their technology. These same companies were the same companies which worked together with potential investors, customers and others in the industry to scrutinize the risks of weakness, deficiencies and inadequacies. This work, along with framing and re-framing the opportunity in an iterative manner, was done in order to discover and assess these

potential risks. Despite working in the mentioned manner, one company discovered that even though their industry partner had funded the initial research, it was difficult to pursue further interest from said partner. Even though the university had acquired numerous patents, it was in a too early stage according to the industry and commercial partners. The academic learnt that the industry lacked a desire to license or co-develop early-stage technologies and instead chose to invest in further developed companies which had shown high probability of generating commercial return. This led the entrepreneur to the conclusion that assembling the necessary resources and developing the capabilities required to exploit the technology himself, was the best route to market.

4.1.1.3. Pre-organization phase

During this phase, the management of the USO can start developing and implementing a strategic plan. This involves making decisions concerning which existing resources and capabilities should be developed, which resources and knowledge should be acquired in the future as well as where and when to access resources and knowledge. It was found that decisions made in this stage had an unforeseeable impact on the future success of the USO, since they affected the path of development and alternatives available for the firm further down the line.

In three of the companies studied, the entrepreneurs were attuned to the challenges of accessing, acquiring and coordinating the resources. They spent more time and effort on both developing existing resources and capabilities as well as the acquisition of new resources and knowledge to allocate new capabilities. By using their social capital, they were able to leverage and gain

commitment of key individuals through their own and their investors' network or by employing professional head-hunters to screen, evaluate and benchmark new members of their management team. This ensured the supply of initial capital and knowledge, enabling the firm to commerce business operations.

In contrast to this, five other companies attempted to launch their USOs with insufficient level of relevant resources. The authors propose that inadequate entrepreneurial experience, along with limited access to advisors, mentors and similar business expertise to advise and guide the shaping of the embryonic USO venture, affects its ability to attain strategic business objectives in the following development phases.

Early decisions might have an immense effect on increasing time to market, lost revenue and lack of venture capital investments. A consequence of this finding is that mistakes made during this time, when the venture has limited resources, can be determinantal of the venture's success forward. This places sincere importance on previous entrepreneurial experience, human capital and access to networks and their expertise. Vohora et al (2004) propose that this phase presents the steepest learning curve for academic entrepreneurs. This is especially important if their prior commercial experience is little to none, if they lack the knowledge in how their targeted industry operates or have few existing relationships with business people, surrogate entrepreneurs, business angels and VCs. The consequences of the "mistakes" made during the pre-organization phase were highlighted during the interviews and were believed to create inadequate capabilities, resource weakness and social liabilities further down the development phases.

4.1.1.4. Re-orientation phase

In this phase, the companies in the study attempted to offer something of value to the customers to generate returns. They faced challenges of identifying, procuring and integrating resources, to later re-configuarate them. This phenomenon was more prevalent in the USOs formed with poor endowment of capital and lack of experience within management, but they gradually became better at obtaining, developing and organizing new resources, information and knowledge. The companies reaching this phase discovered deficits within the company, constraining their growth, and had the problem of trying to fill it by acquiring and integrating necessary resources and expertise on a regular, sometimes daily, basis. All the USOs who entered this phase ran into some level of turbulence concerning their development, due to having to learn how to best manage the evolution of various aspects of the business in parallel. As a result of the actions taken, along with interactions with customers, suppliers, potential investors and competitors, a great amount of change was observed.

Five of the companies studied went through drastic changes, which lead to alteration of three key decisions made in the earlier development phases. The first change was concerning how the entrepreneurial management created value by developing their current technological capabilities and resources. The second change was from whom and where the return was generated from. The third change was concerning how to generate sustainable returns from the market. Making these changes lead to the USO to open their minds to new possibilities, conducting steady iterations and reviewing or trashing the old business plan. This included important realizations e.g., realizing a new customer segment was more profitable that the initial segment, learning more

about how the targeted industry operates and realizing that previous priorities were a waste of resources, which is scarce in a new venture. Most of these USOs managed to adapt their original business plan based on external changes and internal resource constrains.

In the other companies, it became clear that deficiencies, weaknesses and insufficiencies which had existed within the TTOs, surrogate entrepreneurs and individual entrepreneurs, in the previous phases, forebode problems and crises in the coming development phases. Imprudent commitments and strategic decisions made in early phases, resulting in the USOs not being able to create and exploit the value aimed at initially. It seems that during the opportunity phase, a disproportionate amount of emphasis, from the TTOs and entrepreneurs, was put on the development of the technology and too little on identifying, evaluating and targeting key customers. Secondly, since these USOs were less qualified to assess the proper resources, knowledge and information during the earlier phase, they undertook key adaptations concerning unrecognized customer needs, knowhow about new markets and how to assess and obtain additional resources

The authors propose that the success for a USO progressing from this phase into the next one is mainly dependent on the preparatory work done by the entrepreneurs and TTOs in the earlier phases. When faced with strategic or adversity uncertainty, the USOs with the necessary resources, capabilities and social capital, all related back to the previous phases, performed better. Path dependent effects on the ventures in the study suffering from insufficient resource endowment, lack of entrepreneurial mentoring and coaching, inadequate business assistance and social liabilities, were seen to stifle the growth in four of the companies.

4.1.1.5. Sustainable return phase

In the final phase, the USO's ultimate objective is to re-configure and assess resources to put together the capability which enables it to attain sustainable returns. Via the resolution of a precise business model, the USO will have addressed the majority of the early uncertainties. The USO is carrying its own weight and is functioning as a real company, growing and making profits from market returns. It is common that the USO, in this phase, moves off the campus and into a commercial environment, possibly within a university affiliated incubator or science park. Although the USO has moved out of the research laboratory, it will most likely keep close links with the mother university. One way this can happen is that at least one academic inventor stays within the university research department, while acting as the USO's technical advisor.

4.1.2. Critical junctures

In order for the USO to reach its full potential and evolve into an established company making sustainable returns, it must transition between development phases described above. The authors term the transition from one phase to the next one "critical junctures" for the company. They define a critical juncture as "*a complex problem that occurs at a point along a new high-tech venture's expansion path preventing it from achieving the transition from one development phase to the next*" (Vohora et al, 2004, p.159). Unless a USO overcome each critical juncture, it will not be able to move into the next development phase and thereby stagnate. The authors suggest that the problem to overcome each critical juncture are originating from three key deficiencies:

1. Having a scarcity of particular a financial, human, technological or physical resource.
2. Lacking the social capital necessary to access and acquire resources and information through either alliance relationships or partnerships.
3. Insufficiencies in the internal capabilities needed from the venture to employ knowledge and resources to enhance its value and performances.

The four critical junctures are: 1) Opportunity recognition, 2) Entrepreneurial commitment, 3) Threshold of credibility and 4) Threshold of sustainable returns, and can be seen in context with the phases of development in Figure 8.

4.1.2.1. Opportunity recognition

This critical juncture is found between the research phase and the opportunity framing phase and represents between an unsatisfied marked need and a solution satisfying said need, that have been overlooked by others. Hence, opportunity recognition embraces a breakthrough idea which triggers an evaluation, acting as an early formation of commercialization effort. Although little is known concerning the process leading to a new business through opportunity recognition, being in possession of idiosyncratic information allows people to discover certain opportunities, even when not actively looking for them, that others miss. Sometimes a discovery made in a field can be applied in a whole other field, which makes it hard to connect and see the value of it. In order to be able to make the connection between specific scientific discoveries and a commercial opportunity, a special set of skills, insights, aptitudes and circumstances is required.

Overcoming this first critical juncture, is having the ability to synthesize scientific understanding with the understanding of markets. The conflict found at this critical juncture was the fact that universities hold significant technological knowledge yet possesses insufficient know-how regarding how to serve the market and have unrealistic expectations concerning the profit to be made from the technology discovered.

The authors propose that without obtaining, accessing or developing the ability to combine the scientific knowledge and discovery with a commercially possible offer which satisfies an unfulfilled marked need, scientist within the academia will not have success in proceeding towards commercializing their technology. The acquisition of knowledge about the market is needed and requires high level of social capital resources, often found outside the scientific research environment.

4.1.2.2. Entrepreneurial commitment

Entrepreneurial intension is defined as a state of mind, but to overcome this critical juncture, it is crucial to have the entrepreneurial commitment, defined as actions which bind venture champion to a specific course of events. This is needed in order to take the mental vision of the academic and turn it into a formation of a business which is operational, and can is engaging in business transactions. The academic must make an early choice about whether to stay in the academia or throw themselves in full-time in the new venture. This decision will have an impact on how the USO will be perceived in the eyes of investors. This critical juncture arises due to four key reasons, according to the research, when there is a conflict the need for developing a committed

venture champion and an inability to find a person with the necessary entrepreneurial capabilities:

1. The lack of access to successful entrepreneurs as role models, which hindered the academics from commercializing their scientific discovery. They had a reluctancy towards commercializing and the impression that doing so would go against the accepted conventions held by their colleagues, peers and their university institution. This could be due to the fact that academics often have a network restricted to the academia and they lack network possibilities which extend into finance and business.
2. Some academics experienced initial feelings of being unable to frame the opportunity with adequate clarity, which created decision complexity and decision uncertainty. This discouraged the entrepreneurs from fully commit to the pursue of the venturing process, preventing them from further progressing the commercialization of their scientific discovery. A characteristic which is common among academics, is being uncomfortable with ambiguous situations. This feature is what makes them great engineers and scientists, but it holds them back when it comes to the necessary entrepreneurial capital needed for developing and growing a business.
3. The majority of academics interviewed experienced a difficulty in not being involved in every detail of the company's development. This is a consequence of being an eminent director of a group of researchers, having years of scientific training and thereby used to being involved in detailed projects and do not like being told what to do. According to a TTO, a smart academic with a lack of commercial and business

experience knows when they add value and when to sit back and not get in the way of the experts work on, e.g., designing a market plan.

4. The accessing, acquiring and identifying the services of a surrogate entrepreneur turned out to be an extreme challenge. This was primarily a result of their limited social capital and network, but also the offering insufficient rewards and incentives for the surrogate and the academics disinclination of stubbornly holding onto "their company".

These issues could cause inherent weaknesses, inadequacies and deficiencies in the USO restraining entrepreneurial activity and value created in the following development phases. If these matters are left unsolved, the authors propose that the USO venture will most likely remain elusive.

4.1.2.3. Threshold of credibility

This critical juncture concerns the entrepreneur's credibility, which has a direct effect on the ability to acquire and gain access to initial resources required for the business to start to function. Raising sufficient financial resources (seed finance) is a key imperative, paving the way for other necessary acquisitions needed for achieving a fully operational business. Unresolved issues from previous critical junctures and pre-organizational phases concerning deficient social capital, resource weakness and inadequate entrepreneurial capabilities were causing slowness in this critical juncture.

Investors, mainly business angels and VC, sought validation of proof of concept, the entrepreneur's credentials and proof of market. To commit financially, the investors wanted to see a team being emotionally committed and being able to create and deliver value. The entrepreneur often has intangible

technological assets, know-how and published scientific research but demonstrated very little credibility outside of their own domain.

As long as a USO venture is embedded within the university departments and fail to show a distinctive corporate identity, investors, suppliers and customers would not value its product offered, despite presenting the same technological capabilities as originally. Lacking this initial credibility, a high-tech USO will not overcome scepticism from customers and gain access to the market. Evolvement within resource stock, capabilities and social capital, from either the entrepreneurial team or the network offered by their TTO, provided access to the right information, knowledge and resources. At this critical juncture, the entrepreneurs are required to gain access to, acquire and assemble necessary resources for commencing business operations.

Being a USO comes with specific challenges, compared to other high-tech ventures. The non-commercial culture within the universities may cause suspicion in the eyes of external financiers and customers. In this regard, the ties to the university might become a liability.

4.1.2.4. Threshold of sustainable returns

Sustainable returns can take many forms such as revenues from customers for sold services or products sold, investments from current or new investors or milestone payments from collaborative agreements. Achieving sustainable returns is a sign that the venture team has the ability to create value from their development of appropriate social capital, capabilities and resources. But in contrast to the previous critical juncture, there is a need to constantly re-configure existing capabilities, social capital and resources with new knowledge,

information and resources. Resources acquired, relationships formed, and capabilities developed in previous development phases may cease to become valuable in the USO's ability to generate sustainable returns. Therefore, letting these factors undergo a significant transformation might be needed. Inherited resource weaknesses, insufficient capabilities and social liabilities from previous development phases may now be difficult to solve and could thereby prevent a venture from progressing beyond this critical juncture.

USOs have to assemble their scarce stock of resources and coordinate these when building organizational structure, develop policies and routines, while constantly adapt and reconfiguring when necessary. Achieving sustainable returns works as an important signal for existing and new investors that the USO venture is able to reach sustainable growth, leading to higher likelihood of further investments. Not receiving enough financial resources could lead to stagnation for the USO.

