

Sampo Biotechnologies



Business Plan

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Executive Summary

Business

Our vision is to give everyone the chance for affordable therapeutic protein treatment by hindering the unbearable increase of biopharmaceutical selling prices. Our product, VibXPresso together with our consultation services will be pioneering in applying a new protein expression system in the pharmaceutical industry.

VibXpresso - a *Vibrio natriegens* strain enables secretion of larger amounts of proteins in a shorter period of time, enables a reduction in the costs of therapeutic protein production compared to the currently available options. The organization will provide VibXPresso as a customized service for pharmaceutical companies. This includes development of the *vibrio natriegens* strain according to the customer's needs as well as consultation with developing the production process with *Vibrio natriegens*.

We will provide our services for a very minimal cost, guaranteeing its attractiveness to the pharmaceutical companies. By providing our services to the therapeutic protein producing pharmaceutical companies, we aim at having an impact on the high prices of biopharmaceuticals.

The organization is based in Espoo, Finland, and run by eleven young professionals with expertise in microbiology, molecular biosciences, chemistry, translational medicine, bio entrepreneurship, design, and bioinformatics. The organization utilized the effort of university students, life sciences professionals and industry partners to execute daily tasks.

Market

We estimate that the market size for our specific product is up to 71 billion USD and for our services up to 2,6 billion USD. The market is estimated to grow in the near future due to increased interest in developing new biopharmaceuticals and emerging technologies for recombinant protein production.

Vibrio natriegens has not been used for industrial protein production purposes, therefore there are no companies that provide this as a custom protein expression service. Synthetic Genomics that owns the commercial Vmax™

Express cell line is our closest competition. Other possible competitors are companies with protein expression system services or products.

Finances

The main annual revenue is received from the sales of our service. Other sources of income are private investors, government and grants, which count around one third of our total income annually. Investing activities are minimal and do not significantly affect our income. The main expenses come from the salaries paid to employees and purchase of equipment.

The target gross profit on sales is 60 % of sales revenues, which we have achieved. Our turnover from sales was 1 200 000 €. The estimated breakeven point is 600 000 €. Overall, the net profit (45 200 €) is a good margin for a nonprofit and will be used to support the administrative expenses and keep the company running.

Future

VibXpresso - Fast, Affordable, and High Quality therapeutic protein production platform helps pharmaceutical companies in inexpensive establishment of production platform for therapeutic proteins.

We aim to have our first partnerships during the first six months of business, and a pharmaceutical company as our customer within the first two years of business.

Our long term goal is to take over *E. coli* as the most used therapeutic protein production platform. As well as create an attractive internship program for university students and create a continuum in the company.

Our Key Performance Indicators (KPIs) can be divided into two categories: Partnership and Customer KPIs, and internal KPIs.

Partnership and Customer KPIs focus on

- 1) Creating value for stakeholders
- 2) Contribution to society and patients

Internal KPIs focus on

- 1) Quality of product
- 2) Economic and business performance
- 3) Commitment to employees

The Business

Business Structure

Company Name	Sampo Biotechnologies
Y-tunnus / Y-code	2767320-5
Founding Date	1.10.2019
Company Address	Kemistintie 1, Espoo, Finland
Contact Information	team@aaltohelsinki.com
CEO	Ilse Kaaja

Table 1. Business Structure.

Legal Structure

Sampo Biotechnologie will a qualified non-profit association's legal structure. This way we can provide our services for free or low prices. The legal structure also allows for possible tax deductibility.

Organisation Structure



Chart 1. Organization Structure



Ilse Kaaja, CEO, Board Member, has completed her bachelor's degree in Integrative Biology at the University of California Berkeley and is currently finishing her master's degree at the University of Helsinki in Translational Medicine. She has experience in working with various teams and is looking forward to bringing Sampo Biotechnologies to the next level to solve challenges in healthcare and medicine.



of life sciences.

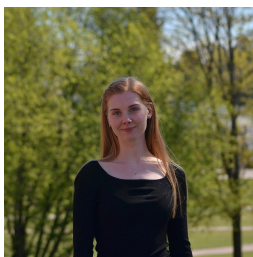
Noora Haapala, Director of Business Development, Vice President, has a Bachelor's Degree in Biomedicine and is currently studying a Master's programme in Translational Medicine at the University of Helsinki as well as bioentrepreneurship at Karolinska Institutet. She has experience in biomedical research and bioentrepreneurship. At Sampo Biotechnologies, she is working in her dream job improving healthcare and solving global problems in the field



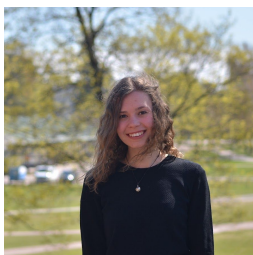
Miika Korpioja, Head of Multimedia operations, President, has a Bachelor's Degree in Biotechnology and Chemical Technology from Aalto University, and is currently studying in Master's programme in Biosystems and Biomaterials Engineering at Aalto University. He is dedicated in working with synthetic biology, health technologies and improve people's quality of life with treatments and diagnostic methods.



Camilla Selenius, Head of Outreach, Secretary, has a Bachelor's Degree in Biotechnology and Chemical Technology at Aalto University, and is currently studying towards a Master's Degree in Biosystems and Biomaterials Engineering. At Sampo Biotechnologies, she gets to work in her dream job improving human health.



Amanda Raitosalo, Head of Laboratory Operations, Board Member, is currently wrapping up her Master's studies in Microbiology at the University of Helsinki. She holds a Bachelor's degree in the same subject. She has experience in working with projects related to oil spill response and in medical microbiology.



Neja Sirc, Laboratory Operations and Communications Specialist, Board Member, has a Bachelor's degree in Chemistry from the University of Helsinki. Currently she is studying towards a Master's degree in Translational Medicine. She has experience in biomedical research.



Antti Pennanen, Head of Product Development, Board Member, is currently studying Molecular Biosciences (BSc) at the University of Helsinki, focusing on genetics and cell

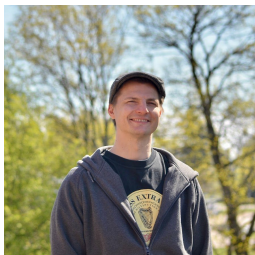
biology. Besides his interest in biology, his future plans include completing a degree in Medicine as a side project. Before starting with science, Antti served as a military pilot in the Finnish Air Force.



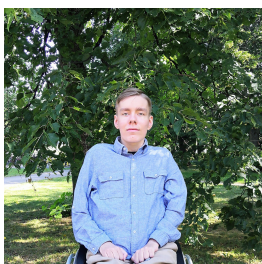
Arina Värä, Head of Modeling and Web Development, Board Member, is currently majoring in Energy and Environmental Technology and minoring in Bioinformation Technology, Bachelor programs, at Aalto University. She has previously studied physics at the Helsinki Open University. Her responsibilities lie in the laboratory, data modelling and statistical analysis, and project website development.



