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Master´s Thesis

From Lab to Market:
A Study on Commercializing A Novel Genomic Solution for Mastitis Diagnosis and Antimicrobial Resistance Control.

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Abbreviations

Acronym	Abbreviation
AMR	Antimicrobial Resistance
WGS	Whole Genome Sequencing
MALDI-TOF	Matrix-assisted laser desorption ionization–time-of-flight
KIA	Key Informant Assessment
TAM	Total Addressable Market
SWOT	Strength, Weakness, Opportunity, Threat
ROI	Return on Investment
CAGR	Compound Annual Growth Rate
NDHRS	Norwegian Dairy Herd Recording System
SCC	Somatic Cell Count
DCC	Differential Cell Count
IMI	Intra-mammary Infection

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Abstract

Bovine mastitis is a major issue in dairy herds because it has a considerable financial impact. Therefore, it is important to quickly and accurately diagnose it in order to prevent financial loss, safeguard milk quality, preserve herd health, stop the misuse of antibiotics and the development of antimicrobial resistance. This thesis investigates the commercial viability of a method that uses whole genome sequencing to rapidly and accurately diagnose bovine mastitis and analyze antibiotic resistance. With superior sensitivity and specificity compared to conventional approaches, this technique may detect infections and antimicrobial resistance (AMR) genes within a shorter timeframe. The market research identifies Norwegian dairy cooperatives as the main focus, with SWOT and PESTEL assessments emphasizing favorable characteristics and potential for collaboration despite competition. The business strategy provides a range of subscription programs that cater to Norway's technologically advanced and environmentally conscious market. The research also sheds light upon future developments that can be considered to make the technology more user-friendly and profitable.

1. Introduction

1.1 Milk market insight

Milk is widely recognized as a fundamental dietary component for people across the globe. It has 32.45% market share amongst all bovine dietary products, making it the largest segment in the market (*Dairy Market Size & Share Analysis - Industry Research Report - Growth Trends*, 2023). Dairy-based food products are considered to be a valuable source of essential nutrients such as proteins, lipids, micronutrients, prebiotics, and probiotics. These components play a crucial role in promoting both food security and human health (Hoppe et al., 2006). Research has demonstrated that the consumption of dairy products exerts a beneficial influence on bone mass, cardiovascular well-being, and the gastrointestinal flora (Garcia et al., 2019). However, the consumption of raw milk presents a potential public health hazard due to its elevated bacterial content and its ability to serve as a favorable environment for bacterial proliferation.

According to the Food and Agricultural Organization (FAO) in Rome, the global population of cattle and buffalo in 2018 was reported to be 1489 million and 206 million, respectively. In 2018, the United States of America (USA) emerged as the leading global producer of cattle milk, generating a staggering 82 million tons. This was closely trailed by India, who produced 47 million tons, securing the second position (*FAOSTAT*, 2019). The predicted gross production value in the Milk market is expected to reach US$85.44 billion by 2023. The projected compound annual growth rate (CAGR) for the period of 2023-2028 is 5.45%, which is predicted to lead to a gross production value of US$111.40 billion by 2028 (*Milk - Worldwide | Statista Market Forecast*, 2023). The worldwide dairy market experienced an 11% increase in value between 2019 and 2023. In 2023, South America is projected to experience a significant increase of 12% in dairy consumption compared to 2019. This growth may be attributed mostly to government initiatives, product developments by manufacturers, and the increasing awareness of healthier options. Europe holds a significant market share of 33.76%, surpassing North America by a margin of 10.9% in 2023. The market's growth in Europe is being propelled by the substantial output of cow's milk and the increasing government investments in the milk industry. A significant portion of the dairy consumed in Europe is domestically produced. European dairy farms yielded 161 million metric tons of unprocessed milk in 2021, with cow's milk accounting for 96% of the total. European governments' efforts in organic farming are fostering prospects for the production of organic milk. The European Commission's Green Deal Industry Plan aims to achieve a minimum of 25% utilization of the European Union's agricultural area for organic farming by the year 2030 (*Dairy Market Size & Share Analysis - Industry Research Report - Growth Trends*, 2023).

1.2 Stakeholders in Milk Production & Processing Industry

Stakeholders in global milk production encompass a diverse range of individuals and organizations that contribute to the advancement, expansion, and sustainable future of the dairy industry. The stakeholders participate in establishing dairy breeding objectives, making decisions related to breeding goals, and guaranteeing the profitability and sustainability of milk production. Several crucial parties involved in milk production and their respective duties include:

Producers: Persons or families who own and oversee dairy farms, where they raise dairy animals and produce milk. Their primary responsibility includes the daily upkeep of the animals, which includes tasks such as feeding, milking, and ensuring the herd's overall health and welfare (Henchion et al., 2016).

Dairy processing companies: Responsible for receiving milk from producers and transforming it into a range of dairy products, including milk, yogurt, cheese, and ice cream. Their responsibility lies in guaranteeing the quality, safety, and uniformity of the dairy products they manufacture (Henchion et al., 2016).

Veterinary Clinics/Hospitals: Responsible for preserving animal health by attending to their clinical needs, curing them, ensuring their well-being by treating their ailments. Veterinary clinics and animal hospitals that take care of dairy cows could be seen as partners because they provide inputs (Pyatt et al., 2017).

Breeding firms: Specialize in the development and enhancement of dairy breeds, with a particular emphasis on attributes like as milk output, health, and fertility. They collaborate closely with dairy processing companies to supply superior dairy cows (Henchion et al., 2016).

Researchers: Offering expert advice and assistance to producers and dairy processing firms, aiding them in enhancing their operations, mitigating risks, and adjusting to evolving market conditions are the main attributes of researchers and advisors. In addition, they engage in research endeavors aimed at advancing milk production and improving its quality through the development of novel technology and methods (Henchion et al., 2016).

Representative groups and public agencies: Serve as advocates for dairy producers, processors, and other stakeholders in the dairy industry. Their objective is to formulate policies, rules, and standards that foster the expansion and long-term viability of the dairy industry (Henchion et al., 2016).

Nevertheless, the dairy industry encounters obstacles, including the need to establish dairy as a significant health and wellness commodity, attaining ambitious environmental conservation objectives, and maintaining profitability despite historically elevated input expenses.

1.3 Historical Context of Infectious Microbes

Throughout the course of human history, numerous pandemics have emerged, leaving a significant impact on the society. These include the bubonic plague, which occurred in the 14th century, the Spanish flu in the 20th century, the HIV/AIDS epidemic spanning the 20th and 21st centuries, and the ongoing coronavirus disease 2019 (COVID-19) pandemic. With a recorded infection rate above 238 million individuals and a death toll exceeding 4.8 million since its inception in December 2019(Advice for the Public on COVID-19 – World Health Organization, 2023), COVID-19 has brought attention to the profound and enduring societal and economic ramifications associated with the advent of infectious diseases. The risk of the emergence of new diseases in human populations is becoming increasingly concerning due to the convergence of various factors related to global environmental change. These factors include climate change, land-use changes such as urbanization, and the practices within the agricultural industry, such as the operation of large commercial animal farms. Furthermore, the aforementioned risk is exacerbated by the escalating resistance to antimicrobial agents and insecticides employed in the control of disease vectors (Rohr et al., 2019), as well as the expanding likelihood of diseases spreading rapidly due to enhanced global transportation (Nuñez et al., 2020). Concerns over the potential hazard of human infectious diseases arising from domestic or wild animal species have escalated from a public health standpoint (Jones et al., 2008). The spillover events and subsequent public health effects of these pathogens exhibit significant variation. For instance, zoonotic illnesses that are strictly limited to transmission from animals to humans require new instances of spillover from a reservoir of vertebrate hosts in order to persist within human populations. This is due to the absence of human-to-human transmission for such diseases, as observed in cases like echinococcosis, toxoplasmosis, and rabies. Additional illnesses, such as bubonic plague (produced by *Yersinia pestis*), Lyme disease (caused by *Borrelia burgdorferi*), and West Nile fever (caused by the West Nile virus), are transmitted by arthropod vectors. However, these infections do not exhibit sustained human-to-human transmission over extended periods (Dharmarajan et al., 2022).

1.4 Microbes and Antibiotics

Microbes are microscopic organisms that require the aid of a microscope for visual observation (*Facts About Microbes*, n.d.). These organisms inhabit aquatic environments, terrestrial substrates, and the atmospheric realm. The human body harbors a vast number of microorganisms. Certain microorganisms can cause illness in humans, while others play a crucial role in maintaining our overall well-being. The categories encompass bacteria, viruses, and fungus ("What Are Microbes?," 2019).

History of first antibiotics traces back to the presence of tetracycline residues that has been detected in human skeletal remains originating from ancient Sudanese Nubia, specifically dated to the time period between 350 and 550 CE (Bassett et al., 1980). The commencement of the transition of conventional medicine is frequently attributed by historians to the emergence of germ theory. Prominent figures in the field of microbiology, such as Louis Pasteur and Robert Koch, along with other esteemed European pathologists, conducted comprehensive investigations on bacteria by employing microscopic techniques and cultivating these microorganisms within controlled laboratory settings (D'Abramo & Neumeyer, 2020).

The integration of antibiotics into clinical practice might be seen as one of the most significant advancements in the field of medicine throughout the 20th century (Katz & Baltz, 2016). In addition to their efficacy in treating infectious diseases, antibiotics have played a vital role in enabling certain contemporary medical operations, such as cancer treatment, organ transplants, and open-heart surgery. Nevertheless, the improper utilization of these vital molecules has led to the rapid escalation of antimicrobial resistance (AMR), rendering certain illnesses essentially incurable (Prescott, 2014). According to the O'Neill report commissioned by the UK Government, it has been projected that by the year 2050, about 10 million individuals per annum may face mortality due to drug-resistant diseases, emphasizing the need for immediate intervention. One of the primary suggestions is to facilitate the initiation of drug discovery in its early stages (*Home | AMR Review*, 2023). A concise summary of the historical background of naturally occurring antibiotics is given below.

Timeline showing the years of Different Antibiotics invention and associated Resistance											
					The most innovative years for Antibiotics						
1900	1910	1920	1930	1940	1950	1960	1970	1980	1990	2000	2010
First systematic analysis on antibiosis by soil bacteria	First synthetic antibiotic used clinically	First report of antibiosis by actinomycetes	Penicillin was discovered	Penicillins were approved for Clinical use		MRSA were first detected			Last class of clinically used NP antibiotic discovered	First actinomycetes genome sequenced	Plasmid-borne colistine resistance in Enterobacteriaceae.
			Resistence to Salvarsan	Streptomycin discovered		Plasmid borne resistence to sulfonamides			Vancomycin resistant enterocci (VRE) first detected	Vancomycin resistant Stephalococcus aureus (VRSA) first detected	UN declares AMR as a fundamental threat
			Resistence to sulfonamides	Penicillin resistence identified							

Figure 1: Timeline illustrating the chronological progression of new classes of antibiotics entering the clinical setting over the course of a decade. The lower section of the timeline displays the discovery of antibiotics and the emergence of antimicrobial resistance. These years encompass the initial documentation of drug-resistant strains such as methicillin-resistant S. aureus (MRSA), vancomycin-resistant enterococci (VRE), vancomycin-resistant S. aureus (VRSA), and plasmid-mediated colistin resistance in Enterobacteriaceae (Hutchings et al., 2019).