4.2. Start-up methodologies

Over time, when either creating a small company, a start-up company or a new business within a larger corporation, there has been a traditional method of handling the process (Blank 2013). Using this method, a company makes a plan for the years to come, which follows certain known steps, in its strive to be successful on the market (Kotsch, 2017). Starting a company in a traditional way is known to be a risky operation and the odds are not in your favour. But recently a new, countervailing approach has risen up, an approach that can make starting a company less risky: “The Lean Start-up method”. (Blank, 2013)

4.2.1. Traditional start-up methodology

The traditional business plan includes, according to Blank (2013), making a five-year forecast for profit, income and cash flow. Before raising money and executing the idea, the entrepreneur will conduct a business plan and try to figure out most of the unknowns of the business in advance. Once the entrepreneur with a convincing business plan has obtained investment, the entrepreneur will begin developing the product. The development involves thousands of hours of work, usually with limited if any customer input. Traditional start-up methodology is considered a static model, moving from step to step through rational thinking and all the steps of traditional start-up methodology can be seen in Figure 9. According to Blank (2013), there are three lessons to be learnt about the traditional approach:

1. A business plan rarely survives the first encounter with a customer, as new information about customer needs and wants are discovered.

2. No one besides venture capitalists request a five-year forecast and business plan covering five years should be considered as fiction, due to the fact that many things can change during this time, leaving the original plan outdated and inaccurate.
3. Start-ups should not be considered as smaller versions of large companies. The successful ones are the ones who move quickly from failure to failure, while adapting, improving and iterating as they continually learn.

Figure 9: Traditional and Lean start-up methodology (Blank 2013)

4.2.2. Lean start-up methodology

The Lean start-up methodology takes a different approach, where focus is on failing fast and learning, using process based dynamic models with continuous iterations. An example of this can be seen in Figure 10. In existing companies, the focus is on executing the business plan, while a start-up is looking for theirs. The three key principles of Lean start-up methodology are: (Blank, 2013)

1. Instead of engaging in months of planning and research, the entrepreneur accepts that on day one, all they have are some untested hypotheses. These hypotheses are summarized in a business model canvas, which is a diagram of how a venture creates value for its customers and itself and can be seen in Figure 11.
2. The Lean approach us a “get out of the building” approach called customer development, as a way to test their hypothesis. By asking potential customers, partners and purchasers for feedback on certain elements of the business model such as pricing, features and distribution channels, important information and feedback is gathered. This feedback is used to revise previous assumptions and the iteration cycle is started all over again, continuously learning and evolving.
3. By using *agile development*, hand-in-hand with customer development, wasted time and resources is eliminated through development of the product iteratively and incrementally.

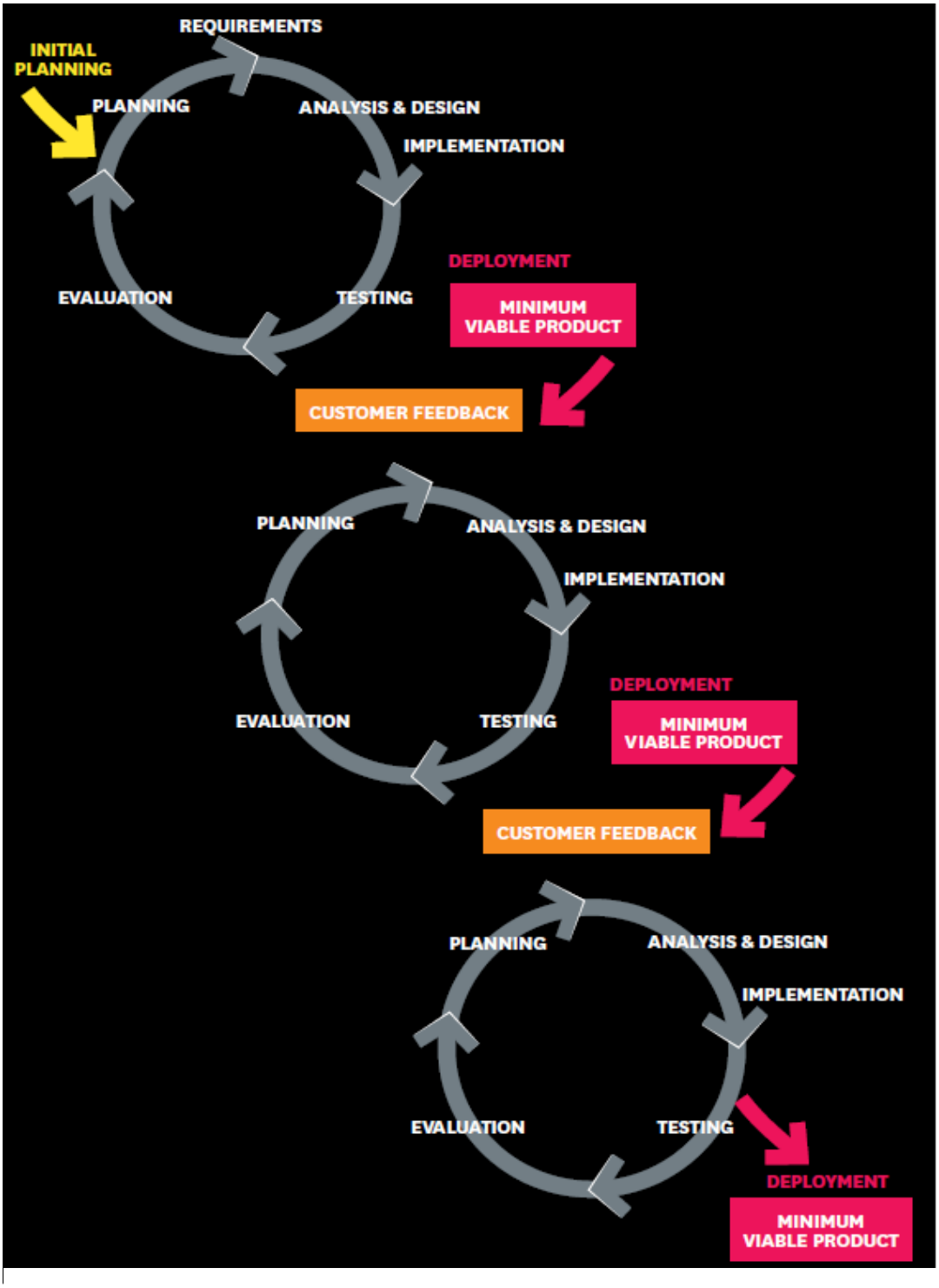

Figure 10: Iterations in the Lean start-up methodology (Blank, 2013)

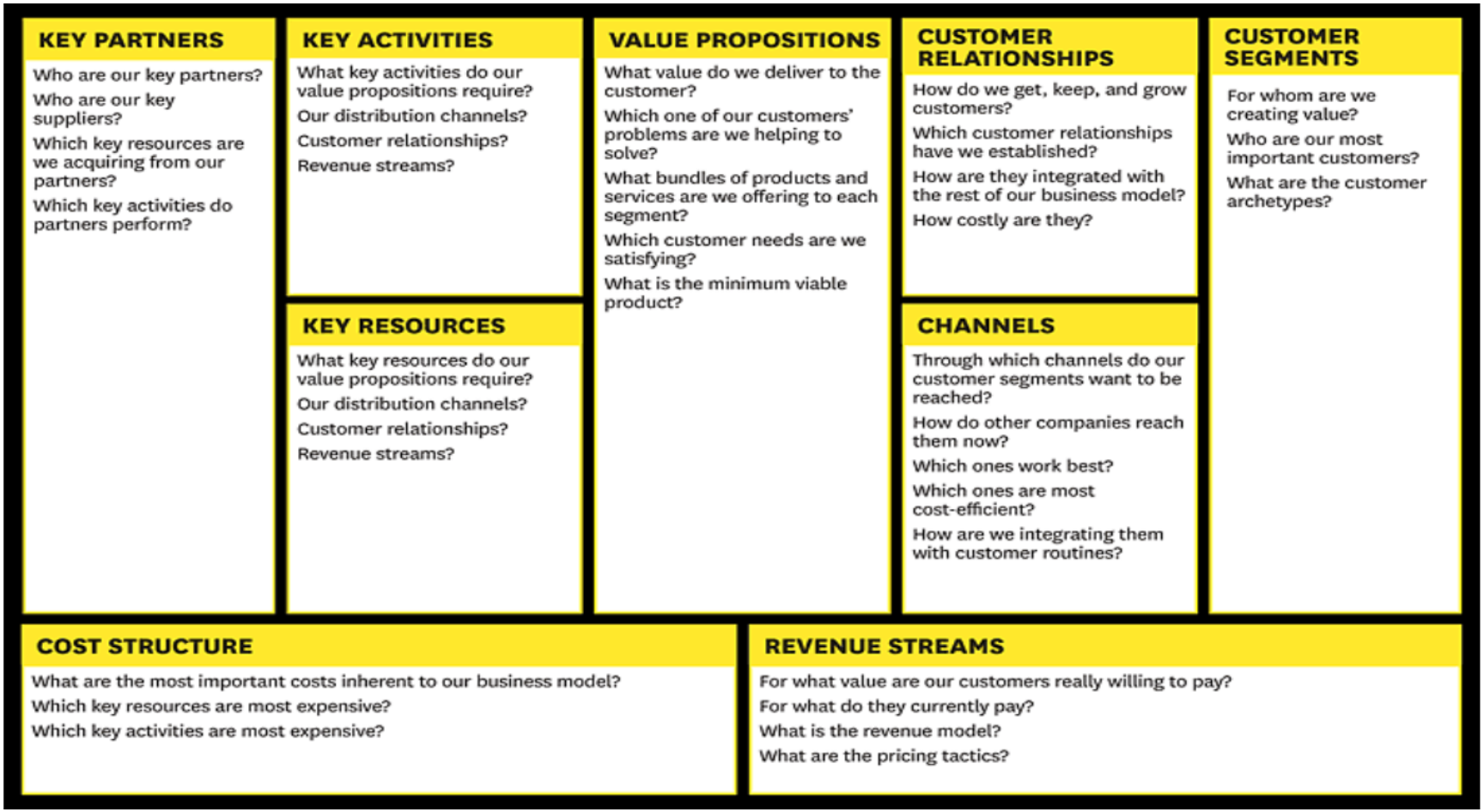

Figure 11: Business model canvas (Osterwalder, 2013)

4.3. The dynamics of technology strategy

When it comes to what motivates a firm's transition to a position of global prominence, the results pointed towards technology strategy playing a big role, according to a study on New Zealand firms (Davenport et al, 2003). By using complexity strategy, the authors were able to identify positive feedback loops driving technological progression, identify complex webs of strategic development and explain why these trajectories take firms on the position of distinctive advantages. (Davenport et al, 2003)

Several processes of differentiation, contributing to a firm's competitive success, were distinguished concerning its technological trajectory. While numerous of these processes involved elements of traditional technology strategy framework, feedback loops and dynamic linkages were not captured in the compartmentalized and static framework. Seven dynamic processes were isolated, which recognize that the technological development of the firm is nested inside other aspects of its competitive evolution. Each of the dynamic

processes are positive feedback loops which strengthen the firm's technological capabilities progressively. As a result of their work, 7 loops are presented

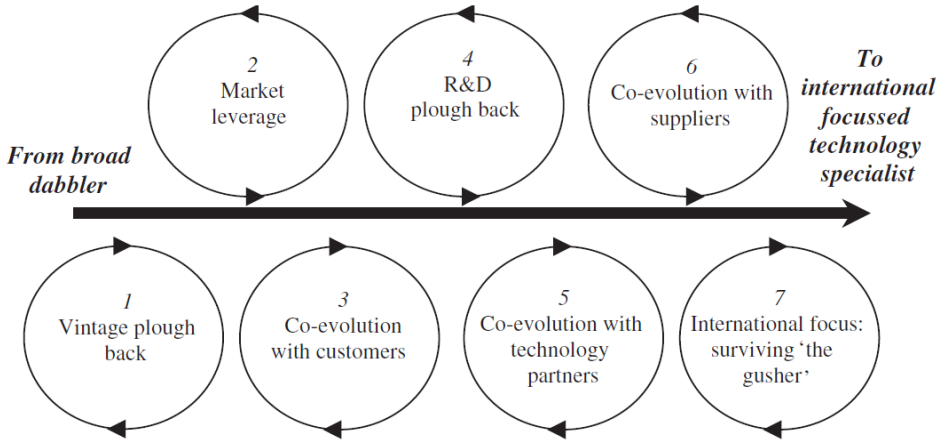

Figure 12: The 7 loops for driving technological progression (Davenport et al, 2003).

and can be seen in Figure 12: (Davenport et al, 2003)

1. **Vintage plough back**: The first loop describes companies' process of going through several "vintages" of products and technology. As a first product, it does not have to be particularly innovative but instead satisfy local demand. The passion and experience of the entrepreneur will to a large degree be reflected the technology chosen. Several positive feedback loops were identified, carrying the firm to successively stronger product offerings:
    a. A successful product offering for the first vintage product could generate a flow of cash. This could give the firm an opportunity to experiment with new technologies, ideas and products, by "ploughing back" these money into new vintages of products.

b. Having a successful product have required the firm to expand their production capacity. This tends to drive the firm to extend their competence within production capabilities and expand both the scope and the market to which the next vintage product could target.
c. Through each development of each vintage, valuable information regarding customer needs, improvement of organizational processes and the discovery of new bases for market segmentation.

The knowledge gained from each vintage cycle is put into the next generation of products, ensuring each vintage to be launched from a higher stock of market and technological knowledge, which can be seen in Figure 13.