Ursula Mikkola, Director of Business Administration, Treasurer, is currently studying Entrepreneurship & Innovation Management at Aalto University School of Business and minoring in Molecular Biosciences at the University of Helsinki, as well as studying Medicine at the University of Oulu. She has experience in business administration and is looking forward to tackle the challenges in healthcare and medicine.



Tuomas Burakowski, Head of Design, Board Member, is currently finishing BA in art conservation, and also holds a degree in electronics. His expertise includes 3D-printers.



Antti Toivanen, Head of Research and Experimental Design, Board Member, is currently studying at the University of Helsinki's Molecular Biosciences bachelor's programme. He has studied some computer science on the side and is planning on focusing on bioinformatics in the future. He has expertise in genetic and experimental design.

Location

Sampo Biotechnologies is located in Espoo, Finland, in direct proximity of Aalto University, one of the leading Finnish universities in biotechnology and biomaterials research. Aalto University has recently introduced an open lab space, Biogarage, which can help us in the growth phase of our company. In the future, we are looking to options to acquire a laboratory space of our own that will be accredited and fitted to the requirements of our customers. In addition we are looking for expansion to other locations in the future.

Products and Services

Our mission is to guarantee equal treatment opportunities for patients whose disease can be treated with therapeutic proteins and advance the development of new therapeutic proteins. We aim at uniting students, professionals, politicians and the industry to work towards this common goal.

Our product, VibXPRESSO - a *Vibrio natriegens* strain that enables secretion of larger amounts of proteins in a shorter period of time, enables a reduction in the costs of therapeutic protein production compared to the currently available options. The resources saved in production will convert into a lower selling price of pharmaceuticals - and we provide our protein production platform VibXPRESSO as a customized service for pharmaceutical companies. This includes development of the *vibrio natriegens* strain according to the customer's needs as well as consultation with developing the production process with *Vibrio natriegens*.

We will provide our services for a very minimal cost, guaranteeing its attractiveness to the pharmaceutical companies. In return, the company purchasing the fast and effective VibXPRESSO platform, would agree on terms obliging them to adjusting the selling price of the therapeutic protein product in return for the saved resources in production.

Key Activities

On demand development of new VibXPRESSO strains for pharmaceutical companies looking into developing therapeutic proteins. Optimization of manufacturing process and consultation with establishing the production facilities.

These include the following activities:

Consultation

- Consulting in custom strain design
- Codon optimization of product
- Consulting in gene-construct design
- Consulting in set-up of production facilities
- Consulting related to culture types/conditions
- Consulting in downstream processing

Laboratory work

- Creating custom *natriegens* strains according to client's specifications
- Creating and optimizing expression vectors
- Expression- and secretion testing of codon optimized constructs
- Optimizing product secretion by determining optimal Tat/product ratio
- Optimizing product periplasmic release and harvest strategy
- Assaying product conformation and activity

Approval of science

We take advantage of the **twin-arginine translocation (Tat) pathway**, which is a protein export system responsible for translocating proteins up to 150 kDa in size through the inner lipid membrane in several bacteria, archaea and plants. *V. natriegens*' Tat complex consists of three subunit proteins, TatA, TatB, and TatC, which play a role in the translocation event. Alongside another secretion pathway (Sec), Tat is a popular engineering target for heterologous protein secretion. Proteins are directed through the Tat system with a special **signal peptide** containing a double arginine (RR) motif. As part of our project, we compare six signal sequences we have identified in *Vibrio natriegens* and their efficiency in protein translocation. Translocation of human growth hormone via Tat pathway has previously been tested in *E.coli*, in a strain called Tat Express (Browning *et al.*).

Methods of action and scalability - VibXPRESSO strain

We are developing a modified *Vibrio natriegens* strain with an inducible Tat-pathway system. This will allow rapid production of different recombinant proteins with increased secretion titers. We utilize tunable promoters to achieve dose-dependent induction. This allows optimization of the ratio of product to transporter, improving the yield by decreasing inclusion body formation.

The Tat system exports fully folded proteins, and has the potential to export complex molecules while retaining their activity. The system also has a "quality

control” mechanism, which rejects incorrectly folded proteins. Protein purification from the periplasm is more efficient, thus lowering downstream processing costs. We’re also developing a scalable protocol for **increasing the leakiness of the outer membrane**, which would enable the protein diffusion into the growth medium. Selected periplasmic proteases are deleted to reduce the proteolysis of secreted proteins, and thus improve the yield of intact, active product. We’re also deleting an extracellular nuclease, DNS, to improve transformation efficiency.

The laboratory team will work on these activities to develop and deliver modified *Vibrio natriegens* strains for therapeutic protein production based on each customers’ needs. Meanwhile the consultation team will be working on customized design of protein production processes and business development team will take care of administrative tasks.

Safety

We take safety seriously and are committed to safe practices throughout our procedures in and outside of the laboratory to ensure the safety of the people and the faculties. Biopharmaceutical compounds are produced in an engineered organism that naturally does not produce the biopharmaceutical compound. This technology enables large quantity production of such pharmaceuticals that have been previously unavailable or difficult to produce. Recombinant proteins are a class of biopharmaceuticals, and include many commonly used medications such as insulin, human growth hormone, and some anticoagulant factors. Well designed and tested biopharmaceuticals are a safer option for medications manufactured by many older methods.

All GMO containing waste is handled properly with cautiousness during the laboratory work of our project. In the media and among the general public genetically modified organisms are still seen sometimes as a threat rather than an opportunity, and we want to do our best in dispelling these preconceptions. The best way to demonstrate this is by working responsibly and transparently in the lab.

Our work focuses on two different safety level 1 organisms, bacterium *Vibrio natriegens*, and bacterium *Escherichia coli*. They both are non-pathogenic, safe to work with and do not possess harm to human beings, although *V. natriegens* is naturally harmful to a handful of marine crustaceans. We used the following strains: *V.natriegens*; ATCC 14048 and Vmax, *E. coli*; DH5alpha and BL21. The *E. coli* strains are laboratory strains with no natural environment. No humans or animals were tested nor harmed in our laboratory experiments.

Intellectual Properties

As our mission is to provide every patient a chance for affordable therapeutic protein treatment by hindering the unbearable increase of biopharmaceutical selling prices, we recognize the conflict between patenting products and guaranteeing affordable medication. Thus, we have decided to forego the option to patent VibXPresso. Instead of patenting VibXPresso, our strategy in entering the market is to exploit First to market -advantage. This will allow us to speed up our product launch. We believe that this strategy will let us develop our product, distribution channels, and branding to gain market advantage until the launch of our product.

