



# LUNDS UNIVERSITET

Lunds Tekniska Högskola

## **Business development of a novel functional food concept**

A case study of a start-up venture from Lund University

*Master's thesis in the Master Degree Programme in Biotechnology Engineering at the Faculty of Engineering, Lund University*

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Lund, August 2015  
Christian Åsheim

# List of acronyms

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**B2B: Business to business**

**B2C: Business to consumer**

**EC: European Commission**

**EFSA: European Food and Safety Authority**

**EU: European Union**

**FF: Functional food**

**FTO: Freedom to Operate**

**IPR: Intellectual property rights**

**MVP: Minimum viable product**

**QA: Quality assurance**

**R&D: Research and development**

**SME: Small and Medium sized Enterprises**

**SWEDAC: Swedish Board for Accreditation and Conformity Assessment**

**VC: Venture captial**

# Abstract

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Functional food (FF) is a relatively new sector in the food industry. FF are products that have an added nutritional value for consumers that is communicated through nutritional and health claims, and act as preventive agents of chronic diseases. Innovation of new FF products has grown to become an important impact in research towards preventing welfare diseases. The rate of innovation in this field is nevertheless low and the willingness of companies to invest in ideas and research projects that will lead to novel FF products is today weak. The main reason is the regulations for health claims.

The purpose of this study is to investigate the venture creation process of FF based start-ups, with a case specific research question of how an analysis technique targeting the food industry can be commercialized. The purpose will be addressed by simultaneously investigating different venture creation activities, and how these activities can be applied for FF.

In order to build a theoretical framework for the analysis, an extensive literature search connected to the key terms yielded four categories of venture creation activities:

- Planning activities
- Establishing legitimacy
- Market activities
- Resource transformation

These categories were connected to four important aspects specific for FF:

- Regulatory approvals
- Product development
- Intellectual property rights
- Consumer acceptance

The methodology used to explore this area and get a deeper insight in the research topic was by conducting qualitative insider action research of one case. The data has been collected through; numerous meetings with founders and stakeholders, daily operation actions, observations, notes, experiences, conversations, memories and joint-actions from one year of venture creation in the case.

The empirical data collection revealed that the studied venture chose to perform an iterative conceptualization process followed by a business model canvas and a timeline of activities in the category of planning activities. The venture met issues when investigating regulatory approvals in the category of establishing legitimacy. Through contact with experts they revealed a path that potentially would not include the health claim regulation. The market activities were primarily focused on customer development where identifying customer demand was considered of major importance. The product/technology development as well as funding applications was left to be performed after the concept was verified by customer demands.

The conclusion consists of a proposed framework of how to commercialize an analysis technique targeting the FF sector. This proposed framework could potentially serve as a general framework when commercializing other FF products or services.

**Key terms:** Functional food, glycaemic response, venture creation, start-up, business development, commercialization, analysis technique

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# 1. Introduction

This master's thesis is based on a case study investigation of a start-up venture, stemming from scientific research at Lund University, called ViscoSens. ViscoSens aim to operate in the food industry with a novel functional food (FF) concept that appeared as a result from one of the founder's research. The research results leading to the concept include an analytical measurement of the glycaemic response, also known as blood sugar level, after consumption of food products. The analysis is performed outside the body (in vitro) and correlated with data from meal studies in healthy humans (in vivo). The aim of the thesis work is to approach the business development of the start-up venture from four strategic areas of venture creation: planning activities, establishing legitimacy, market activities and resource transformation with purpose to create a feasible FF business case. The investigation areas will be split into smaller segments on which the theoretical framework will be based to provide a solid base for analysis. These segments are: regulatory approvals, product development, intellectual property rights (IPR) and consumer acceptance. A schematic overview of the investigation topics and how they are connected is shown in figure 1 below.

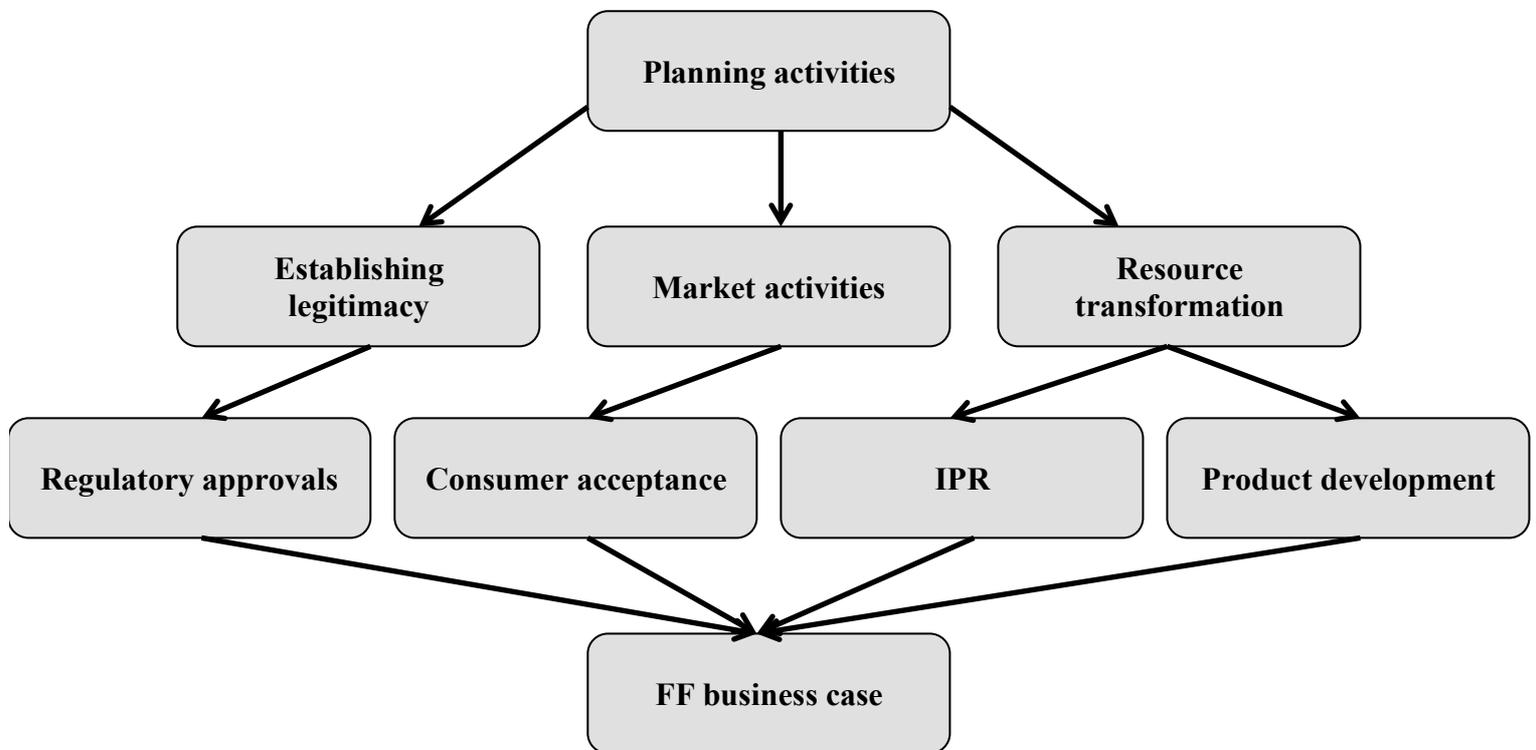


Figure 1: Overview of the thesis topics based on (Liao and Welsh, 2008).

## 1.1 Background

### 1.1.1 Venture creation process

The venture creation process is when a new organisation is formed and how it develops to a revenue generating company. The most relevant activities linked to the venture creation process could be summarized into different categories: Planning activities, Establishing legitimacy, Market activities and Resource transformation. The categories are linked together according to figure 1 above and will be further analysed both theoretically and empirically in the case study below. The lack of research on the creation process of start-up ventures operating in the FF sector led to this thesis since most previous research approaches FF businesses from the perspective of larger corporations such as Nestlé and Kellogg's (Williams Middleton, 2010).

### 1.1.2 Traditional and modern innovation processes

In traditional entrepreneurship literature, the innovation process is described as a linear process from the discovery of an invention/research results to the transformation into an innovation where money is generated from the invention. This linear process viewed in figure 2 below is referred to as a technology push market strategy (Rothwell, 1992), (Brem & Voigt, 2009). This innovation process is widely used for classical university based inventions such as pharmaceuticals and materials, which characterizes that operational systems are created around the invention such as the company formation, sales force establishments and R&D operations, followed by the creation process of a new product. What usually lack in this strategy are customer/consumer interactions and a search for their needs and demands.

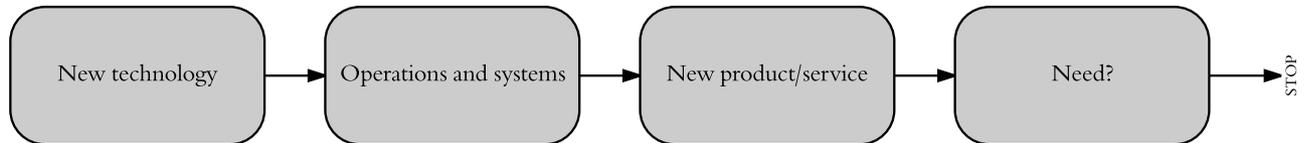


Figure 2: Technology push strategy (Rothwell, 1992).

Modern innovation processes are built on the principle that was missing in technology push strategies, customer/consumer demand. These strategies are called market pull and customer development strategies (Blank, 2012). The principle that characterizes these strategies are that the customers are the most central piece of a business and therefore, they should be a part of the product creation. Moreover, the process is iterative through constant trial and error phases (figure 3). There, the product demand should be revealed and validated before the product is created and the company is formed.

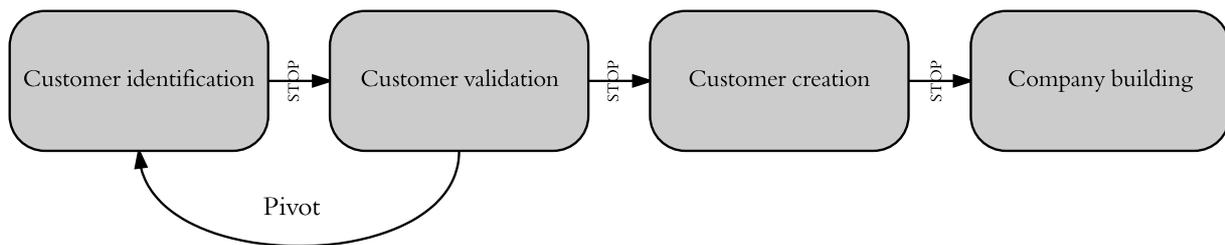


Figure 3: Customer development strategy according to Blank (2012).

### 1.1.3 Introduction to FF

During the second part of the 20:th century the socioeconomic development, in countries such as in Western Europe, improved steadily which led to safe food supply and increased human life expectancy. Furthermore, as the steady supply of food and the growth of the welfare society solved famine<sup>1</sup> in the western countries, it also created an increase in chronic diseases such as cardiovascular diseases, diabetes type-2 and obesity connected to dietary factors and poor lifestyle. The main underlying aspects for chronic diseases are over-consumption of food and malnutrition (Verhagen et al., 2010). However, proper nutritional diets are a main factor to improve the societal health status, which implies that a general improvement of public health will come from changes in dietary behaviour rather than an increase of medical treatments (Verhagen et al., 2010). During the recent years, the interest of new food products with positive health impact on consumers has steadily increased (Malla et al., 2014).

No general accepted definition of FF exists but scientists define it as foods that have an added nutritional value for consumers, communicated through nutritional and health claims (Schaafsma & Kok, 2005). This is also the definition of FF used in this thesis. General principles of FF are that:

- There should not be any side effect due to normal use.
- No disturbance of a healthy eating behaviour .

<sup>1</sup> Famine is referred to a scarcity of food in the society

- Scientifically proven and substantiated health claims.

Furthermore, FFs are considered as a part of a balanced diet (Schaafsma & Kok, 2005). FFs are of today considered as a sustainable trend driven by market forces such as the expanded knowledge in the relationship between nutrition and health, the increased occurrence of chronic diseases and a larger buying power of consumers (Schaafsma and Kok, 2005).