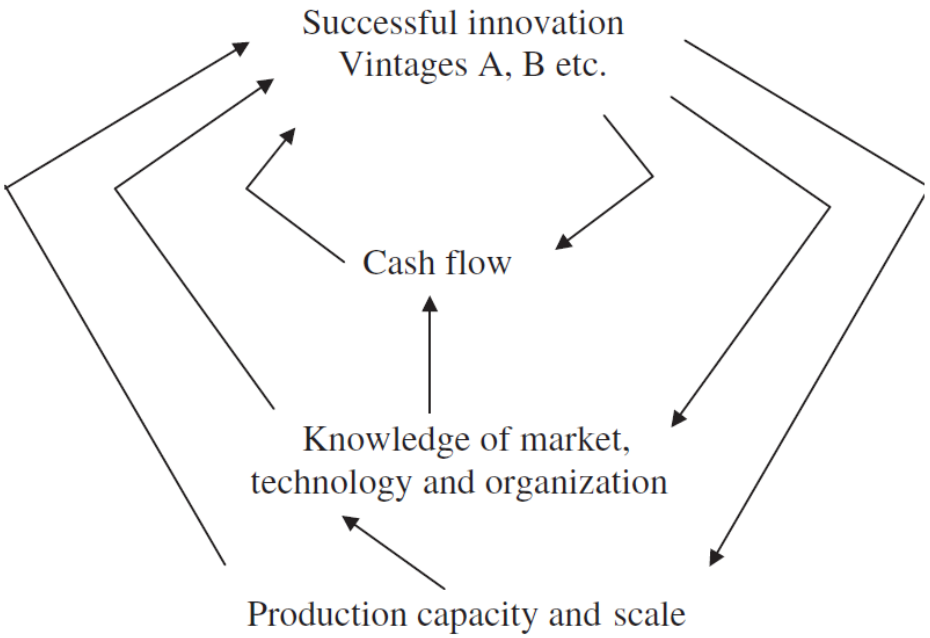

Figure 13: Loop 1, Vintage plough back (Davenport et al, 2003)

2. **Market leverage**: Successive entries to new markets and market segments proceeded parallelly with the successive vintages of products. Leveraging knowledge and experiences from one market segment to the next was observed as a central part of the exploration phase. Due to other suppliers leaving gaps on the market, a firm can choose as strategy to either supply a broader range of products to the same customers or develop a large number of product variations for new customers, or in some cases do both. Another strategy applicable is to licence or develop a range of related products, to optimize the plant's used capacity. Firms starting in the same market segment will pro-

gressively develop differently into unique portfolio of market coverage, as a result of small market adjustments being amplified through the repeated cycle of market specialization (see Figure 14).

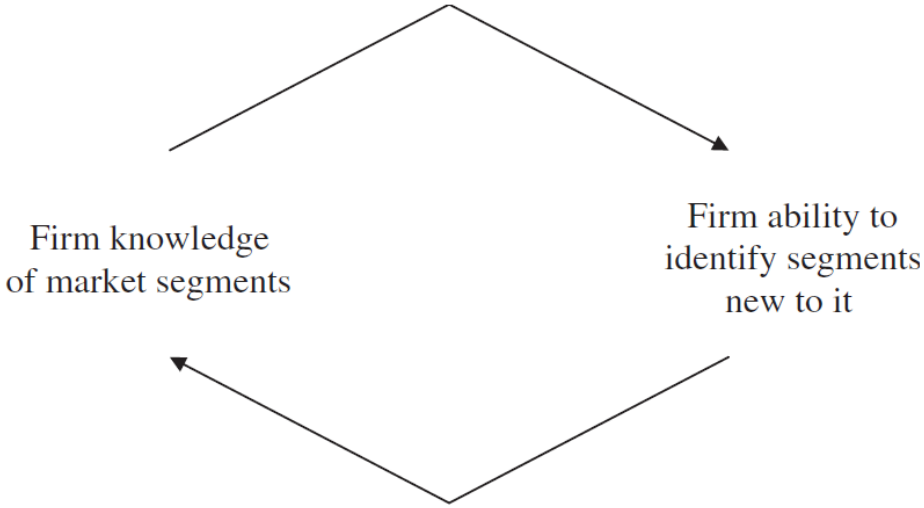

Figure 14: Loop 2, Market leverage (Davenport et al, 2003).

3. **Co-evolution with customers**: Along with learning from vintages and market segments, customer feedback is an important source of information for product development and innovation (see Figure 15). For high-tech products, a key for market success is sharing part of the firm's knowledge with your customers. Another key part of the technology strategy is to educate the customers, and in some cases, the customers' customers. This sharing of knowledge contributes to the development of strong trusting relationships with distributors, encouraging customer loyalty to both the company and its products. Adding close customer contact and careful servicing of distinctive customer

needs, is a promising way for a firm to make the initial innovation locked-in at their customers and increasing the difficulty for imitators to copy.

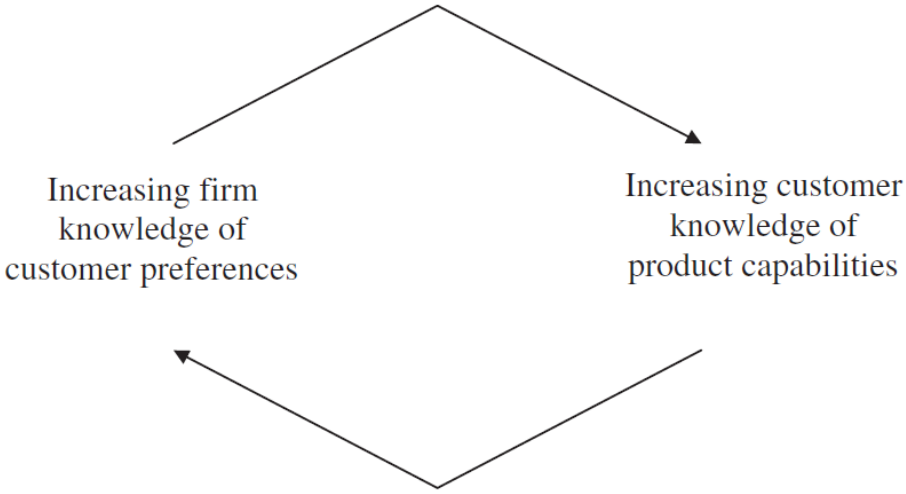

Figure 15: Loop 3, Co-evolution with customers (Davenport et al, 2003).

4. **R&D plough back**: The R&D department is often responsible for bringing new knowledge and innovation in a company. At first, R&D investment are small and usually expressed in time rather than cost. But as margins and sales volume increases, a higher revenue can be made. By "ploughing back" as much as 10% of the revenue, the company increases their chances for an innovative and successful future. As the complexity of their products increase and production methods becomes more streamlined, recruitment and retainment of technically skilled people is crucial for ensuring effective R&D. The two strategies for acquiring the needed competences are to either bring them

indoors or through external contractors. The experts can become significant mentors for the organization and provide guidance along with visions for the future technological directions. Through repeated cycles of accumulating R&D personnel and expertise, the firm differentiates over time through its own distinctive choices regarding hiring, production innovations and new networks, influencing the firm's culture and structure (see Figure 16).

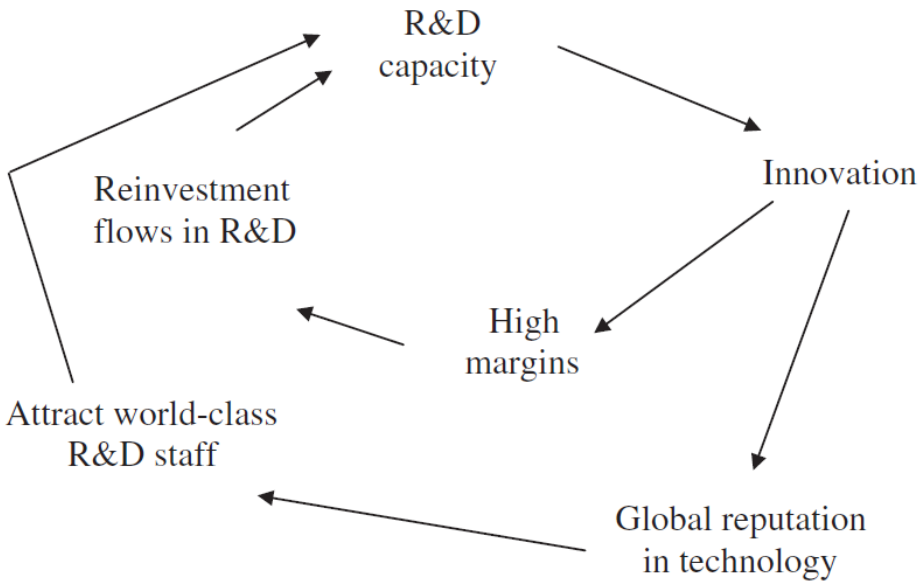

Figure 16: Loop 4, R&D plough back (Davenport et al, 2003).

5. **Co-evolution with technology partners**: Using relationships with partners, the firm can develop a range of alliances and find themselves as a part of a large knowledge-sharing network, typically in a global scope. These networks often evolve as a natural extension of maintaining professional contacts and thereby establishes a network of peer

firms who can grow in tandem. The networks of technological partnerships can vary regarding scope (number of partners) and strength (closeness of contact with the partners) and both work as attributes for positive feedback, which can be seen in Figure 17. As global sources and knowledge in technology grows, the firm becomes better at extending their scope and selecting partners posing mutual technological advantages. The choice of partners and the choice of technologies are two important choices embedded in this loop and these two differentiate the firm from its competitors.

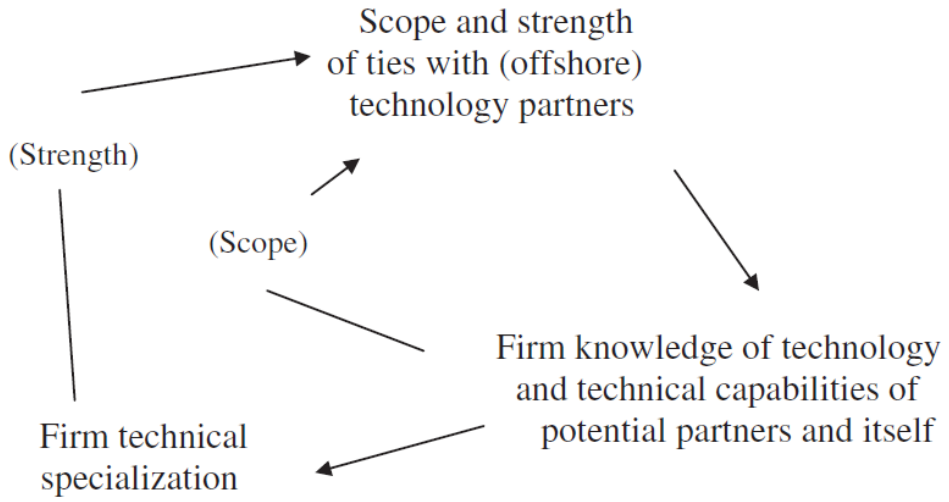

Figure 17: Loop 5, Co-evolution with technology partners (Davenport et al, 2003).

6. **Co-evolution with suppliers**: When a firm develops and grows, it often has a profound effect on the local capabilities. Many firms use local suppliers, and, through their cooperation, the firm can lift the supplier into delivering higher capacity and quality, making both firms grow in tandem. As firms co-evolve, a clustering effect seems to follow. By supporting the development of the firm's suppliers, the suppliers' suppliers will be influenced, and an embryo cluster begins to grow. Through repeated cycles of this loop, the firm will differentiate from its competitors as it and its suppliers develop co-specialized assets, such as expertise within certain steps of the value chain (see Figure 18).

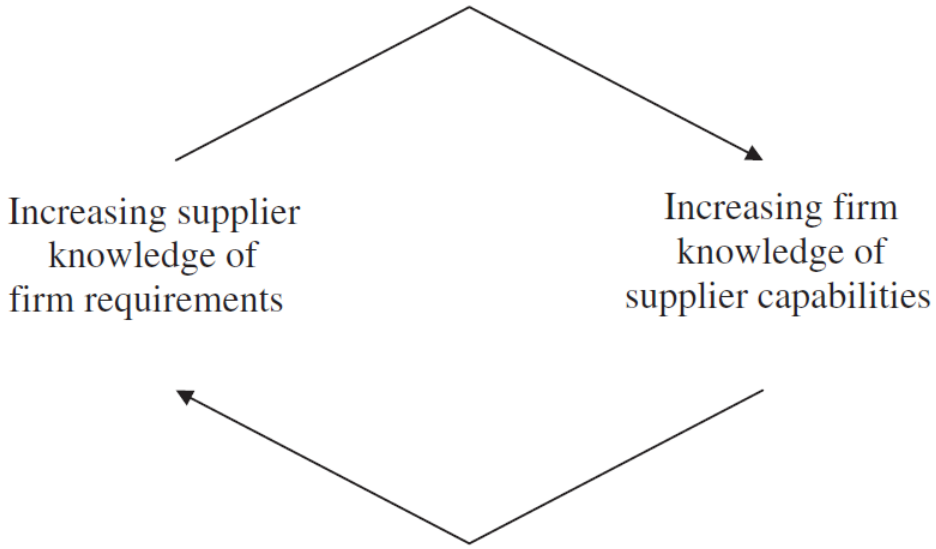

Figure 18: Loop 6, Co-evolution with suppliers (Davenport et al, 2003).

7. **International focus and surviving the gusher**: An innovation with global potential, could lead to the transformation into a global scope.