Our goal is to saturate the market, establish brand reputation while making our solution open source. We acknowledge the risks of freely available product information - however as our business model is a service business in the long term, we believe our solution will remain attractive to the customers. With this approach we want to take steps towards transparency and affordable medication.

To support the brand development we are trademarking our product VibXPresso. The cost for EU trademark is 850 € and for U.S. trademark 400 USD. Patenting costs approximately 10 000 - 17 000 € per region (EU, U.S.).

Business model

The organization will not make a revenue. However, costs are covered by money streams coming from different sources.

Key partners:

These are actors, such as universities, cities, sponsors, foundations and/or the government. Our key partners are our most important cash in flow. Our partners have agreed on supporting our organization with an X amount per year. See financial plan for more details.

These partners benefit from our service is different ways. I.e. the government would save in healthcare costs, universities could utilize our platforms in research or our activities could be integrated to their education. Foundations, who want to push down the prices of therapeutic proteins.

The paying customer:

The paying customer would be those who pay for our services. In this case, the companies that use VibXpresso in their protein production process. The companies pay a minimal fee from the product and the service that they get.

Other funds:

Applying for funding from associations etc. will be a part of the administrative members tasks.

Unique selling proposition (USP)**USP For the pharmaceutical industry:**

The demand for developing new biopharmaceuticals is increasing. Many biopharmaceuticals are therapeutic proteins. The pharmaceutical industry is facing high demand for both developing new biopharmaceutical compounds and producing them. One third of all therapeutic proteins are produced in the bacteria *E.coli*. However, more different production systems are needed to meet the growing variety of therapeutic protein products.

We are introducing a completely new production platform for therapeutic proteins. Our *V.natriegens* based product, will allow therapeutic protein production exponentially faster than in *E.coli*. The increased yield and titer as well as time saved in the process of manufacturing will reduce the production costs of therapeutic proteins significantly.

We also provide valuable services in addition to our product. Our services include consultation about using *V.natriegens* in therapeutic protein production and establishment of the production processes and workflow. This service will be unique, since *V.natriegens* has never been used for industrial production before and we have pioneering experience about the matter.

Due to our non-profit legal structure, our services and products will be inexpensive for our customers.

Our service will have a beneficial effect on the development process of therapeutic proteins from a pharmaceutical company's perspective:

1. Fast & cost-effective production of protein for early R&D purposes
2. Outsourcing establishment the production facilities and workflows will save the company time and money

3. Reduction of long term mass production costs
4. Possible market advantage when the selling price of a product can be reduced

USP for the buyer of therapeutic protein products

The prices of therapeutic proteins are high. In the United States, hundreds of millions of people cannot afford their therapeutic protein treatment. Studies show that increasing competition in biopharmaceutical manufacturing could lead to large price reductions. Therefore a reduction in the selling prices of therapeutic protein can save lives. The people depending on therapeutic proteins will gain better access to biological medication. Everyone will get an equal opportunity to get the treatment they depend on. This will result in significant increase in quality of life among the large amount of people struggling with paying for their medication.

In countries where public healthcare systems covers for most of the costs of therapeutic protein, the price reduction of healthcare costs would benefit the government. The cost reduction would allow allocation of the money saved in therapeutic protein treatment costs to other areas in public healthcare.

Minimum Viable Product (MVP)

Our minimal viable product is a *V.natrieigens* cell line with increased protein expression features. During the course of the iGEM competition, we have taken the first steps required for the minimum viable product. We have produced **human growth hormone (hGH)** in *Vibrio natrieigens* and translocated it to the periplasm via Tat pathway.

For the MVP, we will prove that overexpression of the system components will lead to a significant increase in the protein yield and that this will affect the costs of the recombinant protein production in industrial scale.

Our minimum viable product requires:

- **Proof of concept:** Successful expression of hGH with *V.natrieigens*.
- **Proof for speed:** A significantly faster expression of proteins compared to production in *E.coli*.
- **Proof for saved costs:** A reduction in long term costs for therapeutic protein production
- **Proof for market:** We need to know that companies are willing to utilize our service.
- **Team:** Our motivated, committed and qualified team. The team needs to be knowledgeable enough to perform the work.

SWOT analysis



Chart 2. SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis.

Risk Assessment

Table 1. Risk assessment analysis.

External factors	The risk and the likelihood (1-10)	How to avoid the risk?
Economic factors	Recession, 10	You can't avoid a recession. Mitigate effects by diversifying sources of income. Take risk into consideration in the organization's financials.
Political factors	Changes in funding from state, 8	Changes are inevitable as governments and budgets change. The severity of these changes is uncertain. The company can invest in public outreach to play a small part in electing science-supporting governments that fund us. The company can also actively lobby politicians.
Political factors	Regulatory changes, 3	Public outreach and lobbying.
Social factors	Disinformation about our product, 5	Mitigate risk by external communications, actively moderating the company's social media comments, engaging in scientific education and outreach, and by hiring legal services if needed.
Technological factors	Cell-free protein synthesis technologies make VibXpresso obsolete, 2	This is completely out of our control. However, In the short term, this is unlikely.
Development of the industry	New organism steals <i>V. natriegens</i> ' spotlight, 4	Active marketing of <i>V. natriegens</i> as a platform by the company. Largely out of our control if the new organism's characteristics prove exceptional.
The market & customers	New non-peptide drugs decrease demand of therapeutic proteins, 5	Mitigate risk by diversifying the group of proteins produced with VibXpresso
Competition	Competing startups, 8	Aim for rapid growth to ensure a large market share to make it

		difficult for new startups to compete against us.
Competition	Existing large protein expression companies develop <i>V.natriegens</i> platforms, 7	Same as above. Make sure that it is possible to provide our service for a lower cost than the competitors.
Internal factors:	The risk and the likeliness (1-10)	How to avoid the risk?
Organization & human resources	Interpersonal conflict among employees, 5	Set clear policy on workplace behaviour and harassment. Foster a culture of openness and conflict resolution.
Organization & human resources	Data leaks/breaches, 5	Set a strict security policy and uphold it. Give employees sufficient infosec training. Ensure company infosec technology and services are up-to-date.
Production	Contamination of VibXPresso stocks, 9	Uphold strict hygiene/aseptic policy in relevant places. Train employees in aseptic techniques. Keep multiple backups on- and offsite.
Production	Powercuts, flooding, fires, disasters, 10	Keep multiple backups of data and bacteria on- and offsite. Keep important equipment protected. Maintain alarms, extinguishers, sprinklers and drains. Keep a sufficient reserve of dry ice and liquid nitrogen.
Finances	Unexpected drops in funding, 7	Keep a sufficient reserve of liquid assets to maintain operations while restructuring finances.