#### **1.1.4 Current environment for FF concepts**

Today, innovation is viewed as vital for the success and a source of economic growth in the modern society (Hårsmar et al., 2014). However, the rate of innovation in the food industry is although low and the willingness for companies to invest in ideas and research projects that will lead to novel FF concepts is today weak. Some essential factors influencing the low occurrence of food innovations are the risks with regulatory approvals, low return on investments and the problem with consumer communication through labelling and marketing (Malla et al., 2014). The communication of health benefits to consumers is the key for the ability to create added value in a FF product. The communication link is through health claims that include labelling and marketing communication. Development of credible and communicable health claims can produce benefits for the society in form of improved public health and reduced costs connected to health care (Malla et al., 2014). A new regulation policy has been established in the European Union (EU) from 2007 with an aim to standardize the procedure of granting health claims in all membership countries at the same time. Furthermore, an additional aim of the regulation is to give safe and correct recommendations of appropriate food products to consumers (Regulation EC No. 1924/2006, 2007).

For companies, the aspects of regulatory approvals affects their path of commercializing new innovations in the food industry, both regarding investments into research, product development and IPR management. Baylor (2014) argues the necessity for food industry companies in an early project stage to adapt the regulatory framework to the product development process. This has not been the case historically. The product development require significant amount of research invested in a project. This includes identification of functional compounds and assessing their physiological effect in addition to clinical trials on product efficiency. These are necessary procedures to gain credibility and basic data for the approval process of health claims. If the regulatory requirements remain unidentified through the product and conceptual development, the costs of performing pivots could eventually lead to market failures (Siró et al., 2008).

Initiation of a FF project is a matter of risk. A project needs financial investments to be executed. IPR are generally viewed as an asset that reduces the risk when making an investment decision. The food industry has, however, not fully adopted the possibility to protect investments in research through patents. Instead companies are keeping trade secret as the general mean for protection (Malla et al., 2014). Chong et al. (2008) argues that an investment in IPR such as patents has a low rate of success in the food industry due to the low margins that the producers can obtain and therefore low return on investments. The reason behind a constant price pressure is the relative easiness for copycats to mimic an invention. This factor is an obstacle for R&D based food companies when trying to attract both external and internal capital to be able to grow and develop projects into commercial products (Hårsmar et al., 2014).

To understand the consumer and to analyse their acceptance are major factors to consider for the vitality early on in a development process. According to the strategic triangle presented by Schaafsma and Kook (2008) a FF can only be vital if the consumer acceptance is satisfied. That implicates four factors: the taste, understanding of the concept, emotional fit and reliability of the documented efficiency. If these factors are accomplished the rate of success will increase.

These topics are critical aspects for start-up ventures when entering the FF sector and they are of certain relevance when creating related strategies, leading to a proposal of a FF business case. This qualifies them to be investigated in this thesis work.

### **1.1.5 Case study: ViscoSens**

The data collection will be performed in collaboration with a start-up venture from Lund University called ViscoSens. ViscoSens has been of certain interest for the author already since the venture was formed both since the areas of food technology and nutrition are of personal interest for the author and a personal family relationship to one of the founders. Therefore, the author has followed ViscoSens during the operational years and sized the opportunity to work with ViscoSens when this thesis was accepted. The scope of the thesis has been under constant change during the process. Firstly, the author started working with theories around product development of the analysis technique. After a while, the author thought that the product development aspects contained much sensitive information that could lead to a patent application. Then the thesis seemed too shallow when the most essential parts was removed. Therefore the author decided to change scope to a business development perspective since the author has educational background within entrepreneurship and business design from Chalmers University of Technology in Gothenburg. Also within business development have the scope been changed and been narrowed to the venture creation process of FF businesses.

## **1.2 Purpose**

The purpose of this thesis work is to investigate how a transformation of research results from university into a FF venture could be performed.

Today, little is known of how researchers within FF can work as entrepreneurs and commercialize their inventions in an optimal way. Conclusions from this thesis work have potential to contribute to new knowledge and insights in the area of food technology, nutrition and entrepreneurship. The reader will be guided through a case study of a start-up venture from Lund University, called ViscoSens, on their way to transform research results into a business case. The research question can be summarized as followed.

*How can an analysis technique targeting the food industry be commercialized in the creation of a FF venture?*

## **1.3 Aims**

The aims of this thesis work could be summarized into four bullet points:

- Creation of a theoretical framework that gives the reader insight into general topics regarding FF and venture creation. The theoretical framework will form a suitable base for strategies of how to create a FF business case.
- Empirically collect data from the venture in the case study as a complement to theory to create an analytical framework
- Make analyses of the findings to propose a way to construct a FF business case.
- Make recommendations of further work towards commercialization based on the conclusions.

## **1.4 Delimitations**

This thesis work will focus on specific research from a start-up venture in Lund operating initially on the Swedish market. The scope of this thesis work will be delimited to development related aspects in the FF sector of the food industry. Other aspects regarding start-up ventures as well as other industries sectors and markets are left out of the study.

## 2. Theoretical framework

The theoretical framework is built on the available theory and information regarding venture creation processes and FF. This is served as a base for the empirical study. The theoretical framework and the empirical study are jointly creating the analytical framework that the analysis in chapter 5 will be based upon. The theoretical framework starts with theories around venture creation processes followed by FF specific categories. The categories are: regulatory approvals of health claims, product development, IPR and consumer acceptance.

### 2.1 Venture creation process

The venture creation process could be referred to the process where a new organisation is formed and how it develops into a revenue generating company. However, few studies have of today explored the venture creation process empirically and none of the studies are related to the area of FF. Therefore, a general approach of the venture creation process will be anchored in this theoretical framework. An illustration of the definition of a venture creation process used in this thesis could be viewed in figure 4 below.

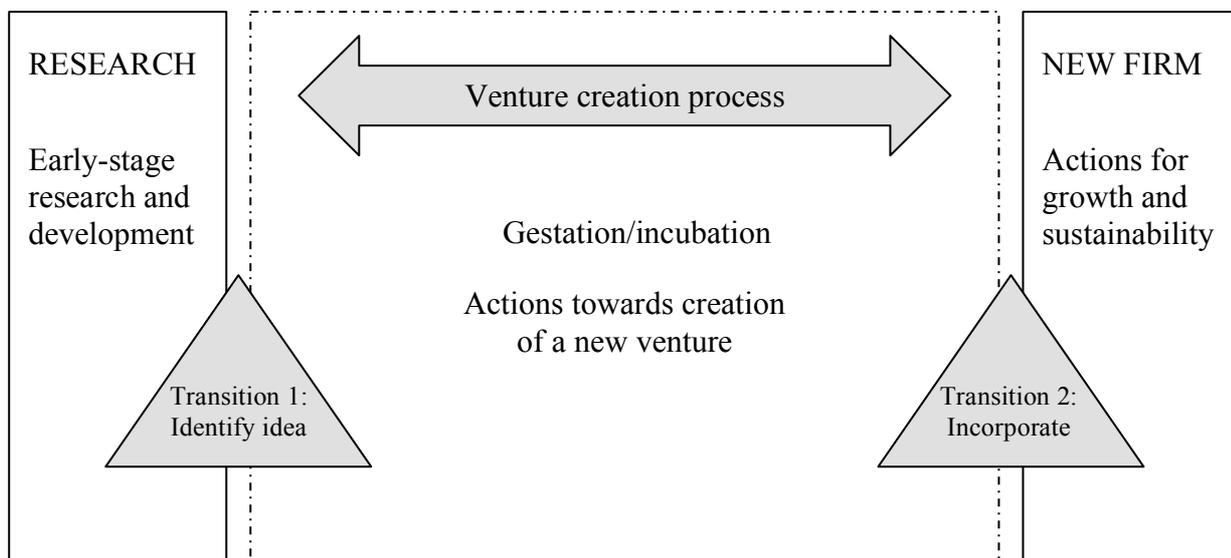


Figure 4: Model for the venture creation process (Williams Middleton, 2010).

The venture creation process is characterized of different events or start-up activities during the gestation time. The latter refers to the time elapsed from the first to the last start-up activity. The process could vary a lot between different start-ups due to that they have to make intentional choices for maximum utilization of limited resources and therefore, a venture cannot perform every desired activity (Liao and Welsh, 2008). Gartner (1985) argues that a new venture is created through series of actions taken by the entrepreneurs. Such events are; developing prototypes, seeking funding, hiring employees and conducting market research. These events take place at different times, to different degrees and in different order dependent on the kind of start-up such as if it is a technology based or non-technology based venture. Liao and Welsh (2008) have identified that there are four different characteristics that dictate how start-up activities evolve. Firstly, not all activities are needed for start-ups, like if money is secured there is no need to seek financial support. Secondly, entrepreneurs need to prioritize since they have limited cognitive abilities and are not able to do all possible activities simultaneously. Therefore, a high degree of variation will occur between certain orders of activities between different start-ups. Thirdly, different activities depend on each other and the ability to start one activity depends on the completion of another. An example could be that a contract with a large customer would enable possibilities of capital injection for the venture. Fourthly, some activities are more important in an early

stage and some in a later stage, therefore the activity importance depends on the stage of venture development. From this argumentation, it is expected that start-up entrepreneurs engage in different patterns of activities during the gestation process (Williams Middleton, 2010).

The argumentation of the non-linear pattern of the venture creation process made Liao and Welsh (2008) distinguish two major categories of activities; planning activities and operational activities. Planning activities refers to events that coordinate activities at the early stage of venture creation. Such events could be conceptualization, value proposition generation, creation of a business model and market entry strategies (Williams Middleton, 2010). Here it is of necessity by the entrepreneur of a venture to recognize opportunities and keep ability to adapt to external environmental factors when it changes. This is especially apparent for ventures competing in a technology-based industry. Consequently, when planning for entrepreneurial activities, they should focus on continuously assessing technology advantages and identifying market opportunities (Liao and Welsh, 2008).

Operational activities refer to events occurring after the planning phase and can be divided into three subcategories: legitimacy building activities, market related activities and resource transformation activities (Liao and Welsh, 2008). Legitimacy establishing can be related to activities that define a physical and legal boundaries, such as receiving a regulatory approval for a physical product before market launch, which in turn generate legitimacy for the venture (Williams Middleton, 2010). Building legitimacy lays the core foundation of a venture and enables access to critical resources such as specific target groups, as well as, building trust towards investors. Market activities are such that can be related to customer relationship activities, customer development, sales and promotions (Williams Middleton, 2010). These activities are considered as important when dealing with technology products due to the intense financial requirements during its development. Therefore, activities exploring market demands are often intense and resource demanding during an early stage of the venture creation process. Resource transformation is the generation of assets that acquire and combine human, financial and technological resources, such as product development and IPR (Williams Middleton, 2010). Ventures need to develop an initial resource base to survive in a dynamic high competitive technology industry where tangible and intangible resources are needed, especially when dealing with venture capitalists. This is considered as necessary assets to develop or acquire but it is also time consuming and could slow the time to market substantially (Liao and Welsh, 2008). Table 1 below shows the categorization of the venture creation activities.

**Table 1: Categorization of the venture creation process (Williams Middleton, 2010).**

<b>Venture creation categories</b>	<b>Venture creation activities</b>
Planning activities	Conceptualization, searching for market opportunities, business model, creation of strategies
Establishing legitimacy	Regulatory affairs, determine legal form of venture
Market activities	Customer development, verification of business model and concept, secure suppliers and distributors
Resource transformation	Product development, IPR, secure funding sources

### **2.1.1 Priority of activities**

This study will investigate the venture creation categories that seem most potential to prioritize in early-stage FF businesses. The category of planning activities will scope the conceptualization process of how the concept is formed in addition to how the value proposition is formed through a tool called business model. The conceptualization usually starts with the “bird-in-hand” principle according to effectuation logic created by Read et al. (2010). The bird-in-hand principle means that the entrepreneurs start with their means by answering three questions: Who I am, what I know and whom I know. This generated possibilities to create a concept that originated from the identified means. The business model is a tool that describes, in a general approach, how the business will be executed and it will set the framework for the concept. The process of business modelling is individual for every start-up venture and could be

performed in many different ways. The most common way of creating a business model is through a framework called *business model canvas*, created by (Osterwalder, 2004). The theory behind business model canvases is broad and mostly target general technology based ventures. Hence, the theory is not specifically targeting FF businesses and therefore it will not be further described in the theoretical framework, instead the author recommends reading more about business model canvas theory in the doctoral thesis by Osterwalder (2004). The operational activity of establishing legitimacy will be through the theory of regulatory approvals. This is of major importance in a FF venture since the regulations will set the boundaries of the concept. Regarding resource transformation, both product development and IPR are prioritized due to the importance when establishing assets in a venture, which often is specific for different industries and sectors. The market activities are dependent on consumer acceptance and therefore, they will be further theoretically described by consumer acceptance theory of FF products.