At this stage, the technology strategy in the firms shifts from exploratory to exploitation. Some firms know that their technology in world leading, while others are in need of self-confidence strengthening and persuasion that their technology has a global market value, enabling them to take the global leap. When entering a new and unevolved market, the company has both the opportunity and the challenge to set the standard and thereby both lock-in new products and lock-out competitors. When discovering and pursuing their global potential, a challenge of rapid increase in demand will put a great deal of stress on the company's functions and abilities for rapid growth, known as '*the gusher*'. Increased stress on delivery, quality control and staff training will all be exposed to challenges and problems while the demand for the company's rises, sometimes tenfold. Offshore experiences, reputation improvement, appeal to potential customers and involvement in setting standard for markets all work together and by using these feedback loops in Figure 19, the company constantly learns and improves their work.

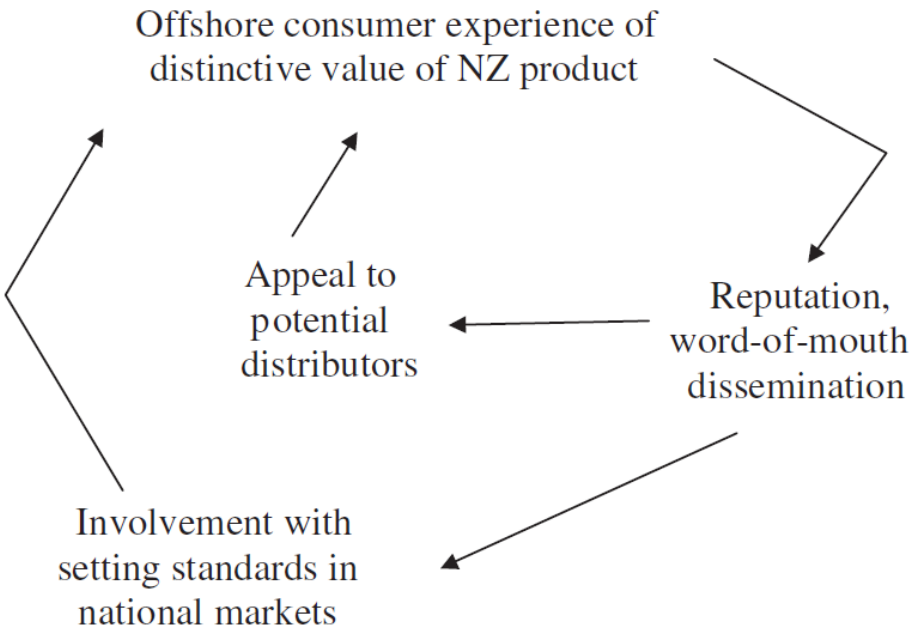

Figure 19: Loop 7, International focus and surviving the gusher (Davenport et al, 2003)

A firm does not have to go through all loops and neither in any specific order. The 7 loops of the model are obviously not independent of each other and working on one loop will lead to a spill-over effect on other loops. (Davenport et al, 2003)

5. Results

In this chapter, the interviews with companies and supporting organisations have been summarized. The three company interviews are presented first and thereafter the three supporting organisation interviews. In the last subchapter, anonymised opinions from the interviews about the MedTech industry are presented.

5.1. Suturion

The company was founded in 2018 by surgeon Gabriel Börner, together with the MedTech engineer Mats O. Christensen. Börner recognized the need for a better method when it comes to closing up after abdominal surgery, which lead to the development of SUTURE-TOOL. SUTURE-TOOL is a classified class II, CE marked hand driven sewing machine for surgery and aims to replace sewing by hand, which is the commonly used method currently. Today about 20% of open abdominal surgery closures result in abdominal rupture due to lack of sufficient quality of the stitches, with hernia as one of the effects.

From the beginning, the entrepreneur had a specific medical knowledge but suffered from a limited network within the business world. Early in the process, Börner began working together with LU Innovation. LU Innovation is considered to have been crucial in their assistance concerning quality ensuring, design changes, documentation within quality documentation and con-

tributed with an extensive network of contacts. Suturion also began a cooperation with Join Business & Technology Lund, concerning prototype development.

LU Holding has supported with building a healthy structure in the company, ensuring that a stable foundation has been build, which reduces the need to redo certain steps in the future. They also made a smaller investment early on, office space and provided surrounding services and help regarding legal questions, experiences, proper accounting, contact with Bolagsverket, patent applications and other advice, to name a few.

At the early start, soft money from Vinnova has been applied for and received, and several other applications for soft money is pending. Some of these applications processes are complicated and require Suturion to hire external help with the application. To be able to grow, several new emissions and investments from external partners have been made. There was a lack of capital until 2021, when Almi Invest, among others, entered financially through a new emission and have since then, as an owner, been assisting with a CEO network, advising services and building the company. Today, Suturion has no loans and aim to continue this way.

Suturion had an external company make a market analysis, which later worked as the foundation for their strategy development. The strategy chosen was to focus on colon surgery and taking market shares from current competitors. Sweden is considered to be the first market for Suturion due to the company's origin and closeness to market, and later the EU market and the US market will be the focus, but it depends on where Suturion gets their licence first.

Possible recruitments were analysed as the company grew, with the help of LU Innovation and LU Holding and their networks, while other services were externally purchased. One strength of Suturion is the competent consultants who have been externally hired, mostly regarding quality regulations and construction. Thanks to the investments made in the new emissions of 2021, Paan Hermansson, with over 20 years of experience within MedTech, was recruited as CEO in the spring of 2022, Suturion has conducted a deeper and more covering market strategy along with better documentation including segmentation analysis. These analyses have confirmed that the previously chosen strategy is the right choice. Suturion is today a small company, which leads to fast decision making without complicated procedures and bureaucracy and aims to stay this way in the future, while growing.

A big focus during the years has been to develop the product and working of the design continues but is not the main focus today, due to the fact that Suturion has limited resources as a smaller company and has many other focus areas. There has been challenges with the technical design and the construction of SUTURE-TOOL, challenges which have been solved along the way. Another challenge has been finding the right partners and contractors for production, especially since SUTURE-TOOL is made up of 11 different injection moulded parts which demand high precision and accuracy, some parts demanding a precision of 0.1 mm. In the near future, the regulatory process connected to MDR is considered to be a challenge.

5.2. MedVasc

The company MedVasc was founded in 2013 by Michael Åkesson, who is doctor in intervention radiology, which is vascular treatment with minimal invasive technique. Åkesson has a research position at Lund University but describes himself as more of a practitioner than researcher, and entrepreneurship has always seemed a more appealing field to him. He has experience in management and has been head of clinic in Ystad, section chief of the vascular clinic at MAS (Malmö Allmänna Sjukhus) and has run a company within medical locum connected to 22 health centres. Åkesson has also been working over 35 years with development, design, testing and advisory within the MedTech industry. About 10 years ago, Åkesson resigned from public health care and works today as partner and senior consultant at the private clinic Scandinavian Venous Centre in Malmö. Åkesson has, apart from medical experience and knowledge, also experience in entrepreneurship, starting up and running companies and development of ideas, but lack knowledge within business strategy, economy and the MedTech industry.

Åkesson got the idea for MedVasc when he in his clinical work wanted to find a more effective and less painful way to treat varicose veins. Solutio, which is MedVasc's invention, differed from the common method of applying local anaesthetics through needles along the whole leg being treated, while Solutio is used to apply local anaesthetics from inside the vein. Using Solutio comes with multiple advantages, such as reducing the post operation time to less than 15 minutes, less pain experienced by the patient, less anaesthetics being used leading to fewer complications and halving the operation time. Solutio is expected to be classified as a MedTech device in class IIA

according to MDR, and MedVasc is currently in the middle of the regulatory process.

In 2013, Åkesson pitched his idea to his accountant, who advised him to start a company and put the patent in the company. The patent for Solutio was financed by Åkesson through his company MedPACS Network AB and sent in in 2014, via a consultancy firm. Currently MedVasc has one patent, Solutio, on several markets around the world, including the US and European markets. MedVasc has a patent pending in China, which is expected to be approved in 2022. In the future, after establishment on the market and growth of the company, MedVasc plans to develop more products, with variation in size and applications areas. The goal is to have a pamphlet of products which can be used in arteries and during oncology treatment of tumours, to deliver cytotoxic drugs locally in a tumour with higher precision than current methods can deliver.

In 2014, Åkesson had a fruitful brainstorming session with an Israeli colleague who he had been working with earlier and developed catheters. After some advice from an entrepreneur colleague, Åkesson got in contact with Person A at Innovation Skåne. Person A guided Åkesson in structuring and projecting the work and making a project plan. Via Innovation Skåne Åkesson got in contact with LU Holding and pitched his invention, successfully. In 2015, LU Holding made an investment in MedVasc, along with Person A and Åkesson himself, and Person A entered as CEO 2016-2019. Person A was considered to be the right person for the position during the first years, but as MedVasc focused more the regulatory process, clinical work and building the organisation, it became clear that Person A did not have the necessary qualities needed in a small company. When recruiting someone in a start-up,

high commitment is important along with being prepared to work with all kinds of tasks, in the insecure environment that a start-up is working in, according to Åkesson.

Through LU Holding's and Malmö based Connect's network, business angels who have experience and knowledge within MedTech were selected to also make investments. Via LU Holding, MedVasc got in contact with SmiLe Incubator and was accepted into the incubator program. At SmiLe, MedVasc has coach meetings once a month and can exchange a lot of experience with the other SmiLe companies, who are in similar positions and can provide important advice. SmiLe has also provided some soft money and contacts resulting in minor investments.

In 2017, MedVasc received soft money from Vinnova, which financed the creation of the prototype and animal trials, but wasn't enough to finance human trials. To finance human trials, new capital is brought in by business angels, LU Holding and Åkesson. MedVasc was also in contact with VC companies, but they were not interested in making investments before the product had reached the market.

By the start of 2020, MedVasc had gathered Almi Invest and several business angels to make a bigger investment that would ensure market entry. But when the pandemic of Covid-19 hit, the investors reoriented away from mechanical MedTech instruments. This was a major blowback for MedVasc and the momentum they had created, since the human study which was planned to be the foundation of the regulatory process in MDR, had to be postponed. During the pandemic the company has been kept afloat through private investments made by Åkesson and through profit made form the clinic, at the same time as costs where cut to a minimum. From the autumn of 2021, the pandemic

seems to be more under control and the future looks brighter, according to Åkesson.

At the start of the company, the main focus was put on securing the patent, but in hindsight Åkesson realises that the regulatory process with MDR, CE-marking and notified bodies should have been started earlier. The greatest challenges for MedVasc have been financially and the regulatory work and process is cost intensive. Applying for capital requires a lot of time, both when applying for soft and hard money. A realisation of Åkesson is that raised capital in the MedTech industry is spent quickly and most of the times cost are higher than calculated. Another challenge has been completing the regulatory work according to MDR, a process where SmiLe has provided advice, and which has been implemented by external consultants. A third challenge has been finding the right competence and experience in recruitment.

Treatment of varicose veins is mainly, but not exclusively, carried out in private clinics. The segment MedVasc is focusing on is private clinics, public healthcare and customers paying for their own treatment, depending on which market is considered. During the years MedVasc has had several strategies during the years, but the experience has taught the company that it has to be altered and iterated as the environment constantly changes.

5.3. MedTech AB

The company MedTech AB (anonymised start-up in the MedTech industry) was founded in 2006 by a senior colorectal surgeon with 30 years of experience within advanced rectal cancer surgery. The founder has a PhD in cellular biology and has, prior to his medical career, worked 5 years as constructor of rear axles for trucks and landing gear for airplanes.

The idea for MedTech AB originates from when the founder in his medical work started thinking about a better method to joint intestines, with a focus on the colon. After 10 years of work at a smaller hospital, the founder started working at a university hospital. There, the founder conducted research within anastomosis together with a professor (further referred to as PU) and together they developed a new technique for anastomosis. The new technique resulted in the Product 1, which years later was developed into Product 2, and comes with several advantages compared to currently used methods: The risk of leakage was reduced from 10% to 1-2% according to current studies, the need for overall medical care is reduced, the risk for temporary stoma is reduced and the patients generally suffers from fewer complications.

Due to the research being conducted at the university hospital, the founder got in contact with LUAB (previous name for LU Holding) in 2005, around the same time as the patent was applied for. Before creating the company, successful animal trials were conducted as the first step of MedTech AB's strategy. LUAB were interested in the founder's idea and assisted in creating MedTech AB and helped develop the company over the years to come. They also assisted in the contact with the patent office and contacts in the MedTech industry. LUAB made MedTech AB's first investment and were active in the

company board during the first years, but has since then stepped aside for other investors, according to their policy, and now has a more passive investor role. PU was active during the first years of development but left the company after a few years. To be able to create the right validity to the product, an important step was to produce the product according to the ISO13485 certification standards. LUAB, using their network, opened up possibility for MedTech AB to meet possible investors.

The first financial round was successful, which lead to the founder deciding to take a leap of absence in 2009 from colon rectal surgery and focus fulltime on the MedTech AB. MedTech AB has made a total of 18 new emissions over the years, where the founder and multiple business angels have invested capital, contributed with their network and joined the company board. In the latest new emissions, a number of Corporate Finance companies have been helpful in securing capital.

Starting a MedTech company demands certain processes being followed according to MDR (or FDA), such as CE marking the product, scientifically proven effectiveness and safety of the product, and following ISO13485 standards, in order to ensure that the foundation is solid. The need for expertise in these areas lead to recruitments, which made it possible for the founder to delegate his previous responsibilities and focus more on certain other areas. The first product, Product 1, which was developed for open surgery, was CE marked in 2010, as a second step of MedTech AB's strategy, thus opening the possibility for conducting bigger clinical trials. A conducted market analysis highlighted that the future colon and rectum surgery methods were moving away from open surgery and towards laparoscopic and robotic surgery. As a result of this, the company board decided in 2013 to start development

of Product 2, to fit the new surgery methods and widen its application area to all type of colorectal surgery. The implant itself is relatively unmodified, but the attachment in the intestine is more advanced in Product 2 compared to its predecessor. Product 2 is classified as class IIA and got its CE marking in 2018. MedTech AB has developed several surrounding features to enable validation of the joint in real time during surgery and post-surgery to monitor the joint, through QR codes, applications in mobile phones and vacuum pumps. In 2020, a private clinic (established in 2021) was founded where Product 2 is practiced in surgery. The clinic serves several purposes, including reducing the queue of patients waiting for surgery, possibility to accredit surgeons with the new technology and create awareness of Product 2. The clinic has so far only performed surgery on a few patients but is profitable and is considered to be a future source of income for MedTech AB through resell to clinical companies. Today, MedTech AB has grown and consists of the board of directors, a new CEO (since April 2022), the founder as CMO (previously CEO 2006 - 2022), two quality managers, two production managers and two salespersons.

According to the founder, the three biggest factors for the success of MedTech AB has been the product and its innovative technology, the team consisting of the founder, the quality manager and the production manager, and the commitment and competence of both the team and the board. By having experience within both medical and production work, the founder has been able to design and develop a product which surgeons would like to use in their work. One of the biggest challenges for MedTech AB has been the need for capital to develop and continue develop advanced MedTech products. Creating new emissions and convincing both old and new investors is a time-consuming process, according to the founder. Another challenge has

been the fact that a new technology always raises suspicion among professionals and people in the MedTech business. A third challenge for MedTech AB was to create interest to produce smaller volumes of goods among producers initially. Producing volumes of a few goods increases the COGS (Cost of Goods Sold) due to fixed costs being divided on fewer products. The cost per product has been reduced from initially SEK 60,000 down to SEK 7,000 today. For financial reason, the founder used his knowledge from working with production prior to his medical career and produced the first prototypes on his own.

The product is being promoted on the evidence basis of scientific studies where reduces leakage frequency and improved health economy are the biggest selling points. The intended customer segments are surgeons and clinics performing surgery on cancer located in the colon and rectum. MedTech AB has signed deals with distributors all across Europe and retailers all across Western Europe, which has led to a contact network of key opinion leaders across Europe. The first target is to establish on the European market and once receiving FDA approval, enter the American market. The interest for the product has exceeded expectations, but it has not reached the market yet and is planned to do so in 2024/2025.

5.4. LU Innovation

Simon Jegou has a long experience within Life Science and MedTech, and was until recently head of the Life Science group at LU Innovation where he worked 5 years as Business Developer helping researchers to translate their research results into new innovative products and solutions that address unmet medical and market needs. Jegou has a PhD in Materials Chemistry from LTH, Lund University, with more than 15 years' international experience in Life Science occupying diverse management roles within Business Development, Innovation, and R&D. Jegou is currently Chief Strategy Officer at Magle Chemoswed.

LU Innovation is the TTO at Lund University and is financed by the university. The purpose of LU Innovation is to support researchers and students in developing their ideas and inventions. Getting help from LU Innovation is free of charge and available for everyone, but for LU Innovation to get involved in a project, certain criteria must be fulfilled:

- The researcher or student shall not have terminated its employment/studies longer than 6 months ago prior to the first contact with LU Innovation
- If a company is already created, at least one of the founders must have a connection to LU
- The researcher must own at least 50% of the company (and eventual IP)
- The company cannot have received more than SEK 1 million in external investment

LU Innovation recommends the researcher to not create their company in a too early stage, before having made a business hypothesis and a business plan. This recommendation holds in any case as it is important that the company has been started in the right way, but also for the entrepreneur to be able to apply for certain soft money grants, specific for e.g., academical projects with high commercial potential.

When LU Innovation gets involved with a project, their main contributions are the following:

- Support with an initial assessment of the market and IP situation (desktop research, access to databases)
- Support in creating a business case for the project
- LU Innovation receives each year a budget from Vinnova and the university which they can use to financially support select projects during the verification and initial development phases. Typical grants are VFT -"Verifiering för tillväxt" (up to SEK 300,000), that can be used to verify a business hypothesis, build a prototype, conduct a deeper market analysis or travel to meet potential customers, or applying for IP protection, and VFS –"Verifiering för samverkan" (up to SEK 150,000) that can be used to initiate or strengthen collaboration between academia and industry around an important market or societal need. A committee of business developers at LU Innovation reviews the project applications each week.
- Aids when applying for grants both in Sweden and the EU
- When applicable share its contact network
- Guidance in IP and patent applications

In their work with a project, LU Innovation uses several well proven methods and models to structure their work. Some of these are NABC (Need-Approach-Benefits-Competition concept by SRI International), which uses four questions to create a robust value proposition, Lean canvas and Business model canvas. Every project requires their own working path and selection of models to e.g., structure the business hypothesis. The business developers of the Life science team at LU Innovation have previous experience from the industry and are familiar with the typical development phases of the Idea-to-Product process and can guide researchers navigate and prepare for them:

1. **Idea phase**: The idea is discovered. The market need is verified and the idea is developed by the researcher.
2. **Development phase**: Development of a first prototype and first evaluation of the regulatory path (MDR) with required documentation for the CE-marking of the intended product/service. LU Innovation do not participate in the regulatory work but can provide initial guidance and contacts to regulatory consultants.
3. **Verification phase**: Technical verification, meaning proof that the technology developed works the way it was aimed to do.
4. **Validation phase**: Consists of two validations: Technical and Clinical. Technical validation, meaning that the production method produces exactly the same product each production cycle without any variation. Clinical validation, meaning clinical studies are performed that prove that the product is safe and efficient fulfilling its intended use. A technical file is compiled and submitted to respective EU or US agencies to obtain permission to commercialize the product.
5. **Commercialisation phase**: Reaching the market and creating turnover, profit and company growth.

Going from idea to market is estimated to take 5-10 years and cost between at least SEK 10 million and SEK 100 million, for MedTech start-ups created by researchers. LU Innovation is involved in the initial phases of the project typically until a company is created (or has taken in more than SEK 1 million in external investments and therefore considered as validated by the market) and a prototype and business plan are ready. After that, the project continues its entrepreneurial journey on its own, via a start-up incubator for instance, and/or through collaboration with LU Holding AB, who can invest and assist in the creation of the company and further capitalization. There is at this point the possibility for LU Innovation business developers to continue assist operatively the company by joining the board of directors (without emolument).

The MedTech industry is a regulated industry, with the safety and the patient's best interest in focus. MDR demands extensive documentation which often requires specialised competence from e.g., external consultancy firms. Products classified as class I does not usually require clinical studies or involvement of a notified body, but for higher classifications, this is a requirement. The MedTech industry is capital intensive and a company's development follows a traditional S-shaped curve, meaning that they are depending on substantial external capital until they can become profitable (often also referred as the "the cash valley of death"). It is an advantage for the entrepreneur to have academic and medical competence for several reasons. One of the reasons being that even when having a CE marked product, the entrepreneur must be able to convince other key medical professionals about the product being safe and efficient. Another reason is being able to plan and conduct clinical studies in the right way.

Success factors for a start-up in MedTech:

- There has to be an engaged team behind the project. LU Innovation assists in building the team, which does not have to be complete from the beginning. It is important that the team consists of all necessary parts needed to run a business, such as experience in sales, entrepreneurship, manufacturing and legal matters.
- There has to be a committed and driven enthusiast in the company, who wants to drive it forward.

Red flags and pitfalls to avoid for (academic) start-ups in MedTech:

- In the academia, focus is on getting your research published. This can lead to the mistake of disclosing the invention or discovery, which then becomes public knowledge and thereby unpatentable. LU Innovation recommends that researchers get in contact with them early in the process, to discuss the possibility to patent the discovery.
- Not having a sufficient knowledge about the proposed market and being too involved in the researcher's own science
- Not having entrepreneurship experience when launching the company on one's own
- Not preparing for the financing and commercialization phases when the patent is submitted. Jegou points out that as soon as the the patent is submitted, "the clock starts ticking". Within about 3 years, the patent must be protected in the countries where the product is intended to be marketed (national phase) which can usually be costly for start-

ups. Therefore, before reaching the national phase the business hypothesis must have been verified and validated, investors found and a plan for commercialisation been created.

- Not reaching out to LU Innovation if unexperienced in entrepreneurship. E.g., to be able to apply for investment, one has to present the commercial potential of the invention, something that could be hard for an academic with limited experience.

5.5. LU Holding AB

Christine Widstrand has been working at LU Holding since 2009 and became CEO in 2020. Widstrand has previously run companies within BioTech (Biology Technology) for 10 years at Ideon in Lund and has been on the board of several companies. LU Holding was previously named LUAB (Lunds Universitets Utvecklingsbolag AB) and together with LU Innovation, they were previously named LUIS (Lunds Universitets Innovationssystem AB).

There are several requirements on the entrepreneur and the project which need to be fulfilled in order for LU Holding to engage fully in a project:

- The innovator must have a connection to Lund University, either as a researcher or as a student
- There has to be a great growth potential in the invention
- The invention should be unique and able to protect against competitors
- The invention must be scalable on a global market
- The invention should contribute to societal benefit
- There must be a team behind the project, which is engaged and ready to invest serious time and energy (the team does not have to be complete and can be completed during the collaboration with LU Holding)

It is common, but not a demand, that the entrepreneur has been in contact with LU Innovation prior to contacting LU Holding. LU Holding usually do not approach projects and entrepreneurs first, but instead the entrepreneur contacts LU Holding. The following are services that LU Holding provides for the companies they invest in:

- Assisting the entrepreneur is creating the company
- Making a first investment in the company, up to SEK 1 million
- Building the company board together with the entrepreneur and making sure that the right competence is recruited (both through LU Holding, investors and board professionals)
- Creating the correct legal agreements
- Providing and pays for accounting during the first 2 years
- Creating stockowner agreements
- Assisting in patent applications
- Building the business and ensuring investments are possible for future emissions and investors
- Distribute soft money from Vinnova, up to SEK 300,000 per project

LU Holding has a good reputation in the business and if they have invested in a company, it is considered a quality mark for future investments, according to Widstrand. Even though the money LU Holding invests are important for the company, the surrounding services are considered the real benefit for the company. By creating a solid and competent company board, the company is considered are more credible, leading to a higher interest from investors. Companies who have collaborated with LU Holding have a high success rate compared to other start-ups, according to Widstrand.

LU Holding is a stately owned holding company which was allocated a start capital in 90's, which they since then have administered and managed. As a result of many successful investments in start-ups, LU holding has increased their capital over the years more than tenfold, giving them the opportunity to invest in more start-ups. Currently LU Holding invests around SEK 10 mil-

lion per year, with a maximum of SEK 1 million per company. Some universities in Sweden are connected to private holding companies, who can receive other types of capital to increase growth of their capital. By being located in Lund, LU Holding has the connection to Lund University and thereby has a steady flow of inventions and entrepreneurial ideas. The focus of LU Holding is on creating local growth and working together with the researchers and are considered to be kinder than private holding companies. VC companies can often put higher demand on proof of profit to invest and are tougher in the negotiations towards a start-up. After an investment from LU Holding, the order for investment is usually business angels, Almi Invest (or similar organisations) and VC companies, according to Widstrand. Lately a new type of VC companies focused on MedTech have appeared.

MedTech is an industry where the lead times are longer than other businesses, with exception from DeepTech and pharmaceutical industry. One reason for this is the regulations surrounding MedTech, e.g., quality systems, CE or FDA marking and notified bodies. The regulatory work is considered to demand advanced knowledge and normally either a recruited quality engineer or external consultants are used for this matter. As a result of this, the MedTech industry is capital intensive and a higher classification of the product leads to that the demand for capital increases.

For a company in the MedTech industry, the time to market is considered to be at least 5 years but is usually longer. Higher classification of the product according to MDR demands more clinical testing and a more advanced quality system, which delays the market launch. LU Holding is usually active in a company during the first years. After being in contact with LU Holding, some companies contact incubators as a next step, while continuing working

with LU Holding. When the company has grown and is independent, LU Holding prepare for a slow and controlled exit from the company.

Success factors for a start-up in MedTech:

- Getting in contact with the market early in the process. Through this, valuable information can be gathered about the industry and possible customers and ensuring that the chosen market exists. Early contact can also provide contacts for future businesses.
- Having an exciting and unique idea
- Having a team which is engaged, driven and has the entrepreneurial spirit
- Getting the right competence into the company and creating a solid board of directors.
- If there is lack of experience within entrepreneurship and the MedTech industry, it is recommended to get in contact with e.g., LU Holding or incubators, who can provide guidance and surrounding services
- Getting the technology to the market, while having the advantage of a new technology'

Red flags and pitfalls to avoid for start-ups in MedTech:

- The entrepreneur not wanting to let go of their control of the company and give up part of the company ownership to investors. By letting investors in this way, the competence in the company increases and thereby the chances of success and reaching the market earlier. "One might keep a smaller piece of the cake, but the cake can grow".
- Believing that a good product will sell itself.