Market Analysis

Market Segmentation

Market 1: Market for biopharmaceuticals

One of the most important applications of recombinant proteins is their use in the development of novel therapies for severe chronic diseases. Recombinant proteins have immense potential in example in cancer therapy and autoimmune disease research and development. Recombinant proteins used for medical purposes are called therapeutic proteins. Therapeutic proteins, together with other therapeutics that are developed or derived with the help of living organism, belong to a group of drugs that are called biopharmaceuticals.

There is a clear trend in the pharmaceutical industry towards increasing amount of research and development of new biopharmaceutical drugs. It is estimated that in 10 years, 50 % of all new medicine are biopharmaceuticals. This is also shown in the expected growth of the market value. According to different sources, the global biopharmaceuticals market is estimated to account for something in between 388 billion - 526 billion USD by year 2025. During year 2017 and 2018, the global market is approximately 186 billion - 237 billion USD.

From the different biopharmaceutical compounds, monoclonal antibodies seem to have the largest market size. According to some resources, posting 115 billion USD in 2018. Also the recombinant enzymes are expected to show rapid growth during the next couple of years.

As in recombinant proteins, North America dominates the market for biopharmaceuticals. The continent is expected to hold the position for the next few years. Asia-Pacific is currently the fastest growing market for biopharmaceuticals. This is due to the increase in the prevalence of diseases, such as diabetes and cancer, and because their regulatory framework which is well suitable for the approval of new biopharmaceuticals.

The first therapeutic protein that we are expressing with VibXpresso is Human Growth Hormone (hGH). HGH is a therapeutic protein used for treating growth deficiencies. Approximately three in every 10 000 people have growth deficiencies. This would mean that roughly 2 million people suffer from growth deficiencies in the world. In 2017, the global market of human growth hormone was valued at USD 3,978.68 million USD.

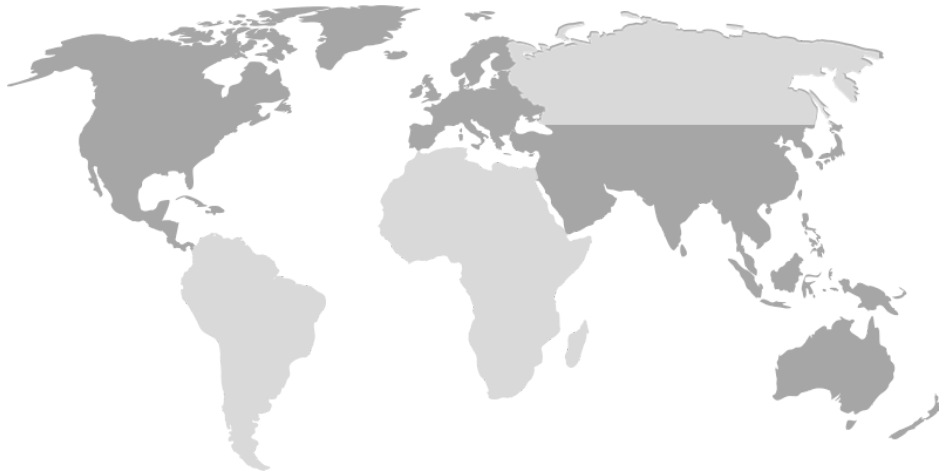


Figure 1. Markets for recombinant proteins and biopharmaceuticals are focused in North America, Europe and the Asia Pacific.

Market 2: Market for bacteria as recombinant protein expression system

Recombinant proteins are produced in different types of expression systems. Different systems are more suitable to other proteins depending for example on the protein's features. The most commonly used expression systems are mammalian cells, bacteria cells, yeast and insect cells.

The price of protein synthesis services ranges from 3 USD to 160 USD per one amino acid. The price depends on the desired purity of the protein product. The price of recombinant protein production services varies also based on the production expression systems, species and the family of the protein.

Advantages of bacterial systems are their low cost, high productivity and rapidity. Fast and cost-efficient expression systems are favoured both in commercial protein production and research. Mammalian cells, on the other hand, are often advantageous compared to bacteria due to their ability to express proteins with folding and generate the same post-translational modifications than in the native endogenous protein.

Table 2. Comparison of protein expression systems.

	<i>E.coli</i>	Yeast	Mammalian Cells	Insect Cells
Applications	Prokaryotic protein, simple eukaryotic protein	Intracellular /Secreted Protein, Disulfide-bonded protein, Glycosylated protein.	Complex eukaryotic protein	Membrane protein, Large-size protein, Viral vaccines, signaling proteins, cytokines, kinases.
Use for biopharmaceutical production	30%	20%	50%	-
Cell growth	fast (30 min)	average (90 min)	slow (24 h)	slow (18 - 24h)
Culture Conditions	simple	simple	complex	complex
Expression level	high	average	low	average
Extracellular expression	secretion to periplasm	secretion to medium	secretion to medium	secretion to medium
Protein folding	refolding usually required	refolding may be required	proper folding	proper folding
Other post-translational modifications	usually no	usually yes	yes	yes

50% of biopharmaceutical proteins are produced in mammalian cells or hybridomas, 30% in *E.coli* and 20% in yeasts. As the market for biopharmaceuticals is 237 billion USD, the share for biopharmaceuticals produced in *E.coli* could be estimated to be around 71 billion USD. If we expect that the same biopharmaceuticals that are produced in *E.coli* can be produced in VibXPRESSO, 71 billion USD would be the current market size for our product.

Market 3: Market for recombinant protein production service

According to the report published by Coherent Market Insights, the global custom recombinant protein production services market was valued at 2.6 billion USD in 2017. We estimate that this is the current market size for our protein expression services (excluding the market for the product).

North America holds a dominant position in the recombinant protein production service market, contributing to nearly half of the global market value. In year 2017 the market value of North America alone was estimated to be 1.15 billion USD. Europe is placed second and Asian Pacific third in the world.

The market size is estimated to grow in the near future. The market is expected to have a compound annual growth rate (CAGR) of 11.2% over the period from 2018 to 2026. According to estimations, the market will surpass USD 6.7 billion by year 2026. Reasons for the growth are increasing demand for recombinant proteins, increased funding in the field of life sciences in the USA and development of technologies used in recombinant protein production.

Customers

VibXPresso is designed for therapeutic protein production. Therefore we are targeting the biopharmaceutical industry. Our primary focus is on pharmaceutical companies operating in Europe, Northern America or Asia Pacific, since they are the largest markets for recombinant protein production.