## 2.2 Functional Foods

Two consultancy firms performed a worldwide strategic survey in the food industry in 2002. The study indicated that 90 % of top managers in food production companies and retail stores expected a strong and expansive progression of the health connected food products. This meant that the integration of health and foods was expected to have a strong impact on food innovations. This trend was a seed for the standardized term in the food industry, today known as FF (Schaafsma & Kok, 2005).

### 2.2.1 Regulatory approval

This study will investigate the most common regulatory classification of FF, called food with health claims. The theoretical contribution to this classification will consist of definitions and background information to the regulation. The chapter of regulatory approval ends with a summarizing table of the classification.

#### 2.2.1.1 Health claims

When the concept of FF was created, most of the European countries viewed it as products that would fall under jurisdiction of each individual nation in Europe. However, some countries such as Germany and Denmark viewed FF as pharmaceuticals, which was possible meanwhile it was a decision for each country. The consequence of individual national perceptions of FF was that free trade could not be established within the EU. In 2006, the EU introduced a new regulation regarding health claims (EC No. 1924/2006, 2007) with a purpose to harmonize the legislation of FF and establish free trade. The filing for health claims was decided to go through a central organisation administered by the European Commission (EC), called European Food and Safety Authority (EFSA), and be approved after opinion from each EU member country. The regulatory process for health claims could be seen in figure 3.

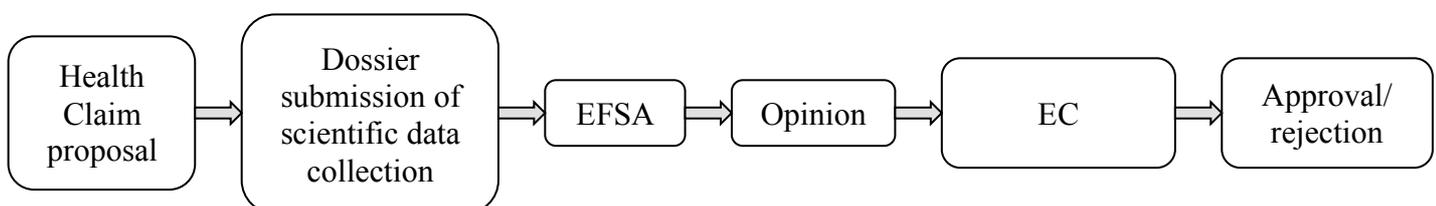


Figure 5: Regulatory process of health claims.

Presently, two generations of FF exist on the market. The first generation is foods with enhanced nutritional values and is frequently connected with nutritional claims. Nutritional claims primarily gives the consumer information about the nutrients present in a product and their physiological significance. An example of a nutritional claim could be “this product is rich in vitamin D, which helps to strengthen your bones” (EC No. 1924/2006, 2007). This first generation of FF presently makes a substantial contribution to the total market of FFs. This mainly due to the non-requirement of extensive nutrition research in the process of substantiating a claim since these claims are based on publically known knowledge from many years back in time. This gives opportunities for food industry companies to, in a relatively cheap way, participate in the FF market.

The second generation of FF is foods with substantiated health claims and physiological benefits. The claims can be differentiated into “reduced disease risk” claims and “enhanced function” claims, dependent on the kind of beneficial effect (EC No. 1924/2006, 2007). A typical example of a second-generation FF is betaglucans, a dietary fibre from oats or barley that has proven health benefits of lower cholesterol levels and lower blood sugar levels (glycaemic response) after consumption. To obtain these claims, it is necessary to extract and purify the betaglucans from the cereal kernels since the fibre level is not originally high enough. The general characteristics of second generation FF are that they have basis in knowledge of health and nutrition and that they claim benefits that exceed the benefits of other traditional foods. This concept triggers the food industry to create new innovative food with added values based on research (Schaafsma & Kok, 2005).

The basic rules to make health claim implies that (Schaafsma & Kok, 2005):

- Consumers have the basic right to be informed of the full characteristics of the foods they are consuming.
- Claims should not mislead consumers.
- Medical claims are not allowed for foods.
- Claims should not interfere with the general guidelines accepted for a healthy diet.

The basic information that needs to be collected to obtain an approved health claim is sufficient scientific evidence of the claimed health benefits. The breakthrough of this regulation, except the free trade establishment, was that reduced disease risk claims prior was considered as medicinal claims, which now became allowed if approved (Siró et al., 2008). During 2010, a new paragraph was introduced to the EC No. 1924/2006 (2007) with a prepared list of allowed health claims, named under a specific paragraph known as §13.1. All stakeholders who wanted to claim health benefits of their products had to file a dossier with scientific argumentation and evidence why their specific substance should receive a health claim. The approved claims were only including specific characterized ingredients on a molecular level that had sufficient scientific studies with clear cause-effect evidence. The cause-effect evidence means that a certain amount of ingredient lead to a measurable response effect of claimed health benefits. A small percentage of the applications were approved, which created a debate because many companies lost their business (Siró et al., 2008). Furthermore, if the health claim was approved, they were free to use for everyone i.e. a stakeholder had to invest in research and development, which external stakeholders could benefit from as well. Nevertheless, when organisations file for new health claims it is most likely based on novel research and therefore the application should be filed according to §13.5 in the EC directive (EC No. 1924/2006, 2007). If the claim is granted as a §13.5 claim, the organisation will be granted a sole property protection of the claim for five years.

However, the present European legislation does not consider FF as a category of food products, rather like concepts (Siró et al., 2008). Therefore, the numbers of rules to be applied are numerous and highly dependent on the natural origin of the food as well as the physiological effects, creating problems for existing companies trying to receive health claim approvals of their products.

A table defining the regulatory approval route of health claims can be viewed below (table 2).

**Table 2: Regulatory approval of health claims (EC No. 1924/2006, 2007).**

	<b>Regulatory approvals of health claims</b>
General criteria	Substantiated with generally accepted scientific data, non-misleading & approved by all EU member states.
Approving authority	The EC by opinion from EFSA and all member states in EU.
General critique	The amount of scientific evidence and labelling rules is too complex and hard so the ability to fulfil all these is very costly. Limited competitive advantage regarding property of claims could be generated. Long time to market.
General procedure	Construct and send in a dossier with substantiated scientific evidence of health benefits to national authority agency, which distributes it further to EFSA. Dossier should contain material of substance characterisation and cause-effect evidence. Scientific opinion from EFSA within 5 months, decision by the EC based on the opinion provided.
Costly procedures	Legal consultant services. Scientific studies and correspondence with approving organisation. Delayed time to market.
Time consuming procedures	Creating the dossier with scientific substantiated data. Recommended frameworks are provided by EFSA in Journal 2012;10 (3):2604. Administration procedure by the authorities.
Impact on company	Long time to approval and market entry. Costly process of receiving an approval. Approved health claim is universal for everyone to use after five years of health claim property of the filing organization.

### **2.2.2 Product development of FF**

The development and commercialization of FF is a complex, risky and expensive process (Siró et al., 2008). Some main factors that need to be taken into consideration before initiating the product development process are technological obstacles, legislative aspects, IPR for investment purposes and consumer demands.

The current product development and commercialization strategies of FF primarily focus on: the conceptualization of the innovation process, identification of market opportunities and how the regulatory environment affects FF innovations (Herath et al., 2008). Menrad (2003) concluded that the total cost of developing a new conventional food product is around US\$ 1-2 million and indicated that the development of FF products would exceed this number by far. Furthermore, these costs could be explained by the demand of resources and knowhow in nutritional and food technology research, in addition to knowledge in the medical field to be able to prove the efficiency of the claims. Moreover, a commercial actor needs to present and fulfil the requirement of strict scientific evidence and verification of efficacy, including statistically validated data from model systems in intervention studies. Menrad (2003) argues that this complex and investment requiring process inhibits industry actors to enter the market segment of FF.

Multinational food companies are companies that possess necessary resources for product development and marketing as well as well-known brands. Therefore, they should be the ones to invest in this market according to Siró et al. (2008). These companies also gain opportunities to differentiate and create competitive advantages if developing products in this segment. Pharmaceutical actors are also interested in the FF sector due to the shorter development time and lower product development costs compared to pharmaceutical products. Furthermore, they also possess an established experience in clinical trials to substantiate health claims (Siró et al., 2008).

There are a limited number of small and medium sized food companies (SMEs) acting on FF market. Menrad (2003) argues that SME companies mostly produce niched products following pioneering products of multinational companies. Furthermore, Menrad (2003) argues that these products only survive a short time on the market. The reason behind this should be that SMEs lack knowhow and financial resources for intensive R&D, marketing activities and regulatory approvals.

### 2.2.3 Intellectual property rights

Unlike the general biotechnology industry, IPR does not appear to have a positive impact on innovation in the FF sector. Herath et al. (2008) argues that patents have a significant negative impact on the number of FF product lines introduced on the market. Moreover, they argue that acquiring IPR from other companies also have a negative impact on the number of product lines in development.

There are some underlying reasons why certain FF projects do not turn out into launched products. One of those is the technology spillover effect. Technology spillover is a type of externality that is created when an innovative and R&D based company invests in research stemming into a new technology that eventually will contribute to a reduction in costs for development of a similar product for competitive companies. This state creates room for companies to “free-ride” on innovative firms and that eventually creates lack of incentives to invest in such research. According to Malla (2014), the technology spillover effect is created because FF based companies internationally uses trade secrets extensively instead of patent protection to protect their investment.

Another cause of the spillover effect described by Chong et al. (2008) is that the greater the market impact of a successful invention, the greater the threat of “copycat” companies bringing competitive products to the market. Aligned with this is the aspect of investments in approved health claims, as described in the health claim section above, that will only generate a five year property protection. Another aspect is that food patents most often exist of substance extraction methods from known food products. These methods are usually relatively easy to reverse engineer with slight difference but with same outcomes, which will not infringe on a patent. Furthermore, this gives the opportunity for copycats to produce a product with lower raw material costs and higher profit margins and therefore, they can offer the product to lower prices (Chong et al., 2008). It has been proposed that this phenomenon is playing a significant role in the relatively low rate of innovations in the FF sector. To counteract these circumstances an industry actor needs to emphasise the importance of trademark establishment strategies (Chong et al., 2008).

Costs for both patents and regulatory approvals add up to a large amount of money, hence it has a great risk connected to the procedure (Chong et al., 2008). This might create a double risk since an invented food product might not pass the criteria to be patentable and if patentable and patented it might not pass a regulatory approval to be released on the market. This creates negative incentives, both for internal and external investors such as venture capitalists and business angels, due to the high uncertainty and relatively low expected return on investments.

IPR cost money, both during the application and for maintenance purpose. Metcalfe (2015) created a financing model based on different funding sources during the venture creation process. In the model, viewed in figure 6 below, ventures can identify in what stage they are and by that tailor the financing activities. In general, the funding sources for early start-ups is self-funding and bootstrapping. Bootstrapping means that a venture tries to keep the cost low by choosing activities that are not expensive and the operational staff have incomes besides the venture Metcalfe (2015). In a validation stage, a venture can apply for governmental funding. During the expansion stage, after the first sales have been performed, private venture capitalists can invest capital in the venture.

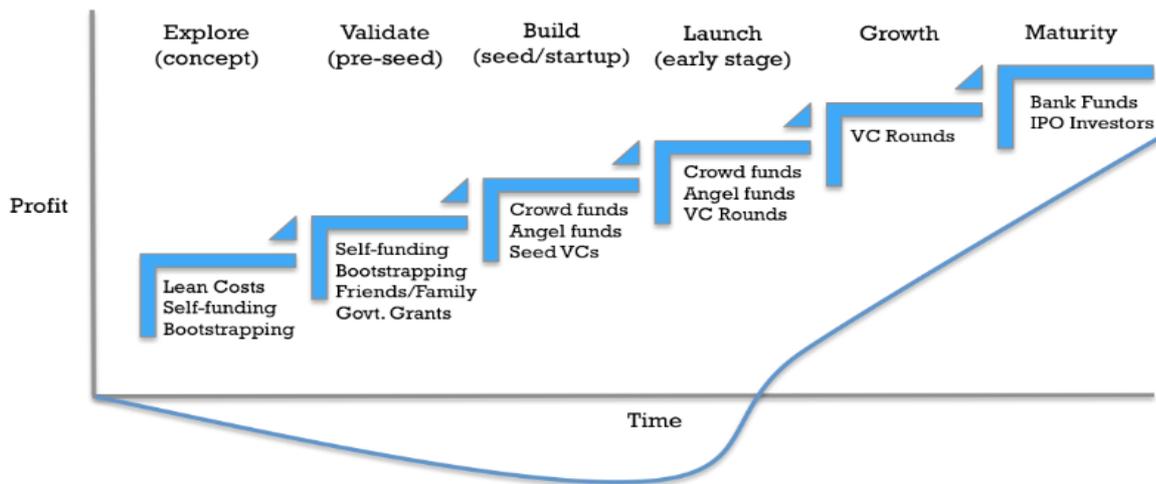


Figure 6: Early stage funding sources model (Metcalf, 2015).