- Living in one’s own bubble and not talking to the market
- If it takes too long time to reach the market, the technology might lose its edge and get overtaken by competitors

5.6. SmiLe incubator

Malin Sjöö holds the position of business developer and coach at SmiLe Incubator since 2020. She graduated from chemical civil engineering in 1999, became doctor within food technology in 2005 and later became docent. A discovery in her university research laid the foundation for starting her own company in 2012. Sjöö worked there fulltime until she sold the company and joining SmiLe Incubator in 2020. She currently has a consultant role in her old company and has collected extensive experience in developing and running a company, which she uses to coach new companies within SmiLe Incubator.

SmiLe Incubator has been operational since 2007 and has been involved with around 100 companies since then, out of which 86% are operational today or have been acquired by another company. SmiLe has a focus on the life science perspective, which includes MedTech, pharmaceuticals, BioTech, diagnostics, digital health and food industry. At SmiLe female entrepreneurship has been important to encourage and about 50% of the companies in the incubator program either has a female founder or a female CEO. There are 30 different nationalities within SmiLe team and the companies, which according to Sjöö makes working internationally easier due to more diversified perspectives being available on the inside. In the team at SmiLe, there is a wide range of experience within life science and entrepreneurship.

SmiLe has a close collaboration locally with LU and Malmö University and the TTOs and holding companies connected to them, which is one way for companies to get in contact with SmiLe. By having open discussions with LU Holding and LU Innovation, they contribute to an environment where new

companies can grow. However, companies do not have to go through these channels but can instead seek contact with SmiLe directly. It also happens that SmiLe seeks contact with companies they find interesting and who have potential. SmiLe works virtually with companies across the entire Sweden if they lack the ability to visit SmiLe's office in Lund. After an initial meeting with the company, SmiLe starts a screening process. The next step for the company is to pitch their company for all SmiLe coaches. For SmiLe to get involved with a company, certain criteria must be met:

- The company must have been started and have some initial funding (either soft or hard money)
- There must be an entrepreneur (a so-called champion) with a will to drive the company forward
- SmiLe must believe that the company idea will work and that it is unique and have an edge on the market
- The idea must be scalable
- There must be a potential for growth, preferably on the international market.
- The company must be considered to contribute to the SmiLe Incubator community

SmiLe is managed by a foundation, which is owned by LU, Lund Municipality, Medicon Village and Region Skåne. The foundation, together with soft money from Vinnova, finances SmiLe. "*No fee, no equity*" is a motto for SmiLe, and like most other incubators in Sweden, do not invest in companies. Instead, SmiLe contributes with the following to the companies in their incubator program:

- Business development, which is the core work for SmiLe
- SmiLe is not operative but are instead advising and mentoring in the companies.
- SmiLe assigns a coach to each company, for regular meetings and coaching
- The company has other companies in the environment at SmiLe and can thereby exchange experiences, advice and provide inspiration
- SmiLe arranges seminars and workshops for the company to participate in within e.g., regulatory processes, HR and hiring and economics
- Take part in SmiLe's network in the industry and get in contact with possible customers, partners, business angels and other financiers
- SmiLe works with the packaging of the product and clarifying what the company is actually selling e.g., technology, license, production, patent rights or individual products
- Assistance in everyday business questions
- Get in contact with more mature companies through SmiLe's alumni network, to exchange experiences and get practical advice
- Subsidized laboratory space and equipment
- Possibility to rent office space via Medicon Village
- Advice concerning classification of products

According to Sjöö, the usual process for a company is getting in contact with LU Innovation, then LU Holding, contact with an incubator and raising external capital from business angels. VC companies normally demand a clearer market potential from the company and are more interested in making invest-

ments once commercialization is proven to work and the model for customers, market and the business are validated. A normal cycle time for a company at SmiLe is 2-5 years, depending on the development horizon of the company. At SmiLe, a company moves through 3 phases:

- **Verification phase**: Working with understanding the market and segmentation of potential customers. This phase last usually 6-12 months
- **Development phase**: Developing the company, conducting contracts and entering the market
- **Scale-up phase**: This phase enters when the company and SmiLe in unity decide that the company should continue on its own. After this phase, the company becomes a part of SmiLe's alumni network, where they can contribute with experience to new companies in the incubator program

If a company is working within MedTech, the regulatory process makes time to market longer compared to other industries. It is considered necessary for an entrepreneur within MedTech to either have a medical competence or recruit this into the company. Many companies within MedTech focus early on either the European or American market, which dictates which regulatory work should be followed. MedTech is also considered a capital-intensive industry, with the regulatory work and clinical studies as main cost drivers.

Success factors for a start-up in MedTech:

- At an early stage, get the proper assistance to understand the demands that the industry and regulations have put up
- Ensure proper IP protection prior customer and producer contact

- Get in contact with the market and potential customers at an early stage, to ensure that the intended market exists and to get contacts needed for future development steps
- Talk to many different actors in the business and evaluate the received advice. If the advice is consistent, it probably means that this is the right way to go, while if they are scattered, it could mean your presentation of your product is inadequate.
- Dare to receive investments in exchange for giving up part of the company shares, since it increases the chance for the company to be successful.
- When taking in investments from businesses angels, the recommendation is to focus on what each angel can bring to the table concerning previous experience and competence, apart from their monetary investment
- Having entrepreneurship in your surroundings, to get support and tips

Red flags and pitfalls to avoid for start-ups in MedTech:

- Not being able to build a team containing the right competence and not ensuring commitment from the team.
- Choosing the wrong market (or discovering that the market does not exist)
- Getting in contact with the market in a too late stage
- The entrepreneur going into the company fulltime too late. The more time that can be put on talking to investors, finding customers and partners, the greater the chance for success is
- Realising too late that clinical studies are expensive and demand external investments

- Taking in too many passive investors, since this might make it more complicated to take in more investors later on.
- Not achieving proper financing
- Not securing the proper IP protection and being suffocated by the competition

5.7. Anonymised opinions about the MedTech industry

In this subchapter, thoughts about working in the MedTech industry are collected and anonymised from the interviews. This is done partly to ensure that thoughts expressed by the interviewed persons cannot be traced back to a specific individual, company or organisation and partly so that the thoughts can be analysed in a broader perspective. All of the advice and warnings flags from the companies and organisations can be found in table 5 and table 6 Appendix 3 and 4.

Working in the MedTech industry is, according to the majority interviewed, an industry where the need for capital is greater, compared to other industries. MedTech approved materials are mor expensive than other materials and all processes necessary to keep a company running are connected with great costs of a several SEK million per year. It was a unison experience from both the entrepreneurs and the organisation representatives that starting a company within MedTech proves to take both severely more time and cost severely more money than initially predicted.

"Creating a MedTech start-up usually takes about 10 times longer and costs 10 times more than initially calculated" – Anonymous interviewed organisation worker.

When the new system, MDR, was introduced, there were some side effects connected to the change of regulations. Changing systems always lead to new interpretations of the new regulations and this is an expected aftermath which is hard to avoid. This aside, the unison opinion is that the biggest consequence

was that all companies and products already on the market needed to be recertified according to the new regulations. This lead to an acute lack of NBs, which created a bottle neck problem where the waiting time for certification increased. This creates a seller's market for the notified bodies and has led to an increase in their prices. According to most interviewed, these factors create a risk for start-ups choosing to approach the US market instead of the European market, due to shorter time to market.

Some entrepreneurs expressed having to face scepticism from other medical professionals, when presenting a new innovative MedTech technology. Presenting a brand-new technology is also more challenging than presenting a modification of an existing technology, since there is no current literature supporting it and therefore the demand for scientific proof of effect increases.

An opinion expressed by some of the entrepreneurs has been the problem of patent processes in certain countries in Asia. Some countries have certain demands of national connection to that specific country and other countries have a weaker IP protection, leading to an increased risk of getting the patent being stolen or copied by companies in certain countries.

Another addition worth pointing out concerns the choice of strategy and models used to achieve this. All of the interviewed companies have been working with one or more of LU Innovation, LU Holding and SmiLe Incubator, who all have models and strategy principles they follow. Even though the interviewed companies might not recall which exact models and working methods they have been working in accordance with, it is safe to say that they have worked with some literature-based strategies and models.

6. Discussion

In this chapter, results of the interviews are combined with the theoretical background and the theoretical framework and analysed. The first subchapter presents each company's connection to the definitions and their usage of theories. The second subchapter presents three big challenge area the companies have had to face. The third subchapter describes the companies' placement into Vohora el al's model (2004) and connects them to the start-up methodologies. In the final subchapter, critical reflections on the chosen research approach and methodology are discussed.

6.1. Definitions

6.1.1. University spinout companies

Using the definition of USO and start-ups presented in Chapter 3, it can be concluded that all three companies interviewed fall under the definition of both USO and start-up. They have all been started in connection with a university, with either the technology developed at the university or the founder having a connection to said university, the two main criteria for being defined as a USO. As a result of this, Vohora et al's model concerning Development phases and Critical junctures (2004) is applicable for all three companies. In accordance with the definitions of a start-up in Chapter 3, the three companies have developed a new product connected to great uncertainty, which was expressed by all interviewed companies.

6.1.2. Job to be done and the four zones of innovation

The three companies interviewed were all founded by medical doctors, who in their work thought about ways to improve patient care and put themselves in the shoes of the patients and medical staff. They asked themselves during their work, how to best develop and improve current treatment methods and all came up with innovative solutions to existing problems. Initially, questions such as “Do you have a job that needs to be done?”, “What workarounds have people invented?” and “What surprising uses have customers invented for existing products?” were asked by the entrepreneurs interviewed. By identifying that there was a job to be done and asking the right questions, the founders have been working, unknowingly, in accordance with Christensen’s theory of “Job to be done”, presented in Chapter 3, while being unaware of the theory behind.

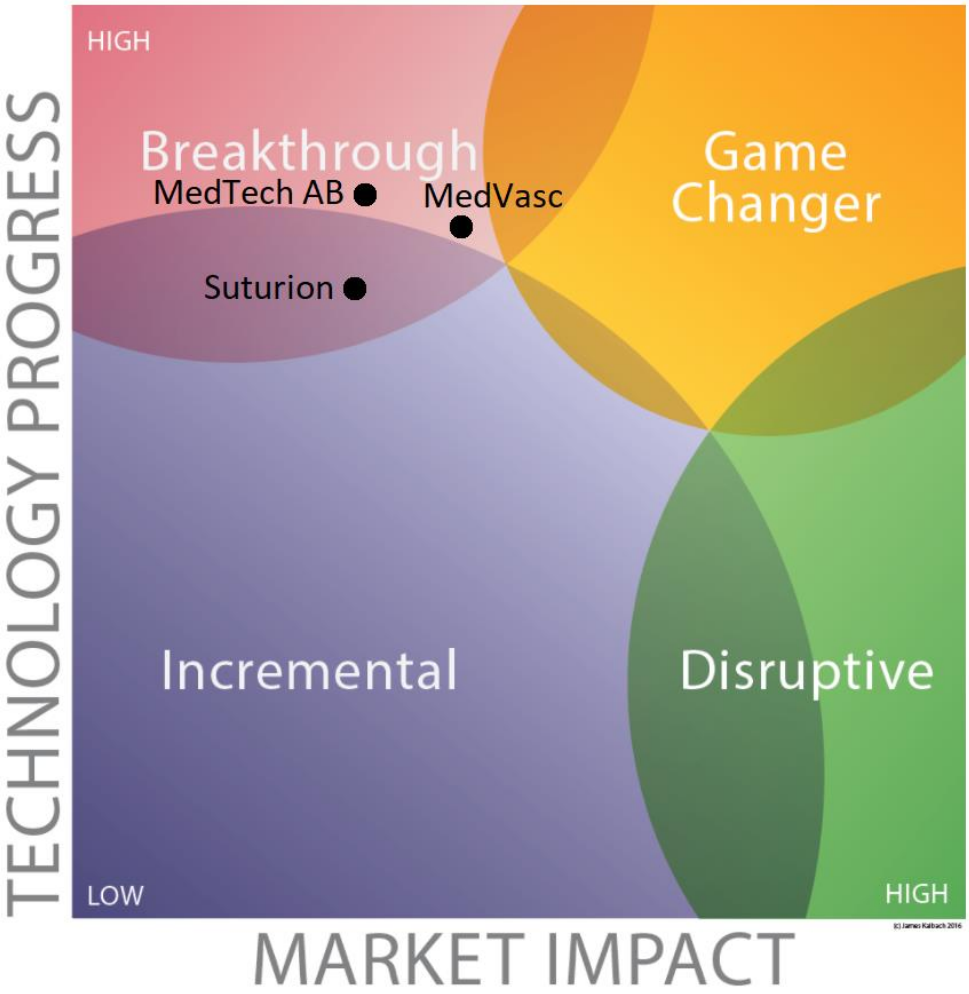

Figure 20: The four zones of innovation with the interviewed companies mapped out (Kalbach, 2012)

In accordance with Kalbach's theory of the four zones of innovation in Chapter 3, the MedTech products of each company have been mapped out in Figure 20. The three companies have all developed a patentable innovation as a result of R&D work and their innovations have positioned them ahead of competitors. Based on this and due to having a high technology progress but a medium market impact, the companies' products are placed into the top left bubble. But, as raised in several interviews with supporting organisations, a good

product is not a guarantee for market success. To do an even deeper analysis of the innovations and their competitors is outside the scope of this master thesis, since it would require extensive medical knowledge beyond a civil engineering degree.

6.1.3. Technology strategies in practice

The technology strategies presented in Chapter 4 were found to have been practiced, by the interviewed companies, while unaware of the theory behind the technology strategies, and can also work as inspiration for their future strategies. MedTech AB used the Vintage plough back loop when using the gathered knowledge from developing Product 1, which constitutes the foundation for the development of Product 2. MedVasc are planning to expand their palette of products and could use the Market leverage loop to reach their goal and broaden their product offering. In the case of Suturion, no technology strategy was identified to have been used. Both MedVasc and MedTech AB have, through practicing their technology at their clinics, used the Co-evolution with customers loop to collect information from their customers and spread knowledge of their technology's existence. As pointed out in Chapter 4, a company needs neither to move through all loops nor go through them in a certain order.

6.2. Challenges

During the interviews, several challenges that companies face have been recurringly mentioned. In this subchapter, the greatest challenges are presented and analysed.

6.2.1. Regulatory process

As described in chapter 3, the MedTech industry is a heavily regulated business due to its importance for medical care and patient safety. Formal demands for processes needed to be followed according to MDR were experienced as complicated by the companies interviewed. Sjöö at SmiLe Incubator, along with Jegou at LU Innovation, recommend a new company to get the appropriate assistance to understand the demands that the industry and regulations have put up. To be able to orientate within the regulations, either recruitments of quality engineers or external consultants were deemed a necessity. An alternative approach, raised by two companies, would be to, if given the opportunity, pair up with a trusted industrial partner having the quality system and regulatory processes in place, thereby shortening the company's time to market.

The introduction of the MDR, replacing the MDD, has had a big impact on the MedTech business in Europe. Whenever a new regulatory system is introduced, a certain level of uncertainty concerning how to interpret the new regulations is expected. This initial rise in uncertainty is expected to flatten over time as experience increases and routines settle. But a side effect connected to the NBs arose. All existing companies and products already on the

market were required to be recertified by the NBs, according to the new regulations. The acute lack of NBs created a seller's market for the services provided by the NBs. One effect following this was the creation of a bottle neck situation, according to the interviews, and thereby a rise in prices for certification. The waiting time for NBs increased and prevented many new companies and their products from entering the European market, since already existing products and companies were prioritised for certification. A consequence of this could be that companies turn to the US market for faster certification, thereby being able to reach the market sooner.

6.2.2. Financing

Financing is a crucial part of starting a company and how to achieve it was brought up in each interview, both with the three companies and the three organisations. All three companies pointed out the importance of soft money at an early stage. This was partly because initially the company is not highly valued and therefore an investment may lead to giving up a larger part of the company early on. By applying for soft money, the entrepreneurs can receive initial funding and try their idea out before raising investments. Jegou at LU Innovation pointed out that the application process for soft money differs from other application processes in the academia and that it might be wise to get assistance in the application processes. The order of investor sources followed a certain pattern for the three companies. This order was also supported by all three organisations, and is in accordance with Murphy's & Edwards's theory in Chapter 3 concerning financing:

1. Soft money
2. Private investments

3. University holding companies
4. Business angels
5. VC companies

Attracting both current and new investors was mentioned as a challenge by all the interviewed companies. The process of making new emissions was described as time-consuming and took focus away from other activities such as developing the product, improving the business plan or talking to customers, producers and partners.

One entrepreneur brought up that unless having proven that there is a market for the product, the interest from VC companies is low and time is better spent to create interest among other types of investors instead. This view was echoed by the interviewed organisations as well. Jegou at LU Innovation, in accordance with Murphy & Edwards theory in Chapter 3, pointed out the danger of entering the Market Focused Biz and Product Development stage and thereby "cash flow valley of death", where the need for financing increases along with the costs before reaching the point of breakeven. This is a critical point for all companies and requires having secured sufficient funding for the future to be able to reach the next stage, the Early commercialization stage.

An advice echoed in several interviews was selecting investors, not only based on the sizes of their investments, but also on what other qualities they could bring into the company. Experience and having a network in the MedTech industry were two main qualities which were deemed important. Investors who bring these qualities are more likely to be invested in the company long-term, known as Quasi-indexers. By recruiting these kinds of investors, the start-up increases its chances of reaching the market, especially if the original entrepreneurial team lacks experience and network width.

6.2.3. Network, contacts and experience

The entrepreneurs behind Suturion, MedVasc and MedTech AB all have a background as medical doctors and researchers but differ regarding their experience outside their fields. Jegou at LU Innovation pointed out the difficulty for an academic to start a company without previous experience in entrepreneurship, business and corporate work. The founder of MedVasc had previous experience of entrepreneurship as well as starting and running companies. In MedTech AB's case, the founder had previous experience within engineering work. These experiences came in handy when founding their companies but in other areas, there was a lack of experience and knowledge.

By getting in contact with the supporting organisations in Lund, the companies were completed. LU Innovation assisted both Suturion and MedVasc in securing their IP protection and in their development of a business plan. LU Holding provided initial investments in all three companies interviewed, but the financial investments were secondary in their opinions. Instead, the surrounding services, such as creating solid foundation for the companies with the proper documentation and board structure, and assisting with accounting and legal questions, were considered among the most valuable contributions. SmiLe Incubator, who was the next step for MedVasc, provided the opportunity to work in an environment where experiences could be exchanged between companies within the incubator program.

But perhaps the biggest contribution from the supporting organisations was the networks they provided. Coming from the academia, one's network within the business and corporate world can be rather limited, according to both Jegou and Widstrand. By cooperating with the mentioned organisations, the

companies were exposed to pitching events and investors, and their boards built with experience and knowledge in completing fields. Without these networks and contacts, the chances of a successful company would drop sincerely. The companies involved with LU Holding and/or SmiLe Incubator have a significantly higher success rate compared to statistics presented by Kotsch and Blank in chapter 3.

A confounder to the results of this master thesis worth taking into consideration is that the companies interviewed have all been in cooperation with one or more of the three supporting organisations focused on in this report. A criterion for all three organisations to get involved with a project or company is that the product is considered to have high market potential, based on the organisations' extensive experience. Thereby, an initial selection of companies has been made and other companies with lower potential have been deselected.

6.3. Development phases and critical junctures

6.3.1. Development phases

The interviewed USOs have been places into the development phases model presented by Vohora et al (2004) and can be seen in Table 3.

Suturion, MedVasc and MedTech AB have all in some way transitioned into the Sustainable returns phase, but none has reached all the way. Early on, the start-ups moved off campus and are now working as real companies. They are carrying their own costs, through investments, and have all made recruitments to continue growth. None of their products has reached the market, meaning that sustainable returns could not have been achieved yet.

Table 3: The interviewed companies' placement in the Development phases model.

USO	***Research phase***	***Opportunity framing phase***	***Pre-organization phase***	***Re-orientation phase***	***Sustainable returns phase***
Suturion	A surgeon developed the product while performing research in collaboration with a MedTech engineer	From interactions with the TTO LU Innovation, a business plan was made, and the product was deemed commercially applicable	Using the network acquired through LU Holding and LU Innovation, the board was composed, and the business plan further developed. Patents were filed and approved internationally.	Initial production concerns were handled and the product refined. Further investments were taken in, and a new and experienced CEO was hired.	The USO has moved off campus and works like a real company. It currently carries its own costs through investments but makes no sustainable returns yet.

MedVasc	A doctor developed a new technology for treatment of varicose veins	The technology was further developed, a prototype was built, and a business plan developed through a TTO.	The board was further expanded with investors and through networks. Patents filed and approved inter-nationally.	Further investments were taken in, and a CEO was hired for a shorter time.	The USO has moved off campus and into SmiLe Incubator. It currently partly carries its own costs through investments but makes no sustainable returns yet.
MedTech AB	A surgeon performed research and developed the technology together with a colleague	The market plan was established in collaboration with LU Holding, a prototype was developed, and initial investments were made.	Quality engineer and salespeople were hired. The board has been completed through networks and investors. Patents filed and approved internationally.	The company reoriented from Product 1 to Product 2. Further investments were secured, and a new CEO was hired.	The USO has moved off campus and works like a real company. It currently carries its own costs through investments but makes no sustainable returns yet.

6.3.2. Critical junctures

The interviewed USOs journey through the critical junctures of the Development phases model presented by Vohora et al (2004) and can be seen in Table 4.

Table 4: The interviewed companies' journey through the critical junctures.

Company	***Opportunity recognition***	***Entrepreneurial commitment***	***Threshold of credibility***	***Threshold of sustainable returns***
Suturion	The entrepreneur recognized the market opportunity and further developed it together with the TTO.	By continuing with his clinical work, the entrepreneur did not commit fully to his company. This is a reason that could have held the company back.	Sufficient funding was secured at a late stage and made necessary recruitments possible, which create credibility among investors. The network improved from collaborations with supporting organisations.	Have secured further investments ensures continuous growth. But not having achieved sustainable returns could potentially hold the company back.
MedVasc	The entrepreneur reached outside the scientific research community and gained market insight from other sources such as his TTO and investors.	By starting to work at his clinic and connect it to his invented technology, the entrepreneur made certain commitment but didn't go into his new company full-time.	The clinic work and its focus are deemed to create credibility among investors. Investments were secured but also lost, due to the global pandemic, outside of the company's control.	The company has not yet reached sustainable returns due to not being on the market. Configurations in the company have been made to ensure further growth.

			The network improved from collaborations with supporting organisations. Investments of private capital created credibility and proved commitment.	
MedTech AB	Recognizing an unmet market need and develop a product for commercialization through contacts outside of the scientific research environment. The entrepreneur also had great use of his engineering experience when developing the product and the prototype.	The entrepreneur early on decided to take a leap of absence and go into his company full-time. Showing full commitment to the company creates more interest among investors and the practicing of the technology at the clinic improves its position.	The network improved from collaborations with supporting organisations. Investments were secured many times over and recruitments were made. Investments of private capital created credibility and proved commitment.	The company have secured sufficient investments and are moving onto clinical trials. Sustainable returns have not been reached since the product has not currently reached the market.

6.3.3. Start-up methodologies

Based on the interviews, the most practices start-up methodology today is the Lean start-up methodology, presented in chapter 4. Although, there are some Traditional start-up methodology element when e.g., making an initial business plan covering the coming years. But according to both MedVasc and MedTech AB, the original plan must be revised when new information come to light and thereby the five-year plan never persists over time. Working according to the Lean methodology means failing fast and revising the business plan and the initial hypothesis, something that the interviewed companies have practiced. Early on, the entrepreneurs got "out of the building" and engaged with potential customers, partners and producers, in accordance with the Lean start-up methodology and the advice from both Widstrand and Jegou.

6.4. Reflections on chosen approach and methodology

The choice of methodology and scope used in this master thesis was deemed appropriate. Though, the companies interviewed were influenced in their procedures through the assistance from collaboration the supporting organisation, which could have had effects on the variety in answers given. Due to the limitations and extent of a master thesis, three companies and three supporting organizations have been interviewed. This has created an accurate but limited picture of the start-up industry within MedTech.

In retrospective, a more extensive study could have been conducted, to give room for a greater variety of perspectives and experiences. By looking at USOs in other industries, other success factors could have been chosen and further connections could have been made. Another approach could have been to interview the supporting organisations first to get a broader picture, and then study more or less successful companies. By selecting companies who have reached the market, a more complete picture of their journey could have been presented. Though, a widening of the scope in this manner would increase the risk of only being able to present general conclusions and the master thesis would thereby lose its edge and sharpness.

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7. Main conclusions

This chapter reports conclusions of the master thesis, and the main research question and the sub-research questions are answered. At the end of the chapter, contributions of the master thesis and suggestions for future research areas are presented.

7.1. Structure and design

The purpose of this master thesis was to investigate the path that university spinout companies take when going into the MedTech industry and identify factors of success.

To be able to analyse these companies, a thorough theoretical background has been conducted. The MedTech business is a heavily regulated industry, and many concepts needed explanation to fully understand the USOs´ challenges. Defining innovation and start-ups along with theories connected to these areas were deemed crucial to ensure that concepts were correctly applied. The presentation of financing options and investor types was considered vital to better understand the decisions these start-ups face. To bring more depth to the analysis, supporting organisations were interviewed and analysed, to better understand the network surrounding USOs in Lund.

The theoretical background concerning start-up models, scaling up processes, development and strategies for USOs. The six interviews, three with MedTech USOs and three with supporting organisations, were conducted and are presented in chapter 5. The theory in chapter 3 and 4 was connected to

practical experience from both the companies and the supporting organisations, creating a deeper and wider analysis, which can be found in chapter 6.

7.2. Answering the research questions

***MRQ**: What are the key success factors for a new innovation start-up company within the MedTech business?*

The main research question is deemed to be answered through the three sub-research questions (RQ1-3).

***RQ1:** Which factors should a MedTech innovation company consider in order to increase their chances of success?*

To answer this question, the frequently expressed advice and warnings given by both the companies and the supporting organisations, in combination with other information from the interviews and the theory, are the following:

- **Contact supporting organisations**: Contacting and working with the organisations presented in this master thesis is free of charge. When working with LU Holding, an investment in exchange for equity will have to be made for a collaboration to take place. This master thesis strongly recommends taking this opportunity, if given, since it opens many doors, mainly through broad contact networks, and helps build a solid company with greater chance for future investments and the company reaching the market, by making sure the right decisions are taken at the right time. This tip is especially important if the entrepreneurial team lack experience and knowledge within certain fields such as business, strategy, the MedTech industry and marketing.