Customer group 1:

Large pharmaceutical companies. These companies' operations include the whole traditional drug development value chain from research & drug discovery to market entry. We focus on companies, that

- have their core focus in developing new therapeutic proteins
- have in house production of their products
- are struggling with the competition and pressure for decreasing selling price

Customer group 2:

Smaller pharmaceutical companies. Meaning companies that don't operate in the whole drug

development value chain, but focus on a specific part of it. We focus on companies, that

- are looking into developing a new therapeutic protein product
- intend to sell their product further before moving to the clinical trials
- wish to speed up the process of developing the active pharmaceutical compound

Customer group 3:

Biopharmaceutical producing companies that are looking for developing orally administered biopharmaceuticals.

Stakeholder Analysis

Key stakeholders to our organization are mapped out in the table below. As our product is a production platform for therapeutic proteins, our organization will first and foremost affect the pharmaceutical industry (and in the future also other companies in the biomanufacturing industry). These stakeholders are also the ones with the most power in our business, since they are our customers.

Patients, physicians and researchers are categorized in the high interest & low power category. Physicians are interested in finding better solutions for treating patients that require therapeutic protein treatment, while not always being able to offer it due to lack of existing treatment and high costs of medication. Researchers in the other benefit from better tools for recombinant protein production. Therefore the work we have put into developing VibXpresso also benefits them.

The most significant effect that our solution can have to the society, is the reduction of selling prices of therapeutic proteins. This would benefit most significantly the millions of patients, who can't afford their therapeutic protein treatment. This would mainly be the case in countries where the government does not cover the healthcare costs. However in countries like Finland, individuals' healthcare costs are almost entirely paid by the government. This means, that in these regions the price reduction of healthcare costs would benefit the government. The cost reduction would allow allocation of the money saved in

therapeutic protein treatment costs to other areas in public healthcare.

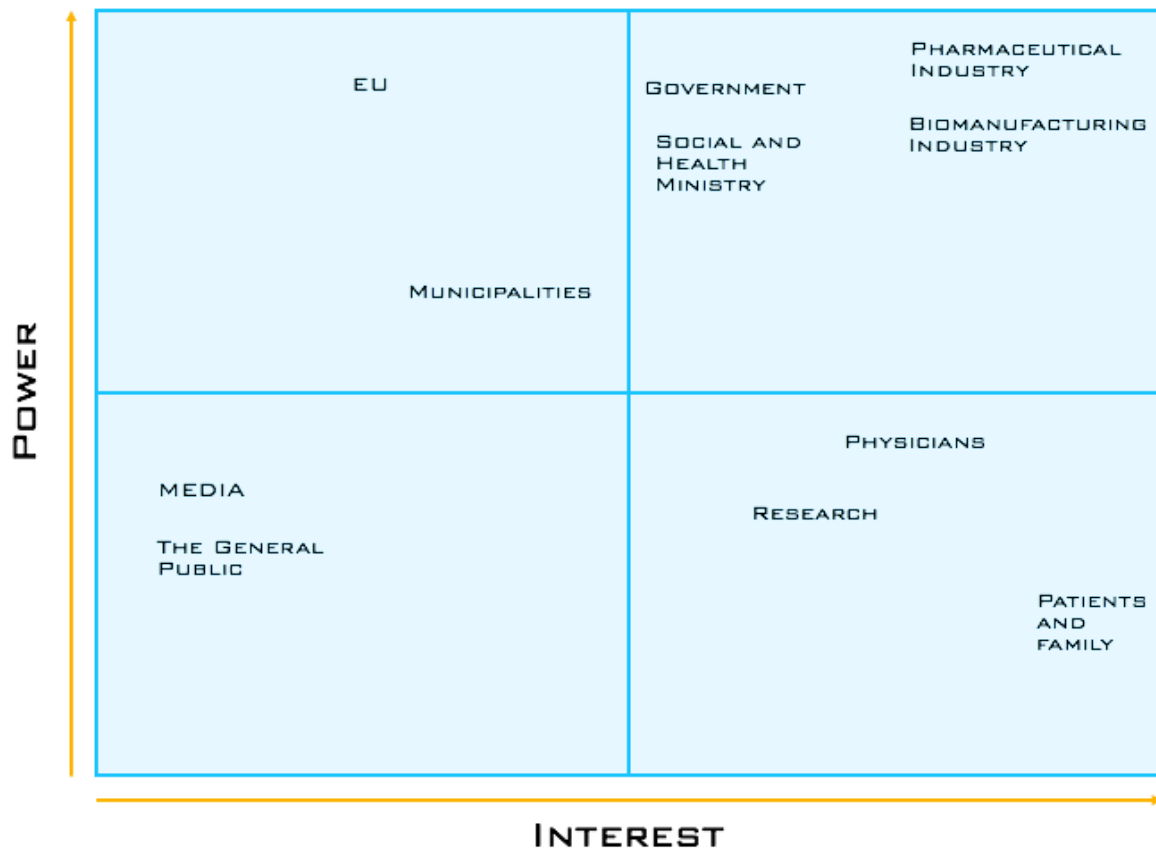


Chart 2. Stakeholder analysis.

Competitors

Vibrio natriegens has not been used for industrial protein production purposes, therefore there are no companies that provide this as a custom protein expression service. However, Synthetic Genomics can be seen as direct competition to our organization. The company owns the commercial Vmax™ Express cell line – a *V.natriegens* cell line optimized for high levels of recombinant protein expression.

In addition, there are several large and small companies that provide customized recombinant protein expression systems. These companies often provide a variety of options for protein expression in organisms like *E.coli*, yeast and mammalian cells. These are indirect competitors to our organization.

Table 3. Competitor analysis.

Name	Year founded	Product Description	Strength's	Weaknesses
Synthetic Genomics, SGI-DNA (Vmax™ Express)	2005	Vmax™ Express is a fast-growing <i>V.natrieogens</i> strain designed and optimized for high-level recombinant protein expression.	Skilled team & experienced company. provides a wide range of products.	Product aimed for research
Biomatik	2002	Custom protein expression system development in bacteria, yeast, mammalian cells and insect.		Not using <i>V.natrieogens</i>
Promab Bio-technologies	2001	Protein expression services utilizing e. coli, baculovirus, mammalian, yeast, gene synthesis and peptide synthesis.	Years of experience. Skilled team.	Not using <i>V.natrieogens</i>
Geneuniversal		Bacterial Recombinant Protein Expression Service Package consists of codon optimization service, followed by gene synthesis and subcloning, all the way through protein expression and purification.	customized service, fast delivery time, cost-efficient, variety of protein production platforms	Not using <i>V.natrieogens</i>
Agilent Technologies	1999	Provides competent cells, vectors, antibodies, antibiotics, transfection reagents, and specialty kits for protein expression and purification applications	One of the world's largest biotech companies.	Not using <i>V.natrieogens</i> . Protein expression is not company's main focus area.
Promega Corporation	1978	Promega provides products for the expression of recombinant proteins in cell-based E.coli	One of the world's largest biotech companies. provides cell free	Not using <i>V.natrieogens</i> . Protein expression is not company's

		systems and a variety of cell-free systems.	protein production technologies.	main focus area.
Research Corporation Technologies	1987	Provides yeast based protein production technologies		Main focus of the company is to provide funding in life science technologies. Not using <i>V.natriegens</i> .