### 2.2.4 Consumer acceptance

FFs can only be a successful category of food products if the consumers accept it. During the previous decades, the consumer demand of food products has changed considerably, where consumers more and more link their habits of food consumption with health (Siró et al., 2008). The increased demand of health related foods could partly be explained by increased costs in healthcare, increased desire for longer life expectancy and a desire for elderly to improve their life quality at increasing age.

The increased awareness provides great opportunities to develop an almost infinite array of new FF concepts. In addition, FFs are considered by consumers to be sold at higher prices, which could result in larger profit margins than conventional foods, creating an attractive sector (Schaafsma & Kok, 2005).

A product needs to satisfy four important conditions that are presented as the strategic triangle theory (figure 7) by Schaafsma & Kok (2005). The most essential and basic requirements are a good taste and an understanding of the concept. Apart from that there must exist an emotional consumer affinity and all claims must be true.

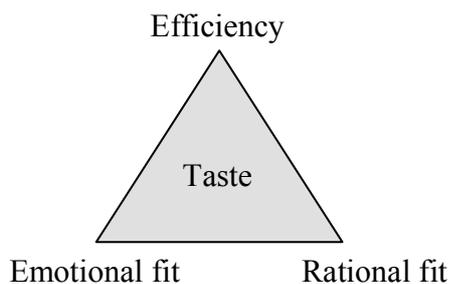


Figure 7: Strategic triangle of consumer acceptance (Schaafsma & Kok, 2005).

Other critical factors for the consumer acceptance of FF according to Schaafsma & Kok (2005) are:

- Perception of personal benefit
- Perceived seriousness of the targeted disease
- Health consciousness of the consumer
- Nutrition knowledge
- Sensory properties
- Price
- Technology used (such as genetically modification)

A market failure that often occurs connected to consumers and consumption is an information asymmetry regarding the social and individual health benefits with consumption of FFs (Malla et al., 2014). Consumers cannot identify health benefits of FF products without correct and credible labelling of health claims. Most often governmental organizations intervene in the labelling to regulate what kind of health claims that can be made. Another kind of market failure that occurs in societies, such as Sweden, is that the individual is not bearing the costs of health care. It is the publically funded health care sector that will face these costs. Moreover, consumer related market failures could lead to production of a smaller quantity of FF than is socially desirable (Malla et al., 2014).

Sweden is in the forefront in the development of FF in Europe and the FF sector of the food industry is one of the most advanced concerning research and technologies in the world according to Stenberg (2010). This development has been possible mainly because the Swedish consumers are highly health-conscious and interested in health and nutrition. The three dominating areas of FF consumption are functional bakery products and snacks, dairy products and functional beverages (Schaafsma & Kok, 2005).

### **2.2.5 Quality assurance**

Quality assurance (QA) is a way of preventing mistakes in manufactured products and avoiding problems when delivering solutions to customer (Hoyle, 2009). QA is of major importance in the food industry to be able to launch a product on the market and it is regulated by the current industry standards for each market. Thus, continuous QA of health claims seem absent as an industry standard. Health claims are connected to fixed quantities of single substances but the consumers often eat food in compositions of several ingredients. Currently, the only QA method available to predict the glycaemic response before a product has been consumed is through meal studies with human test subjects. To create statistic relevance of the data, numerous of people needs to be subjects through long time. This is a costly procedure of several hundred thousand Swedish crowns. Hence, meal studies are unsustainable for use at numerous ingredients since the number of possible compositions is almost infinite. Since QA is an important and necessary feature when producing foods, sustainable QA methods relating to health claim are needed. This creates opportunities for innovation.

# 3. Methodology

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This study will be conducted in a qualitative manner according to Bryman & Bell (2011). This approach will give deep insights into the research topic for the reader. The main novelty is the exploratory investigation of the venture creation process in the FF sector. Furthermore, previous research has not been explaining the venture creation process from a perspective of early stage FF ventures and therefore a qualitative observatory study is required for substantial insights in the process.

The result of the qualitative study will be subjective and cannot be assumed to cover the whole population of start-up ventures according to (Bryman & Bell, 2011). However, the qualitative research approach is preferred in this case over a quantitative approach due to the relative complex research questions that requires action research for the deep insight and understanding.

## 3.1 Research design

The chosen research design is insider action research where empirical data will be collected from one specific case, aligned with the research topic to give credibility to the study. The reasoning behind the design is that the author has insight and accessibility to such a case as well as it allows for continual and longitudinal observations and interventions on a rich, descriptive case that are qualified as fitting the thesis definition of venture creation connected to FF (Bryman & Bell, 2011). In addition, insider action research allows identifying internal insights that a disconnected observer would not be able to capture. In the later stage, the collected data will be analysed and connected to relevant theory. Thereafter, conclusions will be made answering the research question.

## 3.2 Data collection

The data collection will have emphasis on the general venture creation process in the case study and consist of: historically events, notes, experiences and memories from one year of observations. Some data also has been collected in collaboration with the founders of the venture by joint investigations, conversations, meetings, telephone calls and data sharing. In total approximate 60 interactions were made during the data collection period. Mainly, the generated data will be the author's personal data where actions such as meetings with stakeholders, web browsing and workshops were made on a daily basis during the one-year data collection. The collected data will be sorted and placed under the four categories of venture creation that was described in the theoretical framework: 1) Planning activities, 2) Legitimacy establishment, 3) Market activities and 4) Resource transformation. Throughout the findings chapter, where the collected data is presented, discussions of the data will be made.

### 3.2.1 Research object

This thesis work will be based on a case study of a start-up venture from Lund University in Sweden called ViscoSens. ViscoSens is in an early stage, founded by three researchers in 2011. The idea about a venture started already 2005 with an investigation in the need of sensors in the FF sector. Today, the operations are rooted in development and commercialization of a physical analysis technique with ability to analyse health impacts of food products and assure quality of labelled products over time. ViscoSens was chosen as research object based on the criteria that it is an early-stage start-up venture operating with FFs. This validates ViscoSens as a research object, significant for this study.

## 3.3 Data analysis

In the analysis chapter, the theoretical framework will be applied to the empirical data of the case through exploratory discussions. The discussions will be related to each of the venture creation categories and an analytical model will be created connecting the categories. By compiling the theoretical and empirical data in this matter, a hypothesis of a FF specific venture creation framework

can be created. The analysis will be the basis of the conclusion answering the research questions in the conclusion chapter. Later on, recommendations for further research and further actions in this area will be suggested.

### **3.4 Criticism/potential risks**

When doing insider action based research, there will always be a risk of conflicts when the one conducting the research also is involved in the daily operations (Coghlan, 2001). The risk lies in that one could make too many assumptions in a biased way, be reluctant to reframe current thinking or even distort data when being very close to it. On the other hand, there are multiple advantages using insider action research to extract data from an internal project. It can be attractive from a research point of view to look deeper into actions in a project, which is hard to get through external interviews (Coghlan, 2001). The possibility to look deeper arises when the observer has insights in the social setting and how colleagues are reasoning. Therefore, the observer can easily study certain situations, providing richer and more valuable data.

# 4. Findings

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In this chapter, the results presented from one year of observations are connected to how the venture creation process has proceeded in ViscoSens when forming a FF business case. The findings has been compiled and categorized in four categories: Planning activities, legitimacy establishment, market activities and resource transformation. In addition, each category has been deconstructed into several subheadings. The chapter starts with background information of basic facts before the investigation was initiated.

## 4.1 Background information

The author was given full access to the ViscoSens before the empirical data collection was initiated. The access included demonstration of current technology assets, i.e. an analysis technique for quality assurance purposes to predict glycaemic effects of bread. Moreover, the access included underlying strategic decisions of future proceedings to generate revenues. The main obstacles for ViscoSens had been to conceptualize the analysis technique to make it attractive to industry actors as well as ideas of how such concept could create revenue streams. In the process of creating an attractive concept, ViscoSens needed revenues to finance further operations. This led to a pivot, a divergent path from the initial concept, with considerably shorter time to market. The concept included sales of bakery mixes for bread containing high quality betaglucans in ratios 4g per 30g available carbohydrates. This ratio is the requirement according to the EFSA-approved health claim of betaglucans for low glycaemic response claims. This would generate a legitimate business that would be attractive for the small and medium sized bakery actors. The new path met issues in sourcing of high quality betaglucans at reasonable prices, as well as the fact that a high quantity of betaglucans affects texture and sensory properties in bread in a negative way. At the starting point of this thesis work, ViscoSens was turning back to the basic concept of an analysis technique and based on that build an attractive and feasible business case with long term potential.

## 4.2 Planning activities

### 4.2.1 Venture inventory

The first action, before the planning activities started, was to map out all components that belonged to the assets of ViscoSens, both technology assets, through a demonstration on a basic level to understand the most essential elements of the invention, and knowledge assets. The knowledge assets were collected through document sharing and interviews with the founders as well as with ViscoSens investors to determine individual visions and how they wanted to conduct further commercialization. The map out of knowledge assets followed the “bird-in-hand” principle according to effectuation logic by Read et al. (2010). It was considered of major importance to account for every stakeholder’s interest and knowledge areas to create maximum value of the venture. The investigation yielded hypotheses of concepts and value propositions that potentially could suit customer needs. The strength of ViscoSens was determined to be the human capital in the area of food technology and human nutrition. From the investigation it seemed reasonable to aim for a concept with grounded roots in the analysis technique but still with urge for a relatively fast market launch.

The technology demonstration revealed that the analysis technique was based on two scientific research articles published by one of the founders (Östman et al. 2006), (Ekström et al. 2013). The articles describe a way to mimic the human digestion system followed by certain analyses with results that could be linked to benefits of low glycaemic response through correlations with clinical meal studies. This indicated an in vitro method that could replace meal studies in analyses of real time properties in food products.

#### **4.2.2 First concept: health claims**

From these facts, an initial decision was made that the principles of the existing method was a good starting point, though the method needed improvements to work integrated in an industry production process as a quality assurance method. Through the process of working with the planning activities, new information and data was constantly flowing into the venture, as intended in a creative phase. The information consists of external environment factors that need to be considered to make creative plans realizable. This was the case when exploring how a health claim could be fitted into the method, which is further described in the establishing legitimacy chapter. The generated information eventually created entry barriers that forced a decision of a planning pivot.

#### **4.2.3 Second concept: medical device**

The information above showed that many FF concepts, which have experienced the tough health claim regulation, turn towards framing the products as consumable medical devices. The regulatory path for medical devices seemed to have certain benefits such as: shorter administration time, less costs and higher degree of protection of sensitive information. This is mainly due to a decentralized, national, regulation management system. Each national authority are authorized by the EU to approve medical devices by themselves compared to a centralized, EU common approval system for health claims. The medical device regulation enables health claims based on documentation, which is provided to the national authorities. The administration is fast and the claims are not free for other organisations to use. This seemed attractive for ViscoSens but the obstacle was to reframe the concept to fit into the medical device regulation. Therefore, ViscoSens contacted regulatory consultants with expertise in medical devices. The general response was that they liked the idea and saw a great need of such an analysis technique but in itself it could not be framed as a medical device since the analyses were made outside the body and not inside or in connection to the body. Therefore, it was recommended to aim for a validation as a quality assurance method. The analytical data could in that case work as cause-effect assurance that could leverage health benefits claims for medical foods. The suggested path was to accredit the method as a validated analysis technique of the glycaemic response in products and thereafter aim for making it an industry ISO standard for such analyses. These suggestions opened up the idea of another path to communicate health benefits for all FF. This was the seed for the second planning pivot.