1.5 Antimicrobial resistance

Antibiotic resistance is becoming an increasingly alarming global issue (Birkegård et al., 2018) (*Forum*, 2016). The reduced effecacy of antimicrobial treatment in curing infectious diseases in both humans and animals has led to higher rates of illness and death, as well as increased financial costs.

Antimicrobial resistance is a condition arising from microorganisms, including bacteria and fungi, when they develop the ability to override the effectiveness of medications specifically designed to destroy them. Infections caused by resistant microbes makes them difficult to treat, sometimes even impossible to cure. Antimicrobial resistance is a congenital phenomenon that occurs naturally. The use of antibiotics and antifungals is vital for saving human lives. However, it is important to emphasize that their over-use or unprescribed use can contribute to the development and spread of drug-resistant bacteria. Microorganisms have the capacity to develop defence mechanisms against the antibiotics used to kill them, called resistance mechanisms, in order for their survival. DNA contains the necessary instructions for microorganisms to produce specific proteins that are essential for determining their resistance mechanisms. Bacteria and fungi can have genetic components that are linked to various mechanisms of resistance.

If certain pathogens have a combination of resistance mechanisms, which are already difficult to fight against, it can make all antibiotics or antifungals useless. This results in the progression of untreatable diseases. The situation is dreadful because pathogens that are immune to antimicrobial agents can pass on their resistance mechanisms to their next generation, that have not even been exposed to antibiotics or antifungals before. Gram-negative bacteria, for an example, have an outer membrane that acts as a defensive shield. These bacteria have the capacity to utilize their membrane as a means of selectively hinder the entry of antibiotics. *Pseudomonas aeruginosa* bacteria possess the capacity to produce efflux pumps that helps them in the removal of specific antibiotic medications, including fluoroquinolones, beta-lactams, chloramphenicol, and trimethoprim. *Klebsiella pneumoniae* bacteria has the ability to enzymatically produce carbapenemases, which efficiently break down carbapenem as well as most other beta-lactams. Many antibiotic drugs are designed to specifically detect and eliminate specific proteins, or cellular metabolism, within the bacteria. Microorganisms go through genetic mutations that lead to changes in the target, making the drug unable to effectively bind and exert its intended function. *Escherichia coli* bacteria which carry the mcr-1 gene have the capacity to alter the outer surface of their cell wall, which hinders the attachment of the antibiotic colistin (CDC, 2022).

1.6 Mastitis

Mastitis is a disease condition that can be defined as an inflammation of the mammary gland caused by the entry and growth of harmful pathogens. Clinical mastitis is characterized by visible changes in the milk, such as increased water content, thick consistency, presence of flakes or lumps, and the presence of pus, blood, or clots. Additionally, the affected mammary gland often exhibits signs of inflammation, such as: redness, swelling, and soreness. The causative bacteria are classified as major or minor pathogens (Harmon, 1994). The primary pathogens are *Staphylococcus aureus* and *Streptococcus agalactiae*, both of which are contagious. Additionally, coliforms, such as *streptococci*, and *enterococci*, which originate from the cow's surroundings such as bedding, dung, and dirt, are also worth mentioning. The primary pathogens have the ability to induce clinical illness, resulting in altering the milk composition, elevated somatic cell counts (SCC), and potentially fatal outcomes, hence causing significant financial burdens. The coagulase-negative *staphylococci* and *Corynebacterium bovis* are classified as mild pathogens. Infections caused by these pathogens have the potential to induce a mild inflammatory response in the mammary gland, resulting in a minor rise in somatic cell count (SCC). However, alterations in milk composition, significant reduction in milk production, or the development of clinical mastitis are seldom outcomes (Harmon, 1994).

There exists empirical evidence indicating that the composition and prevalence of bacteria responsible for mastitis are subject to changes over time (Myllys et al., 1998). Furthermore, it has been observed that variations in bacterial profiles occur across different geographical regions. For instance, observation dictates that prevailing strains of S. aureus exhibit specificity towards individual Nordic nations (Aarestrup et al., 1997).

Based on historical records, it may be inferred that the practice of milking cow dates back to at least 3100 BC (Henchion et al., 2016). Consequently, it is plausible to surmise that bovine mastitis has been prevalent since that period. Throughout the course of history spanning thousands of years, the intimate interaction involved in hand milking facilitated the straightforward identification of irregularities pertaining to both milk and the mammary gland. However, there remained a limited understanding regarding the origins and effective handling of mastitis. The comprehensive data of mastitis was unattainable until the use of microscopes, which facilitated the identification of microbes as the principal causative agents. The initial reference to bovine mastitis in the Journal of Dairy Science (JDS) can be traced back to the third issue of 1917. This particular mention primarily addressed the potential public health hazards linked to elevated bacterial levels seen in unpasteurized milk. In a seminal study conducted by Breed and Brew in 1917, a methodology for evaluating dairy farms was outlined. This approach involved quantifying the presence of bacteria in milk samples. Notably, the researchers observed that "long chain streptococci" were frequently detected in significant quantities, even in cases where signs of inflammation were minimal to the extent that farmers could not be held accountable for preserving the milk. The researchers presented the bacteriological findings obtained from multiple surveys conducted on raw milk cans. In one particular survey including a sample size of 9,387 cans, it was shown that more than 20% of the milk categorized as "high count milk" might be attributed to issues related to the udder (Breed & Brew, 1917). During that particular time frame, streptococci were identified as the predominant etiological agents responsible for mastitis, while the understanding of subclinical infections was in its nascent stages. Subsequent to that period, there have been significant alterations in infections, animals, and herd management practices. However, it is noteworthy that mastitis continues to persist as a significant health issue affecting dairy cows.

1.7 Financial burden of mastitis

Dairy farmers bear the main financial liability for mastitis. Mastitis incurs a cost of around £225 per cow, every case, resulting in an annual loss of £170 million for the UK dairy farming business (*Dairy Farming*, 2020). The expenses associated with mastitis encompass both explicit costs, such as the reduction in milk production and the expenses incurred for treatment, as well as the additional labor costs and potentially the expenses associated with culling (Aghamohammadi et al., 2018). Mastitis leads to decreased milk yield, the need to remove infected cows from the herd, and the disposal of contaminated milk. These factors are the fundamental elements of the mastitis economic model (Dijkhuizen & Stelwagen, 1981). Mastitis greatly affects the profitability of dairy farms.

The cumulative cost estimation for clinical mastitis is as follows:

- A significant reduction of 31% in milk output has been observed.
- Approximately 24% of individuals are employed in the field of veterinary medicine and pharmaceuticals.
- The percentage of milk that is discarded is 18%.
- There is a surplus of labor demand up to 4%.
- The premature culling rate is 23% (*Bovine Diagnostics - How Much Does Mastitis Cost Dairy Producers Annually?*, 2023).

The United States estimates based on its own data that its dairy industry experiences annual losses of about $2 billion because of mastitis. According to the University of Montreal study, the cost for the Canadian dairy industry is estimated CA $400 million (US $310 million) annually, due to mastitis alone. This translates to approximately CA 500-1000 ($385-$775) cow per year. In several researches estimating, some extra costs associated with clinical mastitis in the dairy cows are in between US$ 128 (€ 105) to US$ 444 (€ 360). (Rollin et al., 2015).

1.8 Perspective of animal health and food security

Mastitis is now known to be one of the main reasons for using antimicrobial drugs to treat dairy cows in modern commercial dairy system. It remains a challenge for the dairy sector, mainly because it affects milk quality, animal welfare, and farm economics (Ruegg, 2017). To reduce the cases of mastitis, it is important to adopt various measures for preventing it since it helps in reducing the cost of production and use of antibiotics. These preventive measures also help reserving animal rights. In the previous decade, there has been an increased interest in the application of genetics in the mastitis resistance of the dairy cattle population. Denmark, Finland, Norway, and Sweden are the sole nations that possess national recording systems for health data in dairy cattle. Notably, Norway holds the distinction of being the first country to implement a comprehensive recording system on a nationwide scale (Heringstad et al., 2000). Since its establishment in 1975, this system has been collecting data on individual dairy cows throughout Norway, making it the most comprehensive and persistent record of dairy cows worldwide. The gathering of milk yield data from local farmers in Grimstad, Norway began as early as 1898. By 1975, it had transformed into a comprehensive nationwide recording system that encompassed the entire country, making it the pioneering system of its kind. During the year 2012, a total of 98% of the dairy cows in Norway were included in this comprehensive recording system (*Norwegian Dairy Herd Recording System*, 2024).

1.9 Dairy business in Norway and Mastitis

Norweigian dairy industry is significant within the country, but is relatively small compared to the leading producers like India, United States or China on global scale, ranking around 65th position among the largest global producers (*Dairy Market Size & Share Analysis - Industry Research Report - Growth Trends*, 2023). The dairy milk production industry of Norway is characterized by a small number of farms and within this 98% of the farms own less than 50 cows (Day, 2019). Most of the farms are family businesses, and people in every age group in the family engage in the farming activities. The Norwegian dairy producers are offered a reasonable price for their milk through a rate of about 5kr per litre. Tine, the national dairy firm, has introduced other forms of incentive to farmers, including the annual bonuses as an incentive to the hard work of the farmers. For the dairy farming to be economically viable in Norway, these factors play the key role: size of the farm, location of the farm and efficiency in farm management (Nikel, 2017). Some challenges that Norwegian dairy farmers have to deal with, is that they are always busy sourcing for grass for the winter season and various other challenges of farming that are always arising. So, these problems are in need for constant monitoring and solving. In spite of these obstacles, Norwegian dairy farming has managed to achieve profitability, a rarity in certain other nations. The Norwegian government also provides substantial support to the dairy industry, further enhancing the total profitability of milk production in the country (Nikel, 2017).

According to data from the Norwegian Dairy Herd Recording System (NDHRS), clinical mastitis is the most commonly reported disease in Norwegian dairy cows, accounting for approximately 34% of cases. In 2021, there were a total of 31,778 reported cases, resulting in an incidence rate of 0.18 cases per cow per year. The entire loss amounted to 103 million NOK (*Statistikksamling for Ku- Og Geitekontrollen 2021*, 2022).

1.10 Advancements in technology for diagnosing bovine Mastitis

Cytological study, particularly milk somatic cell count (SCC), is the most commonly used method for detecting inflammation. The assessment of milk quality for determining premium value or applying penalties to milk pricing is often conducted through the evaluation of SCC (Somatic Cell Count). Milk culturing is a more effective method for detecting intramammary infections (IMI), although the presence of pathogens does not always indicate inflammation. Accurate identification of mastitis pathogens is crucial to implement appropriate management measures, minimize the risk of chronic infections, and focus antimicrobial therapy effectively (Duarte et al., 2015).

Here's a summary of various technological and scientific advancements that have led to the development of diagnostic results that are more sensitive, credible, and quicker.