Table 4. Competitive Value Matrix

Competitive Value Matrix									
		VibXPRESSO		Synthetic Genomics		Biomatik		Agilent Technologies	
	Weighting	Score	Weighted	Score	Weighted	Score	Weighted	Score	Weighted
Marketing	0,18	2	0,35	3	0,525	4	0,7	4	0,7
Brand Reputation	0,18	2	0,35	3	0,525	3	0,525	4	0,7
Product Quality	0,20	4	0,8	3	0,6	3	0,6	3	0,6
Customer Service & Loyalty	0,15	4	0,6	2	0,3	3	0,45	2	0,3
Knowhow in production processes	0,2	4	0,8	1	0,2	3	0,6	2	0,4
Reach	0,10	2	0,2	4	0,4	3	0,3	4	0,4
Total	1,00		3,10		2,55		3,18		3,10

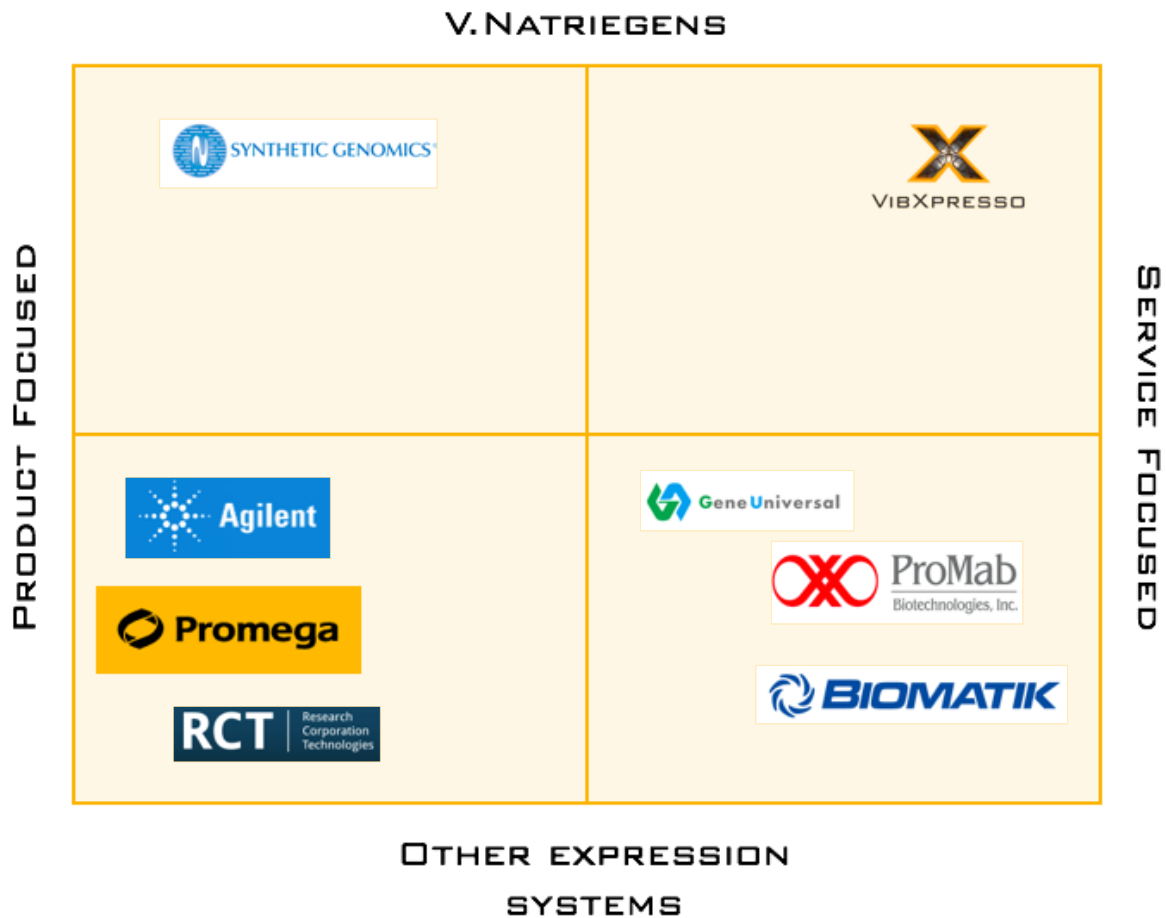


Chart 3. Competitor evaluation.

Supply Chain

Our product's path from raw materials to the customer can be described in six steps.

- 1) **Sales & Marketing.** The first step is to generate customers through marketing and sales activities. This is an important step, because our business is based on rapid growth and acquiring a significant market share in a short period of time. This requires aggressive marketing and sales.
- 2) **Customer Needs Evaluation.** To us every customer is different. And every customer is seen as a new project. Before starting the development process we conduct a prestudy. This is done to evaluate the case's goals and the customer's needs. This includes research about what type of proteins is the customer looking for producing and how can our product fit into their needs as well as what type of consultation they might benefit from.

- 3) **Strain development.** This step will include the actual research and laboratory work of creating a *V.natriegens* strain to fit the customer's need for production of specific protein.
- 4) **Production Process Optimization.** Our team has competitive know-how about utilizing *v.natriegens* in industrial protein expression. We provide this knowledge as a consultation service for the customer to help them develop, optimize and set up their production process.
- 5) **Distribution.** Once the production plants and VibXPRESSO are ready to be utilized in production, the protein expression system is distributed to the customer.
- 6) **Customer.** The last steps includes VibXPRESSO being used in the production of the therapeutic protein production in the biopharmaceutical company.

We will utilize partnerships with pharmaceutical companies, laboratory equipment companies and government funded institutions like Universities to make the supply chain steps achievable for our non-profit organization.