#### **4.2.4 Third concept: quality-quantity analysis**

New technologies and tools possess the power to change frameworks in the society that have been created based on existing technologies at the time when the frameworks were formed. This was believed to be the case when EU formed the directives about health claims. No feasible quality assurance technologies of health claims were available in 2006 when the health claim directive was introduced, and therefore the legislation does not contain such requirements. ViscoSens possesses the ability to change the current legislative framework for health claims in foods. By measuring quality-quantity parameters of ingredients with already approved health claims, the new technology owned by ViscoSens can introduce more accurate health impacting levels. In the case of betaglucans, the quality depends on different factors such as the cereal kernel source and the extraction method, the glycaemic effects, in turn, and thereby the health effect, highly depends on betaglucan quality. Therefore, instead of basing the health claim requirements on betaglucan quantity, it should be based on a measured quality. A hypothesis was made that the decision of analysis data acceptance could be administered on a national level since it is not included in current European legislation. The new, third, concept included communication of measurement data as a leverage of proving health benefits and creating an end consumer communication concept that could be used on product packages. The obstacle would be to educate consumers about the meaning of the data so they could recognize it as a health benefit.

#### **4.2.5 Temporary business model and value proposition**

When ViscoSens decided to try the quality-quantity concept with potential customers, a temporary business model was created. The framework used was *business model canvas* by (Osterwalder, 2004). The temporary business model can be viewed in appendix 1. The business model still was seen as preliminary to be refined or pivoted to a verified model, through interactions with potential customers.

A verified business model will serve as leverage towards investors to fund ViscoSens. The most essential part of the business model canvas was considered to be the value proposition. The value proposition communicates how the assets can be transformed into customer utilities that will create value and profit opportunities for the customers. ViscoSens chose to describe the value proposition as a short-term profit proposition since it was “business to business” (B2B). The main focus was set to attract new customers in order to create recognition and interest among industry actors. The short-term pay-off proposition offered variable costs for the customers instead of investments in assets. The value proposition as well as the other categories in the business model canvas can be viewed in appendix 1.

#### **4.2.6 Timeline and vision**

To realize the business model, ViscoSens created a timeline of important activities, which leads towards the stated vision. The vision was a long-term goal that would guide the actions and operations in ViscoSens: “Performance of physical analyses of health benefits in all kind of food products, both for characterizations in specific ingredients and health impacts in compositions of food products”. The four-year timeline to work towards this vision can be viewed in appendix 2.

### **4.3 Establishing legitimacy**

#### **4.3.1 Regulatory preparation**

Initially, ViscoSens was aware of the hindrance that could occur before market entry due to the regulatory approval requirements for the concept. The analysis technique was not a single food product, more a technology that enabled food producers with claiming functionality and health benefits for their products. Hence, there were problems defining what legal framework that was applicable since the conceptual framing did not fit into any framework. The analysis technique could be viewed as a *health claim enabler* or as a method that need a health claim attached to it. The believed key activity was to start with the regulatory work as early as possible and execute a plan for quick feedback of how the concept could be refined to have an easy passage through the approval process. ViscoSens created hypothetical strategies of possibilities to adapt the current health claim regulation into the concept. Furthermore, ViscoSens learned through conversations with experts within food regulations that the view on the analysis technique actually could be different depending on the rhetorical framing to the approving authority.

#### **4.3.2 Health claims**

While investigating the adaption to health claim regulations, ViscoSens struggled with the high number of health claim rejections for products with low glycaemic response due to difficulties to characterize the heterogeneous carbohydrate compositions. Furthermore, the dependence of the analysis technique for a claim was questioned since the health claim regulation approved to make claims based on specific *quantity* of an approved substance, not based on health effects related to *quality*. ViscoSens knew through initial analyses that there are quality differences in every ingredient, which affects the outcome of health benefits. Hence, one option was that glycaemic response health claims can be quality verified by ViscoSens analysis technique and thereby independent on certain quantities of ingredient additives. Furthermore, this included that EFSA approved the analysis technique as a *health claim enabler* making it possible to claim health benefits for products with low glycaemic response. The analysis technique in itself was concluded to have no direct legal boundaries to be used. However, without the ability to make associated claims on products, companies would, most certain, not see any value in using the technique. The process of receiving a health claim was then studied. The identified obstacles for ViscoSens were; the expected administration time of minimum five months until feedback opinion, the high costs for the approving process as well as the lobbying effort at the EC to get the analysis technique approved.

#### **4.3.3 Medical device**

A hypothesis that the analysis technique could receive an approval as a medical device was made since it measured an actual health effect independent of product. The criterion was that the product should be consumable. Many consumable medical device products have been observed in the market.

The regulations seemed easier in the path Medical device, as was described in the planning activities chapter. Medical foods are foods that are specially formulated and intended for the dietary management of a disease that has distinctive nutritional needs that cannot be met by normal diet alone, and were an up and coming category of foods. It was also discovered that more governmental funding was granted to medical food projects since they could make an easy connection with solution to specific diseases and societal problems. Despite the potentially easier approval, the conclusion had to be made that the analysis technique could not be classified as a medical device. Nevertheless, it seemed as an interesting category if cooperation could be established with medical food producers, whereas ViscoSens method could be used as a quality assurance of health effects. From authorities it is communicated that continuous quality assurance is important for validation of health effects in medical devices. Therefore, the alternative “medical device” stayed as a component in the business model.

#### **4.3.4 Quality-quantity analysis**

The concept of making quality-quantity analyses that was described in the planning activity chapter was considered minimizing the level of regulatory activities since the initial focus was to work with already health claim approved substances. The long-term aim is to develop and create a novel industry ISO standard for analyses of glycaemic response. The ISO standard would work as a platform that companies could adapt by purchasing equipment and methodologies from ViscoSens. By adapting to the ISO standard as a quality assurance system, the companies would be able to launch products with a communication concept that guaranteed certain glycaemic response after consumption. Such claim could be “The blood glucose levels after consumption will remain x % lower compared to a reference product”. The reference product had to be compared to equivalents of a similar reference product such as pure glucose or white bread, dependent on the shape of the launched product. To get the method recognized and accepted by the industry actors, it must be authorized and accredited by a governmental organization. ViscoSens concluded that the Swedish Board for Accreditation and Conformity Assessment (SWEDAC) could be such an organization. The next step towards a regulatory approval is to initiate communication with regulatory legislators at the National Food Agency in Sweden to confirm how ViscoSens can use analysis data in the communication to end consumers.

## **4.4 Market activities**

### **4.4.1 Technology push vs. market pull strategies**

The traditional way of conducting market activities is to focus on development of a product according to a hypothetical specification of needs and postpone customer interaction until the transformation of assets into products is finished, a so-called technology push strategy. This strategy characterizes a venture that prioritizes development over customer interactions and does it as a linear process. It means that the customers will not have the possibility to contribute with their inputs to the product development. In many cases, the customer demands will never be satisfied.

The counter strategy of technology push is called market pull. Market pull is a kind of customer development strategy where identifying customers and revealing customer demands through various Minimum Viable Products (MVP). Market pull strategies had been successful in many start-up settings, although most research has been conducted among software start-ups (Blank, 2012). When a case study starts, the assets were already initially developed into a working prototype in the founder’s academic settings.

Therefore, ViscoSens decided to view their current prototype as the first MVP and focus into a market pull strategy based on customer demands. Moreover, ViscoSens wanted to operate within the outlined field of expertise in health, nutrition and food technology for maximum utilization of knowledge assets. Therefore the spectrum of fully adapting to customer demands was narrowed. This led to a combined technology push and market pull strategy where the linear elements consisted of the relative narrow spectrum of operations and the iterative elements consisted of revealing customer demand within the outlined spectrum.

#### **4.4.2 Customer interactions**

The market activities were considered as a formation of the value proposition and it started in the first customer interactions. The basic idea of the value proposition was to solve identified problem statements. ViscoSens formed and analysed the customer's problems through continuous conversations and meetings in addition to applying the previous knowledge in the field. From there, ViscoSens started to form cases that would be long-term beneficial for all parts. As far as the customer interactions have proceeded, the results are summarized in four bullet points below.

- The current analysis technique has been partly verified to have potential of great use for the customers.
- The prototype, in its existing shape, could work as a MVP that could fill a purpose as a demonstration tool used to show customers the principles of the analysis technique.
- The prototype could generate analytical data on customer's products that could be valuable and thereby sold, which could generate initial revenues for ViscoSens. This without involvement of any health claims when customers sell analytical quality assurance data of their products to other businesses.
- The ability to communicate analytical data to consumers in form of health claims is important to build a concept that is creating added value for consumers. Thus, the analysis technique has potential to change the regulatory framework for glycaemic response related health claims.

The next major activity will be to identify customers who are willing to pay for the data generated by the current analysis technique. The most important conceptual verification will come when a first product has been sold to end consumers. That will generate actual feedback that the concept is attracting and adds value, both for ViscoSens and its customers. Hence, should the customer or consumer demand not be served, ViscoSens is ready to make another pivot since they know that a start-up has to be fast moving and flexible. Moreover, another possible reason for a pivot could be if the regulatory strategy is not working and there is a need to find a new way to frame the concept to pass the regulatory requirements. In addition, financial requirements and time to market are important aspects that also could force pivots.

### **4.5 Resource transformation**

#### **4.5.1 Product development**

Product development is an important activity for FF based ventures and it will remain so even if, in this case, it was considered to be a secondary activity after planning activities, regulatory approvals and customer development. Since no operational personnel have been employed in ViscoSens during this case study, the product development has been on hold. This was seen among the stakeholders to be a preferred status since the considered importance of a formed and customer verified concept before any further product development. Sometimes product development also creates boundaries and limitations. Therefore, the conceptual planning also has included product development aspects. Some hypotheses have been created simultaneously with other activities. Those hypotheses will not be brought up in this thesis since they contain sensitive information that has potential of being the basis for a patent application. Though, the main focus of product development is expected to be put on improving the quality of the analysis technique, making it atomized and cover a wider range of performance parameters to generate more precise and reliable data.

#### **4.5.2 Intellectual Property Rights**

The general response from venture financiers has been that ViscoSens need a patent portfolio. This was considered to be essential both for funding purposes and to be protected on the market when the product starts selling. ViscoSens perceived this recommendation as vital for success. Therefore, a brief freedom to operate (FTO) analysis was performed, which revealed that there was not high intensity of patents in similar fields as the analysis technique, analysing health effect in vitro. The initial conclusion made

from the analysis indicated that the barriers of being granted a patent was not high and there were no hindrance entering the market today. A considered advantage that ViscoSens possesses is that the founders are world-class experts in the research field of nutrition, health and food technology and thereby are pioneers in the field of measuring health effects in food products. Due to this level of expertise within ViscoSens, the probability of other unknown actors patenting similar technologies was considered low and thereby the urge of performing a patent application did not seem very high. Therefore, the possibilities of keeping the technology a trade secret seems reasonable until funding has been received. The issues with trade secrets, that ViscoSens was aware of, is the sensitiveness of information about the technology. Thereby, nothing essential of the technology can be published, otherwise the novelty could be ruined and there will be no possibilities of receiving a patent. Moreover, before the case study was initiated, a patent attorney performed an initial novelty search with positive outcomes of possibilities in patenting the invention. To initially protect the assets of ViscoSens, a trademark was filed and granted with the name and logotype. Thereby, tangible value can be created in the brand valuable for a possible exit.

### **4.5.3 Funding**

Funding is always an obstacle for start-up ventures and especially those who are research based with a long time of development before being able to enter the market. The most reasonable is to in an initial phase apply for governmental grants, which also is called soft funding. The major part of the soft funding in Sweden is granted by a governmental organisation called Vinnova, but there are also a variety of scholarships from funds that could be applied for. The obstacle is that the competition for the soft money grants is huge and the administration time before a decision is long. To only rely on governmental funding is risky but if such money is granted, ViscoSens could focus on more important things of venture creation than apply for funding with a limited amount of spendable time. ViscoSens has identified that they are somewhere between pre-seed and seed phase of the funding cycle by Metcalfe (2015) illustrated in figure 6 in the theory section. As could be viewed in the figure, the expenses are high and the profit is negative.

A potential model for funding that came to knowledge was to get funded by potential customers. This model stemmed from the customer development reasoning. If the customer demand were high enough, they would be willing to partly pay for the development cost of the product. In businesses that target consumers, a so-called business to consumer (B2C) model, a campaign of crowd funding could be created. There early adopters of the product watches a pitch film and decides if they want to donate an optional amount of money in return to receive the product before everyone else or just to make it reality. When having a business targeting other businesses through a B2B model, the best way of funding is for the potential customers to fund the technology development. If funding is received from potential customers this is feedback to ViscoSens that the value proposition targets a real customer demand. Potential customers often say that they are interested in the project and when a product is finished they might also buy it. Moreover, they could even sign a letter of intent saying that they are going to buy the product when it is finished, but this is never a binding document, which could lead to failures if relying on these documents too much.

It would be a possibility for ViscoSens to seek venture capital (VC) and business angel investments. In the current stage, it was considered by ViscoSens to be too early since no sales had been performed. The reasoning behind this was that a first sale would raise the valuation of the venture and by that ViscoSens could receive more capital for less ownership to the funders.

## 4.6 Summary of the case

Table 3 below summarizes the essential outcome of the findings that will be brought to the analysis chapter.

**Table 3: Summary of the result from the venture creation categories.**

Venture creation categories	ViscoSens
<b>Planning activities</b>	<b>Preliminary concept:</b> Communication of measurement data, based on quality-quantity analysis, as a leverage of proving health benefits and creating an end consumer communication concept that could be used on product packages.
<b>Establishing legitimacy</b>	<p><b>Health claims:</b> No quality assurance aspect currently included in the health claim regulation. Observed high barriers of receiving a health claim approval since the analysis technique did not fit into the framework of health claims.</p> <p><b>Medical device:</b> Analysis technique no medical device by itself but with cooperation with medical food producers it could work as a health effect quality assurance, which was necessary to possess be approved as a medical device.</p> <p><b>Quality-quantity analysis:</b> Communication of accredited analysis data of already approved health claim substances where the quantity of ingredient is based on the quality and health effect. The quality assurance technique should be accredited as a validated analysis technique and in the end an industry ISO standard</p>
<b>Market activities</b>	<p><b>Market strategy:</b> Combined market pull and technology push strategy since the first MVP already was developed and a customer demand is important to consider before further product development.</p> <p><b>Customer development:</b> The potential customers have partly verified the concept and believe that important data can be generated with the current analysis technique. The potential customers still emphasise the importance of a communication concept of analysis data to consumers to be able to create added value.</p>
<b>Resource transformation</b>	<p><b>Product development:</b> Product development is considered as a less important activity in the current status of ViscoSens. Though, some hypotheses of further product development have been conducted to be able to realize the venture vision in a realistic manner.</p> <p><b>IPR:</b> Initial FTO and novelty searches have been performed with positive outcomes. There are no patents hindering a market entry. A patent will be applied for when funding is secured. A trademark has been applied for and granted as a sign that ViscoSens is aware of the IPR situation.</p> <p><b>Funding:</b> Governmental grants and funding by potential customers will be the major source of funding. In the next phase will VC and business angel investments be the major source of funding.</p>

# 5. Analysis

The analysis chapter consist of analyses that connect the theoretical framework with the empirical data collection. The emphasis has been on different perspectives of activities when creating a FF business case.

## 5.1 Analytical framework

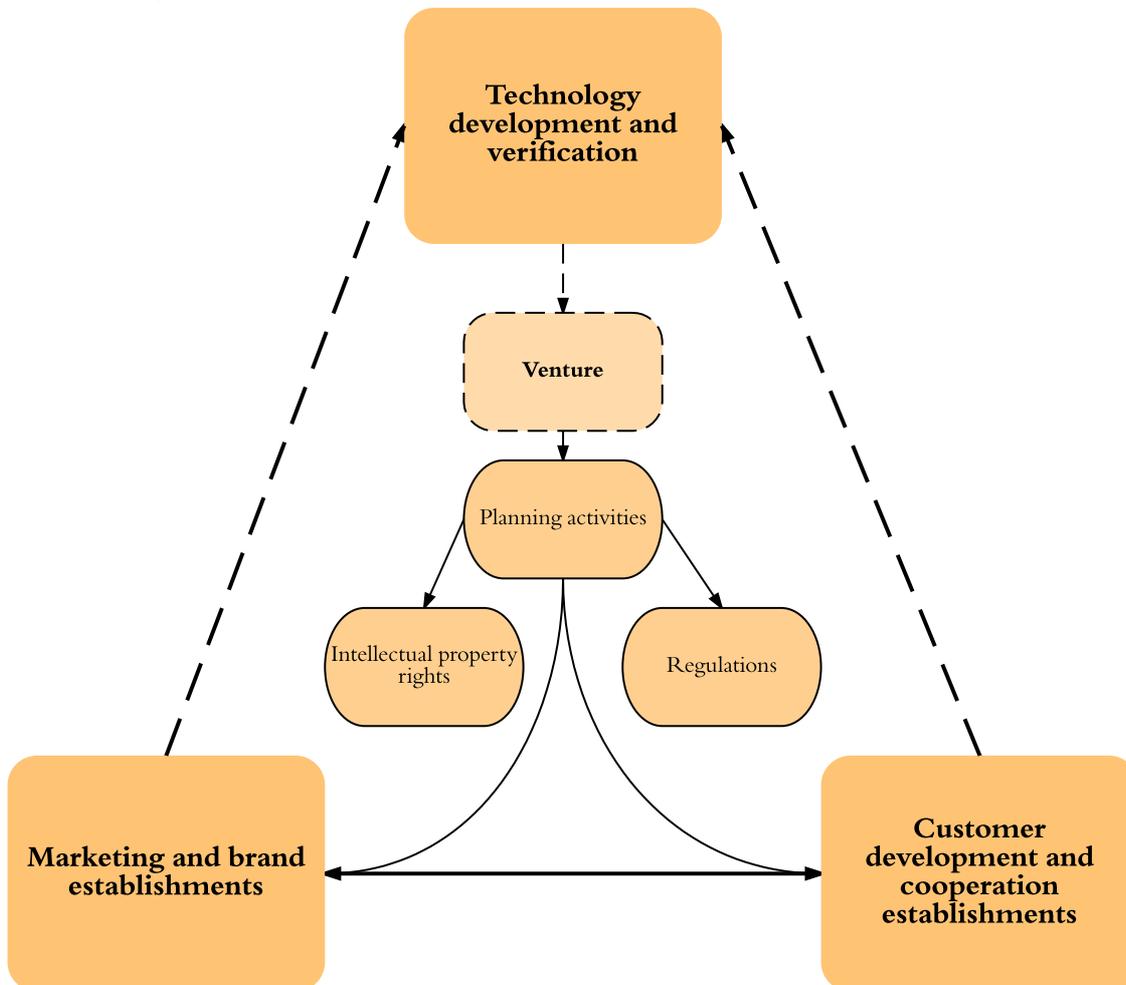


Figure 8: Illustration of the analytical framework of factors influencing a FF start-up venture.

The analytical framework, seen in figure 8 above, has been created to join the theoretical contribution with the empirical data collection and put in perspective of how the activities interact in the creation of a FF start-up venture. No found theory has previously described a proposed framework for venture creation in FF start-ups, which is the reasoning behind an establishment of such a proposal. The activities have been divided into internal, external and fusion activities. Fusion activities indicate both internal and external activities.

## 5.2 Internal activities

The internal activities are defined by activities that are performed inside the venture and work as a scaffold that are necessary in development of a sustainable business.

### 5.2.1 Venture

The figure indicates that the venture creation starts with the formation of venture constellation, as was described in the findings as venture inventory. That could consist of a team of founders accompanied

with some kind of assets, technology, knowledge or both. It all starts with an idea of how some assets could be transformed into a product or service serving a hypothetical market demand.

### **5.2.2 Planning activities**

An idea needs planning to be realized and therefore the idea generation follows by a planning phase, which was established both in theory and findings. The planning activities are a general cause for almost every venture independent of industry direction and central to perform other operational activities in a structured and carefully prepared manner.

The technology assets of ViscoSens differed from the majority of FF concepts, which usually are consumable food products with health benefits. Therefore, the planning activities could be seen as more flexible than when for instance commercializing a FF ingredient since hardware technology could be adjusted to customer demands more easily. Nevertheless, more common FF could focus on specific demand of certain health benefits and then develop applications and compositions according to customer demand. Therefore, it is a necessary activity in all FF ventures to include customer development as a central piece in the planning activities.

ViscoSens chose to focus the planning specifically on concept creation and value proposition generation of the business model instead of further product development. It seems like that choice led to the ability to take an external approach. The cause of starting with these categories was that they got an opinion that this was enough for the planning phase. It is always a utopia to plan all future operations in detail followed by that everything turns out as one thought, but the reality tells you otherwise and as an entrepreneur one needs to value the limited time there are to distribute. Therefore a typical business plan should not be created before some verification or execution has been performed since the risk of being forced to make pivot is high and then the whole plan have to be remade. A business plan usually takes a couple of months to write compared to a business model that is just a way to structure a business hypothesis. Therefore, the creation of a business model seems more reasonable for a better distribution of time.

ViscoSens chose to perform a timeline to structure the activities of commercialization. Such document could be valuable both as an internal document when deciding to prioritize activities and as a presentation document for investors as an illustration of how the plan is going to turn into reality. The necessity of a timeline in an early stage can be questioned. According to the author, that depends on the internal structure in ViscoSens. If the founders/investors are not involved in the operational activities, as in the case of ViscoSens, a timeline is preferred as a decision material. If the entrepreneurs are the founders a timeline could possibly wait until a later stage.

The planning activities category is the gateway to all other venture creation activities except the technology development and verification since it should be performed according to verified customer demand rather than internal ideas.

### **5.2.3 Regulations**

To create a legit business, approvals to release a product on the market needs to be obtained. For FF businesses it is often connected to regulatory approvals. An entrepreneur needs to know the legal barriers to enter the market otherwise a business could fail after huge amount capital and time spending on other costly activities.

Regulations could be viewed both as an internal and external activity but the author has chosen to view it as an internal activity since it highly depends on framing the concept and intended application of use. One must be aware of additional regulations that have not been specifically brought up in this thesis such as a classification called novel food. If a food product has not been consumed or consumed in intended quantities within EU before 15<sup>th</sup> of may 1997 it will be considered as a novel food. The implication of this regulation is that the FF, more or less, will be viewed as a pharmaceutical agent or genetically modified food product and loads of costly toxicology studies during long time have to be

performed. In addition, the health claim regulation needs to be performed separately. In theory, these regulations in combination are not recommended to perform for start-up ventures since the financial assets and necessary experience usually are not settled.

ViscoSens started the venture creation process with a lock-in that FF concepts equal health claims, which still is the most common regulatory route. Though, it seem like a good decision to start investigate other routes as well. That created a wider spectrum of possibilities to frame the concept. Even if the first regulatory investigation will be to introduce a quality assurance parameter of health claim and possibilities of communication validated analysis data without involvement of health claims, the medical device pathway will still be an optional side-track. If ViscoSens will choose to apply for a health claim or performing lobbying work to introduce a novel paragraph in the health claim regulation, the venture should consider looking for collaboration partners with preferred financial and knowledge assets for this matter.

Some critique that has appeared is that EFSA has problem to separate FF from pharmaceutical products where they are applying similar level of safety requirements for FF as for a disease treating pharmaceutical agent, i.e. with numerous clinical studies. Moreover, FFs are not disease treating agents; they are preventive and proactive agents that reduce the risk of getting a chronic disease. From there it could be discussed what kind of framework that is applicable for FF and here opinions differ. EFSA is a young organization, created in 2002, and they need time to adapt to the consumer and industry requirements. Therefore, it will most likely be introduced changes in the safety requirements to open the market of FF further. This because most stakeholders in the FF regulatory arena are agreed that major benefits such as societal savings can be achieved due to a better health of the population.

The awareness of regulatory challenges with receiving health claims in addition to the lack of secrecy when filing for a health claim has increased the rate of medical device classified FF. The medical device directive (EC No. 93/42, 1993) is standardized in different classes with fixed regulatory requirements, which makes it easier for companies to adapt and tailor studies to create safety evidence. The medical device classification is approved on a national level by notified bodies. This increases the interactions and communication between approval institution and companies, which is favourable for everyone due to a faster approval process. When filing for a medical device, the documentation and claim will be seen as property that will make it hard for potential competitors to benefit from others approvals.

#### **5.2.4 Intellectual Property Rights**

Many advisors consider IPR as assets that are necessary when creating value in a technology based venture. That could be discussed from many perspectives. The theory is, in the case of patents necessity as IPR, arguing for that it inhibits the innovativeness in the FF sector. The author argue that patents will generate more venture capital investments to start-ups and that will in the later run create higher incentives and opportunities for entrepreneurs to create new innovations in this field. According to that there are limited available property rights when going through health claims, patents seems like the only way to claim ownership of an innovation for a longer time. Brands and trademarks are of certain importance but it will not inhibit copycat companies from riding on another companies investments in R&D generating FF products with health claims as stated in the theory. Trademarks and brand establishments are the most common way in the food industry to claim any property and to establish customer loyalty. The author argues that branding strategies are preferable for all ventures working with FF as a way of connecting with the target group. It will not likely enhance the probability to receive investments in the research and development phase, as patents, but it will more likely boost the product sales when it reaches the market, which in that case attracts investments for expansion growth.

On the other hand, IPR are expensive to apply for and uphold. Therefore the author argues for the necessity of an established IPR strategy. It is of importance to identify the right moment for a patent application for maximum protection since a patent protects for approximate 20 years from the filing date. Another strategy regarding IPR could be to continuous inventing attributes to the innovation. Then,

others cannot block the innovation on the market in addition to that the components of the innovation will be kept secret from external actors.

## **5.3 External activities**

### **5.3.1 Customer development and cooperation establishments**

The first and most important external activities are the customer development and cooperation establishments. It is a matter of risk factors surrounding a technology based venture. As described before, the most fundamental piece of a business is that someone is going to pay for a product/service. Therefore, a venture will have a less risky path towards creation of a business when the potential customers play a part in the development of the product/service. Cooperation with other players is also fundamental for the speed of venture creation since all knowledge and necessary assets might not be a part of the venture.

ViscoSens is targeting a so-called blue ocean market (Kim & Mauborgne, 2015). This means that ViscoSens is pioneers in creating a new market category in quality assurance of food health effects. A blue ocean market has certain pros and cons. The pros are that there are no established actor and thereby no competition. If a demand is identified in a blue ocean market, there are endless opportunities. Many investors often seek ventures with blue ocean potential due to the opportunities and possibilities to create a global business. The cons are that no market structure is established, for instance with regulatory affairs. In addition, no prior market demands has been identified since there are no other products available and business manage with the existing technology available on the market. This seems challenging when entering the customer development phase. ViscoSens need to develop a demand from scratch at potential customers. This can take time and most probably only early adopters will be interested in what has been offered. The rhetorical preparation before conversations with potential customers will be of outcome importance since it cannot be assumed that they will understand more than a simple and shallow explanation of the concept. When developing a customer demand an emphasis on competitive advantages that are to be created after implementing the product is of necessity. The same reasoning goes for cooperation establishments for awakening interest in potential collaboration partners.

A decision to exclude customer development and adapt to a pure technology push strategy would seem as risky for a FF venture, already overwhelmed with risk factors. Therefore, the author recommends to, as much as possible, continue with the market pull strategy through customer development.

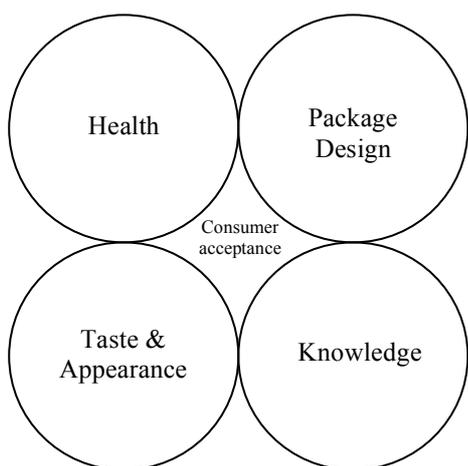
### **5.3.2 Marketing and brand establishments**

At the same time as customer development is an important factor in the B2B setting of ViscoSens, communication with end consumers and external stakeholders is also of importance. As was described in the findings, ViscoSens got much input and information through communication with experts in their field such as regulatory consultants. They played a great role in the concept formation. At the same time it does fulfil a marketing purpose of the new, up and coming, technology that are about to strike the market. By talking to any stakeholder, whether it is consultants, potential board members, customers or end consumers, it starts to establish the product and to create customers.

A recommendation to ViscoSens is to start initiating contact with end consumers for their input. This could be performed by initiating a small scale concepts of baking bread with verified low glycaemic response and bring it to consumer fairs or local bakeries and there initiate contact with the target group.

According to theory are external environmental factors such as consumer trends of importance to adapt to in FF concepts. To include this in the market strategy could serve as bridging between technology push and market pull. An example is the anti-sugar trend, currently present in the society, that if adapted will increase the consumer acceptance of a product. According to the strategic triangle of consumer acceptance in the theory section does the products sensory properties pay a great importance on the

consumers while getting consumer acceptance. Also the design plays a great role, where the communication of evidence based health claims is a central piece. These three are all graspable translations of the triangle in figure 4 above. The author is arguing for addition of a fourth piece, which is knowledge. Consumers are, in the present status of the society, more and more aware of health impacts and how food consumption is affecting health, especially in Sweden (Stenberg, 2010). They are also desperately embracing new knowledge due to the rise in interest. This hunger for new knowledge often creates miscommunication due to communication of hypotheses not based on scientific data. From this reasoning, the author argues that trustworthy and understandable knowledge, not only embedded in the health claim evidence, communicated to consumers is today additionally required to receive consumer acceptance. The new interpretation of consumer acceptance is illustrated in figure 9 below.



**Figure 9: Model of consumer acceptance based on the strategic triangle of consumer acceptance by (Schaafsma & Kok, 2005).**

## 5.4 Fusion activities

### 5.4.1 Technology development and verification

The resource transformation regarding technology/product development is dependent on the customer/consumer demands as well as regulatory requirements. Therefore it is placed as the last category in the analytical framework. As a part of the product development process, FF ventures should investigate: consumer demand of claims that will be attributes to the product, the regulatory requirements regarding research to achieve these claims and how the development could be designed to meet these requirements. From this reasoning it seem obvious that the customer demand and regulatory requirements set the agenda both for the clinical studies that needs to be performed as well as the technology development activities.

To start the construction process of a first MVP as part of the customer development process seems like a fortunate strategy since that will give the potential customer a tangible demonstration of what the invention have possibilities to perform. Though, this could not be viewed as a development process since it needs to be constructed with minimum time consumption. It is a middle step before the real technology development starts.

The theory argues for high costs when developing FF products and thereby funding needs to be collected before the development is initiated. In ViscoSens, financial assets and human resources are in process to be collected. The technology development will eventually lead to an increase in assets and thereby the circle in the analytical framework model is closed.

### 5.4.2 Funding

The category of funding is not included in the analytical framework since it is a necessity for every start-up venture to be able to perform the desired activities.

Before the technology development is initiated, most start-ups can manage the operations by self-funding and bootstrapping. Bootstrapping mean that “every penny counts” in expenses, i.e. no expensive operations are performed and every activity that cost money is weighted against the possible outcome. Hence, when the technology development is to be initiated, the financial assets need to be collected. The theory has a quite negative view on the financial requirement for product development of FF. They also have a view that large multinational companies should make the investments in research and development (R&D) so the small and medium sized companies could ride on their investments. The author would argue that the development costs for start-up ventures are much lower than for a multinational company due to fewer resources, including direct and indirect costs, and a flexible mentality. In addition, the need for start-up ventures and SMEs are necessary for the innovativeness in the industry and therefore should not the development activities only rely on larger multinational companies. Therefore, the author proposes a need of change in the food industry. By benchmarking the pharmaceutical industry, the suggestion states that larger companies should be better in investing in start-up ventures that preferably are based in academia at universities with extensive development experience. Hence, start-ups will have the ability to innovate new FF products that could benefit many actors, including the large companies with less spending on R&D and higher return on investments.

Generally it will be favourable for start-up ventures operating in the FF sector to stay as long as possible as research projects close to universities. This will increase the opportunities to receive governmental grants to fund necessary clinical studies and safety assessments to be able to reach the market. Many initiatives needs this kind of verification money in an initial phase to reduce risk, add value and reduce time to market, which potentially will increase the probability for venture capital in a later stage.

A proposed list of possible financial sources that could help start-up ventures with the financial situation are presented in appendix 1.

# 6. Conclusions

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The conclusions from this thesis is that with the basis of the studied venture ViscoSens, the proposed procedure of commercializing the analysis technique in the setting of creating a FF venture is as follows (also illustrated in figure 10):

## **1. Business model proposal**

Firstly one should perform a venture/project inventory and look at the current assets, technology and knowledge of the venture to see how these could be linked to hypothetical customer needs. When that is done the conceptualization/business model proposal process can be initiated. It is important to remember that a proposed business model is not fixed and should be remade on a constant basis.

## **2. Customer development**

A business starts and ends with customers. Therefore, it is of importance to early identify and interact with potential customers, according to customer development theory, to get an overview of their needs to be able to create an attractive value proposition for them and remake the business model accordingly. In that process could also a first MVP be constructed to show how the technology is intended to perform. In the case of ViscoSens, as a B2B business, it is preferred to also perform end consumer investigations to identify the demand of certain health benefits.

## **3. Business planning**

The business planning is an activity that shows how the business model is going to be realized and that includes e.g. to create an IPR strategy of how to handle the intellectual assets and create a strategy and plan for the technology development. The first three activities most likely have to be funded through bootstrapping.

## **4. Asset generation**

When the business planning is performed, a venture is mature to apply for governmental funding and scholarships to be able to finance the operations. At the same time, the technology development should be initiated dependent on the financial status. When the first draft of a product is developed sales should be initiated to get early feedback from customers.

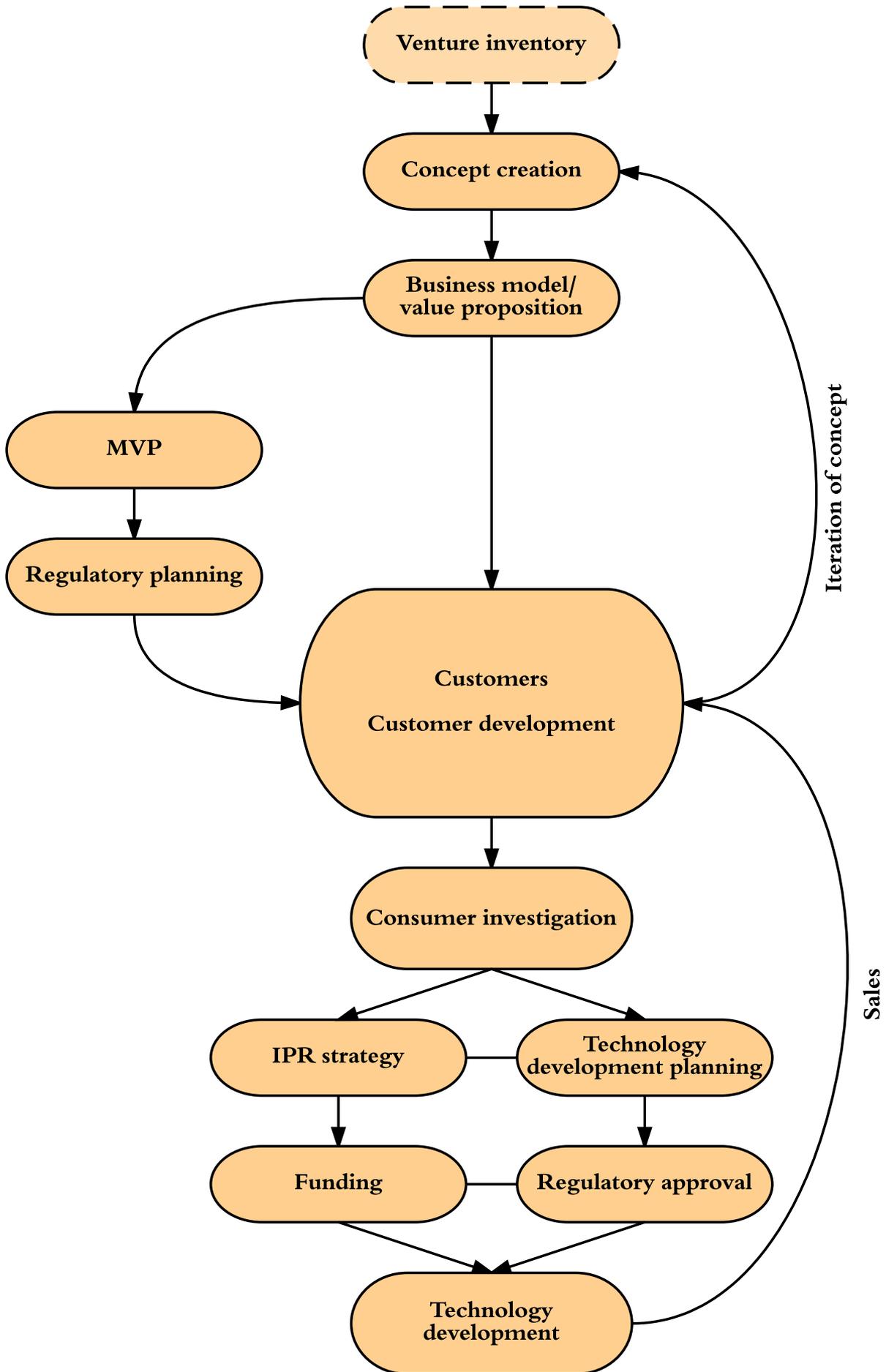


Figure 10: Model of the thesis conclusion.

# 7. Recommendations

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## 7.1 General recommendations

- The conclusions revealed a model of FF venture creation, which could be interpreted as a linear model. A recommendation is to see the model as a non-linear process since it could differ from case to case. The model is a proposal of how venture creation in a FF start-up can be performed.
- A recommendation is also to wait to apply for governmental funding and scholarships until the concept is finished and customer interest is partly verified. This will increase the probability of receiving the grants since the decision makers usually look for well-defined and realizable concepts with already established cooperation agreements between stakeholders and with a well thought through plan of how to perform the commercialization.
- Another recommendation is to not have a lock-in only on external funding possibilities because the best way to fund a venture is through sales. External funding is often attached with some sort of liabilities and the money cannot be used for every activity that the entrepreneurs want to perform. When handling money from sales, they are not bound to anything, which gives flexibilities in intended use as well.

## 7.2 Next steps for ViscoSens

In the next phase of venture creation, ViscoSens is recommended to increase the customer interactions with a larger diversity of potential customers to further reveal the demand. In addition, ViscoSens should try to sell the concept and value proposition to the potential customers to make them fund the technology development. As was observed in the data collection, ViscoSens has a possibility to sell analysis data to customers that can be produced by the MVP.

Furthermore, they need to expand the cooperation network with essential actors, for instance to start cooperate with major suppliers. Simultaneously ViscoSens should start engaging in consumer investigations to hear the voice of end consumers about the demand for products containing health claims with preferable glycaemic response. Concerning that no operational staff are employed at this stage, this could be done by hiring students that are doing projects within academia.

Moreover, the funding is still an issue that needs to be accounted for. Governmental grants should be applied for to spread the risks if potential customers are not interested in funding the technology development. In parallel with the funding collection, the regulatory plan should be executed since this is a time consuming process, regardless of regulatory path.

In the next phase after funding and regulatory execution has been initiated, ViscoSens should start the process of employ operational staff that can lead the technology development as well as collecting data to validate the method. When the technology is under development, ViscoSens should additionally look for novelties in the invention that could lead to a patent application.

The last recommendation for ViscoSens is to try to perform the activities according to a decided timeline because it will give you trustworthiness towards stakeholders, whether it is the shareholders, investors or governmental institutions.

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# Appendices

## Appendix 1

### Business model canvas

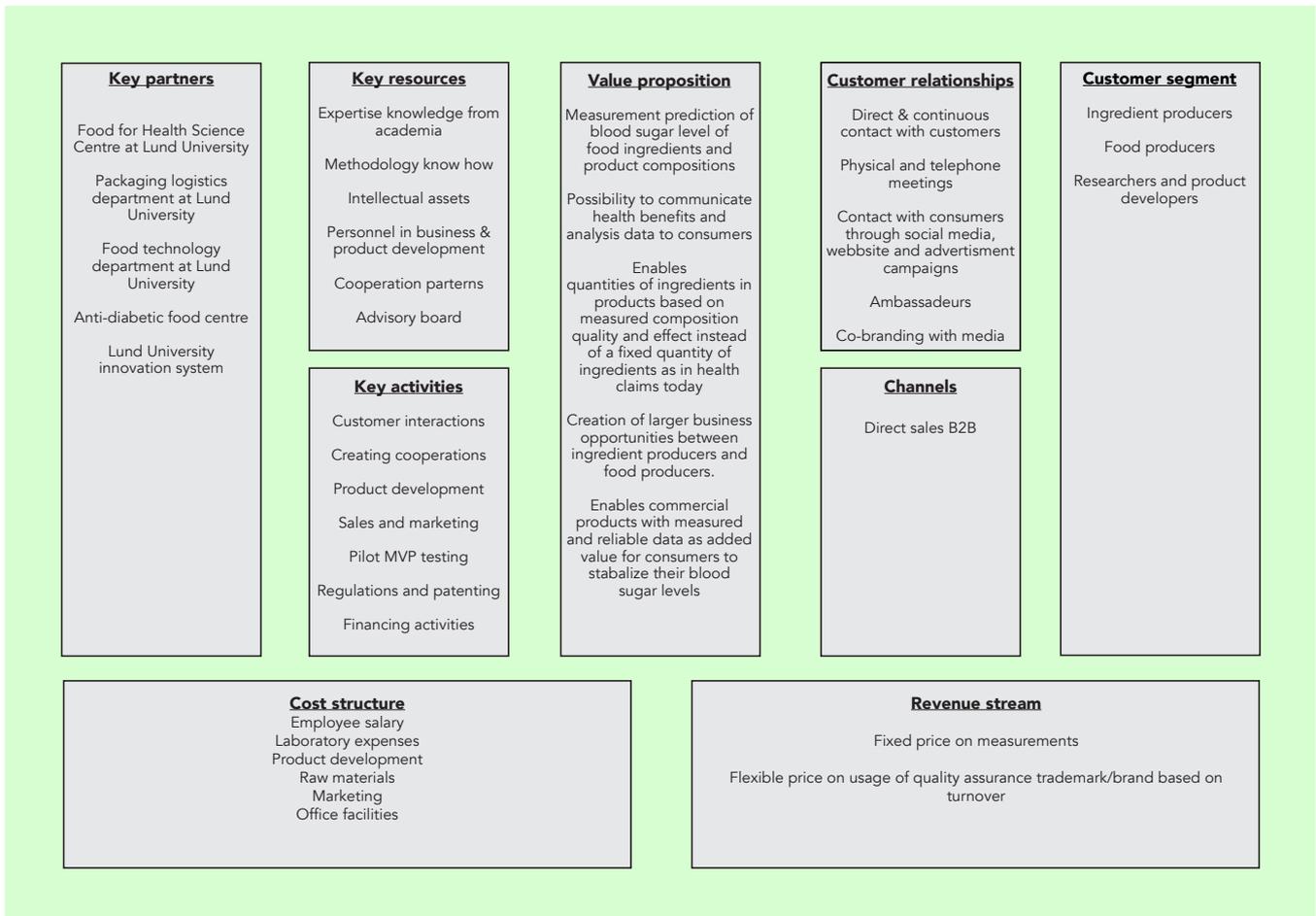


Figure 2: Business model canvas of ViscoSens

## Appendix 2

### Timeline

This is a proposed timeline of important activities for commercialization of the analysis technique for the next four years.

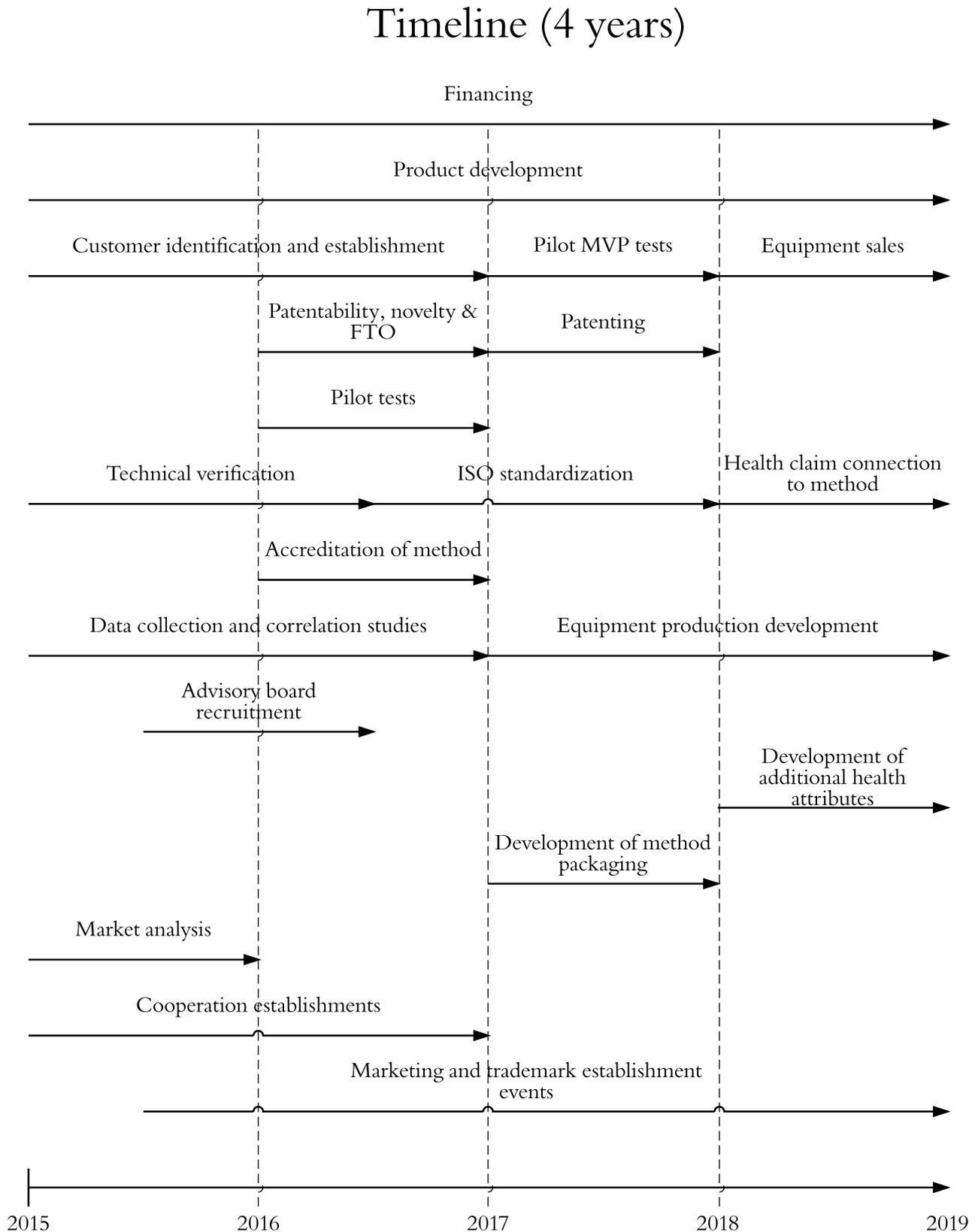


Figure 3: Four-year timeline of activities for ViscoSens.

## Appendix 3

### Funding sources

Table 4: Some funding sources in pre-seed/seed phase.

Financing sources	Explanation
<b>Vinnova VFT 1</b>	Verification grants from Vinnova on up to 300 thousand SEK. Managed by the regional innovation offices/technology transfer offices at the universities.
<b>Vinnova VFT 2 “Vinn-verifiering”</b>	Verification grants to university based projects from Vinnova up to 2 million SEK to commercialize research results.
<b>Vinnova Challenge driven innovation</b>	Supporting mainly triple helix innovation constellations where academia, industry and governmental organizations should, preferably, be involved. This is a three-stage process where the grant in the initial phase is 500 thousand SEK. A requirement is though co-financing from the constellation.
<b>EU project funds (Horizon 2020)</b>	Horizon 2020 is a large EU fund. This is applicable for ventures cooperating in cross-national constellations.
<b>Scholarship funds</b>	There are many scholarships available, especially for innovations targeting societal problems such as proactive foods against chronic diseases. To get a tailored list, a recommendation is to make a scholarship search from stipendier.se.
<b>Almi innovation grant</b>	Almi is handling a grant for high technology innovations and a venture can be granted from 25 000 – 50 000 SEK.
<b>Loans</b>	It is not preferred in an early stage to apply for bank loans. A recommendation is to look at the local innovation system where regional loans with good terms are granted to ventures. Almi also has such a loan.

These financing sources could be a kick-start for a venture but there are numerous other organisations for granting soft money than are mentioned here.

Table 5: Financing sources in expansion phase

Financing sources	Explanation
<b>Venture capital investment rounds</b>	Venture capital financing often targets ventures in an expansion phase with already established sales. Since they are investing private money, they value low risk with the venture strongly. When receiving venture capital financing, a venture should expect to give away a large piece of the venture.
<b>Business angels</b>	Business angel investments are private investments from wealthy persons. These investments are personal and enables through networks and platforms such as the Connect network and angellist.co.
<b>Crowd funding</b>	Some known crowd funding platforms are kickstarter.com, indiegogo.com and fundedbyme.com.