1.10.1 Pathogen identification for intramammary infection

Phenotypic Methods:

Bacterial culture has traditionally been considered the most reliable method for phenotypic analysis in mastitis diagnosis, with the use of culture-enhancement techniques and selective medium leading to enhanced sensitivity (Britten, 2012). Phenotypic identification is based on the assessment of traits like as physical appearance, development, metabolism on different substances, and resistance to antimicrobial agents (R. N. Zadoks & Watts, 2009). Phenotypic-based diagnostic tests are widely used in commercial settings due to their user-friendly nature, wide availability in the market, and relatively affordable price. Nevertheless, the presence of variation in the expression of traits among different strains of the identical species (Gonzalo et al., 2006), coupled with the subjectivity involved in interpretation (Bourry & Poutrel, 1996), act as drawbacks that restrict the ability to replicate results (Riffon et al., 2001). On-farm culture systems are being more commonly employed for their economic advantages (Lago et al., 2011), despite their labor-intensive nature (Gillespie & Oliver, 2005). Research on their diagnostic accuracy demonstrated satisfactory results, while the specificity was very limited (McCarron et al., 2009). Two on-farm systems were able to effectively classify isolates according to Gram-positive and Gram-negative distinction. However, they did not have the capability to identify sample contamination (Lago et al., 2011).

Mass spectroscopy using matrix-assisted laser desorption ionization–time of flight (MALDI-TOF MS) is a rapid and accurate technique for detecting and classifying bacterial species (Raemy et al., 2013) and strains (Böhme et al., 2012) with exceptional sensitivity and specificity (Bizzini & Greub, 2010). The potential of this technology rests in its ability to replace or enhance established identification methods, but its efficiency is dependent on the availability of specific spectrum databases (Bizzini & Greub, 2010). Nevertheless, the present expense of the technology limits its extensive implementation in diagnostic laboratories. Also, the inability to differentiate between closely related species, misidentification due to inadequate database coverage and inability to detect AMR profile remains to be the techniques major drawbacks (Hou et al., 2019).

Genotypic Methods:

Genotypic methods employed in the identification of pathogens causing bovine mastitis involve the use of DNA-based technologies, such as polymerase chain reaction (PCR) (Malou & Raoult, 2011) and molecular typing methods (R. N. Zadoks & Watts, 2009). PCR provides exceptional sensitivity, enabling the detection of nonviable bacteria (Taponen et al., 2009) and beyond the constraints of culture-based techniques (Bexiga et al., 2011). Different molecular typing techniques, including amplified fragment length polymorphism (AFLP), restriction fragment length polymorphism (RFLP), multiple locus variable-number tandem repeat analysis MLVA, ribotyping, and pulsed-field gel electrophoresis (PFGE), assist in identifying species (Heikens et al., 2005) and strains (Heir et al., 1999) at various levels, each offering distinct levels of repeatability and resolution (Munoz et al., 2007). Automated ribotyping exhibits consistent results (Carretto et al., 2005) but requires a significant amount of time, whereas MLVA offers a high level of discriminatory capacity but is limited to specific species (Pinho et al., 2012). Technological advancements encompass the utilization of microarray technology to detect common species that cause mastitis with a high level of sensitivity (Kuo Hua, 2008). DNA chips with ligation detection reaction and 16S rRNA gene analysis exhibit high specificity and sensitivity (Cremonesi et al., 2009). The utilization of capillary electrophoresis in an upgraded tDNA-PCR method provides a precise and cost-efficient means of identifying coagulase-negative staphylococci isolates (Supré et al., 2009). Notwithstanding these progressions, obstacles encompass interlaboratory comparisons and the requirement for precise protocols. Nanopore sequencing technique is the latest addition to this kind of methods.

Immunoassays:

An immunoassay is a biochemical test that quantifies the presence or concentration of a certain molecule in a solution by exploiting the binding interaction between an antibody and its target antigen (*Immunoassays*, n.d.). Immunoassays are frequently used for the detection of bovine mastitis because they are fast, simple, and widely available for purchase (Gosling, 1990). Enzyme-linked immunosorbent assays (ELISAs) are extensively utilized, with detection limits that span from $8 \times 10-4$ to $8 \times 10-3$ µg of antibody per milliliter (Madigan & Martinko, 1997). ELISAs have been created to detect Staphylococcus aureus (Bourry & Poutrel, 1996), although the levels of antibodies in these tests may not accurately correspond to the amount of germs present. Multiple ELISAs can be utilized to detect the presence of S. aureus and Listeria sp. in milk for the purpose of identifying natural contamination (Riffon et al., 2001). A magnetic bead-based enzyme-linked immunosorbent assay (ELISA) utilizing monoclonal antibodies demonstrated potential in the detection of staphylococci in milk (Pour Yazdankhah et al., 1998), whilst another ELISA was able to identify antibodies specific to S. aureus (Bourry & Poutrel, 1996). Nevertheless, the latter method had constraints in terms of precision, particularly when it came to cows in the early stages of illness or those with sporadic shedding patterns (Hicks et al., 1994). A comparative study utilizing immunoagglutination examined six slide tests that are commercially available for the identification of S. aureus in milk. The investigation revealed different levels of sensitivity and specificity among the tests, with one test demonstrating the highest values at 86.7% sensitivity and 90.1% specificity (Zschöck et al., 2005).

1.10.2 Mastitis detection

Somatic Cell Counting:

Somatic cell count (SCC) is an essential indicator used to diagnose subclinical mastitis in dairy cows, which has a significant impact on milk costs. Somatic cell count (SCC), which is primarily made up of leukocytes, may not consistently show a correlation with udder infection and can be impacted by a variety of circumstances (Schepers et al., 1997). The commonly employed SCC cutoff for subclinical mastitis is ≥200,000 cells/mL, however, a suggested lower threshold of 150,000 cells/mL has been put forth to enhance precision (Vissio et al., 2014). Both direct and indirect techniques are utilized to quantify SCC.

Direct approaches employ portable automated cell counters that utilize enzymatic reactions or optical labeling (Duarte et al., 2015). These devices are economically efficient and easy to operate, although they may have limited sensitivity at low signal-to-noise ratios (Viguier et al., 2009). Although laboratory cell counters are precise, they require a significant amount of time and are costly (Gonzalo et al., 2006). The differential cell count (DCC) is a direct approach that accurately identifies inflammatory processes with both high sensitivity and specificity, even when the somatic cell count (SCC) is low (Pilla et al., 2013).

An example of an indirect method is the California Mastitis Test (CMT), which evaluates somatic cell count (SCC) by creating a gel-like substance when there are high numbers of cells present (Viguier et al., 2009). Computerized Maintenance Testing (CMT) is a rapid, uncomplicated, and economical method; however, it may need personal judgment. The Wisconsin Mastitis Test (WMT) conducted on bulk tank milk offers a precise and objective assessment of the gel height, hence improving accuracy in comparison to the California Mastitis Test (CMT). A portable microfluidic sedimentation cytometer provides an indirect approach with a reaction time of 15 minutes and a low detection threshold of 5 × 10^4 cells/mL (Garcia et al., 2019).

Ion variation:

Mastitis causes alterations in the ion concentrations of milk, leading to changes in electrical conductivity as a result of heightened vascular permeability (Kitchen, 1981). This modification, characterized by increased concentrations of sodium, potassium, calcium, magnesium, and chloride, is frequently assessed to identify mastitis in automated milking systems. However, depending exclusively on milk conductivity is not regarded as a dependable or discerning factor for definitive mastitis diagnosis, since it may result in a significant proportion of incorrect positive results. In milking robots, detection is commonly performed by employing a combination of human inspection, electrode-based conductivity testing, and data analysis in herd management software. This process takes into account several aspects such as milk yield and milking frequency (Hovinen et al., 2006).

Biomarkers:

Biomarkers are specific chemicals that can serve as indicators for the existence or intensity of a disease or biological state, such as mastitis. Biomarkers, quantifiable indications of biological processes, are essential in the diagnosis of mastitis (Boehmer, 2011). Specificity to the disease and stability in the presence of associated conditions are crucial for a biomarker to be successful (Issaq & Blonder, 2009). Enzymes, including N-acetyl-d-glucosaminidase (NAGase), β-glucuronidase, catalase, plasminogen, and lactate dehydrogenase (LDH), that are generated during immunological responses and changes in vascular permeability, have the potential to serve as biomarkers for mastitis (Pyörälä, 2003). The cytoplasmic enzyme LDH has exhibited minimal change in cows who are clinically healthy (Hiss et al., 2007). Enzyme concentration assays, such as colorimetric and fluorimetric approaches, assist in the early diagnosis of mastitis (Larsen, 2005). The breakdown of milk proteins by bacteria or internal proteases during bouts of mastitis provides extra peptide indicators. A set of 47 peptides serving as biomarkers has exhibited a sensitivity of 75% and a specificity of 100% (Mansor et al., 2013). Immunoassays, such as ELISAs, are capable of detecting acute phase proteins such as haptoglobin (Hp) (Åkerstedt et al., 2008) and serum amyloid A (SAA)(Szczubial M, 2008), which exhibit elevated levels in response to inflammation. Automated immunoassays utilizing optical biosensors have been created for the purpose of detecting NAGase (Welbeck et al., 2011). Nevertheless, there are certain constraints associated with this method, such as its capability to identify only a single protein at a given moment and its reliance on antibodies that are specific to particular species, thereby limiting the exploration of new inflammatory agents (Boehmer, 2011).

Comparative analysis:

Phenotypic approaches are still more frequently used than genotypic methods for identifying mastitis pathogens, even if they encounter difficulties such as a considerable percentage of incorrect negative results in the analysis of milk samples from mastitis cases (Taponen et al., 2009). The failure to identify the causative agents responsible for intramammary infections (IMI) in a significant number of cases might result in undiagnosed infected cows, hence undermining efforts to prevent mastitis in the herd (Koskinen et al., 2009). To tackle this issue, it is recommended to utilize genotypic approaches, specifically multiplex PCR, as an additional strategy to improve identification, particularly in situations when false negatives occur (Raemy et al., 2013). Phenotypic approaches are commonly seen as less costly (R. N. Zadoks & Watts, 2009); however, their cost-effectiveness is contingent upon variables such as sample size and frequency. Automation for test interpretation in laboratories that handle a large volume of samples might be advantageous in some situations, as it can make phenotypic approaches financially viable (Ieven et al., 1995). Nevertheless, the possibility of requiring further testing and the subsequent rise in expenses and processing duration might reduce the disparities in cost and time between phenotypic and genotypic identification. Furthermore, it is important to take into account the precision of the results and the financial consequences of incorrect conclusions (Ieven et al., 1995). The high cost of equipment limits the use of various genotypic approaches, making them less practical for regular diagnosis in specific situations (R. N. Zadoks & Watts, 2009).

Future perspective:

The investigation of novel biomarkers and technological developments for enhanced sensitivity and specificity, as well as the creation of quick, effective instruments appropriate for on-site usage, are crucial to the future of diagnosing bovine mastitis. The identification of biomarkers and gene expression profiles is made possible by recent advancements in transcriptome and proteome analysis, which offer insights into intricate molecular pathways in cell physiology and pathology (Klopfleisch & Gruber, 2012). Novel proteins linked to mastitis have been discovered using proteomic techniques such mass spectroscopy and 2-dimensional gel electrophoresis, which present prospective targets for treatments and diagnostic indicators (Smolenski et al., 2007). Utilizing whole genome sequences (Cash, 2000), advances in microbial proteomics have improved our knowledge of the patterns of protein expression in infections that cause mastitis (Viguier et al., 2009).

Emerging as the instruments of the future, biosensors are essential in many domains, such as biodefense, agriculture, food control, environmental research, and medicine (Lazcka et al., 2007). These sensors make use of transducers and biological receptor molecules to indicate particular biological events, which makes it easier to find disease biomarkers. The diagnosis process has become much more rapid and accurate thanks to pathogen detection based on nanotechnology, which also shortens the time between sample collection and outcomes (Driskell & Tripp, 2009). Through lab-on-a-chip platforms, which combine electronics, sampling, and detecting modules for quick, precise, and economical analysis, the portability of biosensors has been investigated (Driskell & Tripp, 2009). A variety of biochip types have been exhibited, demonstrating the adaptability of these technologies by utilizing a range of detecting principles, including chemical (Pinijsuwan et al., 2008), mechanical (Gfeller et al., 2005), optical (Gunnarsson et al., 2008), electrical (Gonçalves et al., 2008), and magnetic (V. C. Martins et al., 2010).

1.11 Our Proposition: A Culture and Amplification independent rapid method for identification of Pathogens and AMR profile

The brilliant scientists of INN wanted to devise a very effective technique for isolating bacterial DNA from milk samples containing bovine mastitis. This involved evaluating four different commercially available kits, each with different additions and procedures. The method successfully detected antimicrobial resistance (AMR) genes such as Tet(A), Tet(38), fosB-Saur, and blaZ. The utilization of MinION nanopore sequencing enabled the technology to achieve prompt and simultaneous identification of pathogens (within a time frame of 5 hours) and AMR profiles (within a time frame of <9 hours) without the need for culture or amplification. The findings indicate a potentially effective and flexible method for enhancing the therapeutic management of mastitis on farms (Ahmadi et al., 2022).

1.12 Aim of the study

The objective of the thesis is to investigate the possible business strategies for utilizing nanopore sequencing as a method for detecting mastitis and determining antimicrobial resistance profiles. Additionally, a thorough analysis will be conducted in order to develop a viable business plan.

1.13 Objective(s) of the study

- Market research for the bovine mastitis diagnosis.
- Technology assessment for the current practices.
- Business model design for intended product.
- To assess the possibilities and challenges that the business will face.

1.14 Research questions

- What is the present state and degree of demand for mastitis diagnostics and antibiotic susceptibility testing in the dairy industry? This includes identifying the key stakeholders, their challenges, and their views on antimicrobial resistance.
- What are the advantages and limitations of whole genome sequencing technology for mastitis diagnosis include challenges in accurately and efficiently addressing complexity such as milk sample composition and host DNA depletion?
- What all-encompassing approach may be implemented to determine the appropriate pricing, customization, and distribution of the product in order to meet the varied requirements and capabilities of target customers?
- What is the value proposition of the whole genome sequencing-based diagnostic tool, and how can it differentiate itself in the market?
- How will the business model adjust to short and long-term changes in technology, legislation, and growing market demands?
- Which price model is the most appropriate for the target market?
- How will the business model adapt to differences in dairy farm sizes and production capacities?

2. Methods

2.1 Database search

Research and data collection involved the utilization of both primary and secondary sources. Secondary sources encompassed preexisting publications such as review articles, research papers, case studies, reports, and books. Various web data sources were analyzed to gather the statistical data and information. The search terms employed included "Bovine mastitis", "financial burden of bovine mastitis", "Methods used in detecting bovine mastitis", "history of bovine mastitis", "nanopore sequencing technology", "milk and mastitis", "business models for developing new strategies in pharmaceutical testing kit", as well as other relevant terms such as production, potential, challenges, market analysis, and business model canvas. The search tool provided by the Oria database search engine at Høgskolen i Innlandet was utilized to locate appropriate research papers, eBooks, journals, theses, and books pertaining to the subject matter. Additional search engines such as Google Scholar, Science Direct, Springer Link, ACADEMIA, ResearchGate, and NCBI were utilized throughout the course of the research. Research and data collection involved the utilization of both primary and secondary sources.

2.2 Interview

The research work included conducting a Key Informants Assessment (KIA) to gather data for market survey and develop an end-user profile.

2.3 Market segmentation

Bill Aulet's Disciplined Entrepreneurship approach defines market segmentation as the systematic identification and categorization of several potential consumers (market segments) that may show interest in a product or idea. This approach emphasizes starting the entrepreneurial process by focusing on the customers, rather than the product itself (*Lecture 6*, n.d.). Segmentation is essential since businesses cannot successfully promote products to the entire global population, and not everyone is interested in a specific product. The method entails segmenting a huge population into smaller client groups based on shared needs, wants, preferences, location, demographics, and purchasing behaviors.

Aulet's approach highlighted the fundamental aspects of market segmentation. It entailed shifting from a product-focused approach to a customer-focused perspective by asking "who is interested in this idea or product?". The objective was to generate a multitude of distinct potential client segments and organize them in a segmentation matrix or list. Segments were categorized according to attributes such as demographics, psychographics, behaviours, industry verticals, use cases, and so on. Engaging in this process compelled me to thoroughly analyse the customer's viewpoint and ensure that everyone is in agreement over the possible markets. It established the foundation for subsequently selecting a single primary target sector to initially concentrate on. Market segmentation is an essential initial stage that must be completed before performing thorough primary market research on the most favourable groups. Aulet highlighted the importance of conducting thorough market segmentation at the beginning to prevent the development of a product or service that lacks demand. This involved gaining a comprehensive understanding of the many client segments that could potentially find value in the concept (*Disciplined Entrepreneurship by Aulet, Bill. 9781118692288. Innbundet - 2013 | Akademika.no*, 2017)

The process of market segmentation identified numerous possible business opportunities. After compiling a list of potential markets, conducting a focused analysis using market research had assisted in identifying the most suitable markets for our technology. The objective of the research was not to offer an impeccable solution, but rather to show a comprehensive range of market options for me to consider as I determined the focal point of my research. Engaging in primary market research, which entailed direct communication with customers and careful observation, was absolutely the most effective method for identifying lucrative market prospects. This research assisted me in identifying a beachhead market for the next part (*Disciplined Entrepreneurship by Aulet, Bill. 9781118692288. Innbundet - 2013 | Akademika.no*, 2017).

2.4 Beachhead market establishment

In "Disciplined Entrepreneurship: 24 Steps to a Successful Startup," Bill Aulet emphasizes the critical need of identifying a specific market opportunity where potential customers are likely to engage with, purchase, and adopt a product or service. It outlines the importance of the discovery stage, including brainstorming new ideas, characterizing possible users, and finding relevant sectors. The second part in the series focuses on identifying the "start-up sweet spot" where a product or service connects not just with potential buyers but also with targeted end users who become dedicated brand ambassadors. The third crucial component, according to Aulet, is "finding the primary beachhead market." The beachhead market, similar to the WWII battle of Normandy, is where paying customers congregate and acts as a strategic launchpad for market dominance. Aulet comments that gaining supremacy in this industry offers the strength to expand into neighboring markets, ultimately resulting in the formation of a larger organization. The beachhead market is a fundamental and strategic step that is critical to the success of any firm (*Launching a Successful Start-up #3: The Beachhead Market*, n.d.). The following were the essential steps for choosing a beachhead market:

- I generated a comprehensive inventory of possible market categories that may exhibit interest in my product by employing brainstorming techniques and market segmentation analysis.
- Specified the standards I will employ to assess and contrast the various market categories. Typical criteria consisted of decision speed, sales cycle length, size of the market and possibility for generating revenue, level of competition, level of product-market fit and distinctiveness.
- I determined the relative importance of each criterion by assigning weightages based on their perceived significance in my hypothetical circumstances.
- Evaluated each prospective market category based on the criteria, either through research but mostly by my initial best guess.
- Constructed a weighted scoring matrix by calculating the product of the scores and weightages for each section.
- Examined the overall results to determine the 6-12 market categories with the greatest scores, which can be considered as potential prospects.
- Finally chosen one market sector from these contenders to fully concentrate on initial beachhead market. The foundation of this were:

  Maximum cumulative score

  Alignment with my expertise

  Compact enough to swiftly establish dominance, yet substantial enough to hold significance (targeting a total addressable market of $20-100 million).

  I excluded all other market segments. Focusing resources exclusively on a single target market is essential for achieving initial success and aligning the product with the needs of the market (*Disciplined Entrepreneurship by Aulet, Bill. 9781118692288. Innbundet - 2013 | Akademika.no*, 2017).

2.5 Total Addrressable Market (TAM) Analysis

Total Addressable Market (TAM) refers to the revenue opportunity available if a company achieves 100% market share, which is critical for resource allocation considerations. It is evaluated using approaches such as top-down (huge population restricted to target segment), bottom-up (primary research-based), and value theory (measuring added value reflected in pricing). TAM, SAM (Serviceable Available Market), and SOM (Serviceable Obtainable Market) refer to subsets of market potential. TAM is important because it forecasts possible sales and revenues for new items or customer categories, which is required for financial modeling and valuation. TAM applications include calculating market size and share. TAM is a key indicator for strategic decision-making and business success (York, 2018).

2.6 Full life cycle use case

In the Full Life Cycle Use Case, it is pertinent to outline the process by which the Persona identifies that their current needs are not being fulfilled by existing products, as well as how they would become aware of the product. Given experience in conducting thorough primary market research, it is important to consider how the Persona would have become aware of the product if they were a completely new prospect.

Understanding the customer's current workflow is crucial for seamlessly integrating the product into their operation. By gaining insight into their existing process, we can effectively tailor our solution to meet their needs. Customers who are generally content with their workflow may be hesitant to make significant changes to their process, even if our product offers advantages over their current system (*Disciplined Entrepreneurship by Aulet, Bill. 9781118692288. Innbundet - 2013 | Akademika.no*, 2017).

2.7 Quantify the Value Proposition

In marketing, a value proposition is a brief description that explains the benefits a firm provides to its customers as well as why its products or services outperform competitors. It makes a commitment to customers and helps target the correct audience. An effective value proposition is concise, intuitive, and frequently contains a strong headline and sub-headline that emphasize essential benefits. Companies conduct market research to develop compelling value propositions that appeal to their target audience (Payne & Frow, 2005). The value proposition quantifies the advantages that target customers receive from the product, aligning them with the customer's primary or multiple priorities. Products frequently possess a multitude of advantages. From a simplified perspective, advantages can be classified into three distinct categories: "Better," "Faster," and "Cheaper." The objective of the Quantified Value Proposition is to precisely articulate how the advantages of the intended product align with the specific areas of improvement that target consumer desires the most (*Disciplined Entrepreneurship by Aulet, Bill. 9781118692288. Innbundet - 2013 | Akademika.no*, 2017).

2.8 Value chain analysis

Value chain analysis examines each step in the process of making a product or providing a service to identify costs, value delivered, and potential for optimization. It helps businesses comprehend their competitive edge by assessing each activity's cost-effectiveness and differentiation possibilities. This research enables businesses to choose operations that bring the most value and contribute to their overall strategy (*What Is a Value Chain Analysis?*, 2020).

2.9 Unique selling proposition (USP)

The key to successful selling, especially in a competitive market, is to identify and promote a unique selling proposition (USP). This entails identifying what distinguishes the company from competitors and exploiting that differentiation to successfully target your sales efforts. Identifying unique selling point necessitates an analysis of client demands, motives, and preferences, as well as an evaluation of rivals' methods. Once defined, USP should be applied to all parts of the business, from product qualities to price and promotion, in order to differentiate and attract clients. A company's unique selling proposition might be based on product attributes, price structure, placement strategy (location and distribution), or promotional strategy. These are what marketers refer to as the "four P's" of marketing. They are adjusted to give a company a market position that distinguishes it from competitors (*Unique Selling Proposition (USP) - Entrepreneur Small Business Encyclopedia*, 2024).

2.10 Business Model Canvas

The Business Model Canvas (BMC) is a one-page strategic management tool that helps describe and communicate a business idea or concept effectively. It organizes the core components of a business or product, emphasizing both external (consumer) and internal (business) variables. The canvas centers on the value proposition, which is the exchange of value between the company and its customers. The BMC aids in swiftly forming an image of the business concept, comprehending the business, making connections, and evaluating consumer decisions. It is made up of several essential components, including the value proposition, customer segments, customer relationships, channels, key activities, key resources, key partners, cost structures, and revenue streams. Each component focuses on a certain area of the business, such as fixing customer problems or producing money. The Business Model Canvas (BMC) is a versatile tool for creating, analyzing, and refining business models across industries and stages of development (Sheda, 2022).

2.11 SWOT Analysis

A SWOT analysis is a strategic planning technique that identifies internal strengths and weaknesses, as well as external opportunities and risks. Its goal is to provide a complete awareness of the elements that influence business decisions. SWOT analysis should be performed before committing to any business activity, whether it is investigating new ventures or revising existing policies. The study entails identifying and categorizing aspects within and outside the company as strengths, weaknesses, opportunities, and threats. Strengths and weaknesses refer to internal resources and processes, whereas opportunities and threats are to external factors. Recommendations and plans are developed based on the results of the SWOT analysis to capitalize on strengths and opportunities while addressing weaknesses and threats. SWOT analysis should also include team participation to gather varied perspectives (Schooley, 2024).

2.12 PESTEL Analysis

A PESTEL analysis or PESTLE analysis (formerly known as PEST analysis) is a framework or tool used to analyze and monitor the macro-environmental factors that may have a profound impact on an organization’s performance. This tool is especially useful when starting a new business or entering a foreign market. It is often used in collaboration with other analytical business tools such as the SWOT analysis and Porter’s Five Forces to give a clear understanding of a situation and related internal and external factors. PESTEL is an acronym that stand for Political, Economic, Social, Technological, Environmental and Legal factors.

However, throughout the years people have expanded the framework with factors such as Demographics, Intercultural, Ethical and Ecological resulting in variants such as STEEPLED, DESTEP and SLEPIT (Bruin, 2016).

3. Results and Discussions

3.1 Market segmentation

Brainstorming		
Defining the technology		
Utilization of MinION nanopore sequencing to achieve rapid and real-time identification of pathogens (within a time frame of 5 hours) and AMR profiles (within a time frame of 5-9 hours) without the need for culture or amplification.		
What industries could use the idea or technology to apply to		
Industry or Similar Category	**End users**	**Their use for technology**
Dairy farms/Cooperatives	Quality Control Department	Timely detection of mastitis is crucial to prevent milk contamination, safeguard milk quality (S. A. M. Martins et al., 2019). So, their use of technology is effective detection of mastitis, ensure the milk quality, product safety.
Veterinary hospitals	Doctors/Nurses	Early identification of mastitis enables prompt and effective treatment and management strategies (Tommasoni et al., 2023). So the use is effective use of antibiotic, preserving animal health.
Research institutes	Researchers	Researchers dedicated to creating innovative diagnostic methods as well as improving the current ones in practice. They can focus on advancing the technology and creative solutions.

Figure 2: Brainstorming to decide what my technology can offer the end users.

Industry	End User	Application	Benefits	Lead Customers	Market Characteristics	Players	Size of market
Dairy farmers/Cooperatives/Companies	Farm manager/Quality control department	Ensure milk quality by effectively detecting mastitis.	Culture independant rapid detection within limited time.	Tine SA (Norway) Nestle (Switzerland) Arla (Denmark) Danone (France)	Need for rapid and accurate diagnosis technique complementary to existing techniques.	CIEL, QMMS, Bio-Rad, Thermofischer	$2.2 billion with in 2023, will grow $5.2 billion by 2023 with 7.2% CAGR.
Veterinary hospitals	Doctors/Nurses	Early detection of mastitis for better herd management and preserving animal health.	Rapid and real-time identification of pathogens (within a time frame of 5 hours) and AMR profiles (within a time frame of 5-9 hours).		Constant need for effective diagnostic method to help choosing the right treatment method .		
Research institues	Researchers	Further advancements in the technology.	High-thoroughput genome sequencing with AMR profiles.	Kansas State University (USA) NMBU (Norway) INN (Norway)	Enhancing current technologies in practice or inventing new technologies to solve the present and future problems.		

Figure 3: Market segmentation chart

3.2 Beachhead market establishment

Beachhead Market Selection Worksheet			
Criteria	Dairy farmers/Cooperatives/Companies	Veterinary hospitals	Research institues
Economically attractive	4	3	2
Accessible to sales force	4	4	1
Strong value proposition	4	4	3
Complete product	4	3	1
Competition	1	1	3
Strategic value	4	3	2
Personal alignment	4	3	3
Overall rating	4	3	2
Rating (Market segment)	29	24	17
Key deciding factor	Early adopter of new cutting edge technology and funding to afford it.		
Ranking	1	2	3

Figure 4: Market segmentation chart (Rating Market segmentation from 1-4, 4=Most attarctive, 3=Attractive, 2=Less attractive, 1=Least attractive)

I have used the Beachhead Market Selection worksheet to gather my observations on potential Beachhead Markets and to assess and determine which one will serve as my primary focus. As to rate the potential segments on set criterias, I have rated them from 4 to 1, where 4 represents the most attractive, 3=Attractive, 2=Less attractive and 1 being the least attracive. As shown in the Figure: 4, Dairy Farmers/Cooperatives/Companies are rated 4 in every set criteria, except in competition (rated 1), as there are already available technologies in practice and hence a lot of competitions. The key deciding factor for my beachhead market is the early adopters of new cutting edge technology and the funding to afford it. Based on the total score, the segments are ranked 1,2,3, where 1 is the Primary focus.

Based on the each segments funding to acquire new technology, compelling reason to buy, my ability to deliver the whole product, competition, influencing other segments on leveraging my current selection, alignment with my goals with the target segments goals and rating from the beachhead market selection worksheet (Figure: 4), I am selecting Dairy cooperatives and companies as my beachhead market.

3.3 End user profile for beachhead market

Quality Control Manager in Dairy Company/Cooperative	
End User Profile for beachhead market	
Gender	Male (50%), Female (50%).
Age	35-45 years, avaerage age being close to 40.
Level at Company	Manager.
Income	$100k per year, depedning on region
Education	PhD/Master's degree in Biotechnology, Veterinary Medicine, or a closely related discipline. Preference may be given to obtaining further certifications or training in quality management systems.
Assigned job responsibilities	Supervising quality control procedures to guarantee the manufacturing of superior quality milk products. To effectively mitigate and control the standards of the produce, it is imperative for the manager to use appropriate procedures.
Expertise	Proper expertise in managing operations within the dairy business, specifically emphasizing quality control and assurance. Knowledge of dairy herd management techniques and prevalent health concerns, such as mastitis. Familiarity with the regulatory affairs and standards that regulate the manufacturing of dairy products.
Proficiency in Technological Skills	Demonstrates adeptness in utilizing technologies and software applications for the purposes of data analysis and quality management. Experienced in operating laboratory equipment and diagnostic instruments often employed in food safety testing.
Requirements and Objectives	The Quality Control Department places a strong emphasis on ensuring the manufacturing of milk products of superior quality that align with both consumer expectations and regulatory requirements. It is crucial to identify and control mastitis in the dairy herd in order to uphold the quality of the products. The department is in search of diagnostic instruments that provide efficient and cost-effective solutions for the detection and management of mastitis. The search for associated technologies is the key to minimize production losses and veterinary expenses.

Utilising data for decision making	Having access to precise and rapid diagnostic data allows for well-informed decision-making when it comes to managing milk quality, herd health and using treatment methods. The process of integrating into pre-existing systems is essential to seamlessly integrate the new technology with current quality control and management systems in order to optimize operations and maintain data consistency.
The challenges	Rapid identification of mastitis is crucial to stop the transmission of infection within the herd and mitigate the consequences on milk yield and quality. The incidence of mastitis outbreak can result in a decrease in milk production and a decline in product quality, hence presenting obstacles in achieving production objectives and satisfying consumer requirements. Ensuring compliance with regulatory bodies mandates pertaining to the quality and safety of milk requires the implementation of efficient techniques for managing mastitis and the meticulous documenting of diagnostic processes.

Figure 5: End user profile for a beachhead market.

In this particular instance, let's call our target company "Farmfresh Dairy Enterprises",a milk cooperative company in Norway, where Mr. Michael Scott is the Quality Control manager.

3.4 Total Addressable Market (TAM) Analysis

The dairy industry in Norway experiences a substantial financial burden as a result of mastitis. Mastitis is linked to several economic losses, spanning impaired milk supply, expenses related to treatment, loss of milk, costs associated with medications, veterinary services, laboratory fees, and a higher labor burden for farmers. Both clinical and subclinical mastitis can cause a reduction in milk production and quality, higher rates of culling, and additional costs associated with treating mastitis, resulting in significant financial losses. The mean occurrence of clinical mastitis led to a cumulative economic expenditure of $444, comprising $128 in direct expenses and $316 in indirect expenses. The direct costs encompassed several expenses, such as diagnostics ($10), treatments ($36), non-saleable milk ($25), veterinarian service ($4), labor ($21), and mortality loss ($32). The indirect costs encompassed the potential loss of future milk production ($125), the loss of premature culling and replacement ($182), and the potential loss of future reproductive capacity ($9) (Rollin et al., 2015).

Right now in Norway, the total number of dairy cow is 203, 327 (*Livestock Husbandry*, 2023). If we take the per cow cost of diagnosis as 100 NOK, the total addressable market size (TAM) would be 20,332,700 NOK or 20 Million NOK.

This estimated amount is reliable as it aligns with data derived from Tine 2021, where there were a total of 31,778 reported cases, resulting in an incidence rate of 0.18 cases per cow per year. The calculated overall loss amounted to 103 million NOK (*Statistikksamling for Ku-Og Geitekontrollen 2021*, 2022).

3.5 Full life cycle used case

Some key factors are outlined here that are essential for the persona in this case to consider in order to integrate a new mastitis diagnostic technology into the current quality assurance operation:

1. Determining the need and/or opportunity to increase product quality and search for a new mastitis detection technology

   To start with, FarmFresh Dairy Enterprises has to recognize the necessity for an enhanced and economical mastitis detection system to fortify herd health management and product quality. The company has to take substantial economic consequences of mastitis, including reduced milk yield, substandard milk quality, and premature culling of livestock in account. FarmFresh's motivation to reduce production losses, veterinary expenses, and antibiotic consumption by employing sophisticated mastitis detection techniques may fast-track the integration. The quality control department may consider forming a team with experts from R&D that will conduct thorough research on different mastitis diagnostic tools available in the market, or from the universities who are working on developing new mastitis diagnosis techniques. The assessment variables that should be considered are: run-time, precision, efficiency, user-friendliness, and compatibility with current systems. They can select a very promising mastitis detection technology that matches their expectation and set criteria and accordingly, they can initiate the process of procuring and integrating it.

2. Analysing the product:

   The procured new mastitis detection tool has to go through analysis in terms of its precision, promptness in diagnosis, compatibility with herd management and current quality control systems, and its capacity to help minimizing production losses and veterinary expenses. The team deals with set criteria, and has to compare them with standard. The team also have to assess the efficacy of the technology in quickly detecting cases of mastitis and facilitating focused therapy to manage the spread of infection within the herd. Rapid detection of the causative pathogen along with AMR profile can be the set priority for the herd management, precise use of antibiotic and most importantly, ensure milk quality.

3. Product procurement:

   The team of experts now have to collaborate closely with the technology supplier to incorporate the new mastitis detection tool into their own operations and quality control procedures. The organization providing the technology has to make sure that all the staff related to the operation, such as QC managers and lab technicians, receive training on the correct utilization and comprehension of the new diagnostic method.
4. Product installation:

   As FarmFresh implement the new mastitis detection technique, the quality assurance team carefully observes its performance and improves the processes and workflows to smoothly integrate it into daily operations. The organization utilizes the data produced by nanopore sequencing technique to make better-informed choices regarding overall quality control and other intended criteria.

5. Using the product:

FarmFresh Dairy Enterprises will include the latest mastitis detection technology using nanopore sequencing into their quality control procedures and herd management protocols. The company will utilize the tool to rapidly detect cases of mastitis, causative bacterias, to map out probable antimicrobial resistance profile, facilitate focused treatment, and monitor trends in herd health. The diagnostic data will be smoothly integrated into FarmFresh's current farm management and quality control systems to enhance decision-making.

6. Determining the value gained from the product:

FarmFresh will rigorously assess the efficacy of the new mastitis detection technology in terms of how precise the results are in nature, how swiftly the technique is diagnosing the samples, how rapidly it can plot the possible AMR profile, and its capacity to mitigate production losses, veterinary expenses, and antibiotic consumption. The organization will assess the tool's influence on enhancing herd health, milk quality, and overall operational efficiency and profitability.

7. Payment for the product:

With solid financial background as an established company, FarmFresh Dairy is well-equipped to invest in the acquisition and implementation of the advanced technologies. The organization can consider utilizing subscription-based pricing structure. In this way, the company pay the technology provider to handle the initial expenses, maintenance, tech support and upgrade, without having to pay for a huge capital.

8. Receiving support for product

FarmFresh can collaborate closely with the technology developers to enable a flawless adoption of the new mastitis detection technology into their operations. The developers will provide thorough training to all essential staff members on the correct utilization and understanding of the diagnostic system. Continued technical assistance, upgrades, and maintenance services will be essential for FarmFresh to fully optimize the long-term value of the technology.

9. Long-term business relationship by spreading awareness

   If this new mastitis detection technology keeps providing significant efficacy and efficiency, it will help persuade FarmFresh to contemplate extending its implementation to its auxiliary dairy farms or facilities. We can use the company's positive experiences and success stories with the technology to enhance awareness and stimulate adoption among other dairy producers. FarmFresh may offer feedback and suggestions to the technology developers in order to enhance the product and more effectively cater to the requirements of the dairy industry.

By thoroughly evaluating these criteria, FarmFresh Dairy Enterprises can guarantee the successful integration of the new mastitis detection equipment into their operations, resulting in concrete advantages such as enhanced herd health, superior product quality, and increased overall profitability.

3.6 Quantify the Value Proposition

Existing state-of-the-art pathogen detection technologies, scuh as MALDI-TOF, rely on bacterial culture, which is subject to inherent speed restrictions. Certain bacteria exhibit a higher rate of growth compared to others, and it is possible to achieve a positive result for a gram-negative species such as E. coli within 12 hours, particularly if the bacterial concentration in the sample is high. Additional mastitis-causing microorganisms, such as *Trueperella pyogenes*, may require up to 72 hours to develop noticeable colonies on solid media. Typically, mastitis diagnostics are conducted overnight, meaning they require an incubation time of 18-24 hours. The turnaround time is associated with the sensitivity and specificity of the test. While the test may not be able to detect all diseases within 24 hours (limited sensitivity), it may not be necessary to administer antimicrobials for pathogens that take longer to proliferate (increased specificity), specially if the goal is to identify cows that require antimicrobial treatment. An illustrative instance is T. pyogenes, where the efficacy of antibiotic therapy against this organism with a sluggish growth rate is seldom achieved (R. Zadoks et al., 2023).

Nevertheless, the conventional culture-based methods are laborious and have limited sensitivity in detecting slow-growing microorganisms. Therefore, it is highly probable that these approaches underestimate the presence of invading foreign agents and their antimicrobial resistance (AMR) profiles. This might potentially result in greater economic losses. Antimicrobial treatment is frequently initiated prior to the availability of culture findings. Thus, in order to reduce the likelihood of antibiotic resistance in mastitis and promote improved animal welfare, it is crucial to have a prompt and precise diagnosis of the primary bacteria and their antibiotic resistance profile (Ahmadi et al., 2022).

In short, Nanopore-based mastitis detection technology offers quick, thorough, and practical diagnostic information, which can aid in more focused and efficient mastitis care. This can result in enhanced animal well-being, decreased antibiotic usage, and substantial economic advantages for dairy farmers.

Priorities of persona	**MALDI-TOF**	**Nanopore sequencing technology**	**Quantified Benefit**
Cost efficiency	The price for analyzing each sample varies from $5 to $10, and there is an initial equipment expenditure of around $270,000.	The price per sample ranges from $2 to $4, while the initial equipment investment amounts to approximately $50,000.	Nanopore technology minimizes the cost per sample by up to 60% and the initial expenditure by around 81%.
Run-time	Comparable to conventional microbiological techniques, it is necessary to wait for a culture to develop for 24 to 48 hours before moving on to the identification of a specific isolate using MALDI-TOF. Consequently, organisms that do not exhibit growth on typical substances cannot be identified by MALDI-TOF. After acquiring bacterial colonies from the culture, the MALDI-TOF analysis is swift, requiring less than an hour per isolate to determine the genus and species of the bacteria.	Nanopore sequencing, a culture-independent technology, yields data within a timeframe of 6 to 9 hours, including the antimicrobial resistance (AMR) profile.	Nanopore technology accelerates the detection process by up to 61%, enabling faster intervention and treatment.

Sensitivity and specificity	The sensitivity and specificity are often high, typically ranging from 90-95%.	Estimated at 100% sensitivity and 92.3% specificity, the sensitivity and specificity are either comparable or greater.	Nanopore technology has the ability to enhance diagnostic accuracy by 3-5%, resulting in a more dependable detection of mastitis.
User friendliness and Portability	Necessitates a laboratory that is adequately equipped and have trained personnel.	Highly portable and user-friendly, capable of being used in field settings with limited instruction.	Nanopore technology improves the ability to access and use, enabling testing to be done on-site (if required) and minimizing the requirement for specialist laboratory infrastructure.
Overall impact on operations	An effective diagnostic tool, but its utility is constrained by factors such as inability to detect mixed infections,requirement of pure bacterial culture, high cost, time constraints, and operational intricacies.	Provides a more efficient and economical solution that enhances the management of herd health and minimizes financial losses caused by mastitis.	By implementing nanopore technology, dairy businesses have the potential to achieve significant cost savings of up to 50% in diagnostic expenses, decrease mastitis-related losses by up to 30% through expedited treatment, and enhance herd health management efficiency by 40%.

Figure 6: Quantified value proposition

3.7 Defining the Core

In order for me to simplify this step, I will start by naming my Company based on the used technology. The name of my company is: **BioOmitech** (biotech solutions using Bioinformatics)**,** and the brand name of the mastitis detection technology is **RapidoMast-Dx**, highlighting the use of advanced nanopore sequencing technology for Rapid, amplification free detection of Mastitis and AMR profiling. The name comes from combining the Rapid detection by Nanopore sequencing for Mastitis Diagnosis (Dx stands for diagnostics).

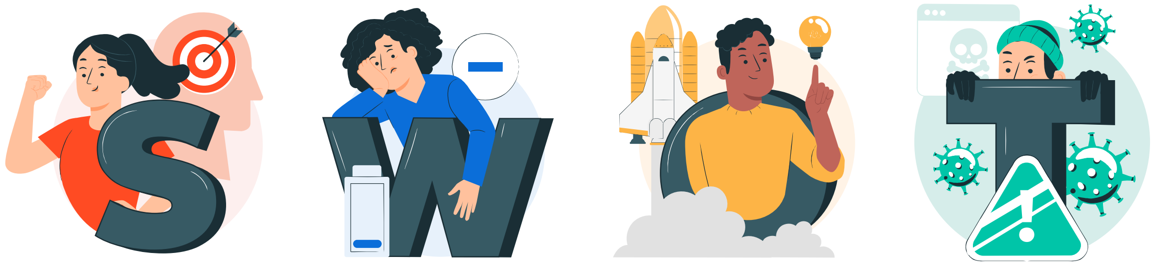
RapidoMast-Dx's core value prioritizes the rapid and accurate diagnosis of mastitis using nanopore sequencing technology, with a focus on comprehensive pathogen identification and profiling antibiotic resistance.

Proposed Core Value	Rapid and Accurate Mastitis Diagnosis with Comprehensive Pathogen Identification and AMR Profiling.
Why is it Unique	The core value focuses on the key benefits of the technology: • **Fast:** Rapid detection + AMR profile within 5-9 hours. • **Accurate:** High sensitivity (100%) and specificity (92.3%). • **Comprehensive:** Ability to detect broader range of bacteria and provide AMR profile.
Why is it important to our target customer	• Faster diagnosis compared to traditional cultured based techniques. • Have the ability to detect both the gram positive and negative bacteria • Identification of bacteria and their antimicrobial resistance (AMR) profiles, enabling precise and focused antimicrobial therapy, and reduced use of antibiotics.

Figure 7: Core value proposition for RapidoMast-Dx.

The sole focus of RapidoMast-Dx is mastitis detection and AMR Profiling using nanopore technology, and is to offer inovative, precise, and environmentally-friendly solutions that prioritize the well-being of animals, responsible utilization of antibiotics, and cooperation with industrial partners. The business's major skills are in nanopore sequencing, pathogen identification, on-farm testing, data integration. These areas enable the company to provide rapid and thorough mastitis diagnosis to the dairy industry.

3.8 SWOT Analysis



Strengths

- Rapid and Effective Detection
- AMR Profiling
- Real time monitoring and Portability
- High Coverage

Weaknesses

- Host DNA Depletion
- Deep understanding of methods
- Initial Cost

Opportunities

- Integration
- Growing demand
- Technology adoption
- Individualized treatment
- Additional benefits
- Opportunity of expansion

Threats

- Existing competitors
- Lack of interest
- Contamination
- New technology
- Perceived complexity

Figure 8: SWOT Analysis for RapidoMast-Dx.

3.8.1 Internal Factors:

Strengths:

Rapid and Effective Detection: Culture and amplification independent, rapid, precise detection of pathogens directly from milk samples with high sensitivity and specificity (sensitivity of 100% and specificity of 92.3%), with the capability of identifying a wide range of pahtogens causing mastitis.

AMR Profiling: Ability to identify AMR profile of the causative pathogens, thus facilitating precise treatment options.

Real time monitoring and Portability: Real time monitoring of the results, with the possibility of on-farm testing.

High Coverage: The technology provides long read lengths and high depth of coverage for enhanced taxonomical classification that in terms helps better identification.

Weaknesses:

Host DNA Depletion: Effective DNA depletion technique is required to reduce the larger number of host DNA in provided sample, to get required accurate result.

Deep understanding of methods: Sample preperation and data interpretation requires specialised bioinformatic knowledge.

Initial Cost: Initial cost for the nanopore sequencer, and subsequent usables is higher compared to conventional culture based methods.

3.8.2 External factors:

Opportunities:

Integration: Possibility to seamless imntegration with current herd management systems and databses.

Growing demand: Gorwing demand for the new detection technology that is time saving and cost effective with a promise of effective detection is a vital opportunity.

Technology adoption: Creating a scope for technology adoption by collaborating with dairy cooperatives, research institutions and other industrial stakeholders.

Individualized treatment: Scope for individualised therapy, based on AMR profile.

Additional benefits: Utilization of technology for the purpose of observing and overseeing zoonotic pathogens in farm setting.

Opportunity of expansion: Possibility of expanded application in other farm animals and livestock.

Threats:

Existing competitors: Direct competition with other already established diagnosis tools already in use, such as: MALDI-TOF, PCR, Culture based techniques.

Lack of interest: Lack of interest in accepting a new technology without a sample size large enough to draw a decisive conclusion by the veterinary or dairy industries.

Contamination: Chances of sample contamination, and/or sequencing error that can affect the accuracy of the result.

New technology: Competition from companies inventing new methods belonging to similar but upgraded genre of technology.

Perceived complexity: Resistance from probable customers due to perceived complexity of the technique, or cost to benefit ratio.

3.9 Business Model Canvas

Business Model Canvas	Designed for:	Designed by:	Date:	Version:
	RapidoMast-Dx	**Shuvagata Dhar**	**03.06.2024**	**1.0**

Key Partners

- MinIon Nanopore sequencing Device manufacturer: For supply, technical support and development of the used device.
- In-house scientists: For developing concrete ideas on sample preperation/reagents/used kits.
- Research Institutions: For research collaboration and further technology development (e.g. INN, NMBU, NOFIMA.)
- Government agencies: For regulatory affairs, Patenting and funding.
- Technology providers: For development softwares for data interpretation, data integration (e.g. B3).
- Logistical support: For distribution and supply chain management.
- Dedicated sales and marketing team as the business grows.
- Finance department.

Key Activities

- Sequencing of milk samples using nanopore technology and identification of causative pathogens (e.g. Bacteria) and simultaneous characterization of antimicrobial resistance (AMR)
- Development of software for statistical data analysis (e.g. software like Mango, Voyager).
- Integration with existing structure.
- Training on how to interpret data.

Key Resources

- Proficiency in nanopore sequencing.
- Proficiency in bioinformatics and data analysis (e.g. software for data interpretation).
- Specialized methods for preparing samples.
- Intellectual property rights (legally protected patents and trade secrets).
- Highly proficient staff members (scientists, technicians).

Value Propositions

- Rapid and precise identification of mastitis (within a 5 hours).
- Detailed identification of pathogens and AMR profiling (within 9 hours).
- Possibility of conducting on-farm testing and real-time monitoring.
- Precision in treatment, proper antibiotic utilization.
- Enhanced livestock management and improved milk quality.

Customer Relationships

- Acquire customers by directly approaching them through a formal meeting, followed by a demonstration of the technology we are offering, or by inviting them to our company. We can also meet them in scientific expo or conferences.
- We are going to retain our customers by offering them our value proposition. We can personalise our offering catering to their specific need.
- We will expand by sharing our success stories that we have achieved from the collaboration with our existing customer, and also through further development of our existing product.

Channels

- **Direct approach:** Directly approaching the Dairy companies for a formal meeting and a subsequent demonstration of the technology.
- **Industrial events:** Participating in industrial events like dairy trading expo or conferences.
- **Existing contacts:** Leveraging the existing academic/personal relationship with the decision makers in the target company.

Customer Segment

- Industrial-sized dairy operations/dairy cooperatives/ companies. The end user is the Quality Control Department of the company. (e.g. Quality Control Department of FarmFresh Dairy Enterprises).

Cost Structure

- Expenditures related to research and development.
- Costs associated with sample preparation, instrumentation and software development.
- Costs associated with sales and marketing activities.
- Expenditures related to the wages of employees, including scientists, technicians, and sales personnels.
- Expenses related to regulatory affairs, and obtaining patent certifications.

Revenue Streams

- Tier-based subscription fee (Basic Plan, Standard Plan, Premium Plan).
- Centralized subscription fee: Offer to use the central laboratory of **BioOmiTech**, that encompasses the sample preperation, bioinformatic analysis and result with AMR profile, and subscription to software and cloud support.

This part is discussed more in detail in the **Business model for revenue generation segment of this paper.

Figure 9: Business model Canvas for RapidoMast-Dx.

3.10 PESTEL Analysis

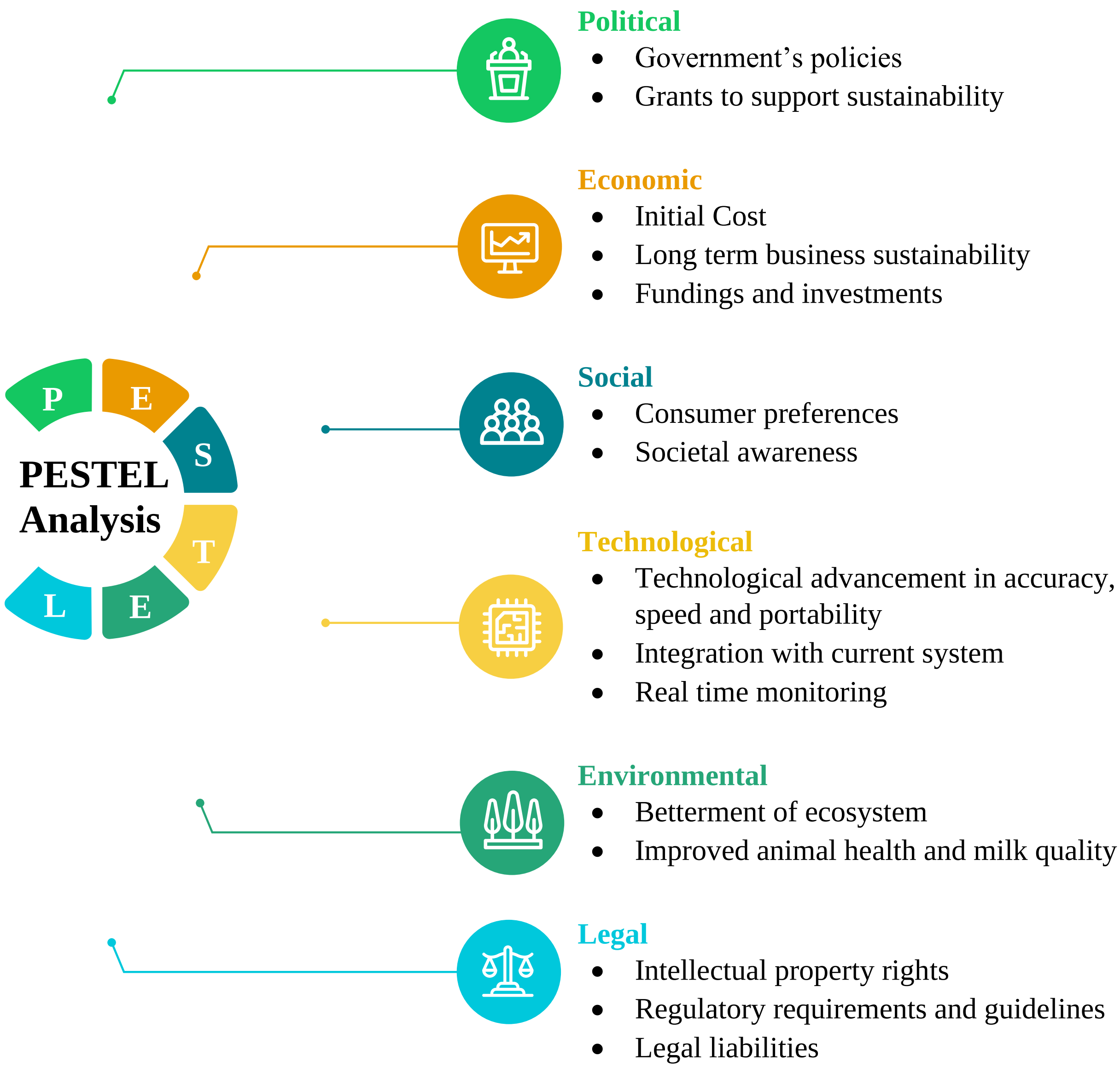


Figure 10: PESTEL Analysis for the proposed technology.

Political factors:

Government's Policies: Governments rules and policies set to retain food safety, animal health and human health in much broader sense, may impact the adoption and utilisation of technology.

Grants to support sustainability: The endorsement of sustainable and responsible methods in dairy farming by government agencies or dairy industry associations could incentivize the implementation of efficient and precise diagnostic instruments.

Economical factors:

Initial costs: The initial cost covering the nanopore sequencing technology including kits required for sample preperation, software for data intepretation along with training may make it difficult for the small scale farmers to adopt the technology.

Long-term business sustainability: In the long run, the resultant betterment of herd-health, reduced veterinary and antibiotic expenditure and improved milk quality will yield to maximise profitability due to technological adoption.

Fundings and investment: By collaborating with other research institutions or dairy cooperatives or even governments patronization can help support in development and commercialisation of the technology.

Social Factors:

Customer preferences: The increasing consumer consciousness and desire for sustainable and ethical dairy farming methods can lead to the implementation of technology that enhance animal welfare and minimize the usage of antibiotics.

Societal awareness: Overuse of antibiotics, antimicrobial resistance and it’s long term effect on human health can facilitate a favorable adoption of this rapid and accurate diagnostic tool amongst socially aware customers.

Technological factors:

Technological advancement in accuracy, speed and portability: The rapid progress of nanopore sequencing technology, encompassing enhancements in precision, acceleration, and flexibility, has the potential to augment the value proposition of this diagnostic technology.

Integration with current system: Seamless integration with current technology in practice can make this technology even easier to adopt and implement.

Real time monitoring: The ability to conduct on-farm testing and monitor in real-time has the potential to provide a major technological edge compared to conventional approaches.

Environmental factors:

Betterment of ecosystem: The specific targeted antibiotic therapy through proper diagnosis may reduce the spread of antibiotics in nature, and in long term can reduce the spread of antimicrobial resistance, thus preserving the ecosystem.

Improved animal health and milk quality: Enhancing animal health management and improved milk quality has the potential to promote the overall sustainability of dairy farming operations.

Legal factors:

Intellectual property rights: Intellectual property rights, such as patents, can play a pivotal role in the process of bringing the nanopore-based diagnostic technology to the market and determining its adoption and implementation in the industry, as well as positioning in the market.

Regulatory requirements and guidelines: The acceptance and use of the technology in the dairy industry may be affected by regulatory requirements and standards for diagnostic testing, antibiotic use, and food safety.

Legal liabilities: Legal liability issues, such as diagnostic accuracy, potential health hazards to animal health, or probable loss of of the farmers can facilitate the adoption of the technology.

3.11 Choosing B2B (Business-to-Business) Business Model for Revenue Generation

Business-to-business (B2B) corresponds to the exchanges or engagements that occur only between business organizations, as opposed to those involving firms and individual consumers. It encompasses the transfer of products, services, or knowledge between two or more enterprises. B2B transactions generally cover greater magnitude and entail more intricate negotiations compared to B2C (business-to-consumer) purchases. B2B spans several arrangements, including manufacturers engaging in transactions with distributors, wholesalers engaging in transactions with retailers, or companies collaborating with other businesses to develop novel products or services. Moreover, B2B transactions can also take place between organizations operating in essentially different in kind of industries or demographics (Pereira, 2023). A prominent feature of B2B transactions is their tendency to establish ongoing long-term relationships between the participating businesses. The reason for this is because B2B transactions frequently necessitate substantial investments of time and money, such as the creation of novel products or the establishment of supply networks. Trust and reliability are essential elements for effective B2B collaborations (Pereira, 2023).

For our Min-ION nanopore sequencing based technology for rapid and accurate mastitis detection with AMR profile of the causative pathogens (RapidoMast-Dx), I have chosen B2B business model.

3.11.1 Reasons why B2B business model is best suited for RapidoMast-Dx:

1. **Type of Target Customers:** The main client for our rapid and precise mastitis diagnostic technique RapidoMast-Dx are Dairy Companies/Co-operatives. They are mostly corporate entities, which makes a business-to-business (B2B) model suitable for the business.
2. **Alignment of the Value Proposition with target customer:** The key value propositions, such as the ability to quickly identify pathogens within 5 hours, detect antimicrobial resistance (AMR) genes for targeted and precise antimicrobial treatment, ability to comprehensive detection of both gram-positive and gram-negative pathogens, and the potential for on-site/on-farm testing, are particularly relevant for

business customers in the dairy sector who are seeking to enhance milk quality, herd health management and antimicrobial vigilance.

3. **Seamless Integration:** Integrating RapidoMast-Dx with existing Quality Control management system and equipment and workflows is more practical in a business-to-business (B2B) scenario.
4. **Scalability and constant revenue generation:** RapidoMast-Dx can gain scalability and regular revenue streams, which are significant advantages of a B2B strategy, by providing subscription-based models or centralized testing services to dairy businesses.
5. **Regulatory compliance:** In the fields of livestock diagnostics and food safety, strict adherence to regulations is generally required. This can be comparatively easy to manage when working with established business customers in a business-to-business (B2B) model, rather than directly selling to consumers.
6. **Strategic Partnership:** The B2B approach facilitates strategic partnership between RapidoMast-Dx and FarmFresh dairy in terms of validation, development and process simplification, which in terms can help us gain more customers.

3.11.2 Revenue generation:

Tier based Subscription Plan depending on volume of test:

Basic Plan		**Standard Plan**		**Premium Plan**	
Monthly Fees	10,000 NOK	**Monthly Fees**	20,000 NOK	**Monthly Fees**	50,000 NOK
Number of Samples	100	**Number of Samples**	200	**Number of Samples**	Unlimited.
Access	To one Nanopore sequencing device with Kits and reagents.	**Access**	To two Nanopore sequencing devices with Kits and reagents.	**Access**	Unlimited access to dedicated device and testing kits.
Feature	Basic data analysis and reports.	**Feature**	Comprehensive data analysis and reports.	**Feature**	Advanced data analysis with AMR profile and reports.

Tech support	Email and online support.	**Tech support**	Priority email and online support.	**Tech support**	24/7 tech support through phone, email and online availability.
Training	Access to prerecorded webinars and materials.	**Training**	Annual on-site training sessions.	**Training**	Quarterly on-site refreshers training sessions and consultations.
Access to software	N/A.	**Access to software**	Regular software update and added features.	**Access to software**	Regular software updates with customised reports.

Centralised subscription	
Monthly Fees	100,000 NOK.
Lab	Dedicated company lab for the target customers.
Feature	Advanced data analysis with AMR profile and reports, customised to the customers need, with treatment suggestion, annual usage tracking.
Tech support	24/7 tech support through phone, email and online availability.
Performance meeting	Quarterly on-site performance meeting and consultations.
Software	Dedicated software for real time monitoring of data and upgradation.
Account manager	Account manager solely responsible for the overall operations with the target customer.
Support	Logistics and transportation support for sample.

Figure 11: Subscription plan based on volume of test.

Some add-on enhancements to increase the appeal of the subscriptions:

- Reduced pricing in comparison to individual testing.
- Expedited sample processing and accelerated turnaround time.
- Ability to obtain the most recent software and protocol updates.
- Specialized technical assistance and instructional services

This subscription based B2B model will provide FarmFresh dairy enterprises with a convenient, adaptable, and economical mean of utilizing our cutting-edge mastitis detection technology **RapidoMast-Dx**.

4. Discussion

Bovine mastitis has become widely accepted as a significant disease in dairy herds, mostly due to its associated financial losses. The complexity of the disease and the growing importance of the dairy industry, along with public health issues, made it necessary to come up with an accurate, rapid, and comprehensive diagnosis for mastitis, along with a scope to reduce the unnecessary use of antibiotics and to slow the spread of antimicrobial resistance. In this thesis paper, I have explored the business avenues for whole genome sequencing-based mastitis detection and AMR profiling solution (RapidoMast-Dx). Starting with a brief discussion about mastitis, its associated market size, current technologies in practice, and our offering that will advance the disease detection and AMR profiling of the causative pathogens, I moved to the potential steps that are needed to be taken to successfully commercialize this diagnosis tool. In this section of the paper, I will summarise the findings and draw significant conclusions.

The key value proposition emphasized in this study is the capability of RapidoMast-Dx to identify mastitis pathogens within 5 hours and detect their antimicrobial resistance (AMR) genes within 5-9 hours from the time the sample is collected, with high sensitivity (100%) and specificity (92.3%). This significantly reduces the time it takes to diagnose compared to traditional culture procedures. In addition, the technique effectively identifies both gram-positive and gram-negative bacteria, together with a diverse array of AMR genes, resulting in a more comprehensive diagnostic assessment.

The market segmentation was done by acknowledging each of the segment's end users' needs and their use of the technology. The beachhead market selection was done by scoring the segments according to their alignment with our offering, based on how we can focus on serving them with available limited resources. I have chosen the the dairy companies/cooperatives in Norway as my beachhead market, and proceeded to do an end-user profiling, to understand what is their needs, wants, motivations, and capability of buying new technology and how I can fulfill them. I personified the fictional company based on real evidence, naming it FarmFresh Dairy Enterprises, and the end-user was the Quality Control Department. Then I proceeded to a TAM analysis, to understand my market opportunity. The full life cycle use case was done to outline the needs that are not being fulfilled by the existing products, and how we can fulfill those needs stepwise by seamlessly integrating our technology into their current practice. Then I quantified our value proposition against the current state-of-the-art technique in practice, to pinpoint the criteria in which we outweigh the present method in use. I have defined the core value proposition of RapidoMast-Dx based on what is unique about the technique, and how it aims to serve our target customers' needs. SWOT analysis was done for RapidoMast-Dx, which shows the strength of the product and the opportunities that we have to start and grow a sustainable business plan in Norway. Despite the threats of being a comparatively new technology and competition from existing well-established companies, our strength surpasses these by leveraging the unique value propositions and shows the opportunity to seamlessly integrate this technology in current practice and portability.

Creating an effective business plan for a novel technology like RapidoMast-Dx requires a comprehensive and diverse strategy. The business model Canvas depicted how we are going to do business with our target segment from every possible viewpoint. PESTEL analysis was done to see how our business will accommodate itself in the Political, Social, and Economical environment of Norway, a country that thrives on sustainability, yet so welcoming to new technologies. In the B2B business model, I showed how we are going to do business and how we are going to generate revenues from multi-tiered subscription plans. I have also justified in the section why the B2B approach is best suited for my product, and how it will help us in generating revenues, both in short-term and long-term perspective.

5. Conclusion

Enhancing mastitis diagnostics facilitates the rapid and accurate identification of mastitis. Additionally, this approach reduces economic losses and ensures the protection of public health by preventing mastitis and improving the management of dairy animals. Technological advancements have resulted in a significant transition from using conventional diagnostic methods with low specificity and/or sensitivity to employing highly complex, fast, and dependable molecular diagnostic techniques that offer high accuracy. The business model of RapidoMast-Dx, a pioneering nanopore-based technology for rapid and accurate diagnosis of mastitis with an antimicrobial resistance (AMR) profile, aims to meet customer needs by offering a sustainable, cost-effective, and environmentally friendly solution for preserving animal health,, with an ultimate goal to provide significant benefits to humanity.

6. Future Perspective

The future outlook for this business is highly favorable. Important areas for development encompass technology progressions, such as enhanced sensitivity, automated procedures, and extended applications to various diseases affecting livestock. Market expansion can be accomplished by establishing a global presence and forming alliances with herd management systems. Providing education and support to customers, as well as obtaining regulatory approvals, will increase the acceptance and trustworthiness of the product. Implementing cost management measures, such as leveraging economies of scale and adopting subscription models, can effectively reduce the overall expenses associated with the technology, making it more accessible and cheap. To strengthen its market position and influence in the dairy farming industry, it can focus on sustainability, animal welfare, and utilizing comprehensive dataset and AI for predictive analytics.

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