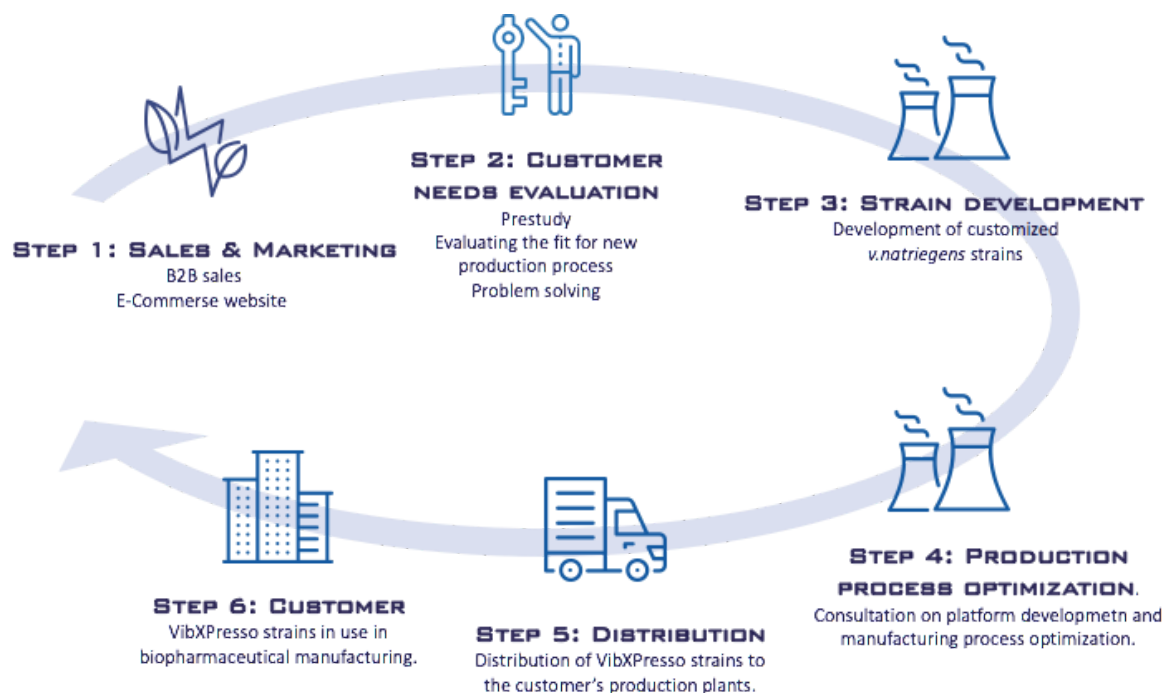


Chart 4. Supply chain.

Technology Readiness Plan

Currently, Sampo Technologies is in the Technology Readiness Level 4 with the aim to be at level 7 by end of Q2 of 2020, and level 9 by the end of 2021.

Table 5. Technology Readiness Plan with current and future goals in technology readiness levels.

Technology Readiness Level	Definition
TRL 1	Basic Research: Initial scientific research has been conducted on <i>Vibrio natriegens</i> and Tat pathway.
TRL 2	Technology formulation: Practical applications of Tat pathway and its signal sequences in therapeutic protein production have been identified.
TRL 3	Needs validation: Applied research advances and early stage development with VibXPresso as a protein production platform, early mathematical model created.
TRL 4 Current level	Small scale prototype: Design, development and testing of VibXPresso at laboratory-scale with results suggesting MVP is possible.
TRL 5	Large scale prototype: Testing protein production with VibXPresso in a large-scale bioreactor
TRL 6	Prototype System Verified: Validating the technical and commercial viability of VibXPresso-based protein production
TRL 7 Goal by Q2 of 2020	Integrated System Demonstrated: VibXPresso in small scale production of therapeutic proteins. Process to gain regulatory approval started.
TRL 8	System Incorporated in Commercial Design: VibXPresso strain qualified through test and demonstration of therapeutic protein production in a whole-scale industrial setting. Full regulatory approval gained.

TRL 9 Goal by the end of 2021	Full commercial application: VibXPresso strain proven through successful operations in therapeutic protein manufacturing, and ready for full commercial deployment.
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Value Chain

The value chain graph below indicates how Sampo Biotechnologies plans to create value for our stakeholders as well as the society. We have included references on how we are going to take the United Nations' Sustainable Development Goals into consideration.



Chart 5. Value Chain

The Finances

Financial Plan

Cash flow statement:

Cash flows from operating activities	€
<i>Cash received from service recipients</i>	900 000
<i>Cash received from contributors, government and grants</i>	200 000
<i>Cash received from contributors, private investors</i>	200 000
<i>Sale of equipment</i>	100 000
<i>Miscellaneous receipts</i>	10 000
<i>Cash paid to employees</i>	(432 000)
<i>Cash paid to suppliers</i>	(200 000)
<i>Purchase of equipment</i>	(400 000)
Net cash used by operating activities	378 000
Cash flows from investing activities	
<i>Interest and dividend received</i>	500
<i>Sale of investments</i>	4 000
<i>Purchase of investments</i>	0
Net cash provided by investment activities	4 500
Cash flows from financing activities	
<i>Payments of annuity obligations</i>	(100 000)
<i>Payments on debt</i>	(80 000)
Net cash used by financing activities	(180 000)
Net decrease (increase) in cash and cash equivalents	202 500
Cash and cash equivalent at the beginning of the year	(104 000)
Cash and cash equivalent at the end of the year	98 500

Profit and loss:

INCOME (€)	Credit	Debit
Sales revenues	1 200 000	
Cost of goods sold		450 000
Gross profit on sales	750 000	
EXPENSES		
Variable costs		
Lab equipment		100 000
Other expenses		80 000
Fixed costs		
Rent		75 000
Salaries		432 000

Total operating expenses		687 000
Net income (g. profit – expenses)	63 000	
Interest income	500	
Interest expense		300
Net profit (loss) before taxes	63 200	
Taxes		18 000
NET PROFIT (LOSS) AFTER TAXES	45 200	

6-month budget:

Monthly income	January	February	March	April	May	June
Annual governmental support	150 000€	-	-	-	-	-
Annual grants	50 000 €				-	-
Private investors	20 000 €	75 000€	-	100 000€	-	5000€
Sold services	75 000 €	100 000 €	50 000 €	125 000 €	75 000 €	25 000 €
TOTAL	295 000 €	175 000 €	50 000 €	225 00 €	75 000 €	30 000 €

Monthly expense	January	February	March	April	May	June
Rent	6 250€	6 250€	6 250€	6 250€	6 250€	6 250€
Salaries	90 000€	90 000€	90 000€	90 000€	90 000€	90 000€
Lab equipment	10 000€	-	8 000€	-	8 000€	-
Miscellaneous	1200€	700€	1050€	2500€	800€	1200€
TOTAL	107 450€	96 950€	105 300€	98 750€	105 050€	97 450€
Inc. - Exp./mth	187 550 €	78 050 €	(55 300 €)	126 250 €	(30 050€)	(67 450 €)

The variance between monthly profit or loss is due to the grants that are paid annually in the beginning of the year.