- **Build the right team**: Taking in the right individuals, committed to the company and having a wide range of competence, has proven to be crucial for a company's development and creation of a solid foundation to build the company on.
- **Get in contact with the market early on**: At an early stage, get in contact with the intended market. Interact with potential customers, partners and key individuals to ensure that the company's scope is the right one and to get early input which can be used to develop and tweak the product. It is important to have a solid IP protection approved and to have other parties sign a non-disclosure agreement before engaging into mutual deeper conversations.
- **Apply for soft money**: Soft money is an opportunity for a start-up to receive funding without giving up equity at an early stage of development, when the company's value is low. This advice was formally given by only one company but indirectly supported in all interviews.
- **Bring in investors who can contribute with more than capital**: When taking in investors, look at their background and how they can contribute to the development of the company as knowledge partners, rather than only looking at the monetary size of their investment.
- **Consider investments in exchange for equity**: Being "afraid" of giving up equity in exchange for investments may hold a company back. One should remember that investments make market entry more probable and thereby the chance of success. "Keeping a smaller part of the cake, while it is increasing in size" can raise the value of the entrepreneur's part even though the proportion is smaller than initially.

- **Be prepared for a long and expensive journey**: It is important to realise that the journey within the MedTech business will cost multiple times more than initially calculated, both concerning time and invested capital.
- **Team up with an industrial partner**: If given the opportunity of teaming up with an industrial partner who has the required quality systems and procedures according to e.g., the MDR, in place, this will considerably shorten the time to market. Though, this advice should only be followed if there is full trust between the entrepreneur and the industrial partner.
- **Ensure that the IP protection is strong enough**: If coming up with an invention through research, do not publish before having investigated its commercial potential. Get in contact with a TTO and ensure an IP protection strong enough to build a business on.

RQ2*: What role do supporting organisations play when it comes to the development of MedTech innovation companies?*

The supporting organisations presented in this master thesis have played a big role for the USOs' development. When coming from the academia, there is deep knowledge within the entrepreneur's field of expertise, but usually lack of business and industry-specific knowledge. Contribution of expertise and network from these organisations has proven crucial for the USO's development, according to all three company interviews. Start-ups are recommended to contact supporting organisations in the following order: 1) TTO (Technical Transfer Office), 2) university holding company and 3) incubator (Figure 21).

Figure 21: The contact order of supporting organisations.

By working with a TTO, such as LU Innovation, the company receives quality input concerning their innovation and its possible application areas in a commercial perspective along with a network for further development, free of charge. IP protection is crucial for the innovation to become commercially applicable.

Contacting LU Holding and raising interest for an investment was of the utmost importance in the three USOs' cases. By receiving an investment from LU Holding, the USO is deemed credible in the eyes of future investors and all three companies secured more financing through LU Holding's network of investors. The financial support was valuable, but the surrounding features brought the most value, such as getting assistance with creation of a solid company, proper foundation, and correct documentation. To make the right recruitments to the company's board, a broad network of contacts was provided by the organisation. Having a well put together board and a solid business case, improves the chances of reaching the market with future success.

When joining the incubator program at SmiLe Incubator, another dimension of network was presented. Working side by side with companies in the same

situation and with similar experiences gave the opportunity to exchange strategies and practical approaches. Having an experienced coach dedicated to a company gives the availability to a sounding board, where ideas can be discussed which cannot be brought up with the company board.

All three supporting organisations also provide funds for, and professional assistance in applying for, soft money. Soft money was pointed out as an important source of capital, due to the fact that the company does not have to give up ownership in exchange for money, which is of high importance for a new company, not highly valued yet.

***RQ3**: Which phases of a company's development are critical junctures and how have these been handled in a successful or unsuccessful way?*

The opportunity recognition is the first critical juncture and was handled well by all three interviewed companies. Suturion and MedVasc were both in contact with a TTO, which is deemed a successful move, in contrast to MedTech AB. MedTech AB developed their technology on their own but could have gained valuable insights in collaboration with a TTO.

One juncture which proved difficult to navigate was the Entrepreneurial commitment. Only one interviewee decided to invest full-time in his company. The main reason for hesitation at this tough decision seems to have been uncertainty of the future, since it would require giving up current full-time work and main source of income. According to the theory, investing full-time in a new company is vital, but this advice could be perceived as risky, especially before proof of market has been confirmed.

In the Threshold of credibility, all companies have experienced financially hard episodes, such as MedVasc due to the COVID-19 pandemic, Suturion

before Almi Invest's investment, and MedTech AB before several of their new emissions. Currently both Suturion and MedTech AB have secured sufficient funding, and MedVasc is on its way there. The three companies have been able to present solid business cases and managed to turn their university connection into an advantage rather than something holding them back.

The Threshold of sustainable returns is hard to evaluate, since the companies only partly have gone through this critical juncture. All three companies moved off campus at an earlier stage than predicted according to Vohora et al (2004). Both Suturion and MedTech AB have employed several people, including new CEOs, and are working as proper companies. MedVasc has been delayed by the pandemic with revocation of investments. All three companies are carrying their own costs through investments, rather than generating sales and thereby sustainable returns, which could be deemed the final step in this critical juncture.

7.3. Main contributions to academia and industry

This master thesis presents an exploration into the MedTech industry for start-ups in Sweden, with a focus on Lund. Interviews with three new companies have given the opportunity to learn from their individual experiences. Similar interviews with three supporting organisations, which have worked with many new companies over the years, have, together with previous research, provided broader and deeper understanding and benchmarking of start-ups within the MedTech business (Figure 1).

Contributions to the academia:

- Deeper understanding of start-ups in the MedTech industry
- The current theory was applied and validated in practise

Contributions to practice:

- Developed a method for start-ups within the MedTech industry

The conclusions drawn in this master thesis could be considered as a road map for mainly start-ups but also supporting organisations, to give them several angles when approaching the MedTech industry. Hopefully this master thesis contributes to a more lucrative start-up environment and increased regional growth.

7.4. Suggestions for future research

Due to limitations in scope and in time, three companies and three supporting organizations have been interviewed. This has created an accurate but limited picture of the start-up industry within MedTech.

Future research projects, primarily based on questionnaires or semi-structured interviews, could be designed to evaluate

- a wider range of start-up companies in the MedTech industry,
- other focus areas within the MedTech industry, such as international comparison of regulations, and roles of other supporting organisations, and
- other stakeholders within the MedTech industry.

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Appendix

Appendix 1: Interview questions for companies

Grundläggande information

Hur ser entreprenörens bakgrund ut?

Hur ser omsättning, vinst och utveckling ut för företaget idag och historiskt?

Hur många anställda är ni idag?

Bakgrund och tillkomst:

Hur kom ni på idén till ert företag?

Vilket problem löser er produkt?

Vilka var med och startade bolaget?

Hur gick ni vidare, från idéplanet till ett företag?

Startade ert arbete i samband med ett universitet eller annan akademisk institution och hur påverkade detta i så fall era förutsättningar att lyckas?

Har ni några patent för er produkt och vilken del av process skaffade ni i så fall dessa?

Strategi

Vad hade ni för strategi när företaget började ta form?

Följde ni något ramverk eller mall från forskningen, i framtagandet och utvecklingen av er strategi?

Hur såldes produkten in? Hur skedde segmenteringen och vilka kunder inriktade ni er på?

Hur svarade marknaden på er produkt?

Har er strategi med tidens gång förändrats och i så fall, på vilket sätt?
Har ni efterhand utvecklat nya produkter, för att utveckla företaget och er marknadsandel?

Resurser

Vilka är era viktigaste resurser i företaget?
Hur tänkte ni kring finansiering för ert företag?
Humankapital och kompetensutveckling
Skulle du vilja berätta om det nätverk ni hade tillgängligt, internt inom företaget och senare via andra parter?
Vilken kompetens fanns i företaget vid starten?
Hur tänkte ni kring rekrytering av nya kunskapsområden in i företaget?

Utmaningar

Vilka utmaningar har ni stött på längs vägen?
Hur tog ni er an dessa?
Beskriv er kontakt och upplevelse av Notified bodies, regulationer, CE-märkning och MDR?

Framgångsfaktorer

Vilka var era främsta styrkor i företaget?
Vilka faktorer har, enligt er, medverkat mest till er framgång?
Tips till ett nystartat Medtech-företag
Vad har ni för tips för ett nystartat Medtech-företag idag?
Vilka fallgropar ska man undvika och hur undviker man dessa?

Appendix 2: Interview questions for supporting organisations

Hur ser din bakgrund ut?

Urval

Hur kommer (blivande) företag i kontakt med er?

Vad har ni för krav för att engagera er i dessa?

Vad kan göra att ni väljer bort vissa företag?

Brukar ni även medverka i att utveckla och förfina företagets färdiga produkt?

MedTech

Vad skiljer MedTech från andra teknikområden och hur påverkar detta innovationsbolags möjligheter?

Är MedTech en kapitalintensiv bransch i jämförelse med andra branscher?

Används globala standarder generellt eller är det skillnad på kravställningen i Sverige jämfört med övriga Europa och världen?

Bidrag och stöttning

Vad skiljer er från andra organisationer i er bransch?

Vilka tjänster stöttar ni nya företag med?

Vad är, enligt er, de viktigaste delarna som ni bidrar med till nya företag?

Utveckling

Hur lång tid brukar det ta för ett företag att gå från idé till försäljning?

Brukar företagen ni arbetar med utveckla nya produkter efterhand för att fortsätta vara relevanta på marknaden alternativt för att öka sin marknadsandel?

Framgångsfaktorer

Vilka framgångsfaktorer ser ni som viktiga hos nya företag i allmänhet och MedTech i synnerhet?

Vad skiljer, på ett tidigt stadium, ett lyckat från ett mindre lyckat innovationsbolag?

Vilka vanliga misstag upplever ni att företag begår under sina första år?

Appendix 3: Advice for future MedTech start-ups

In Table 5, the advice for start-ups within the MedTech industry can be seen, based on the interviews conducted. The number of companies and organisations giving each advice can be seen in the second and third column of the table.

Table 5: Advice for MedTech start-ups from the interviews.

Advice	***Number of companies giving the advice***	***Number of organisations giving the advice***
Securing enough financing is crucial	2	0
Realising that the company's journey will be more costly and take more time than initially calculated	2	3
Having certification processes, production and quality system in place	1	0
Put focus on developing the idea and company	1	0
Start the company with an experienced partner	1	3
If given the opportunity, join venture with an industrial partner you trust and who has the	2	0

required processes and quality systems in place		
Apply for soft money	1	0
Find investors who can contribute with experience and financing	1	1
Find engaged people to work with	1	0
Focus on understanding the regulatory process	1	0
Invest your own capital	2	0
Segmentation of the market is crucial. Having an excellent product will not be enough	1	1
Find partners with experience and networks in the business	1	0
Bring in partners such as LU Innovation or LU Holding, who can make sure the right action is taken at the correct time	1	3
There has to be a committed team with a great width of competence	3	1
Someone in the company must be fully committed to the idea	0	1
Getting in contact with the market early, both with customers and potential partners. Gathering information concerning customer groups and the business.	0	2

Having an exciting and unique idea	0	1
Having a committed team with entrepreneurial spirit and motivation	0	1
Getting the right competence into the company board	0	1
Being able to prove the market potential and thereby convince investors	0	1
The shorter time-to-market, the lesser risk of being overtaken by competitors	0	1
At an early stage, bring in knowledge to understand all required demands of the MedTech business	0	1
Securing the patent before approaching the market, partners or investors	0	1
Discuss with multiple sources of information and evaluate their advice. If receiving unison advice, the chances are that the advice is correct	0	1
Dare to take in investments that include giving up partly ownership of the company. This increases the chances of the company to reach the market	0	1
When taking in investments, ensure that the company increases	0	1

in value in proportion to the investment		
Take in investments, if necessary, at an early stage	0	1

Appendix 4: Warning flags for MedTech start-ups

The collected warning flags from the interviews are presented and summed up in Table 6.

Table 6: Warning flags for MedTech start-ups.

Advice	***Number of companies giving the advice***	***Number of organisations giving the advice***
Try to solve all steps necessary on one's own	1	0
Avoid digging into administrative functions too early	1	0
Avoid discussions with VC companies before being ready for market, since their interest is low before this point	1	0
Having too weak financing/Not achieving proper financing	1	1
Committing fully to the company too early in the process	1	0
Academics risk losing their patent possibility of their idea if they publish before IP protecting	0	1
Not having enough knowledge of the proposed market	0	1

Not having previous business experience	0	1
Expecting that a good product is going to sell itself	0	2
Trying to secure financing on one's own without a network	0	1
The founder not wanting to give up partly ownership of the company	0	1
Not talking to the market but instead being in one's own bubble	0	1
Taking too long to reach the market increases the risk of being overtaken by competitors	0	1
Choosing the wrong market (or the market does not exist)	0	1
Talking to the market at a late stage	0	1
Realising the necessity of clinical studies too late	0	1
IP protection not being strong enough	0	1
Not having the right team with the necessary competences	0	1
Having too many passive investors.	0	1
The entrepreneur committing too late to the company	0	1