18-month budget:

3-month income	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun
Government	150 000€	-	-	-	150 000€	-
Grants	50 000€	-	-	-	-	100 000€
Private investors	100 000€	105 000€	-	-	-	50 000€
Sold services	225 000€	225 000€	300 000€	445 000€	250 000€	100 000€
TOTAL	525 000€	330 000€	300 000€	445 000€	400 000€	250 000€

3-month expense	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun
Rent	18 750€	18 750€	18 750€	18 750€	18 750€	18 750€
Salaries	108 000€	108 000€	108 000€	108 000€	108 000€	108 000€
Lab equipment	25 000€	50 000€	10 000€	15 000€	40 000€	10 000€
Other	132 500€	110 000€	127 000€	160 500€	200 000€	150 000€
TOTAL	284 250€	286 750€	263 750€	302 250€	366 750€	286 750€
Inc.-Exp./3mths	240 750€	43 250€	36 250€	142 750€	33 250€	(36 750€)

5-year budget:

Annual income	Year 1	Year 2	Year 3	Year 4	Year 5
Government	150 000€	150 000€	150 000€	150 000€	150 000€
Grants	50 000€	130 000€	180 000€	200 000€	250 000€
Private investors	200 000€	150 000€	300 000€	600 000€	1 000 000€
Sold services	1 200 000€	1 100 000€	1 300 000€	1 400 000€	1 500 000€
TOTAL	1 600 000€	1 530 000€	1 930 000€	2 350 000€	2 900 000€

Annual expense	Year 1	Year 2	Year 3	Year 4	Year 5
Rent	75 000€	75 000€	75 000€	125 000€	125 000€
Salaries	432 000€	432 000€	720 000€	1 080 000€	1 080 000€
Lab equipment	100 000€	120 000€	300 000€	400 000€	400 000€

Other	530 000€	600 000€	650 000€	700 000€	800 000€
TOTAL	1 137 000€	1 227 000€	1 745 000€	2 305 000€	2 405 000€
Inc. - Exp. /yr	463 000 €	303 000€	185 000€	45 000€	495 000€

Year 3, 4 & 5: Hiring more people. Private investors are becoming more interested.

Balance sheet:

ASSETS		LIABILITIES & EQUITY	
Current assets		Current liabilities	
Cash	98 500€	Accounts payable	230 000€
Accounts receivable	130 000€	Salaries	36 000€
Laboratory equipment	300 000€		
Other	200 000€	Long-term liabilities	
		Loans	450 000€
		Owner's equity	12 500€
TOTAL ASSETS	728 500€	TOTAL LIABILITIES & EQUITY	728 500€

Financial ratios:

The **gross margin ratio** compares the gross profit of a company to its net sales to show how much profit a company makes after paying off its cost of goods sold:

Gross margin ratio = Gross profit / Net sales.

$$750\,000 / 1\,200\,000 = \mathbf{0,625}$$

The **return on assets ratio** measures how efficiently a company is using its assets to generate profit:

Return on assets ratio = Net income / Total assets

$$45\,200 / 728\,500 = \mathbf{0,062}$$

(Companies that require large initial investments, such as Sampo Biotechnologies, generally have lower return on assets. Additionally, the aim is to keep the company running - not profit itself.)

The **cash ratio** measures a company's ability to pay off short-term liabilities with cash and cash equivalents:

Cash ratio = Cash and cash equivalents / Current liabilities

$$98\,500 / 266\,000 = \mathbf{0,37}$$

(The low cash ratio indicates that our company is very dependent on the governmental grants that it receives at the beginning of each year)

The Future

Expansion

Market penetration

We are penetrating the market of recombinant protein expression system providers. We will take customers from our competitors with aggressive marketing and a competitive product and services.

Market development

The domestic market in Finland is small, therefore we are aiming at expanding to other geographical locations. Starting with Germany and other big industrial European countries and then moving to North America. Our ultimate goal is to replace E. coli as a therapeutic protein production platform. This would account for about 30% of the current global therapeutic protein market^[10].

Product development

Our research and product development teams will constantly be developing our products and services to fit the changing market. This will mean the creation of general VibXPresso-strains for the whole market, as well as custom strains for individual customers.

Diversification:

Once Sampo Biotechnologies has established a solid workflow and customer stream, we can expand our product supply to provide a variety of expression systems. Meaning for example mammalian cell based systems or cell-free systems. This will allow the production of a larger variety of biopharmaceuticals to expand our market share and drive down the price of more therapeutic proteins.

On top of this, we are aiming at expanding our business to other industries. We will target industries that utilize recombinant protein production methods. This includes for example recombinant proteins produced to serve in water purification and biofuel production, or industrial enzyme production. We are committed to continue the research on how VibXPresso could be utilized in these industries to fight other global challenges such as climate change and pollution.

Human resources:

Sampo Biotechnologies aims to create a competitive internship program to attract a vast amount of university students: this way we can ensure stability and continuity at the same time by maintaining enough human resources while being a non-profit organization. We carry the responsibility of providing said interns extensive training and work experience, boosting their careers.

Vision Statement

Our vision is to give everyone the chance for affordable therapeutic protein treatment by hindering the unbearable increase of biopharmaceutical selling prices. We aim at uniting students, professionals, politicians and the industry to work towards this common goal.

Business Goals

We have divided our business goals into short term and long term goals. Our goals can be summarized with SMART (Specific, Measurable, Achievable, Relevant, and Time-framed) concept. Short term goals are summarized in the following figure called Next Steps.

VibXPRESSO Next Steps



Chart 6. VibXPresso short term SMART goals.

Long Term Goals:

- Have some of the biggest biopharmaceutical producing companies as our customers within a 5 years time-frame.
- Create an attractive internship program for university students to guarantee workforce during the first two years of business, but also to create a continuum in the company
- Achieving and keeping a leading market share of *V.natriegens* based protein expression systems within 10 years of starting the business. This will be achieved with active marketing, partnerships in both private and public sectors, and community involvement. Starting in Nordic countries and Europe and next moving to the United States.
- Taking over *E. coli* as the most used therapeutic protein production platform

Milestones

Development of a *V.natreigens* platform for therapeutic protein production, that would save the biopharmaceutical company 20% of current production costs compared to the existing platforms.

We aim to have our first partnerships during the first six months of business, and a pharmaceutical company as our customer within the first two years of business.

We utilize Key Performance Indicators to evaluate our progress. Performance is evaluated through KPIs in every quarter.



KEY PERFORMANCE INDICATORS

VibXPresso

Partnership and Customer KPIs

1) Creating value for stakeholders

- R&D expense per new drug developed
- Number of clinical trials
- Number of new drugs developed
- Manufacturing expense per new drug developed



2) Contribution to society and patients

- Number of patients receiving treatment with drugs produced with VibXPresso
- Contributions to healthcare institutions
- Contributions to patient organisations
- Emissions and waste produced

Chart 7. Customer and Partnership Key Performance Indicators.



Chart 8. Internal Key Performance Indicators.

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This guide has been created by the UNSW iGEM team to allow scientists to turn their ideas into a commercial product. This business scaffold is constructed based on the necessary requirements within a global context.

In Conjunction with:



Approved By: