# Defining A Business Model For A Non-Profit Research Core Facility For Nano Delivery Systems Of Nucleic Acid Therapies

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MASTER THESIS

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# Abstract

Nucleic acid therapies represent a groundbreaking approach in modern medicine, capable of potentially curing previously untreatable diseases by modifying gene expression at the DNA or RNA level. Despite their promise, effective delivery of these therapies remains a significant hurdle. Addressing this challenge is the central mission of the soon-to-be-established Chalmers Precision HealthTech Hub. This organization aims to facilitate collaboration between industry and academia, focusing on the formulation and characterization of delivery methods for nucleic acid therapies. By providing the necessary infrastructure for collaborative research, the organization seeks to translate scientific discoveries into practical healthcare solutions. The non-profit nature of the organization introduces complexities in developing a sustainable business model. This master's thesis investigates these challenges, proposing a robust business model to ensure the organization’s longevity. Through interviews with key stakeholders including researchers, start-ups, big pharma companies, and international experts, the study examines critical aspects such as stakeholder needs, the future landscape of Advanced Therapy Medicinal Products (ATMPs), and business model strategies for non-profit entities.

The project culminates in the development of a two-layer business model canvas that differentiates programmatic operations from fundraising activities, addressing the unique complexities faced by non-profit organizations. Additionally, a flexible payment model is proposed to accommodate the financial capacities of various customer segments. The thesis concludes with recommendations for the Hub's future sustainability, emphasizing the need for continuous adaptation and strategic planning. This study contributes to the understanding of business model development for non-profit research centers and offers practical insights for the operational success of Chalmers Precision HealthTech Hub.

**Keywords:** Nucleic Acid Therapies, ATMPs, Business Model, Non-profit Organization

# Sammanfattning

Nukleotidbaserade läkemedel representerar en banbrytande metod inom modern medicin, med potential att bota tidigare obotliga sjukdomar genom att modifiera genuttryck på DNA- eller RNA-nivå. Trots dessa möjligheter återstår en betydande utmaning gällande effektiv leverans av dessa terapier. Att adressera denna utmaning är en central del för det snart etablerade Chalmers Precision HealthTech Hub. Organisationen syftar till att underlätta samarbete mellan industri och akademi, med fokus på formulering och karakterisering av leveransmetoder för nukleotidbaserade läkemedel. Genom att tillhandahålla nödvändig infrastruktur för forskningssamarbeten strävar organisationen efter att översätta vetenskapliga upptäckter till praktiska hälso- och sjukvårdslösningar. Organisationens icke-vinstdrivande karaktär introducerar komplexiteter i utvecklingen av en hållbar affärsmodell. Masteruppsatsen undersöker dessa utmaningar och föreslår en robust affärsmodell för att säkerställa organisationens långsiktiga hållbarhet. Genom intervjuer med intressenter, inklusive forskare, start-ups, stora läkemedelsföretag och internationella experter, undersöker studien kritiska aspekter såsom intressenters behov, framtiden för Advanced Therapy Medicinal Products (ATMPs) och affärsmodellstrategier för icke-vinstdrivande organisationer.

Projektet resulterade i en tvådelad business model canvas som särskiljer aktiviteter inom organisationen mot aktiviteter gällande extern finansiering och adresserar därmed de unika komplexiteter som icke-vinstdrivande organisationer står inför. Vidare föreslås en flexibel betalningsmodell för att kunna tillgodose de ekonomiska kapaciteterna hos olika kundsegment. Uppsatsen avslutas med rekommendationer för organisationens framtida hållbarhet, med fokus på behovet av kontinuerlig anpassning och strategisk planering. Studien bidrar till förståelsen för affärsmodellutveckling för icke-vinstdrivande forskningscentrum och erbjuder praktiska insikter för Chalmers Precision HealthTech Hubs operativa framgång.

**Nyckelord:** Nukleotidbaserade läkemedel, ATMPs, Affärsmodell, Icke-vinstdrivande organisation

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Gothenburg, May, 2024

Ida Björsing and Joel Wramås

# Table of contents

# Abbreviations

| | |
|---|---|
| ATMPs | Advanced Therapy Medicinal Products |
| sCTMPs | somatic Cell Therapy Medicinal Products |
| TEPs | Tissue-Engineered Products |
| GTMPs | Gene Therapy Medicinal Products |
| LNP | Lipid Nano Particle |
| AAV | Adeno-Associated Virus |
| ASO | Antisense-Oligonucleotide |
| PI | Principal Investigator |
| NPO | Non-Profit Organization |
| BMC | Business Model Canvas |
| OP-BMC | Osterwalder and Pigneur Business Model Canvas |
| SMEs | Small and Medium-Sized Enterprises |
| RCOV | Resources, Competencies, Organizational Structure, and Value proposition |
| IP | Intellectual Property |
| FDA | Food and Drug Association |
| EMA | European Medicines Agency |
| CEO | Chief Executive Officer |
| CTO | Chief Technology Officer |
| CSO | Chief Scientific Officer |
| RQ | Research Question |

# Definitions

*ATMP*
Advanced Therapy Medicinal Product (ATMP) is a classification specific to the EU, ensuring that these products are regulated as medicines throughout the region under the ATMPs regulation (EC/1394/2007). These classified products are medicines for human use with an active therapeutic substance based on at least one of the following: technology to modify patient genome, recombinant nucleic acids or genes, substantially manipulated cells, cells intended for a different essential function in the patient versus the donor, or engineered tissue. ATMPs is an umbrella concept that includes a series of subcategories such as gene therapy medicinal products (GTMPs), somatic cell therapy medicinal products (sCTMPs), tissue-engineered products (TEPs) and combined products (tissue or cell-associated to a device). [1]

*Business model*
Currently, there exist no universally accepted definitions of the concept business model. However, many are often linked to Peter Drucker's pioneering questions regarding the identification of the customer and their values. In addition to addressing these queries, a sustainable business model must also tackle one of the most fundamental questions within an organization, namely: *"How is the organization intended to make money?"*. [2; 3; 4]

*Non-Profit Organization*
A non-profit organization (NPO) is established and operated with the aim of serving charitable or socially beneficial purposes rather than generating profits. These organizations may be dedicated to religious, scientific, educational, charitable, literary, health-related, or animal welfare causes [5]. A key difference between non-profit and for-profit entities is their core missions. For-profit organizations seek to generate profits for their owners or shareholders, whether individuals or corporate entities. In contrast, NPOs operate without a concept of ownership, instead focusing on serving a

broader public purpose. This fundamental distinction shapes their objectives and priorities [6].

*Nucleic Acid Therapies*

Nucleic acid therapies, also known as nucleotide-based therapeutics, are composed of nucleotides, which serve as the basic structural units comprising nucleic acids such as DNA and RNA [7]. Even though many nucleic acid therapies fall under the category of GTMPs, and can thereby be considered as ATMPs, there are some exceptions. Since oligonucleotides and mRNA vaccines do not meet the criteria of GTMPs, they are not considered as ATMPs by the regulatory frameworks [1; 8]. In contrast to conventional medications that focus on proteins, nucleic acid therapies alter gene expression at the DNA or RNA level to achieve therapeutic outcomes. These therapies present a groundbreaking approach capable of addressing diseases previously considered untreatable [8].

*SMEs*

The primary criteria for categorizing an enterprise as a Small and Medium-sized Enterprise (SME) include its staff headcount and either its turnover or balance sheet total. An enterprise with fewer than 250 employees and either a turnover below €50 million or a balance sheet total under €43 million qualifies as an SME. Additional considerations apply to determine whether the enterprise is classified as small or micro. [9]

*Stakeholder*

Stakeholders are individuals, social groups, or entities with vested interests, legal obligations, moral rights, or other concerns related to the decisions or outcomes of an organization, often a business, corporation, or government entity. These stakeholders can impact or be impacted by the organization's goals and objectives. [10]

*Sustainability in context of non-profit organizations*

Sustainability is commonly characterized by three dimensions: social, economic, and environmental [11]. Yet, for a non-profit organization, sustainability takes on a more focused meaning. In this context, sustainability relates to the organization's ability to persist and carry out its mission effectively. For non-profits, sustainability ensures that they can fulfill their obligations to clients, patrons, and communities over time [12].

# 1 Introduction

*Before exploring the full breadth of this report, it is imperative to grasp the background of the thesis project. This section provides a concise overview and a comprehensive empirical context, enabling the reader to understand the significance of investigating this subject. Furthermore, it introduces the problem formulation and the research questions that underpin the master thesis. Additionally, this section identifies the target audience and outlines the delimitations of the project, followed by a detailed thesis outline to offer the reader a holistic view of the report.*

## 1.1 Background

The rapid evolution of nucleic acid therapies has introduced a paradigm shift in disease treatment. Unlike traditional medications, which primarily target proteins and aim to alleviate the symptoms of a disease, nucleic acid therapies operate on a deeper level. By modifying gene expression at the DNA or RNA level, these therapies address the root causes of diseases, offering the potential for more effective and long-lasting therapeutic effects. These treatments represent a revolutionary approach with the potential to address previously untreatable diseases [8]. Over recent years, this field has attracted significant attention and investment from pharmaceutical industries and academia alike, signifying its growing importance [7; 13].

However, despite the promising therapeutic potential, significant challenges persist in delivering nucleic acid therapies effectively to target cells within the body. Achieving precise delivery requires the development of sophisticated delivery vehicles capable of protecting the therapeutic material from physical barriers and the immune system while ensuring accurate release at the right location and at the right time [8]. Addressing this challenge demands a more comprehensive analysis and characterization of both nucleic acid therapies and delivery methods.

In 2017, researchers at Chalmers University recognized this knowledge gap and launched an initiative known as FoRmulaEx, dedicated to advancing research in this area. As this initiative nears completion, there is a growing interest in continuing this work in a new organization, known as Chalmers Precision HealthTech Hub. However, establishing a suitable business model for this organization presents a unique challenge due to its intended non-profit nature. Many of the research and frameworks concerning business models are intended for for-profit organizations [14], posing a challenge in identifying a suitable model for a non-profit entity focused on promoting research. Additionally, the organization will operate in a complex sector, constantly evolving and changing at a rapid pace. Therefore, the main objectives of this thesis are to develop a suitable business model for Chalmers Precision HealthTech Hub and to ensure its long-term relevance in a rapidly evolving industry.

## 1.2 Empirical Context

To provide a clear understanding of the research project's objective, this section presents an empirical context focusing on the forthcoming establishment of the center. Firstly, the empirical context explores the Advanced Therapy Medicinal Product (ATMP) industry in Sweden. Although Chalmers Precision HealthTech Hub will not be exclusively focused on ATMPs, its infrastructure and activities will be highly pertinent to this sector. In this context, it is crucial to be aware of the various initiatives established to promote research in this field, as they could serve as potential collaborators with the organization in the future. Furthermore, this section elaborates on the success of the preceding initiative, FoRmulaEx, upon which the upcoming organization, Chalmers Precision HealthTech Hub, will be built. Additionally, it introduces the initial ideas behind Chalmers Precision HealthTech Hub, and the challenges associated with developing a business model for a non-profit entity. It is noteworthy that existing research on business models primarily focuses on for-profit organizations, thus intensifying the complexity of this task.

### 1.2.1 **ATMP Industry In Sweden**

Recently, there has been rapid growth in this therapeutic area, with the establishment of both regional and national initiatives and companies

stemming from the technology of ATMPs [7; 13]. Various initiatives originate from different universities across Sweden, and some of the initiatives are mentioned in Table 1.1. These initiatives aim to strengthen development and collaboration within the ATMP industry in Sweden.

**Table 1.1. Example of ongoing regional initiatives in the ATMP industry in Sweden [1].**

| ***Initiative*** | ***Origin*** | ***Purpose*** |
|---|---|---|
| GeneNova | ***Royal Institute of Technology (KTH)*** | For safer, more efficacious, and accessible AAV gene therapy |
| Eatris | ***Uppsala University*** | Making Swedish ATMP research infrastructure accessible |
| IndiCell | ***Lund University*** | Developing and consolidating a sustainable, collaborative, and world-leading innovation milieu based on Individual cell therapy |
| NextGenNK | ***Karolinska Insitiutet*** | For novel, safe, affordable, and curative cancer treatments based on Natural Killer Cells |
| SWECARNET | ***Karolinska Institutet*** | SWECARNET is an open network of key representatives in the Swedish CAR T field from academia, healthcare, and industry working towards knowledge exchange and development of standardized processes for CAR T delivery and follow-up |
| CCRM Nordic | ***Gothenburg*** | Nordic infrastructure for development, manufacture, and commercialization of ATMPs |

Besides the regional initiatives, there are also national initiatives regarding ATMP in Sweden. In this context, ATMP Sweden is the industry organization in Sweden that serves as an umbrella for the majority of ongoing regional initiatives, thereby holding responsibility for the Swedish ATMP ecosystem. Furthermore, ATMP Sweden has initiated a project called ATMP 2030, which aims to establish a vision-driven innovation environment for the long-term transformation of the systems necessary for the successful development and implementation of advanced cell and gene therapies. The project's objective is to convene relevant stakeholders with the goal of positioning Sweden as a global leader in the development and implementation of advanced therapies by 2030. [1]

However, despite this visionary goal and the considerable expertise within both industry and academia, there is a lack of cohesive collaboration and

infrastructure for the characterization and delivery of nucleotide-based therapies.

### 1.2.2 **FoRmulaEx**

In 2017 researchers at Chalmers University recognized the knowledge gaps regarding the characterization and delivery of nucleic acid therapies, and a collaboration between three different universities in Sweden was initiated, known as FoRmulaEx. The initiative aimed to establish an industrial research center fostering collaboration between academia and industrial partners in Sweden to advance research in this domain. The project received funding from Stiftelsen för Strategisk Forskning (SSF). During the mid-term evaluation, the initiative was praised for its achievements in the field, and further, the initiative is considered successful due to the collaborations that were developed between academic researchers and companies within the industry [15; 16]. However, as FoRmulaEx approaches its conclusion in 2025, a need arises to establish an organization that can carry forward the achievements of FoRmulaEx [17], sustaining and accelerating the momentum generated. This realization was reinforced in 2023 through a market analysis conducted by Triathlon Group, which highlighted the growing scope of nucleic acid therapies and the need for ongoing efforts to address the challenges concerning delivery of nucleic acid therapies, as well as the evolving opportunities within the industry [17]. Thus, the concept of Chalmers Precision HealthTech Hub emerged.

### 1.2.3 **Chalmers Precision HealthTech Hub**

The Chalmers Precision HealthTech Hub, an upcoming non-profit initiative led by Chalmers University, is nearing establishment. Scheduled to launch in 2026, it coincides with the completion of the GoCo research facility in Gothenburg. The organization is aimed at fostering collaboration between industry and academia and providing the necessary infrastructure to facilitate breakthroughs in drug delivery. Such an organization would not only offer a dedicated space for collaborative endeavors but also adapt to the changing needs of the dynamic therapeutic landscape. Furthermore, its primary objective is to catalyze the development of ventures and facilitate the effective utilization of research findings. Ultimately, this effort aims to translate these findings into medicines that can be used in patient care.

To bring this vision to reality, the hub will provide a dedicated space for collaborative initiatives, adeptly adjusting to the evolving demands of the dynamic therapeutic landscape. Figure A.1 in Appendix A.3 delineates the primary activities envisaged for the center:

1. Service and Infrastructure
   The center will offer formulation and advanced bioanalytical services provided by researchers and affiliated service providers, utilizing state-of-the-art infrastructure. Importantly, this infrastructure provision is intended as a "fee-for-service" part of the organization.

2. Advisory Board
   An advisory board comprising renowned researchers will be established. This board will integrate research assistance, strategic development, and a commitment to research quality to ensure impactful outcomes.

3. Entrepreneurial Postdoc Program
   The center will implement a program designed to provide participants with a dual focus on academic and business experiences, enhancing their career opportunities.

While these three activities may seem straightforward, it's crucial to note the complexity that arises. As the center has yet to be established, various stakeholders hold different opinions and visions regarding its purpose and operation. This diversity of opinions adds layers of complexity to the development process. This complexity is furthered by the need to develop a suitable business model for the proposed center**.**

### 1.2.4 **Challenges In Adapting Business Models For Non-Profit Organizations**

A business model delineates how a company defines, produces, delivers, and presents value tangibly [3]. Developing a business model for an organization may seem simplistic; however, existing research and frameworks in management literature predominantly focus on for-profit organizations, which prioritize profit generation. This poses a significant challenge when considering non-profit organizations (NPOs), as they operate with distinct goals and motivations. Unlike for-profit organizations, the success of NPOs is typically measured by their impact within their respective fields. While

for-profit organizations focus on financial gains, NPOs prioritize achieving, for example, social, scientific, or environmental objectives. Consequently, their activities are dynamic and heavily reliant on their business ecosystem. [14]

Given these differences, several considerations must be carefully addressed and tailored to the unique objectives of NPOs. This necessitated a deeper exploration of this area to gain valuable insights into how NPOs navigate and overcome this challenge. Understanding how to adapt existing business models and frameworks to the context of NPOs is crucial for ensuring their long-term success and sustainability.

## 1.3 Problem Formulation

The emergence of nucleic acid therapies represents a transformative frontier in medical science, promising targeted and personalized treatments for many, previously untreatable, diseases. In the context of Gothenburg, the proposed establishment of Chalmers Precision HealthTech Hub introduces a significant initiative aimed at advancing research and development in this domain. The success of this endeavor hinges not only on scientific advancements but also on the formulation of a robust and adaptive business model that addresses the diverse needs and expectations of stakeholders while ensuring sustained relevance in a rapidly evolving landscape.

Central to this initiative is the exploration of suitable business models tailored to the unique characteristics and requirements of the envisioned center. Understanding the spectrum of stakeholders involved – spanning academia, industry, healthcare practitioners, and regulatory bodies – is paramount in devising a model that effectively balances their needs and expectations. Consequently, the primary objective of this thesis is to elucidate a comprehensive understanding of the stakeholders' needs, requirements, and expectations and delineate how these can be integrated into the organizational structure of Chalmers Precision HealthTech Hub.

This thesis will explore the essence of a business model and distinguish it from a revenue model, laying the theoretical foundation for subsequent analysis. Drawing insights from existing literature and case studies, it will analyze various potential business models applicable to a non-profit research center, with a focus on how similar organizations navigate critical questions

such as payment models, academia versus industry dynamics, and the utilization of personnel resources.

Furthermore, in the face of a dynamic and rapidly evolving landscape within nucleic acid therapies, the sustainability and relevance of the proposed center pose significant challenges. This thesis endeavors to address these challenges by projecting future trends and assessing the center's capacity to leverage its resources and expertise to stay ahead of the curve. Additionally, potential risks and barriers to the center's continued relevance will be identified, and strategies for their mitigation will be proposed.

Moreover, this thesis aims to provide actionable insights and recommendations that will inform the development of a resilient and adaptable business model for Chalmers Precision HealthTech Hub. By doing so, it seeks to contribute to the broader goal of advancing research and innovation in nucleic acid therapies while fostering collaboration between industry and academia within the life science sector.

Ultimately, the goal is not only to establish a suitable business model for the proposed center, but also to provide insights to individuals active within the non-profit sector of the life science industry. These insights will illustrate what a business model is and how it can be adapted to the unique characteristics of NPOs.

## 1.4 Research Questions

This thesis aims to investigate two primary research questions:

1. *What is a suitable business model for the proposed center adapted to the requirements, characteristics, and needs of different stakeholders?*
2. *How can the center ensure continued relevance and a sustainable value proposition considering the dynamic and rapidly evolving field of nucleic acid therapies?*

Note that, in the remaining sections of the report, these research questions will be referred to as RQ1 and RQ2.

## 1.5 Target Audience

The primary audience for this master thesis is decision-makers and stakeholders involved in NPOs within the life science sector, especially nucleic acid therapies, as they can apply these findings to their knowledge when developing or collaborating with complex organizations such as non-profit research centers. Furthermore, the conclusions in this report may also apply to decision-makers and stakeholders within other, rapidly evolving, sectors than life science. Additionally, this report is also targeted toward researchers, academics, and university students who are interested in topics such as life science, nucleic acid therapies, business development, and business models.

## 1.6 Delimitations

Within the scope of this project, it is recognized that the development of a robust business model is an iterative process, subject to refinement as new insights and information become available. However, in alignment with the research questions outlined in section 1.4, priority has been given to addressing these inquiries. This approach ensures that the research remains focused and directed towards its intended objectives.

Moreover, time constraints represent a significant consideration. Time is a crucial factor that must be carefully managed to determine the number of interviews feasible within the allotted time frame. It is important to acknowledge that due to these constraints, not all relevant stakeholders could be interviewed. Therefore, a distinction was made between primary stakeholders, who were addressed within the scope of this project, and secondary stakeholders, who, while important, were not addressed within the project's scope. Among the secondary stakeholders are healthcare professionals and regulatory bodies. Additionally, it is necessary to define the tasks and analyses achievable within the project's duration to effectively manage expectations and ensure the project's feasibility and success.

Besides the stakeholder prioritization, the project did not extensively address the funding aspect of the organization's business model. This decision was primarily driven by time constraints and the prioritization of other research areas. Nevertheless, it is important to acknowledge that funding and

financiers significantly influence the development of an organization's business model.

## 1.7 Thesis Outline

**Table 1.2. Summary of the chapter-by-chapter focus.**

| *Chapter* | *Focus* |
|---|---|
| ***1 Introduction*** | Introduces the reader to the relevant background and empirical context required to understand the problem formulation. Furthermore, the research questions, target audience and delimitations are presented. |
| ***2 Methodology*** | Presents the research approach and method design of the project. It also presents the study's goal, scientific, research and work methods along with the techniques for gathering data and how to ensure reliability of results. Lastly the section includes the research methodology overview and research ethics. |
| ***3 Literature Review*** | Presents the literature review including topics that will be relevant for the project. The section includes an overview of ATMPs, Business models and Non-Profit-Organizations with included subsections of relevant topics. |
| ***4 Results*** | This section gives an overview of the results obtained from the interview study conducted in the project and the structure is organized in alignment with the research questions and the subquestions that were developed based on these. Lastly the suggested business for Chalmers Precision HealthTech Hub is presented. |
| ***5 Discussion*** | Firstly, a gap analysis is presented where the results from the interviews are compared to the literature review. Moreover, a thorough elaboration of the suggested business and additional payment model are presented in terms of development, advantages and disadvantages, and adaptability and sustainability. Lastly the generalizability of findings is discussed. |
| ***6 Roadmap and Final Recommendations*** | Suggestions of important aspects for the project leaders of Chalmers Precision HealthTech Hub and other similar organizations are highlighted. Among the topics are continuous development of the business model, future financial opportunities, potential risks and barriers and how they can be mitigated, the importance of facilitating important partnerships, and competence development. |
| ***7 Conclusion*** | Concluding results are presented and the research questions are answered briefly. Moreover, the research reliability, limitations, and contribution to further research are discussed. |

# 2 Methodology

*This section presents the research strategy and method that was used in this master's thesis, intending to provide insights into the research process and explain the reason why specific methods were chosen. A seven-step process was followed to increase the results' reliability and validity.*

## 2.1 Research Approach And Method Design

Research work involves a systematic investigation with the overarching goal of developing and refining theories, and in some cases, the solution to problems [18]. The need for research arises from missing adequate and systematized information to answer certain given problems [19]. Further, the reasons that motivate one to conduct research may either come from a theoretical gap or a practice demand. The latter is known as applied research, to apply the results in practice to assist professionals in their day-to-day work [19]. As the purpose of this master's thesis is to conclude findings and recommendations for non-profit organizations within the life science sector, the purpose of this project stems, primarily, from a practical demand.

There are certain procedures one can follow to carry out effective research work which guarantees the reliability of the results. In 2014, Dresch et al. illustrated the methodology by adopting a certain pendulum [20], with the following parts:

1. Reasons to conduct a study
2. Study's goal
3. Scientific methods
4. Research methods
5. Work methods
6. Techniques for gathering and analyzing data
7. Reliable results

This specific framework was applied when the structure of this master's thesis was planned, but also re-evaluated throughout the project. The following sections will go through these seven steps, by elaborating on the theory underpinning the concepts and detailing their implementation in this thesis project.

### 2.1.1 **Reasons To Conduct A Study**

Initiating scientific research begins with defining the reasons for undertaking the investigation. The motives for conducting a study can be many, including the desire to share a new and compelling piece of information, address a crucial issue, or provide a comprehensive understanding of a specific phenomenon [21].

The motivation for conducting this master's thesis was to increase the knowledge of business models for non-profit organizations within the life science sector, with the hope of developing one for a specific project. Thus, this thesis stems from a combination of the reasons above, with an emphasis on providing an increased understanding of a specific phenomenon.

### 2.1.2 **Study's Goal**

In addition to defining the reason behind the research, the goals that one wishes to achieve with the research must also be defined by the researcher. Dresch et al. presents four different types of research studies, which are whether one wishes to: explore, explain, describe, or predict some behavior of the phenomenon that is being studied [20]. In this context, explore means to dig into an idea or phenomenon to come up with guesses or broader ideas from specific examples. Conversely, explain involves developing or elaborating on a theory to elucidate the relationship between concepts, the underlying reasons for events, and the mechanisms of their occurrence. Describe means to point out and talk about the phenomenon and its related factors or possible reasons, while predict involves leveraging existing knowledge or theories to anticipate future events. [22]

In this study, prior research was utilized to gain a comprehensive understanding of the relevant industry, non-profit organizations, and business models, primarily focusing on descriptive aspects. Furthermore, a

deeper insight into these domains, along with stakeholders' needs, expectations, and requirements, was achieved through extensive exploration via multiple interviews and one workshop. The ultimate goal of the study was to develop a suitable business model for the proposed Chalmers Precision HealthTech Hub.

### 2.1.3 **Scientific Methods**

After defining the research goals, a researcher must adopt a strategy and state the scientific method that will serve as a guide when developing the research. Dresch et al. propose three different types of scientific methods, these are inductive, deductive, and hypothetical-deductive [20]. The inductive method involves deriving an idea from data that has been previously ascertained or observed. Within the inductive method, observation is the key point in constructing scientific knowledge. Based on these observations, one can propose theoretical foundations for the object of study. In the deductive method, on the other hand, the researcher starts with a certain theory, to propose elements that may serve to explain or predict some given phenomena. The hypothetical-deductive method involves identifying a problem based on prior knowledge, and formulating and testing hypotheses, leading to predictions and explanations [20].

In addition to these three scientific methods, one could also add the abductive method, which is regarded as a combination of the inductive and deductive methods. The abductive method is driven by empirical data and hypotheses in parallel, and an equal engagement with empirical data and existing theory [23].

In this master’s thesis, the scientific method was mostly inductive, as knowledge was developed based on findings through literature review and multiple interviews, with limited pre-defined hypotheses and theory. During the early stage of this thesis, some assumptions and hypotheses were made, however, each interview and data collection was based on open-ended questions, and not formulated to test assumed knowledge. In addition, as new and important areas emerged during the interviews, the literature review was updated to include certain topics. Hence, the approach adopted was also deductive. The integration of inductive and deductive methodologies leads to the conclusion that the overall scientific method employed was abductive.

### 2.1.4 **Research Methods**

There are numerous research methods that one can use for different purposes, depending on the research problem [20]. A cross-sectional study was used in this master's thesis. Cross-sectional studies are observational investigations that analyze data from a population captured at a specific moment in time, which is useful for establishing initial evidence for future more advanced research [24]. This approach was deemed suitable for this research problem, as it allowed for the exploration of multiple dimensions of the phenomena under investigation within a manageable time frame.

Other research methods, such as longitudinal studies, cohort studies, and experimental studies, were not chosen due to their respective limitations or unsuitability for the scope of this study. For example, longitudinal studies would have required a longer duration to observe changes over time [25], while experimental studies may not have been feasible given the nature of the research problem [26].

The data was gathered through numerous semi-structured open-ended interviews. The choice of semi-structured open-ended interviews was deliberate, as it allowed for a deep exploration of participants' perspectives, experiences, and insights regarding the research topic. Unlike structured interviews, which restrict responses to predefined options, semi-structured open-ended interviews strike a balance between guidance and flexibility. While questions were prepared in advance to ensure coverage of key topics, the discussion remained open-ended, allowing participants to talk freely on relevant aspects and share their unique viewpoints.

### 2.1.5 **Work Methods**

The work method outlines the logical sequence of steps the researcher will undertake to achieve the study's objectives. The work method must be well-structured and diligently followed to ensure the replicability of the study. The method is rooted in the defined scientific method, and its design should reflect this. In essence, the research methodology serves as a methodological guide [20].

Initially, a series of subquestions were formulated and aligned with each primary research question, as outlined below. This approach was undertaken

to gain a deeper understanding of the specific aspects that needed to be investigated during the following steps of the project to propose a suitable business model for the organization by the end of the project.

*1.1 Who are the stakeholders for the center?*
*1.2 What are the different stakeholders' needs, requirements, and expectations, and how are these addressed in the business model?*
*1.3 What is a business model and what differentiates it from a revenue model?*
*1.4 What important aspects need to be considered when developing a business model applicable to the non-profit research center?*
*1.5 How do lab core facilities set up their business model, and how are they handling questions such as payment models and academia vs. industry pricing-margins?*

*2.1 What are the challenges in the industry and how is it expected to change/evolve over time?*
*2.2 How can the center leverage its existing resources and expertise to stay ahead in the rapidly evolving field?*
*2.3 How flexible is the proposed business model in adapting to changes in the nucleic acid therapies landscape?*

Following the initial step, a series of subsequent steps were undertaken throughout the project, as illustrated in Figure 2.1. These steps were formulated based on the selected scientific model, encompassing the abductive exploration of concepts such as business models, ATMPs, NPOs, and other relevant aspects.

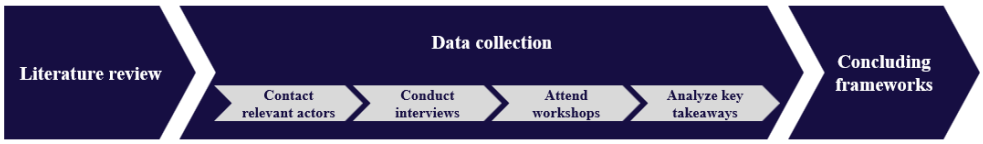


**Figure 2.1. Research strategy employed in the master thesis project.**

Although the process was depicted as linear, it was, in fact, iterative to ensure the successful completion of the project. For example, following interviews with some of the participants, additional exploration of relevant literature was conducted to gain deeper insights into the topics discussed.

### 2.1.6 **Techniques For Gathering And Analyzing Data**

The utilization of techniques for collecting and analyzing data is essential to operationalizing the research methods and the work method outlined by the researcher. Before choosing a technique for an investigation, the researcher must thoughtfully evaluate the sought-after data, including considerations such as how and when it can be acquired, and who can access it [20].

Dresch et al. mention several examples of techniques for data gathering, these are documentary, bibliographic, interviews, focus groups, questionnaires, and direct observations. For data analysis, the following techniques are given by the same authors: content analysis, discourse analysis, and multivariate statistics [20]. Content analysis is a research method used to understand the sometimes disorganized content of messages, whether they're texts, images, symbols, or audio data [27]. Content analysis is distinct, for several reasons, as can be noticed in one often-cited definition: it is *"a research technique for making replicable and valid inferences from texts (or other meaningful matter) to the contexts of their use"* [28]. Discourse analysis, on the other hand, encompasses a wide range of approaches, generally concerned with how meaning is constructed and understood within a specific context. Often, this analysis leads to a critical and evaluative assessment of how these communicative processes influence the social environment [27]. Lastly, multivariate analysis encompasses various statistical methods aimed at examining the relationships between multiple variables in a dataset. Its primary goal is to explore the interdependence among these given variables [29].

In this project, content analysis and discourse analysis were employed as key methodologies to examine both the literature review and interviews conducted with various actors. Content analysis facilitated the examination of textual data gathered from diverse sources, such as research papers, articles, and reports, enabling a structured approach to understanding and interpreting the information presented. Conversely, discourse analysis allowed for a deeper exploration of the meanings and interpretations embedded within the language used during the interviews, shedding light on how participants constructed and conveyed their perspectives and insights.

In this master's thesis, the primary techniques for data collection were bibliographic (through literature review) and interviews. Additionally, one workshop was attended, involving relevant actors in the sector, serving as

additional means for gathering data. The combination of a literature review with interviews and one workshop was appropriate as it allowed for a comprehensive exploration of the research topic from both theoretical and practical perspectives.

### 2.1.7 **Reliable Results**

When conducting research of any kind an important aspect to consider is the reliability of the results that were derived. The reliability will depend on how the research has been conducted, and using scientific methods will ensure objectivity. In this master's thesis, quality and trustworthiness were judged based on four separate criteria; *credibility, transferability, dependency,* and *confirmability* which were introduced by Lincoln and Guba [30]. Credibility will determine the confidence in the 'truth' of the findings. Transferability determines whether the findings have applicability in other contexts. Dependability refers to whether the findings are consistent and if the research can be repeated with the same results. And lastly, confirmability, which reflects what degree of neutrality the results have or to which extent the respondents shape the findings of the study and not by researcher bias, motivation or interest [30].

Credibility was ensured through the diverse array of actors that were interviewed, providing a comprehensive spectrum of perspectives for examination. Furthermore, a multitude of sources were referenced in the report, with critical fact-checking conducted, to validate key information derived from these sources and confirm findings across various literature.

Transferability was ensured through the detailed explanation of the planning, execution, and utilization of both the literature study and interview study within the report. This thorough documentation allows for the replication and application of the research methodology in similar contexts. Furthermore, the results obtained from this project extend beyond the specific organization under study. They hold relevance for other organizations operating within similar contexts. This broad applicability is supported by the utilization and consideration of various perspectives from a diverse range of actors, thereby enriching the scope of the findings and their potential implications.

The dependability of the study was achieved through thorough documentation of the methodology process. This opens the ability for other researchers to reproduce the study and replicate the results that were derived.

Confirmability was ensured through continuous validation and guidance from supervisors, which ensured that the findings were based on the literature that was explored and further, from the data gathered during the interview process.

Lastly, to ensure the reliability and quality of the results, interviews were exclusively conducted with reputable industry experts and highly renowned researchers. This deliberate selection criterion aimed to enhance the credibility and validity of the study's findings.

## 2.2 Research Methodology Overview

This section provides an overview of the research methodology employed in the thesis project, presenting three distinct methods utilized to investigate the research questions outlined in Section 1.4.

### 2.2.1 **Literature Review**

To gain theoretical knowledge about the different aspects of the project, a literature review was performed in alignment with *Writing the Literature Review: A Practical Guide* by Efron and Ravid, which was published in 2019 [31]. The authors state that a literature review is a *"systematic examination of the literature about the topic, and it critically analyzes, evaluates, and synthesizes research findings, theories, and practices by scholars and researchers related to the area of focus"* [31]. In this project, the literature aimed to explore the current knowledge regarding NPOs, business models, ATMPs among other areas suitable for the project. Developing and conducting a comprehensive literature review entails a structured six-step process including the following:

1. Selection of a relevant literature review topic
2. Identification of relevant sources
3. Thorough analysis and evaluation of the sources

4. Organizing and synthesizing the literature and building an argument
5. Establishing a writer's voice, while adhering to established writing conventions
6. Precise composition, editing and refinement of the literature review

It is important to acknowledge that, despite its apparent linearity, the literature review process is often iterative, as underscored by the authors [31].

Within the scope of this project, the initial phase involved the consolidation of two primary research questions, followed by a series of subquestions as explicated in section 2.1.5. Subsequently, the second phase encompassed desktop searches on platforms such as Google Scholar and LUBsearch, among other reputable sources, aimed at identifying relevant literature to the topics under exploration. The ensuing step involved an iterative process of perusing articles to discern suitable sources for anchoring the literature review. Following this, the selected articles underwent a thorough examination, with relevant aspects being assimilated into the review. Ultimately, the literature review was crafted, edited, and refined to encapsulate the theoretical insights derived from the exploration.

### 2.2.2 **Observation Of Similar Structures**

In the expansive exploration undertaken in this thesis project, RQ1 endeavors to craft a viable business model for the envisioned organization. This task necessitates a thorough analysis of existing organizational frameworks to identify relevant components adaptable to the forthcoming business model. The methodology employed for this examination diverges from conventional benchmarking due to the unique circumstances surrounding the organization being in its early stages of development.

The approach pivots on identifying salient features within existing business models that hold potential applicability to the forthcoming venture. This entails a thorough examination of various organizational frameworks rather than a direct comparison with established entities. The process seeks to derive actionable insights to shape the design of the forthcoming business model.

Comprising three iterative stages, the methodology unfolds as follows. Initially, a comprehensive desktop search is conducted to identify organizations and models deemed relevant to the project's objectives. Subsequently, an in-depth examination of these models occurs, with a keen focus on discerning elements conducive to the envisioned organization's goals and ethos. Finally, insights gleaned from this analysis are synthesized and applied iteratively to refine the business model, fostering its alignment with the project's overarching objectives.

It is imperative to acknowledge the inherent limitations within this methodology, primarily stemming from the absence of a pre-existing organizational structure. As such, the emphasis lies not on benchmarking against existing entities but rather on distilling adaptable components from a diverse range of organizational frameworks.

### 2.2.3 **Interview Study**

The interview study aimed to acquire a comprehensive understanding of the concept of a business model. This term encompasses not only the organizational structure but also the activities necessary for the profit generation within an NPO. In pursuit of this understanding, various aspects of a business model were explored, including the needs, requirements, and expectations of potential stakeholders of the organization, examining similar and relevant organizations (national and international) regarding business models, payment models, and sustainability efforts. In this context, sustainability refers to the ability of an organization to remain relevant and profitable over the long term. Additionally, the interviews sought to gain deeper insight into the ATMP industry, including the interviewees' perceptions of its future, identifying both positive aspects, potential challenges, and pitfalls that may arise. This holistic approach was undertaken to ensure the development of an adaptive and flexible business model capable of addressing future challenges and opportunities within the industry.

The first phase of the interview study focused on identifying relevant actors for interviews. Initially, a list of approximately 50 actors was compiled through various methods including relevant Google searches (depending on what type of actor that was of interest) and discussions with supervisors and project leaders. These actors were then categorized roughly into eight groups: Researchers, national industry experts, international industry experts, similar initiative employees, managers of lab core facilities, potential customers,

potential collaborators, and others. The category of “Other” includes a representative from Chalmers along with one of the project leaders of Chalmers Precision HealthTech Hub. These two interviewees fall into the category “Other” since these interviews were held to increase the author’s knowledge of the project (especially its history and funding related to the project) and Chalmers’ involvement, providing rules concerning the business model and payment model. Although only one formal interview was conducted with a representative from Chalmers Precision HealthTech Hub, continuous meetings were held with the project leaders. These ongoing discussions ensured that the project remained aligned with the organization's goals and vision.

The categorization of eight groups was useful since it ensured a comprehensive exploration of relevant themes and perspectives. However, after further exploration of the background of the interviewees, several overlaps were identified, presented in Figure 2.2. As a result of this, every interview was tailored to the background of the interviewee in question, and the appropriate topics were discussed to gain as much from the interview as possible. Section A.1 of the Appendix presents the questions that guided the discussions of the interview depending on the primary focus of the interview.

Initially, relevant actors were identified and added to an interviewee list, which included their contact details (when available) and their level of relevance (low/medium/high) based on their potential contribution to the project's research questions. These actors were sourced through various means, including personal connections, membership lists of industry organizations, academic reports, LinkedIn, and Google searches. Some companies were also initially contacted through "info-emails" and contact forms on their websites. Subsequently, the potential interviewees were contacted by phone (if available) and email. The initial email provided an overview of the project and explained why the company/person was being contacted. Following the initial dialogue, interviews were scheduled with interested actors. Some interviews were scheduled to be on-site, while others were conducted digitally, either via Teams or Zoom. In addition to scheduling the meetings, an extensive desktop search was conducted regarding the interviewees to finalize the appropriate topics for discussion during the interviews.

During the interviews, all participants were asked to provide recommendations for additional contacts (persons or companies) who could be engaged in further discussions. This process expanded the interviewee list to include approximately 60 actors. Out of these, 39 actors were contacted, leading to 22 interviews being conducted. Some of the interviewees belonged to multiple categories, such as researchers who also engage in potential service providers or partners. In such instances, the interview was categorized based on the primary focus of the discussion. Figure 2.2 shows the number of interviewed actors per category.

| Interviewee | Researcher | National Industry Expert | International Industry Expert | Similar initiative employee | Lab Core Facility | Potential customer | Potential collaborator | Other |
|---|---|---|---|---|---|---|---|---|
| 1 | | x | | | x | x | x | |
| 2 | x | x | | x | | x | x | |
| 3 | x | x | | | | x | x | |
| 4 | x | | | | | | | |
| 5 | | x | | x | | x | x | |
| 6 | | x | | | | x | x | |
| 7 | | | | | x | | x | |
| 8 | | x | x | | | | x | |
| 9 | x | | | | x | | x | |
| 10 | x | x | x | x | | x | | |
| 11 | x | | | | | | x | |
| 12 | | | | | | | | x |
| 13 | x | | | | | x | | |
| 14 | x | | | | x | x | x | |
| 15 | | x | | x | | x | x | |
| 16 | | | x | x | | | | |
| 17 | x | | x | x | | | | |
| 18 | x | x | | x | x | x | x | |
| 19 | x | x | | | | | x | |
| 20 | | x | | x | | x | x | |
| 21 | | | | | | | | x |
| 22 | x | | x | x | | | | |

**Figure 2.2. illustrates a matrix summarizing the number of interviewed actors per category. A total of 22 interviews were conducted during the project.**

The majority of interviews (14) were conducted via Zoom or Teams, while 8 were conducted in person. The questions varied depending on the perspective and background of the interviewee, allowing for coverage of diverse viewpoints, see Appendix A.1.

The interviews, typically lasting between 30-60 minutes, were most often documented during the interview itself. Alternatively, if the interviewee consented, the interviews were recorded and subsequently transcribed after the session. Once the transcription process was completed, the recordings were deleted, retaining only the transcribed content. It's important to note that regardless of whether the interview was documented during the session or recorded and transcribed afterward, all interviewees remain anonymous.

During the interviews, the questions and topics discussed varied depending on the categorization of the interviewee. Each interviewee's responses were then categorized and grouped together based on specific areas of interest. These areas included discussions on business models, payment models, the general attitude towards Chalmers Precision HealthTech Hub, the ATMP sector, sustainability efforts, the potential stakeholders' needs, requirements and expectations, and other insights and tips related to the idea and structure behind the organization. These insights and tips were gained when participants were provided with a one-pager that served as a pilot, illustrating a preliminary view of how the organization's structure might be designed and outlining the main areas and services it would focus on. This one-pager is depicted in Appendix A.3.

### 2.2.4 **Development Of The Business Model And Answering The Research Questions**

Drawing from the insights gained through the literature review, observation of similar initiatives, and interviews, the final step was to synthesize this information to develop an appropriate business model for Chalmers Precision HealthTech Hub. This process involved close collaboration with supervisors and project leaders to ensure that the finalized model aligned with the project's objectives. Further details regarding the development process are provided in Section 5.2 of the report, where the finalized business model is discussed.

## 2.3 Research Ethics

During the execution of this master's thesis, ethical considerations were thoughtfully examined and analyzed. According to the Swedish Research Council (Vetenskapsrådet), ethical aspects in research concern both the research content and the researchers' engagement with the task [32]. In this thesis, two main ethical considerations were discussed and examined: bias and integrity.

In line with Yin's (2018) guidance, it is imperative for researchers to actively steer clear of bias [33]. To ensure the avoidance of researcher biases, ongoing external reviews throughout the thesis process are necessary. This involved weekly meetings with supervisors at both the University and Triathlon, as well as a persistent review of the written report by the supervisors. In addition to this, researchers must protect the integrity of the parties involved. Yin (2018) mentions numerous ways this can be achieved. To begin, research participation must be voluntary, requiring participants' consent to be included in the study. Secondly, the utmost respect for participants' privacy and confidentiality is crucial, aligning with their specified level of discretion. Lastly, researchers must uphold honesty, particularly during data collection. This involves securing voluntary participation in interviews, explicitly inquiring about the preferred level of anonymity, and implementing peer-review processes among the authors to ensure integrity [33].

## 2.4 Utilization Of Artificial Intelligence During Project

During the course of this project, artificial intelligence (AI) has been instrumental in assisting the authors, particularly considering that English is not their primary language. AI tools, notably ChatGPT, were utilized to correct grammatical errors in the text and identify appropriate synonyms, thereby enhancing the overall quality of the writing. Additionally, AI was employed to suggest relevant search terms during the literature review process, facilitating efficient and targeted exploration of pertinent scholarly resources.

# 3 Literature Review

*This section offers a comprehensive review of the literature concerning various aspects related to the project. The topics covered include ATMPs, GTMPs, Nucleic Acid Therapies and their delivery. Additionally, the section delves into business models, providing historical perspectives, different definitions, and frameworks. Furthermore, NPOs are examined, including definitions, differentiation from for-profit organizations, categorizations, and other important aspects. Examples of proposed business model frameworks applicable to this specific type of organizational structure are also discussed. The review is organized into several subsections, each addressing different facets of the topic.*

## 3.1 ATMPs

ATMPs represent the current frontiers in medicine, offering potential breakthroughs in treating conditions that were previously difficult or even impossible to address. This section aims to introduce and explain the regulatory and scientific background of this term.

ATMP is a classification specific to the EU, ensuring that these products are regulated as medicines throughout the region under the ATMPs regulation (EC/1394/2007) [1]. These products have during recent years shown potential to significantly alter the course of numerous debilitating diseases within society, including Alzheimer's disease, Parkinson's disease, cancer, muscular dystrophy, and others [34]. The term, ATMPs, is an umbrella concept that includes a series of subcategories such as gene therapy medicinal products (GTMPs), somatic cell therapy medicinal products (sCTMPs), tissue-engineered products (TEPs) and combined products (tissue or cell-associated to a device). GTMPs involve introducing, removing, or changing a patient’s genetic material to treat or prevent disease. Somatic cell therapies are treatments that use cells, either from the patient or from a donor, to treat or replace damaged or dysfunctional cells. Lastly, TEPs involve using

a combination of cells and supporting structures to replace, repair, or regenerate damaged tissues to treat conditions [1]. GTMPs will be further discussed in the literature review as some nucleotide-based treatments fall under this category, and additional information regarding TEPs and sCTMPs are found in section A.2 in the Appendix.

### 3.1.1 **GTMPs**

As defined by the regulatory frameworks, *"GTMPs are products of biological origin containing recombinant nucleic acid(s) and that have a therapeutic, prophylactic, or diagnostic effect related directly to the recombinant nucleic acid sequence"* [35]. During the past few decades, the field of gene therapies has shown tremendous potential for use as a standard clinical intervention for treating several conditions, including cancers, infectious diseases, cardiovascular disorders, etc. Current gene therapy is, however, not limited to the delivery of DNA only. Other therapeutic nucleic acid materials such as RNA have also been included in the protocols for GTMPs [36]. Some examples of treatments that fall under the category of GTMPs are plasmids of biological origin, genetically modified human cells (eg. CAR-T-cells) and parts of nucleic acid therapies [37].

### 3.1.2 **Nucleic Acid Therapies**

Nucleic acid therapies, also known as nucleotide-based therapeutics, consist of nucleotides, fundamental building blocks found in DNA and RNA [7]. Unlike traditional medications that target proteins, nucleic acid therapies modify gene expression at the DNA or RNA level, offering a groundbreaking approach to addressing previously untreatable diseases [8].

Nucleic acid therapies encompass a wide range of treatments, spanning based small interfering RNA (siRNA), self-amplifying RNA (saRNA) oligonucleotides, vaccines and many others [7; 8; 38]. Even though many nucleic acid therapies fall under the category of GTMPs, and can thereby be considered as ATMPs, there are some exceptions. Since oligonucleotides and mRNA vaccines do not meet the criteria of GTMPs, they are not considered as ATMPs by the regulatory frameworks [1; 8]. As these classifications can appear rather complex, and misconceptions can occur, Figure 3.1 presents a simplified illustration of the classifications of ATMPs and Nucleic acid therapies.

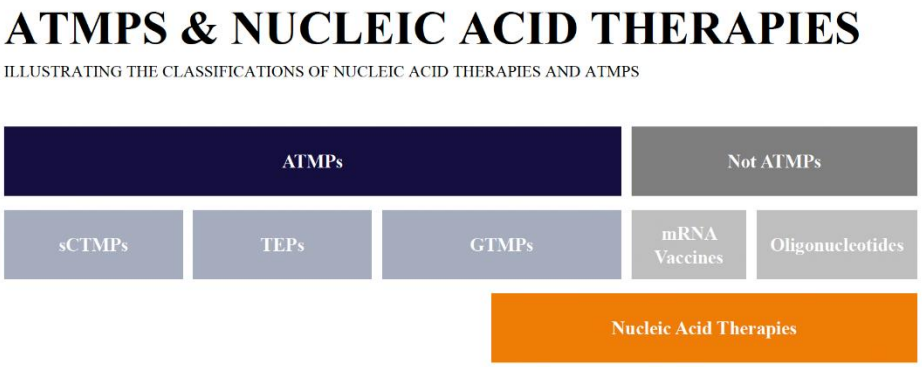


**Figure 3.1 Presentation of a simplified schematic overview of the classifications of nucleic acid therapies and ATMPs.**

### 3.1.3 Delivery Of Nucleic Acid Therapies

As previously indicated, nucleic acid therapies represent a highly intricate category of therapeutic interventions. This complexity extends beyond mere classification, encompassing the scientific aspects of the field. Numerous therapeutic modalities have demonstrated significant promise in addressing some of society's most debilitating diseases. Nevertheless, the development and application of nucleic acid therapies encounter various challenges, especially regarding the selection of an appropriate delivery method. Effectively delivering nucleic acids to their intended targets within cells presents significant challenges. These challenges stem from the inherent characteristics of nucleic acids, including their low stability and rapid clearance when outside cells, as well as their poor permeability through cellular membranes due to factors such as negative charge, high molecular weight, and hydrophilicity [39]. To address these issues, the delivery methods must be able to improve stability, facilitate internalization and increase target affinity [8].

Two promising delivery methods for nucleic acid therapies are adeno-associated virus vectors (AAV vectors) and lipid nanoparticles (LNPs). These delivery methods are approved delivery technologies that, through different modes of action, enable gene therapies in the clinic. [8; 39; 40; 41; 42]

AAV vectors is one delivery method that employs viruses to transport nucleic acid sequences to precise locations within the human body. However, despite

promising research advancements in viral vectors, a few notable drawbacks have been associated with this method. Some of the drawbacks include poor target cell specificity, inability to transfer large-sized genes, being substantially costly and lastly associated with some severe adverse effects. [8; 39; 40; 41; 42]

Over the last 25 years, LNPs have undergone significant evolutions from their initial compositions, and have during recent years shown significant promise as the realistic alternative for achieving better efficacy in delivering nucleic acid therapies. The fact that two of the successful COVID-19 vaccines that were launched are based on this delivery method, provides further confirmation of its efficacy [8]. LNPs offer several possibilities, including the capacity to facilitate cellular entrapment and mitigate immune responses directed against the drug under consideration. However, similarly to other delivery methods, several challenges persist that must be addressed to ensure the full safety and efficacy of these therapies. Foremost among these obstacles is the need to guarantee nanoparticle stability to prevent aggregation within the liver, thus enhancing the longevity of nucleic acid therapies within patients. [8; 39; 40]

One could also mention antisense oligonucleotides (ASOs). Although not a delivery method for other nucleic acid therapies, ASOs serve both as a nucleic acid therapy and as a delivery carrier for itself. Therapeutically effective ASOs are heavily modified, eliminating the need for an additional delivery carrier. ASOs are synthetic molecules designed to interact with cellular RNA by pairing up with RNA strands using a specific type of base pairing. This interaction allows ASOs to effectively regulate gene expression. However, despite their promise as an alternative, a significant concern with ASOs is their specificity, as they currently lack the ability to selectively target specific genes. Additionally, challenges arise regarding their rapid degradation and clearance upon in vivo introduction. [8]

## 3.2 Business Models

A business model is a complex term that, to date, doesn’t have one recognized definition. This section aims to review and clarify some of these definitions, ultimately concluding two different frameworks available, important parts of a business model, and the importance of continuous development to ensure the sustainability of companies.

### 3.2.1 **Historical Perspectives Of Business Models**

The term Business Model is relatively new in the field of strategy research. The first attempts at formulating this concept began in the period between 1990 and 2002 by numerous authors, usually related to technological and innovation orientation [2; 43; 44]. During these times, the concept of business models was seen as *"the interaction of operating processes, management systems, organizational structures, and corporate culture"* [43], and *"stories that explain how enterprises work"* [2]. Among practitioners, the interest in business models arose with the arrival of the internet, often in the context of internet startups [2]. As the interest among practitioners arose, so did the interest among researchers. Moreover, when the amount of research related to the concept increased, so did the number of definitions [45]. To date, there is no commonly accepted definition of the concept, but it is frequently associated with Peter Drucker's pioneering questions of *"who the customer is and what the customer values"*. Besides these questions, a sustainable business model also needs to answer one of the most fundamental questions within an organization, that is: *"How is the organization intended to make money"* [2; 3; 4]? By answering these questions, the business model results as a reflection of the recognized strategy of the firm [46]. Another famous definition that encapsulated these questions was stated by Slywotzky in 1995. He explained the concept of a business model as *"the totality of how a company selects its customers, defines and differentiates its offerings, defines the tasks it will perform itself and those it will outsource, configures its resources, goes to market, creates utility for customers, and captures profit. It is the entire system for delivering utility to customers and earning a profit from that activity."* [47]

### 3.2.2 **Distinguishing Between Business Model And Revenue Model**

To grasp the concept of a business model, it is crucial to elucidate the distinction between a business model and a revenue model. Clarifying the difference is essential for a comprehensive understanding, as these terms are sometimes used interchangeably among individuals who are not actively involved in business model development, leading to confusion in discussions about organizational strategies and operations [48]. Even though the business model declares how the company makes money, the revenue model describes a specific mechanism behind the revenue generation. The revenue model, thereby, outlines the sources, volume, and distribution of revenue [49]. This makes the revenue model an important part of the business model, which is

defined as the means by which value is captured by an organization [50]. In essence, possessing a revenue model does not by itself define a company's business model, although it constitutes a vital element within the broader framework.

### 3.2.3 **Business Model Frameworks**

Returning to the numerous definitions of a business model and its various components, researchers have sought to render it more accessible to industry users by establishing frameworks. The objective was to develop a shared language that facilitates both the description and manipulation of the business model, thereby enhancing strategic development [51].

Business model frameworks delineate how a company defines, produces, delivers, and presents value tangibly [3]. The framework must define not only how internal resources and processes will be utilized, but also the relationships with entities outside of the organization. Recognizing this importance, researchers developed various frameworks to make this complex environment more navigable. One such framework, the "Resources, Competencies, Organizational structure, and Value proposition" (RCOV-framework), was created by Demil and Lecocq in 2010 [52].

Some researchers argue that managers operating within competitive markets need to identify the internal sources of advantage for the firm [3], thus further enhancing the framework developed by Demil and Lecocq. By answering this question, managers assist the organization in determining the firm's core competencies and position it effectively against its competitors.

It is widely believed that the firm's internal capabilities and market positioning significantly impact its overall competitiveness and ability to thrive in the industry. However, merely defining the value proposition, market segment, production, and positioning is insufficient. Given that one of the most fundamental objectives of a company is to generate revenue, this aspect must be incorporated into the business model. This is achieved by carefully considering pricing factors and production volume in relation to other aspects of the business model. [45]

A framework that encapsulates all these aspects is formulated by Osterwalder and Pigneur and is recognized as the Business Model Canvas (BMC) [53].

This framework stands as one of the most renowned and widely utilized to date, with its success attributed to its tangible benefits [51]. The framework, shown in Figure 3.2 consists of nine basic building blocks that cover the four main areas of a business: customers, offers, infrastructure, and financial viability [53]. The nine building blocks are the following:

1. Customer segments
2. Value proposition
3. Channels
4. Customer Relationships
5. Revenue Streams
6. Key Resources
7. Key Activities
8. Key Partners
9. Cost Structure

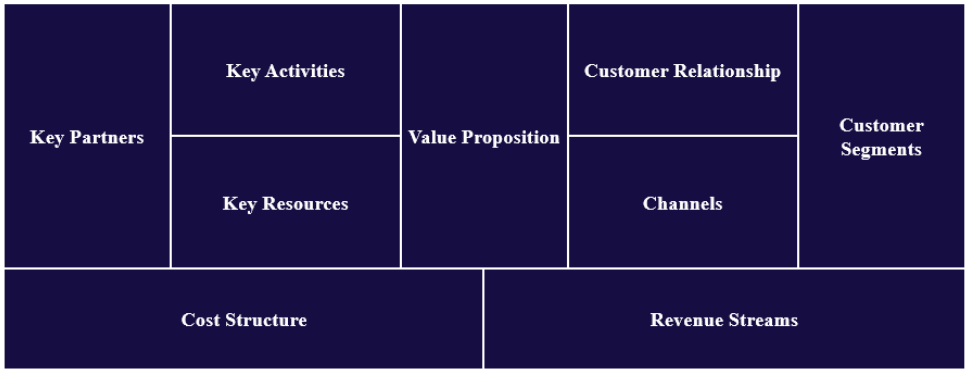


**Figure 3.2. Business Model Canvas, by Osterwalder and Pigneur [53].**

To gain a comprehensive understanding of this framework it necessitates a detailed examination of each component, starting with customer segments. This block delineates the diverse groups of individuals or organizations targeted by the company. The value proposition, in turn, encapsulates the array of products and/or services that generate value for the identified customer segments. Channels elucidate the means through which the company communicates its value proposition to the customer segments. The fourth building block, customer relationships, outlines the nature of relationships established with specific customer segments. Revenue streams encapsulate the essence of the revenue model, delineating the income derived from each customer segment. Key resources, activities, and partners individually elucidate the critical assets, operations, and partnerships

essential for the functionality of the business model. Lastly, the cost structure encapsulates the mechanisms by which all operational costs are sustained to facilitate the functioning of the business model. The individual building blocks do not only provide distinct definitions for various components but also establish interconnections. Because of this, the framework can be viewed as a blueprint for a business strategy to be implemented through organizational structures, processes, and systems. [53]

The development of a business model is a matter that involves a high degree of complexity, however crucial for the organization, and despite agreement on its importance to an organization's success, the concept itself is still vague, and there is little consensus regarding its compositional facets. [46; 54; 55]

### 3.2.4 **Continuous Business Model Innovation: Navigating Change And Ensuring Viability**

One might assume that business model development is complete once a framework has been established; nevertheless, there are still aspects that require further refinement. Due to permanent changes, companies constantly need to contend with new challenges. Refining and enhancing business models can facilitate adaptation to constantly evolving environmental conditions and foster competitiveness within a dynamic industry landscape [56]. The establishment of a business model is, thereby, not a one-time event; rather, it is a continuous process often referred to as Business Model Innovation [57; 58]. Ultimately, this process aims to achieve economic success by providing customers with unique offerings, thereby ensuring the viability of ideas, products, and services [59]. Such a continuous refinement of its business model represents a challenging task for companies [60], but nevertheless vital for survivability. An empirical study from 2009 shows that business model innovation can give a greater potential for success than comparable product and process innovation [58]. This further underscores the importance of business model development for a company's viability.

Moreover, the question arises of how companies can develop business models continuously and consistently in high quality [61]. It seems that several obstacles need to be addressed to refine this concept effectively. One of the major hurdles is presented by Henry Chesbrough in his article *Business Model Innovation: Opportunities and Barriers*. He suggests that resistance stemming from conflicts with the prevailing business model could impede

business model innovation. Moreover, he offers several examples for managers seeking to overcome this barrier and experiment with business model innovation. One of the promising approaches that he proposes utilizes structured maps of business models to elucidate their underlying processes. This approach enables organizations to explore alternative combinations of processes, facilitating experimentation and innovation within the company [62]. Returning to the BMC framework introduced in section 3.2.3, this provides company managers with a good foundation to this approach, with a comprehensive overview of various aspects of the organization. It enables them to identify areas requiring modification to maintain the company's sustainability [56; 62].

## 3.3 Non-profit Organizations

To understand the complex dynamics of NPOs, a nuanced examination of critical factors becomes essential. This section goes into the distinctive aspects of formulating a business model for NPOs, encompassing considerations such as the differences between a NPOs and a for-profit organization, the unique characteristics of the non-profit sector, and strategies for sustaining social impact and sustainability.

### 3.3.1 **Understanding NPOs: Definitions And Key Characteristics**

Before diving into the concept of NPOs, it is important to provide a clear understanding of the term "non-profit." In the US, the term nonprofit is a designation given by the Internal Revenue Service (IRS) to describe organizations that are allowed to make a profit but that are prohibited from distributing their profit/earnings to those in control of the organization [6]. This term aligns well with the definition of NPOs from the European Council of Non-profit Associations (CEDAG), which states that an NPO is generally defined as an organization characterized by a non-distribution constraint, i.e. whose members may not receive any direct return from the activity of the organization, be it in cash or kind [63].

Moreover, NPOs typically possess several key characteristics. These include a public service mission, an organizational structure resembling that of a not-for-profit or charitable corporation, governance structures designed to prevent self-interest and personal financial gain, exemption from federal

taxes, and a special legal status specifying that donations made to the organization are tax-deductible [6].

### 3.3.2 **Distinguishing Non-profit And For-profit Organizations**

One crucial distinction between a non-profit and a for-profit corporation lies in their respective missions. The for-profit organization aims to generate profits for their owners or shareholders, ranging from individuals operating as sole proprietors, or through corporate ownership facilitated by share purchases. In contrast, an NPO operates without the concept of ownership, which results in an entirely different focus. The mission of the NPO is geared towards serving a broad public purpose, which conflicts with the concept of ownership and personal gain. However, the constraint of "private inurement" within the NPOs does not hinder them from providing salaries to their employees, including executives such as the Chief Executive Officer (CEO) and Chief Financial Officer (CFO). Board members typically contribute their time voluntarily as a public service, without receiving compensation. Importantly, these constraints do not impede NPOs from generating revenue. Much like for-profit entities, non-profits can earn money. However, a key distinction arises in the requirements that any funds earned by the NPO, must be directed towards the public purpose for which the NPO was established, reserved for its mission, or transferred to another organization with a public purpose. Therefore, a defining characteristic of all NPOs lies in utilizing the earnings from their endeavors to advance organizational goals, rather than enriching the owners or stockholders. [6]

### 3.3.3 **Categorization Of Non-profit Organizations**

NPOs exhibit a diverse range of structures and purposes, allowing for various categorizations based on their operational models and areas of focus. They can be categorized as either commercial, where they generate the majority of their revenue through operations, or donative where they rely primarily on external sources of funding [64]. NPOs can also serve diverse purposes, encompassing many areas such as public health and safety, charitable activities, education, clothing, sports, politics, religion, advocacy, and civil rights [65].

### 3.3.4 **Balancing Challenges With Innovation In Non-profit Organizations**

NPOs have been widely recognized for their contribution to the third sector of the economy, which refers to the non-profit sector, including organizations that are neither part of the public sector (government) nor the private sector (for-profit businesses). This is because they provide goods and services that the business or public sector does not deliver. In addition to this, NPOs create employment opportunities, develop necessary skills, and foster pathways for social inclusion. [66; 67; 68]

Despite this, there is a growing consensus between practitioners, policy planners, and researchers that the competitive environment regarding NPOs is increasing. NPOs aim to address needs that the business sector may not serve, likely since doing it profitably is a challenge [64; 69; 70]. Given the inability of NPOs to rely on profits, and the absence of taxing authority, which the government sector possesses [64], NPOs adopt a distinctive operational model. Furthermore, NPOs rely on the support of various stakeholders to acquire the resources necessary for delivering their services [12].

The increase in external environmental challenges confronting NPOs has attracted the attention of several researchers. These researchers have argued that NPOs should embrace certain entrepreneurial approaches into their operations [71; 72], incorporate innovative practices [69; 73; 74], as well as to align their focus with outcomes outlined in government policy and seek innovative ways of delivering value to the target market to acquire competitive advantage [72]. However, some researchers propose market orientation to deal with increased competition [75], while other researchers recommend the adoption of business models that may clash with the core ideals of NPOs, especially their social mission [76].

### 3.3.5 **Sustainability In Non-Profit Organizations: Challenges And Strategies For Long-Term Viability**

Sustainability is often described as having three dimensions; social, economic, and environmental [11]. However, for an NPO, sustainability refers to the NPOs ability to survive and continue delivering its mission. Non-profit sustainability means that NPOs will be capable of fulfilling their commitments to their clients, patrons, and communities [12].

Managing sustainability within for-profit organizations has for many decades been a central focus of strategic management literature. This is to address the need for for-profit organizations to gain competitive advantages, that generate superior financial performance and ensure organizational survival and growth. Unfortunately, the literature on NPOs does not place a comparable emphasis, despite the increased vulnerability and threats to these organizations' continuance [77]. The differences previously mentioned between for-profit and non-profit entities may hinder a direct application of theories from the business sector.

To maintain a sustainable NPO, researchers have observed key differences in certain focus areas, compared to for-profit organizations. Regarding the focus between customers or clients versus donors, it has been observed that NPOs (particularly donative) must place a reduced emphasis on customers or clients than on donors. Clients can contribute to enhanced service delivery, however, the link between clients and customers and revenue generation in NPOs are generally unconnected. This is because donors frequently play the central role in delivering revenue streams to the NPO, to keep it sustainable. In addition, other important sources of finance for NPOs are often provided by governments and entrepreneurial business initiatives. [12]

Another important factor when managing NPOs is the balance between money and mission. This issue has been a focus for several researchers [69; 78]. If one first examines the financial aspect of the scale that necessitates a balance between money and mission, researchers have suggested multiple strategies that NPOs can embrace to gain financial sustainability. These are revenues generated commercially [65], business principles applied to fundraising [78; 79], utilization of relationship marketing [80], donations based on identity and relationship [81], and social alliances between companies and NPOs [82]. These are all strategies to increase revenue, however, researchers have also suggested different strategies to reduce costs. A few examples are the increase of volunteerism and its productivity [83], and in-kind donations and collaborations [84]. Instead of focusing on the mission aspect of the scale, the goal of NPOs is to enhance social value. However, there has been a disagreement regarding the emphasis of the social goals of the entrepreneur, and what it implies [85]. Some strongly believe that the social mission is explicit and central for social entrepreneurs and that any wealth generated is only a way to achieve the social end [85; 86]. On the other hand, some see social entrepreneurship as a mechanism to create and

sustain social value, and to achieve this can potentially incorporate financial activities into it [87].

Given the heightened competitiveness within the non-profit landscape, several researchers have studied numerous NPOs, spanning various sectors. This to understand if and how the NPOs have managed this competitive environment, and what strategies they have applied to be sustainable in the long run. An empirical investigation has shown that these environmental dynamics have forced NPOs to adopt entrepreneurial and business-like strategies, to build a sustainable organization. In addition, to achieve greater financial stability, these NPOs adopted operational and innovative strategies, both revenue-enhancing and cost-reducing. [12]

### 3.3.6 **Business Models For Non-profit Organizations**

In the realm of NPOs, understanding the complexities of their business models is essential for understanding their operational strategies and sustainability efforts. This subsection, which investigates the business models of NPOs, explores how they generate revenue, allocate resources, and fulfill their social missions while navigating the complexities of the non-profit sector. This literature review on NPO business models is paramount, particularly considering that this report aims to map out a sustainable business model for an NPO. Understanding the insights from existing research and studies will become crucial in formulating effective strategies for achieving sustainability in the non-profit sector. Therefore, this section will cover several studies on this matter, providing a broader context for the discussion.

Limited attention has been given to the study of business models in the non-profit sector. The research that does exist mostly seeks to shed light on the complexities and unique characteristics that illustrate how NPOs function and generate their value [14]. However, empirical studies on non-profit business models have been made. These studies will bring up several important aspects to consider when implementing a business model for an NPO, ending with an example of a proposed business model framework for NPOs.

*One Size Does Not Fit All*

One study was conducted within the media industry, specifically the periodical publishing segment. The findings from this study suggested the

fact that the pursuit of a singular non-profit business model that fits all could prove to be insufficient, given the presence of multiple viable models, even in a narrow sector like this one. Every facet of the non-profit business is closely examined and assessed by various stakeholders, including customers, donors, and competitors, which places extra demands on the NPOs to maintain stability and find the optimal mix of revenue streams [88].

*Social Purpose vs. Economic Interest*

Another important aspect when developing a favorable business model for an NPO is to consider the trade-off situation between social purpose and economic interest that NPOs need to face. A study in 1998 observed differences in certain hospital care services, under different levels of competition. Some of these services were provided by for-profit hospitals, and some by non-profit hospitals. The study showed that during heightened competition, the non-profit hospitals exhibited a greater will to admit uninsured patients, which aligned with their social responsibility. But on the other hand, the sustainability of their operations faced some challenges, since the cost of care increased. The for-profit hospitals, however, had limited access to hospital care for those who were uninsured [89]. This is one example where the presence of both internal factors such as cost and risk management, and external factors like competition, places the NPOs in these types of trade-off situations.

*Unfamiliarity Of The Concept of Business Models In The Non-profit Sector*

Coming back to the ambiguity around business models within the non-profit sector, in 2020, a study was conducted on ten different NPOs in Croatia. Here, a minority of the interviewees were familiar with the term business model. Only one interviewee, among the 10 NPOs that were interviewed, was familiar with one of the most common and widespread frameworks for assessing business models, which is the BMC [14]. This framework was also used in the study, to describe and compare the NPO business model. Despite this, all interviewees were able to describe the different components of what they perceive as the business model of their organization. Interviewed NPO leaders highlighted challenges stemming from a lack of understanding and transparency, coming from supporting governmental institutions.

In addition to this, they expressed concerns about an escalating administrative burden, which diverted a substantial portion of the NPO resources toward administrative tasks, rather than on their mission fulfillment. The NPOs that were heavily dependent on project-based funding

also viewed a decline in government support as a significant threat to their sustainability. To navigate this challenge, the NPOs often adapted by either refining their mission to increase their competitiveness for EU and national funding or adopting a more business-like approach [14]. Some key similarities among these NPOs were found, all interviewed NPOs highlighted the importance of personalized relationships and direct contact with partners and customers, and that this approach represented the only way to do business. In addition, nearly half of the NPOs nominated financial resources as crucial for the sustainability of their business model [14].

*Challenges Faced By The Non-profit Industry And Additional Mitigation Strategies*

When developing a suitable business model for an NPO, it is important to consider the major challenges they face. The biggest challenge that most NPOs have is a lack of resources, especially financial [14]. To lower this barrier, Hartnett and Matan in 2015 suggested several strategies that could be embraced when moving away from traditional funding and instead favoring other funding sources. These suggestions are [14; 90]:

1. *Social media*
   By connecting and engaging philanthropists with the work of non-profit.
2. *Crowdfunding*
   By engaging individual donors and creating a buzz.
3. *Virtual initiatives*
   Creates an opportunity to showcase goodwill and other ads.
4. *Reverse auctions*
   Enabling the NPOs to swiftly generate funds for essential supplies.
5. *Corporate support*
   By providing societal impact and demonstrating economic benefits, NPOs can retain corporate donors' attention.

The study on the ten Croatian NPOs confirmed the thought of the non-profit sector as diverse. By being in this nature, creating simplistic generalizations about business models for NPOs could be a dangerous path, and may not contribute significantly to a deeper understanding of the field. At a broader level, the NPOs are primarily concerned with the impact they employ on local communities or wider society. The emphasis lies not on financial outcomes and profits, but on social or environmental benefits. Thus, when applying a business model for an NPO, the success should revolve around

measuring their impact, rather than focusing solely on the financial results. [14; 90]

*Example Of Proposed NPO Business Model Framework*

Taking all these factors into account, examining a concrete example of a business model framework for NPOs would be advantageous. In 2020, a business model framework for NPOs in France and Switzerland was introduced. This study was carried out since business models often are too adapted to the for-profit sector, and there are many reasons why business models should be adapted for usability and applicability to NPOs [91]. To begin with, there exists a distinction in organizational models between for-profit and NPOs. Secondly, the complexity of NPOs arises from multiple income streams and diverse stakeholders. Thirdly, funding poses a challenge as NPOs require long-term strategies to achieve their mission, however, NPOs often have only short-term project funding [91]. The fourth point is about the evolving environment. In continuously changing environments, such as the environment that NPOs face, the business models require constant vigilance [92]. In the study from 2020, a conceptual business model framework for NPOs was created, derived from the Osterwalder and Pigneur business model canvas (OP-BMC), shown in Figure 3.3.

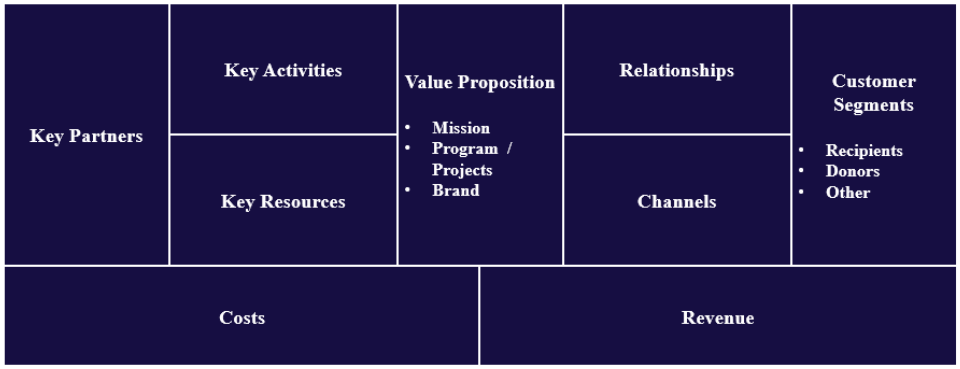


**Figure 3.3 Conceptual business model framework for NPOs, derived from OP-BMC [91].**

The figure contains the same nine building blocks as the original BMC, the contents of this figure were previously explained when figure 3.2 was presented in section 3.2.3. However, the language has been reformed with the ambition of making the framework more fitting for NPOs and their operations. In addition to this, a larger focus has been placed on important aspects regarding NPOs such as mission and donors.

After this, the researchers held interviews with four non-profit experts to validate the conceptual model that was created. Eight different NPOs were then studied in a case study that involved semi-structured interviews, participant observation, and document reviews. Apart from the interviews, the conceptual framework derived from OP-BMC was tested on all different case studies. This involved describing and visualizing the organization's business model, utilizing available documentary material. The results were that all case studies confirmed the need to further adapt the language and definitions of the conceptual framework, as these were too profit focused. In addition, the nine-component framework was not optimal for the NPOs with multiple income streams, due to the complexity of NPOs [91]. These results led to the creation of a two-layer business model framework for NPOs, with separate programmatic and operational sections, connected via the organization’s value proposition. The proposed two-layer business model framework for NPOs that was developed in the study is shown in Figure 3.4.

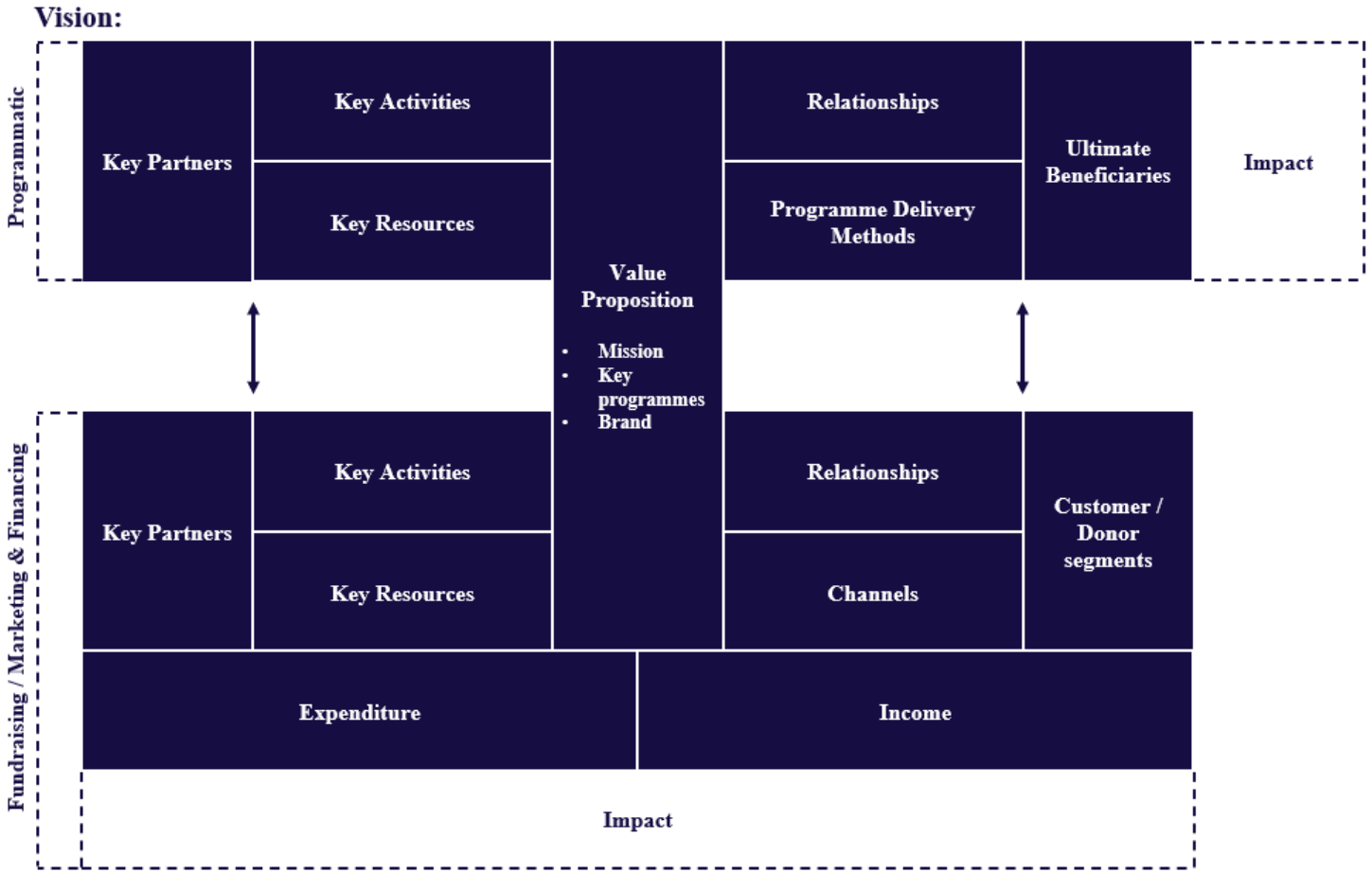


**Figure 3.4. Proposed two-layer business model framework for NPOs [91].**

Table 3.1 provides the definitions of the components of the two-layered business model framework for NPOs.

**Table 3.1. Definitions of the terms used in the two-layered business model framework for NPOs [91].**

| ***Key definitions*** | ***Description of key definitions*** |
|---|---|
| ***Vision*** | Outlines what the organization wants to be. It can be emotive and is a source of inspiration |
| ***Mission*** | Defines an organization's fundamental purpose and succinctly describes why it exists and what it does to achieve its vision |
| ***Key Partners*** | The network of cooperative agreements with other people or organizations, including governments, necessary to efficiently offer and distribute the organization's programs and achieve its mission |
| ***Key Activities*** | The main actions that an organization must perform to create its value proposition |
| ***Key Resources*** | The physical, financial, intellectual or human assets required to make the business model work |
| ***Value Proposition*** | The organization's mission, main programs and brand |
| ***Relationships*** | The type of relationships the organization has established or wants to establish with each key beneficiary or donor segment |
| ***Programme Delivery Methods*** | The method the organization uses to achieve its mission or develop program activities for its beneficiaries |
| ***Ultimate Beneficiaries*** | The target group that the organization principally aims to reach and serve to achieve its vision/mission |
| ***Channels*** | The communication, distribution and sales methods used by the organization to connect with its customer/donor segments |
| ***Customer/Donor Segments*** | The different groups of customers and/or donor segments that the organization targets for its fundraising activities. In this component, the customers tend to relate more to the organization's merchandising section, and the donors tend to relate to its fundraising section |
| ***Income*** | The income or funding streams, which could include donations, grants, merchandise/sales, investments or other income streams available for the organization to work on its value proposition |
| ***Expenditure*** | The total expenses the organization incurred or will incur to implement the agreed activities |
| ***Impact*** | The higher-level outcome of the project/program |

The separation was made since NPOs need to distinguish the unique strategies they must serve their programmatic customers (the beneficiaries) and their financial customers (the donors). Because here, the value creation and the value capturing are two different processes [12]. In other words, the framework differentiates between receiving stakeholders and paying stakeholders, and by doing this, the framework separates the operational and fundraising activities of the organization. All case studies declared that this new framework provided greater clarity, making it more useful for them. After adjusting the terminology, the case studies also acknowledged the suitability of the framework for NPOs with a single income source [91].

# 4 Results

*In this section, the synthesis of findings from interviews with key stakeholders across various sectors, including representatives from pharmaceutical companies, academia, industry experts, and organizational bodies, is presented. The findings are structured around addressing the two primary research questions guiding this project (presented in section 1.4 of the report). Each section is then divided into further subsections, addressing the subquestions (presented in section 2.1.5 of the report).*

## 4.1 RQ1

To ensure the success of the development of a suitable business model for Chalmers Precision HealthTech Hub, RQ1 was divided into five subquestions, previously presented in the methods section of the report. This approach was taken to thoroughly investigate various important aspects essential for the project. By doing this, section 4.1 will be divided into several sections, covering these subquestions, before ultimately leading to the proposal of the business model.

### 4.1.1 **Who Are The Stakeholders Of The Center?**

Understanding and meeting the needs of various stakeholders is essential for the success of any organization. In the context of this study, stakeholders encompass a diverse array of individuals and groups who are directly impacted by or have a vested interest in the organization's activities and outcomes. Table 4.1 provides a summary of the potential stakeholders along with a brief description of their involvement with the organization. Following the table, a more detailed explanation of each stakeholder's role and engagement will be provided.

**Table 4.1. Summary of potential stakeholders that will be relevant to Chalmers Precision HealthTech Hub.**

| *Stakeholder* | *Description of Involvement* |
|---|---|
| ***Chalmers*** | • Development and establishment of the organization<br>• Build competence regarding delivery of nucleotide-based drugs and ATMPs from the ground up, through the university<br>• Source of post-docs |
| ***Other Swedish universities*** | • Build competence within the ATMP sector<br>• Source of post-docs |
| ***Principal Investigators and other involved employees*** | • Principal Investigators will be involved in the advisory board<br>• Other employees will be involved through administration, board of directors and other operational roles |
| ***Customer segments spanning: Academia, Start-ups, SMEs & Big Pharma Companies*** | • These customer segments will be involved as the organization aims to assist them in their various research questions |
| ***CCRM Nordic, OligoNova and other similar initiatives within the ATMP industry*** | • Through potential collaborations regarding projects, expertise and infrastructure |
| ***Service Providers*** | • Contributing to a certain project through expertise, instruments and infrastructure |
| ***Hospital and Healthcare Professional*** | • Administer and treat patients with ATMPs, playing a critical role in the direct delivery of these therapies to patients |
| ***Financiers*** | • Funding to the organization |
| ***ATMP Sweden*** | • Enables important networking within the sector<br>• Builds knowledge through events and conferences |

As previously mentioned in the literature review, one distinct characterization of non-profit organizations is the involvement of various stakeholders. Therefore, when proposing a suitable business model for this organization, identifying all these potential stakeholders in the "Swedish ATMP ecosystem" is imperative.

Looking at the organization from within, some key stakeholders can be found. For starters, Chalmers will be taking the lead in its development and establishment, hence the name Chalmers Precision HealthTech Hub. Furthermore, Chalmers will also be an important stakeholder through the

academic route. Since one goal of this initiative is to maintain and increase the research knowledge of ATMPs within Sweden and the Nordics, it is important to be closely related to academia, and in this way build competence from the ground up with universities. For example, through the postdoc program. This also means that other Swedish universities will be stakeholders.

> *"Must create excellent expertise (state of the art), not lock itself into yesterday's or today's technologies but also create the ability to handle tomorrow's challenges. It's important to build from the ground up with universities, which provide expertise."*
>
> *- Industry expert*

Secondly, the Principal Investigators (PIs). These researchers will operate within the advisory board, where the main tasks will be to integrate research assistance, strategic development, and commitment to research quality for the various incoming projects to the organization. In addition to the PIs, the organization will include various employees spanning from administration, board of directors, and other operational roles.

> *"The advisory board serves as a facilitator in ensuring the excellence of the services within the organization."*
>
> *- Industry expert*

Identifying the various stakeholders outside of the organization is more complex, given the nature of the non-profit sector. When looking at the customer/beneficiary segment, three main stakeholders can be identified. These three are academia (researchers coming from academia), start-ups, and lastly, Small and Medium-sized Enterprises (SMEs) and big pharmaceutical companies. By offering expertise within the ATMP sector and infrastructure, the organization could assist these three customer segments in further exploring their research questions.

In terms of collaborations, it is important to observe other similarly structured organizations that are present within the ATMP industry. As previously mentioned in the empirical context two of these are CCRM Nordic and OligoNova, both based in Gothenburg. CCRM Nordic supports academic, small, and large industrial ATMP developers to translate research and early-

stage clinical programs into treatments for patients. OligoNova is a Swedish initiative, addressing challenges in the R&D of therapeutic oligonucleotides and supporting the development of novel therapies. Collaboration with CCRM Nordic and OligoNova is pivotal since the organization's activities exhibit similarities across various aspects in relation to Chalmers Precision HealthTech Hub. However, they also differ in some aspects. CCRM Nordic addresses bottlenecks in the translation and commercialization of ATMPs, whereas the primary purpose of Chalmers Precision HealthTech Hub is to promote research and development for safe and efficient nucleotide delivery for next-generation nucleotide-based therapies. And, as previously mentioned, OligoNova focuses on the research and development of therapeutic oligonucleotides. Given the intersecting nature of these organizations, it is imperative to avoid encroachment and instead seek opportunities for mutually beneficial outcomes. This could be achieved through collaborative endeavors encompassing projects, expertise, and infrastructure. The discussion surrounding these two entities and their relationship with Chalmers Precision HealthTech Hub was raised by multiple interviewees.

*“How will this organization relate to other similar initiatives, such as CCRM Nordic and OligoNova?”*

*- Several interviewees*

Another important stakeholder to this organization is service providers. These stakeholders can collaborate with Chalmers Precision HealthTech Hub by offering their companies’ technologies, expertise, and infrastructure when needed, for the organization to assist a certain project.

Given the organization's objective to facilitate the translation of healthtech, scientific advancements, and innovation into nucleic acid therapies, establishing close collaboration with healthcare providers is essential. Several interviewees emphasized the significance of involving healthcare as a key actor in this process.

*"Despite Sweden having strong regions and strong hospitals, we don't have the collaboration that is needed."*

*- Industry expert*

*"It doesn't matter how many centers we build if we don't get healthcare properly involved."*

*- Senior researcher*

*"It's important to involve Sahlgrenska to some extent; it's about treating patients, and it needs to be closely linked to research. It's important to consider that from the beginning."*

*- Senior researcher*

NPOs often get financial support from various actors, this organization is not dissimilar. Even though the organization will have an income stream from incoming projects, funding is crucial, especially in the build-up phase. This makes financiers an important stakeholder, from private to regional to government.

*"It is important to have sufficient funding in the beginning, so that it doesn't just end up being something that's half-heartedly thrown together (..) so that one can survive for at least a year."*

*- Big pharma employee & Industry expert*

Regarding the "Swedish ATMP ecosystem", another stakeholder appears. ATMP Sweden is the national network of Sweden's activities within medicines based on genes, cells, or tissue engineering. As Chalmers Precision HealthTech Hub is a center focused on the delivery, formulation, and analysis of nucleotide-based therapies, having a close connection to ATMP Sweden would be beneficial for many reasons. For example, by being involved in ATMP Sweden's conferences and events, the organization can increase its networking, stay up to date in new research and technologies, and enhance its brand recognition.

Identifying the stakeholders for an organization that has yet to be formed is a multifaceted undertaking. However, addressing this specific research question within this project is pivotal. It is essential to possess initial insights

into the key stakeholders that are going to be crucial for the organization and with whom collaborations can be forged, enabling the organization to flourish and succeed. Some stakeholders encompass broad categories, such as service providers and financiers, wherein various potential actors can be grouped.

### 4.1.2 **What Are The Different Stakeholders' Needs, Requirements, And Expectations, And How Are These Addressed In The Business Model?**

As previously mentioned not all of the stakeholders listed in section 4.1.1 were interviewed due to the time constraint. However, this section presents stakeholder insights regarding the organizations that align with their respective needs, requirements and expectations. Some important stakeholders that are included in this section are academia, start-ups and potential collaborators to Chalmers Precision HealthTech Hub. Through interviews and engagement with these stakeholders, their unique perspectives, priorities, and expectations have been gathered. By synthesizing their inputs, valuable insights emerge regarding the critical considerations necessary for the development of a sustainable and effective business model tailored to meet the diverse needs of the organization's stakeholders.

*Stakeholder Insights: Organization Overview And Feedback*
In this subsection, the insights gathered from stakeholder interviews are presented. During the interviews, a one-pager, presented in Appendix A.3, outlining the organization for which a business model is being developed was provided to the interviewees. This document served as a reference point for discussions, allowing interviewees to speak freely and provide valuable insights from their perspectives on the organization's development and operational phases. Table 4.2 provides a summary of the interviewees' insights from observing the one-pager, highlighting key topics discussed during the interviews. Following the table, a detailed explanation of these topics will be provided to give a comprehensive insight into the perspectives shared by the interviewees.

**Table 4.2. Summary of the Stakeholder's insights concerning the organizational structure of Chalmers Precision HealthTech Hub and additional feedback.**

| *Key takeaways from interviews* | *Description of key topics* |
|---|---|
| ***Market gap in terms of delivery of nucleotide-based therapies*** | • Many initiatives concerning ATMP-industry, but no initiatives that solely focus on the delivery issue<br>• Enables the ability to collaborate rather than compete |
| ***Positivity regarding the non-profit nature*** | • Enables collaboration with other entities in the ecosystem<br>• Enhances researcher engagement |
| ***Important to create synergies with other initiatives in the ecosystem*** | • Imperative to distinguish Chalmers Precision HealthTech Hub from other entities<br>• Industry with many different ongoing initiatives, important to become the missing piece of the puzzle<br>• Communication regarding who you are and what you do will become important |
| ***Important to involve the right individuals in the proposed organization*** | • Involvement of competent people both internally and externally is important in the beginning<br>• Creating a trustworthy board of directors will be strategically favorable for the organization<br>• Involvement of well renowned stakeholders might enhance credibility of the organization |

The majority of the interviewees seemed to have a positive attitude towards the organization. Many emphasized that there is a need to join efforts to solve the problems that the center is intended to target. Moreover, despite having many different initiatives concerning nucleotide-based therapies, there are yet none that solely focus on delivery and characterization.

*"I think you are needed because there is no equivalent to you today."*

*- Industry expert*

A recurring theme in discussions was the favorable reception towards the non-profit nature of the organization. It was emphasized multiple times that being non-profit does not necessarily entail breaking even, but rather underscores that the organization's primary objective is not profit generation. This aspect holds significance on various fronts: firstly, it fosters collaboration, as many industry stakeholders perceive the organization not as

a competitor but as a potential partner. Secondly, it enhances researcher engagement, as there is a prevailing belief among researchers that for-profit entities do not prioritize research promotion and often have misaligned missions. By operating as a non-profit, the organization counters this perception, a sentiment corroborated by insights from interviews with researchers.

*"Being non-profit facilitates collaboration with companies. If it's for-profit, there might be conflicts with companies, as you can't be as open with results, publications, etc."*

*- Senior researcher*

*"When you are starting, people are more willing to give the time for free to give you advice, if you are not-for-profit. I think government and policy bodies are more willing to be free and open with you. And they might support you more freely because you are not a competitor."*

*- International industry expert*

Some interviewees highlighted the challenge of finding relevant actors within the sector in Sweden. This difficulty often leads companies to seek partnerships abroad, resulting in both money and knowledge flowing out of the country, and the Nordics. A hub that could connect researchers or companies with relevant service providers or partners could therefore be beneficial.

*"We searched high and low for producers of viral vectors in Sweden but found none. We needed to acquire a lot of expertise abroad, the investment ended up abroad."*

*- Industry expert*

Several interviewees, representing diverse backgrounds and professional roles, highlighted the significance of organizational clarity regarding research focus and the researchers it aims to support, whether engaging in exploratory or applied research. They underscored the necessity for a clear understanding of whom the organization can assist and how to effectively support them. Moreover, one interviewee noted that technical researchers

may grasp the organization's offerings better than those involved in medical ground research. Additionally, to enhance clarity for potential customers, specifically researchers, a succinct and precise organizational title is deemed crucial. It was also suggested that the title should be restrained to instill trust in potential customers.

> *"Something to consider, then, is perhaps to be even clearer about which phase of research it is, is it exploratory research, is it applied research, who are the ones being helped, that's also something we receive feedback on quite often."*
>
> *- Industry expert*

> *"Here the question is: which researchers are the ones who should use this? If they are technical researchers then I think they can grasp this and understand. But those who are engaged in medical basic research, it's not certain that they understand who they should contact and how to get involved. So how do you find them?"*
>
> *- Senior researcher and Industry expert*

Once the organization is established and operational, it becomes crucial to involve relevant individuals from the outset. One interviewee emphasized the importance of forming a board of directors early in the process and having individuals whom you rely on could prove beneficial to include on the board.

> *"One must have a board fairly early on, which one trusts. In your case, it should include Chalmers, preferably also some industrial partners experienced in board work. You need to gather those whom you rely on to some extent."*
>
> *- Industry expert*

This was also echoed by many international initiative directors who further stressed the importance of involving the right individuals in establishing the organization, both internally and externally with partners and stakeholders. This is crucial for several reasons, particularly in terms of building trust. For the organization to grow successfully, there must be a shared understanding among employees regarding its vision and objectives. Having competent individuals whom one can trust to fulfill their roles is paramount in this regard. Furthermore, this approach is essential for fostering a unified vision

and ensuring clear communication with stakeholders, thereby enhancing trust among stakeholders, customers, and partners.

*"In the early days, all the work was embedded in very few people, and then leadership, and a trustworthy team, became very important."*

*- International industry expert*

*"We employed very knowledgeable people in the beginning, some of the best in the field. We weren't shy to say how good we were."*

*- International industry expert*

In summary, the general sentiment towards Chalmers Precision HealthTech Hub was overwhelmingly positive, with many interviewees acknowledging the gap that this organization could effectively address. However, it is crucial not to be perceived as a competitor to other initiatives, but rather to seek opportunities for collaboration and partnership. Additionally, the organization must develop a clear vision regarding its target customers and how to effectively reach and educate them.

*Academia*

This section presents the most frequently discussed aspects concerning the needs, requirements and expectations of employees of the academia. Table 4.3 summarizes some of the key topics discussed during these interviews.

**Table 4.3. Summary of the needs, requirements, and expectations addressed during interviews with researchers from academia.**

| *Key takeaways from interviews* | *Description of key topics* |
|---|---|
| ***Time is of the essence*** | • Many researchers express that they have limited time<br>• Have to create an attractive environment for researchers to want to be involved |
| ***Interdisciplinary collaborations are appreciated among researchers*** | • One of the success factors of FoRmulaEx, needs to be forwarded into Chalmers Precision HealthTech Hub<br>• Could serve as an enabler for researchers to want to enter |
| ***Postdoc program will become an enabler for researcher engagement*** | • Always an issue within the industry that resources are limited<br>• Interesting opportunity to have 1-2 postdocs / PI<br>• The environment at GoCo will attract competent postdocs |
| ***Research must remain as the primary occupation*** | • Need to ensure that the researchers are allowed to be researchers first hand, and advisory board second<br>• Important that the organization doesn't become a contract research organization (CRO)<br>• If the researchers of the advisory board are allowed to conduct research within the organization, this could increase the interest among PIs |

There is a notable concern among the PIs regarding the urgency of time. Alongside this concern arises the challenge of ensuring that the engagement of PIs is worthwhile. Many PIs express the belief that the postdoc program could provide the necessary incentive to attract and garner support from well-established researchers in the field. Furthermore, a recurring theme in many interviews is the importance of researchers prioritizing research as their primary occupation. Allowing them to conduct research within the organization could serve as another facilitator for their involvement. Additionally, many interviewees emphasized the significance of selecting the right individuals for involvement. They must possess the appropriate mindset and be willing to dedicate the required effort. Despite the size of the research community in Sweden, there is a recognition that unsuccessful collaborations could jeopardize existing relationships, potentially leading to future complications.

Furthermore, the expectations among researchers regarding the future trajectory of this center are somewhat divided. Many of the researchers interviewed were formerly associated with FoRmulaEx and displayed a high level of enthusiasm to participate, citing successful collaborations fostered under that initiative. However, a crucial point highlighted during the interviews is that the center must evolve beyond merely continuing the previous initiative. It must also identify the current needs of the industry to remain relevant and effective. Moreover, although the PIs will undoubtedly become integral to the organization, it will be crucial to delineate their roles and responsibilities. Establishing clear expectations for the tasks of the PIs, through mutual agreements between the organization and the PIs, will foster further successful collaboration.

*"I can imagine being involved, looking at projects and such. Also, being able to have industry postdocs to help and drive the development I'm doing, and to use infrastructure for analysis and such, which I wouldn't have in the lab. So yes, at that level. It's an academic obligation to be involved in promoting research, of course, it can't be too much, and time is the biggest limitation. Not much more than 3 hours per month on average is what I could contribute."*

*- Senior researcher*

*"I think it's very important for Chalmers to consider this, and not just rely on researchers wanting to stack up tasks and that we have endless resources. We also have some other things in life that we want to make time for."*

*- Senior researcher*

Another aspect that emerged was the previous success of FoRmulaEx, attributed to interdisciplinary research efforts wherein researchers from diverse disciplines collaborated on various projects. It was noted that collaborations among researchers with similar expertise were not as successful. Hence, Chalmers Precision HealthTech Hub must emulate the approach of FoRmulaEx by promoting interdisciplinary research projects.

*"I have had a successful collaboration with an organic chemist, I like the principle that different disciplines get the opportunity to do this. We could do better in the future, if we end up at GoCo, we can collaborate with more actors and do even better."*

*- Senior researcher*

*"If you're already collaborating with someone who can do exactly the same things as yourself, then it's not as obvious why you need each other, maybe you just manage to push the research forward a bit faster. But here, it's about research projects that each individual couldn't have done alone, you need input from each other and to help each other with different things. I believe that's an important concept for success."*

*- Senior researcher*

It is important to note that the overall view from researchers was positive and that many of them are eager to contribute and be a part of this new initiative.

*"I find it exciting; I think there are things there, and for me, who doesn't have FoRmulaEx as the main research area, it's also a way for me to keep a foot in the research."*

*- Senior researcher*

*Start-ups*

During interviews regarding the needs, requirements, and expectations of start-ups potentially becoming both customers and collaborators of the organization, several key aspects were highlighted.

Firstly, it was noted that the needs, requirements and expectations are likely to vary from company to company and that finding a common thread can be challenging. Moreover, these depend on various factors such as the company's stage of market launch, customer segments, and activities. However, some similarities were mentioned by several interviewees, one of which was infrastructure.

Many start-up companies in the life science sector are relatively small and have limited resources to invest in the infrastructure necessary for their operations. As a result, they often rely on universities or other organizations

that have the required resources. Therefore, it was mentioned that access to infrastructure through Chalmers Precision HealthTech Hub could serve as an enabler for engaging start-up companies as customers.

> *"For us, infrastructure is also highly relevant. We are still a very small company, and there are numerous tools and external expertise available from other players that we need to leverage."*
>
> *- CEO of start-up company*

Another aspect that was highlighted is the opportunity to increase exposure through collaboration with the organization. Partnering with Chalmers Precision HealthTech Hub would facilitate valuable customer interactions that would continue to be beneficial beyond the project's completion. Therefore, it is important not only to view these companies as customers but also as partners and potential service providers.

> *"That we can be part of an organization like this is very advantageous for us as well. It allows us to attract the customers or individuals who come to you. By doing so, we can understand the actual needs and then tailor our services accordingly."*
>
> *- CEO of start-up company*

An issue that emerged during the interviews and one workshop, and consequently becomes a prerequisite for attracting start-ups as customers are Intellectual Property management (IP-management). In short description, IP is a term used to determine who has ownership of the results from the laboratory work. Since start-up companies often require investors to facilitate growth and expansion, it becomes crucial for them to have ownership of the IP that underpins their technology. This is an aspect that Chalmers Precision HealthTech Hub will need to address to gain the trust of these companies, and further, to engage them as partners and customers.

*Potential Collaborators*

Currently, the ATMP industry hosts numerous initiatives and organizations. Many interviewees emphasized the significance of identifying Chalmers Precision HealthTech Hub's unique niche, positioning it as a complementary entity rather than duplicating existing efforts. Effective communication emerged as a recurrent theme, both in disseminating the hub's focus areas to the community and fostering connections with other initiatives. This

emphasis on communication is integral to facilitating collaboration, a cornerstone of Chalmers Precision HealthTech Hub's mission. While most organizations express openness to collaboration, some argue for the necessity of developing regional ecosystems before engaging in broader partnerships.

One interviewee stressed the importance of building networks, asserting that forging significant collaborations is essential for growth and establishing credibility within the industry.

*"What's crucial is to find interfaces between the different organizations so that they don't perceive each other as competitors, but rather as entities that can assist one another. Because no one can do everything, that's the reality."*

*- Similar initiative employee*

Another aspect highlighted during the interviews is the expansive scope of collaborations, which extends beyond initiatives solely focused on the specific niche of ATMPs. It is proposed that collaborations should also involve other lab core facilities, even those with activities beyond ATMP. This approach aims to establish partnerships that leverage each other's strengths. The life science research industry requires substantial infrastructure investment. Facilitating such collaborations presents opportunities for mutually beneficial outcomes, particularly when another organization possesses the equipment necessary for a specific project. This dynamic adds further complexity to the ecosystem that requires establishment.

*"I see a potential marriage between our organizations."*

*- Manager of a lab core facility*

*"I find it intriguing, there seem to be points of connection between what you are doing and what we are doing, even though there are some differences. In many respects, achieving the same goals. I see the potential for results that could come from facilitating a relationship here."*

*- Manager of a lab core facility*

### 4.1.3 **What Is A Business Model And What Differentiates It From A Revenue Model?**

During the interviews that were conducted to gain insights into various business models, it became evident that there is considerable ambiguity and lack of clarity surrounding the definition of the term business model. While some interviewees from similar initiatives within the industry shared their organizations' business models to provide further insight, the diversity in these presentations was striking.

While some simply described their organization and labeled it as their business model, others outlined the various stakeholders involved. Additionally, one interviewee presented their business idea, value proposition, and business plan as their business model. This variability underscores a persistent misconception regarding the definition of a business model within this context.

Moreover, understanding and differentiating the concepts of business models and revenue models is pivotal when proposing a suitable framework for the center, since these terms have often been conflated, resulting in confusion. The literature review delved into these definitions, providing clarity on their distinctions, thereby addressing this aspect comprehensively.

### 4.1.4 **What Important Aspects Need To Be Considered When Developing A Business Model Applicable To The Non-Profit Research Center?**

Before delving into the specific aspects of developing a business model for the non-profit research center, it is valuable to explore the insights shared by the interviewees regarding important considerations when operating within a non-profit organization. Understanding these broader perspectives can provide valuable context for developing a business model tailored to the unique needs and objectives of the research center. Table 4.4 presents some of the topics discussed in the context of important aspects to consider when implementing a business model applicable to a non-profit research center.

**Table 4.4. Summarizing topics discussed concerning important aspects to consider when developing a business model for an NPO.**

| *Key topics from interviews* | *Description of key topics* |
|---|---|
| ***Aspects of NPOs*** | • Not-for-profit is not equal to not being allowed to make money<br>• Not having responsibility towards shareholders may increase the risk-taking of the organization<br>• Important to consider sustainability to ensure survival<br>• Involvement of the stakeholders is a complex but vital task for NPOs<br>• This industry is not very lucrative, which means that being not-for-profit is positive in many aspects<br>• Positively viewed among researchers and other actors within the industry |
| ***Aspects of Business models for NPOs*** | • The term business model is viewed differently in the industry. However, it is important to build despite being a non-profit entity<br>• Establishing a network can become a vital factor for success<br>• Important to not only build but also foster the relationships over time<br>• Identifying the market gap that your organization intends to fill will become very important to create a unique value proposition<br>• Changing the value proposition in alignment with industry changes will ensure that you not only survive but thrive |

*NPOs*

When discussing the intricacies of NPOs, it was evident that interviewees had different perspectives of what an NPO is, and how they operate. When explaining the organization during the various interviews, some interviewees perceived the organization as potentially break-even, where revenues match expenses. Conversely, other interviewees envisioned it as capable of generating profits, albeit with the caveat that these earnings would be reinvested rather than distributed to owners or shareholders.

*"There is a general misunderstanding of what differentiates a not-for-profit and a for-profit organization. Because being not-for-profit doesn't equal not wanting to make money. It doesn't mean that you want to make a profit, but you do want to make money because you want to be able to reinvest and get additional activities."*

*- International industry expert*

Another important note that was brought up by an international actor involved in an NPO was the fact that since they are non-profit, they do not need to chase the money in terms of satisfied shareholders. Instead, they were able to take risks that for-profit organizations would not do. This was seen as a major advantage. Moreover, this acknowledgment suggests that NPOs can have the upper hand in certain scenarios, leveraging their freedom from shareholder demands to tackle significant challenges and to take calculated risks that for-profit entities might shy away from. It underscores the importance of utilizing this advantage wisely to maximize societal impact and organizational effectiveness.

*"We don't need to chase the money in terms of satisfied shareholders, which allows us to take risks and look at those big challenges, that if you were a for-profit organization, you wouldn't do. Because you have to answer to your shareholders. So it allows you to take risks, and it allows you to have a longer view which I think is quite important."*

*- International industry expert*

When interviewing non-profit actors, another topic of interest was sustainability efforts, and how these NPOs work day by day with these types of questions in a fast-evolving and changing industry such as life science. One interviewee affiliated with an NPO addressed that their sustainability efforts are still in the early stages.

*"That's a good question because it's something we've recently noticed, that we haven't had a really good process for that."*

*- Manager of lab core facility*

However, there has been a noticeable uptick in such initiatives, likely accelerated by the heightened competitive landscape facing NPOs. Many interviewees mentioned that their organizations had designated employees

responsible for addressing sustainability concerns, such as having state-of-the-art instruments and infrastructure. For these questions, one interviewee mentioned that they appointed a Chief Sustainability Officer (CSO), while another interviewee mentioned that they appointed a Chief Technology Officer (CTO). However, in some cases, it was noted that all employees within the organization in some capacity addressed these questions, indicating that sustainability had become ingrained in their organizational culture.

*"I think we all work with these types of questions, more or less."*

*- International industry expert*

In the context of NPOs, the involvement of various stakeholders is paramount for success. However, during an interview session with an international actor, it was highlighted that aligning the interests and objectives of these diverse stakeholders can be a challenging task.

*"Because these public-private partnerships are very complex. They involve many different stakeholders, so trying to align those is very hard."*

*- International industry expert*

It was further noted that the scientific industry, as a whole, is not particularly lucrative, and therefore, being a non-profit entity is advantageous from this perspective. Additionally, it was suggested that many of the customers of these organizations are scientists, and the non-profit status increases their willingness to utilize the services provided.

*"Being a not-for-profit is kind of necessary to become what we call an honest broker, and to be the connection between industry and academia."*

*- International industry expert*

*"Since our organization is within the industry of advanced therapies, and within the research part of advanced therapies, we needed to build a lab with additional expensive equipment in it. This means that the organization required significant amounts of investments to begin with, and is thereby not suited to be a for-profit entity. Because once we begin to operate our activities, the primary goal is to promote research, not to generate profit."*

*- International industry expert*

*Important Aspects Regarding Business Models*

Having explored the insights gleaned from interviews regarding crucial aspects of NPOs, attention now shifts towards presenting essential considerations for implementing a business model tailored to an NPO setting, attained through the interviews.

Before looking into the findings within this subject, it is important to note that the term business model was not universally understood in the same way by all participants. Indeed, perspectives on what constitutes a business model varied significantly depending on the interviewee's role and background. However, the lack of clarity was still particularly notable, with some ambiguity surrounding the concept.

One notable insight gleaned from the array of interviews is the recognition that despite the organization's non-profit status, it remains important to establish a robust business model that encompasses revenue-generating mechanisms. And that this revenue, when appropriately managed, can serve as a vital resource for reinvestment into the organization. By strategically channeling revenue back into the organization, it becomes possible to enhance its overall impact and efficacy, ultimately furthering its specific mission and objectives.

*"Just because an organization is non-profit doesn't mean it can't have an ambition for parts of its activities to be revenue-generating, which can then be internally allocated to initiatives that contribute more broadly to ecosystem value creation."*

*- CEO of a life-science organization and Industry expert*

When developing a business model, several interviewees emphasized the importance of identifying the market gap that the value proposition intends

to address. This is particularly crucial in the context of NPOs, where the involvement of multiple stakeholders amplifies the significance of this task.

*“It is all about aligning the interests of the stakeholders, it is all about having suitable value propositions.”*

*- International industry expert*

Accordingly, identifying stakeholders and soliciting their input regarding their needs will help establish the organization's value proposition. It is not only essential to seek stakeholder input at the outset but also to make it an ongoing practice. This approach ensures that the business model remains flexible, and the organization maintains continuous relevance. Furthermore, it was suggested that the business model can be kept relatively narrow and precise, avoiding unnecessary complexity. While the business model itself may remain somewhat rigid, it is crucial for the value proposition to maintain flexibility.

*"If it's the business model you're going to develop, I would just say don't overdo it, keep it narrow and precise.”*

*- Similar initiative employee*

*"The business model may be somewhat rigid, but the content of the value proposition must be flexible."*

*- Industry expert*

During interviews with international organizations, a topic that was brought up several times was the importance of establishing a network. By establishing a network, you can get an idea of who your stakeholders are and what their needs and expectations are of the organization. Once you’ve established a network you can build an ecosystem of individuals that will be important for the success of your organization.

*"A lot of what drives my organization is understanding that network is very important. It's about connecting stakeholders, aligning their interests, building connections between technologies and people, and institutions to, in the end, build ecosystems."*

*- International industry expert*

*"So first of all you have a purposeful plan of how you are going to build the organization, and then you always want to network with someone that is more networked than you are. You have to find academic leaders that then can help you draw in other academic leaders, or other institutions etc."*

*- International industry expert*

### 4.1.5 How Do Lab Core Facilities Set Up Their Business Model, And How Are They Handling Questions Such As Payment Model And Academia Vs. Industry Margins?

When developing a business model, a strategic approach involves observing similar organizations and analyzing their business models to gain insights and inspiration that can be applied to the new business model. This section presents the results of interviews conducted with employees from lab core facilities, including an overview of their organizational structure, pricing margins, and user base. These interviews provide valuable tips and strategies for the development of the payment model for Chalmers Precision HealthTech Hub.

In addition to assessing laboratory core facilities from a collaborative perspective, these organizations were also analyzed to gain insights into their operational structure, business models, and payment systems. This was aimed at gathering valuable insights that could later be applied to the project. When observing their operational structure, various aspects of these organizations were discussed during the interviews. Figure 4.1 illustrates some of these key aspects.

| | Organization X | Organization Y | Organization Z |
|---|---|---|---|
| Usage | 98% Academic users | • Occupancy rate of 70%<br>• Certain split between non-economic (research & education) and economic (startups) users | • 80% Academic users<br>• 20% Commercial users |
| Pricing model (based on users) | • Full cost model for commercial users<br>• Full cost model for international scientific users | • Cost by access-fee for instruments<br>• Cost based on ”government-support-regulations”<br>• Full-cost-model for commercial users (40% more access-fee / week) | Pricing categorised into three categories:<br>1. Academic users<br>*”We subsidize as much as possible, primarily from universities”*<br>2. Start ups / Micro companies<br>3. Commercial users |
| Pricing model (based on instrument) | • Cost based on the complexity of the instrument<br>• Priced based on depreciation costs | • Break-even model, pricing altered based on occupancy rate | • *”If you have 750 items, then it's 750 devices that would cost differently, but we've grouped them”*<br>• A reasonably coarse-grained model<br>• They are in different categories, with different prices |
| ”Do It Yourself ” vs. In-house operation of instruments | • Some cases: Short education by staff scientists, then DIY-lab<br>• Some cases: DIY-lab<br>• Some cases: Some instruments have a high sensitivity and thereby require in-house staff scientists to operate them | DIY-lab | • Majority DIY-lab<br>• Have staff scientists that can assist with project planning etc. |
| IP-management | 30% ownership of IP, rest to the scientists themselves | Scientists get complete ownership of IP | Scientists get complete ownership of IP |

**Figure 4.1. The figure summarizes the observations of three different lab core facilities in Sweden.**

In terms of usage, it is evident that the majority of users in all observed organizations are of academic origin. One director mentioned that their organization has a 98% academic usage rate. This high academic involvement is partly attributed to the close relationship the organization maintains with the university. They consider it integral to their activities to train university students, PhDs, and postdoctoral researchers in laboratory procedures. Additionally, they view facilitating commercially viable outcomes from research projects as an essential component of their business model.

*"Making competence and infrastructure available to academic researchers for conducting translational research to be further developed for clinical use."*

*- Director of organization X*

In the other two organizations, a significantly higher percentage of usage was commercial. This was attributed to economic factors, as commercial users typically have greater financial resources. The increase in commercial usage is seen as a means to generate more revenue for the organization, thereby ensuring its sustainability.

*"We aim to break even, plain and simple. This also means that we must cover our costs somehow, and we do this by charging an access fee for all projects that come in. That's how we finance ourselves."*

*- Director of organization Y*

In the realm of lab core facility payment models, distinctions arise across organizations. Nonetheless, a prevalent practice entails differentiating pricing structures between academic and commercial users. It is recognized that academic users often possess more limited financial resources compared to their commercial counterparts, thus necessitating careful consideration in pricing strategies. Because of this, there was an implicit consensus within this industry that academic users would receive maximum support.

Pricing instruments based on their individual characteristics poses a considerable challenge. Each instrument has its own cost and throughput capacity, making pricing a complex task. Moreover, the three organizations vary in size, resulting in differences in the number of instruments they

possess. In the larger organization, Z, a pricing system has been developed for its instruments. Instruments are categorized based on their complexity and cost to create a simplified pricing model.

Further, since the organization of Chalmers Precision HealthTech Hub is intended to be more than just a lab core facility, several of the interviewees highlighted the importance of the selection of the instruments that the organization should possess.

The inquiry also extended to whether customers were permitted to independently operate the instruments or if they were assisted by in-house staff scientists. Given the high sensitivity of the instruments commonly utilized within this industry, a requisite level of training is often necessary to ensure optimal results. This aspect is particularly significant in terms of usage, as academic institutions typically provide training to their staff before accessing these facilities. In contrast, commercial users may have less familiarity and require training before being granted access.

IP management was also brought up for discussion during the interviews. This is a sense of conflict in the industry as Swedish Scientists by law have complete ownership of the results of their work at universities. However, since these organizations are independent of these legislations some of them have decided to claim a portion of the ownership. The reasons for this were not discussed during the interviews but will be further discussed in the future recommendations section below.

To conclude the findings from interviews with directors of lab core facilities, there is a diverse strategy approach in all of these aspects, and several aspects need to be considered when composing the business model and operational approach of Chalmers Precision HealthTech Hub.

### 4.1.6 **Finalized Business Model**

This section presents the proposed business model, including the payment model developed specifically for this project and organization. These models are the result of synthesizing insights from the literature review, interviews, and consultations with involved personnel within the project. The section details the key components and rationale behind these models, outlining the

strategies and approaches tailored to meet the organization's goals and objectives.

The business model was developed using a framework derived from the existing literature. Insights obtained from interviews were then integrated into this framework. As outlined in the literature review section, the business model comprises two distinct parts: Programmatic and Fundraising. As fundraising fell outside the scope of the thesis project, this aspect was developed in collaboration with the project leader at Chalmers Precision HealthTech Hub. The finalized business model is presented in Figure 4.2.

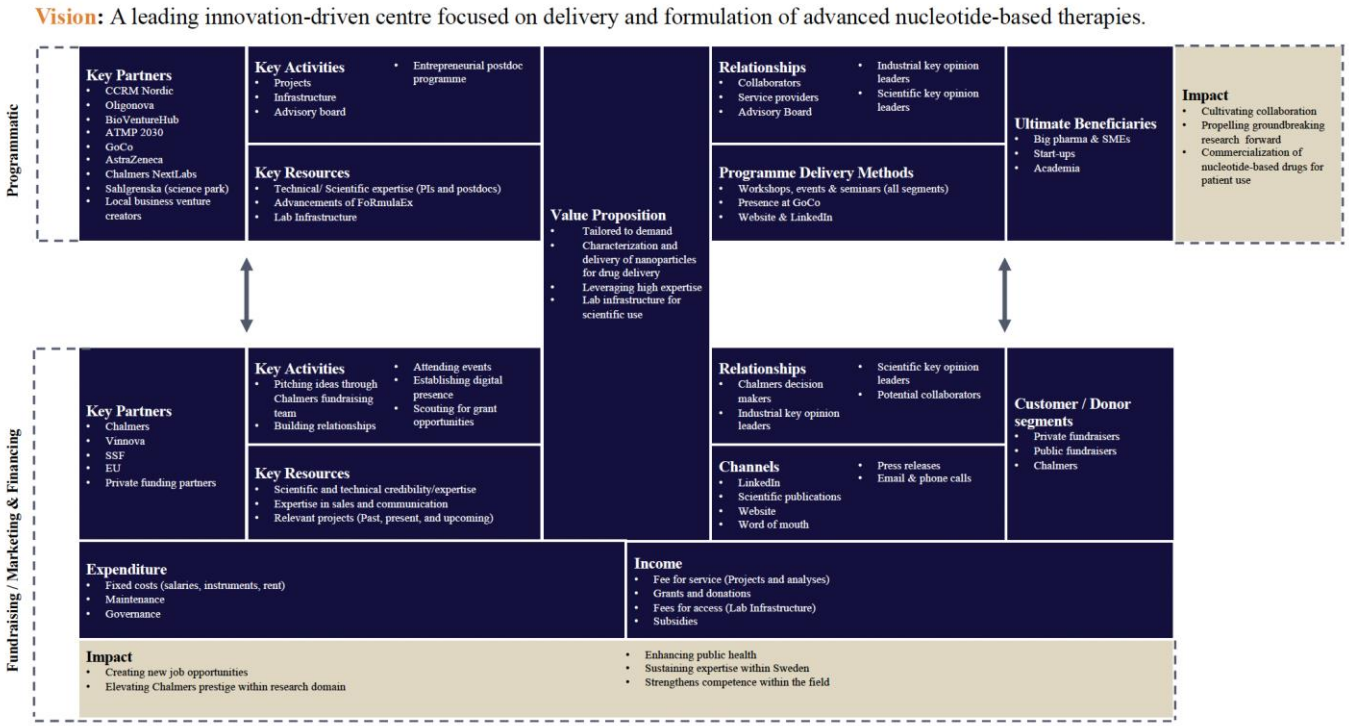


**Figure 4.2. Finished Business Model proposed to Chalmers Precision HealthTech Hub.**

The different components of the framework have been explained previously in the literature review. Here, the contents of the different components will be presented, starting on the programmatic segment.

*Vision*
Having a clear vision is important for any organization, as it outlines what the organization wants to be. The vision of Chalmers Precision HealthTech Hub is to be a leading innovation-driven center, focusing on the delivery and formulation of advanced nucleotide-based therapies.

*Key Partners*
The potential key partners illustrated in the figure are CCRM Nordic, OligoNova, BioVentureHub, ATMP Sweden, GoCo, AstraZeneca, Chalmers NextLabs, Sahlgrenska (Hospital and Science Park) and local business venture creators. These actors were decided as key partners due to numerous reasons; potential collaborators, providing infrastructure, linkage between research and healthcare, and contributing with expertise and personnel in the form of postdocs. It is important to note that these actors are all potential partners, and that partnerships with them have not been confirmed.

*Key Activities*
The key activities that Chalmers Precision HealthTech Hub will actively work with are through projects, offering infrastructure and expertise through the advisory board, as well as contributing to competence development through the postdoc program.

*Key Resources*
In the pursuance of contributing to these activities, resources are required. These are technical and scientific expertise through the advisory board and postdocs, lab infrastructure, but also using the knowledge gained from the advancements of FoRmulaEx.

*Value Proposition*
The value proposition encompasses the organization's mission to be tailored to the diverse demands of incoming projects. Additionally, the organization will focus on the characterization of various delivery methods for nucleotide-based drugs, leveraging its high degree of expertise. The organization will also provide essential infrastructure for scientific use, further enhancing its value to stakeholders.

*Relationships*
The relationships that need to be established for this to work are with collaborators, service providers, the advisory board, and industrial and scientific opinion leaders. For the projects to be deemed successful, collaborators, service providers and the advisory board need to be in place. Close relationships with key opinion leaders, both industrial and scientific, are vital for the organization to stay abreast of the latest developments in the field, access expert knowledge, and foster collaboration. These opinion leaders provide valuable insights, guidance, and validation for the organization's initiatives, ensuring alignment with industry trends and best practices. Additionally, their endorsement and support can enhance the organization's credibility and facilitate access to resources, funding, and partnership opportunities.

*Programme Delivery Methods*
The programme delivery methods are key for spreading the word about the organization, illustrating its reliability and expertise, and gaining ultimate beneficiaries. This will be done through workshops, events and seminars within all segments, that is researchers, start-ups, SMEs, and big pharma companies. In addition to this, being located at GoCo would be beneficial since having its presence where actors within the same sectors operate increases the likelihood of new projects and collaborations. A website and LinkedIn page for the organization will also be of importance, having a landing page where stakeholders can be educated, interested, and contact the organization if necessary.

*Ultimate Beneficiaries*
The ultimate beneficiaries, as shown in the figure, are big pharma companies and SMEs, start-ups, and researchers. These diverse actors can be assisted by Chalmers Precision HealthTech Hub in their various research questions, either during a short period of time where the hub's expertise, infrastructure and instruments can contribute to a certain question that must be answered, or during a long-term project, depending on the scope and size of the research.

*Impact*
When assisting and collaborating with these ultimate beneficiaries, the goal is to create an impact where collaborations between academia and industry are cultivated. And by doing this, propelling the groundbreaking research

forward in order to increase the commercialization of nucleotide-based drugs for the intended patients in need.

As financing was not within the scope of this project, the section of the business model concerning Fundraising, Marketing, and Financials was completed with the assistance of the project leader, whose expertise lies in these areas. Therefore, its content will not be presented more thoroughly.

Besides this filled out framework, an additional payment model was developed as a part of the business model to understand important aspects of how the organization is intended to generate revenue besides getting grants and donations. The payment model presents the organization's possible revenue generation from activities performed within the organization. The finalized payment model is presented in Figure 4.3.

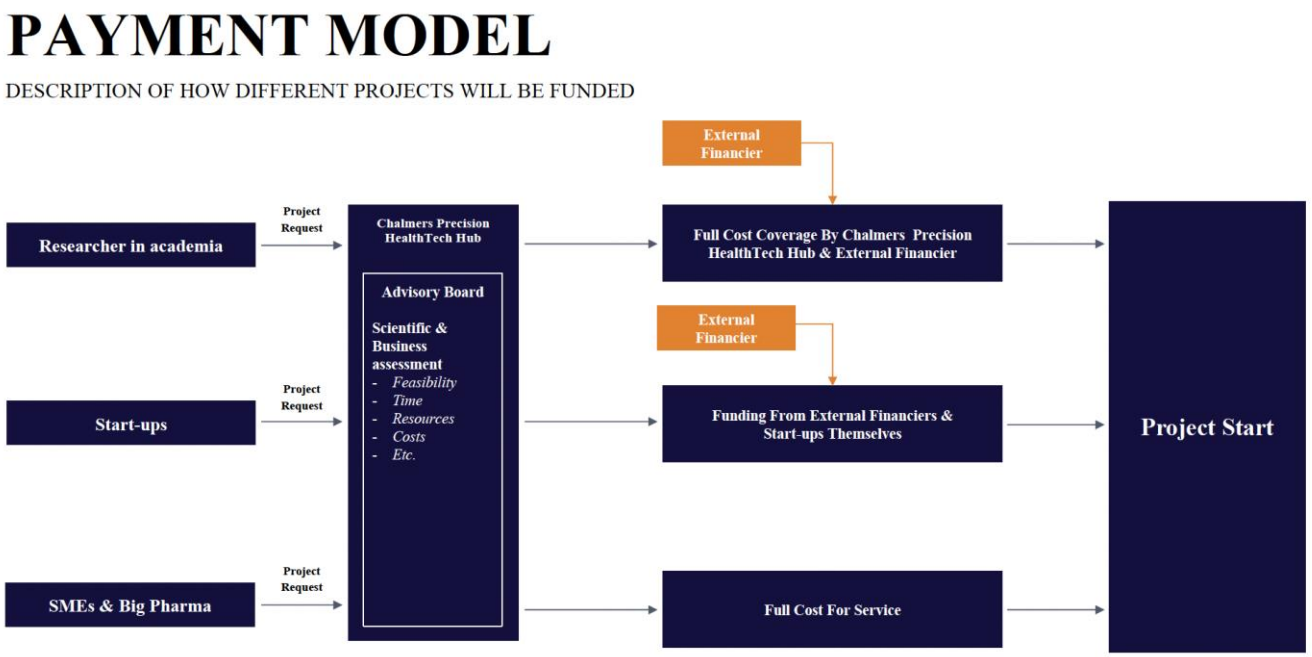


**Figure 4.3. Finished Payment Model (as part of the business model) proposed to Chalmers Precision HealthTech Hub.**

The payment model is structured into three sections, each catering to distinct customer segments based on their financial capabilities. These three customer segments include the ultimate beneficiaries, shown in the business model: researchers, start-up companies, and SMEs and Big Pharma companies.

The decision to divide the customer segments into three parts was based on valuable interviewee insights. Many interviewees emphasized that a "one size fits all" approach was not suitable in this context. Hence, the authors made this division to better address the diverse needs of different customer segments.

> *"I think it's good to have (not just one model) because, as you mentioned, you will have different customers. So, having flexibility regarding pricing or regarding the business model is probably a good idea."*
>
> *- Industry expert*

Furthermore, the payment model outlines the process from the customer's project request to the commencement of the project. Consequently, the advisory board of Chalmers Precision HealthTech Hub is involved, as they will evaluate key project aspects before approval. These aspects include feasibility, project timeline, required resources, costs, and others.

Once the advisory board determines whether Chalmers Precision HealthTech Hub should undertake the project, it proceeds to the funding stage. During this phase, the amount of financial support is determined based on the customer's requirements. Upon completion of the funding arrangements, the project begins.

## 4.2 RQ2

Given the dynamic and rapidly evolving field of nucleic acid therapies, it is imperative for the center to ensure continued relevance and to maintain a sustainable value proposition. To answer these questions, RQ2 has been divided into three subquestions, addressing certain aspects that need to be covered.

### 4.2.1 What Are The Challenges In The Industry And How Is It Expected To Change / Evolve Over Time?

The sustainability aspect refers to the survival of the organization over time in a competitive and dynamic market landscape. A flexible business model is imperative for this to be achievable. In this section, the interviewees' general attitude toward the future of the ATMP industry is presented, including both optimistic views as well as important hurdles to consider. Moreover, two different aspects of sustainability were examined during the interviews. The first is the interest from a scientific point of view, and the other from a financial perspective looking at investments that have been made over the last few years, and further predicting the future of the industry.

*General Attitude Towards The ATMP Industry*

The responses from interviewees regarding the future of ATMPs and the industry varied slightly among the interviewees. While all expressed positivity, the degree varied. Some offered solely positive perspectives, whereas others highlighted significant hurdles or gaps that must be overcome.

*"This type of smart drugs, that's the future."*

*- Senior researcher*

One major hurdle that was addressed by several interviewees was their concern regarding the cost of ATMP therapies, and that models need to be made for how society and healthcare can use these therapies in a sensible way for treating patients. If the cost of these therapies is too high, the impact of ATMPs disappears, regardless of their potential to cure diseases. Interviewees also brought up challenges regarding the toxicity and cellular uptake of ATMPs but were still optimistic about solving these challenges.

*"We must bring down the cost of goods. It's not just about what ATMPs will be able to offer; we also need to find models for how society and healthcare can use them sensibly."*

*- Industry expert*

Another hurdle that could be worth mentioning is around the regulatory authorities and the impact that these authorities will have on the ATMP industry, as therapies continue to evolve. This was brought up by one interviewee.

> *"I believe that it will continue to evolve significantly, but that the regulatory authority will be a little stricter in 5-10 years regarding some of these things, what you can and cannot do."*
>
> *- CEO of start-up company*

Overall, the interviewees' view of ATMPs and the future of its industry were optimistic. Some major challenges need to be addressed and solved, but they considered the future of ATMPs promising.

*Scientific Future*

The interviewees' insights regarding the sustainability of ATMPs from a scientific point of view are summarized in Table 4.5. The contents of the table are then brought up and explained in more detail.

**Table 4.5. Summary of the interviewees' attitudes towards the scientific future for the industry of ATMPs.**

| ***Key takeaways from interviews*** | ***Description of key topics*** |
|---|---|
| ***ATMP industry shows great promise*** | • ATMPs present a paradigm shift in the pharmaceutical industry<br>• Delivery is the primary obstacle that still needs resolving |
| ***Different delivery methods currently under investigation*** | • Examples of delivery methods: Exosomes, Adeno-associated vectors, LNPs, and Polymer-based nanoparticles<br>• Nanotechnology has in recent years become more important |
| ***Different delivery methods require different infrastructure*** | • Despite similar objectives, different delivery methods require different infrastructure<br>• Important for the organization to select and create expertise within 1-2 different methods to create credibility in the industry |

In the scientific discourse, the diverse delivery approaches for nucleotide-based treatments were examined. Several interviewees emphasized the

pivotal challenge of delivery in shaping the future trajectory of the pharmaceutical industry. Moreover, there exists significant anticipation regarding the potential advancements facilitated by this technology. Currently, various delivery methodologies are under scrutiny, including LNPs, exosomes, polymer nanoparticles, and AAVs, among others. It is crucial to recognize that despite their shared objectives, these techniques operate distinctively, necessitating diverse research infrastructures. Many interviewees underscored the significance of concentrating on one or perhaps two of these delivery methods and effectively communicating this strategy to stakeholders to gain credibility in the industry. The preceding FoRmulaEx initiative has delved into the science of LNPs. Nonetheless, a prevalent sentiment among industry experts suggests that nanoparticles hold significant promise for the future. However, it is imperative for the center to adopt a broader perspective encompassing various types of nanoparticles, rather than solely concentrating on LNPs. This holistic approach is essential for achieving sustainability, vital for the center's continued viability.

*"Optimistic about resolving the initial issue. The industry experiences cyclical trends, and presently, we are at a pinnacle. This category of intelligent pharmaceuticals represents the future."*

*- Industry expert*

*"Yes, indeed, this is just the beginning. As we deepen our understanding of chemistry, mastering the ability to precisely navigate them, entirely new opportunities will emerge. It won't be limited to just liver diseases, there will be many other applications. That's what I believe. Previously, LNPs were essentially toxic, when we injected them into mice, the reactions were far from pleasant. So, I think there's still much to explore in that realm. However, It is important to not place all the eggs in one basket"*

*- Industry expert*

### *Financial Future*

Table 4.6 illustrates the key topics that were discussed during the interviews regarding the financial future of ATMPs and its sector.

**Table 4.6. Summary of the interviewee's attitudes towards the financial future of the industry of ATMPs.**

| *Key topics from interviews* | *Detailed description of key topics* |
|---|---|
| ***COVID-19 important eye-opener to the possibilities with the technology for the general public*** | • The COVID-19 vaccine was an important advertisement to the public<br>• With increased interest among the public, investments will follow<br>• Investments in any industry occur in waves, and currently, this technology is experiencing a surge in funding |
| ***Significant investments regarding ATMPs have been made, confirming the interest in the field*** | • Many new initiatives concerning the topic regionally and nationally<br>• Many large pharma companies are expressing interest in the technology<br>• More treatments have gained FDA approval<br>• More patients are treated using the technology |
| ***Fragmented industry, based on many initiatives and a lack of collaboration*** | • Many ongoing initiatives<br>• Too many initiatives are doing the same thing, which creates inefficiency<br>• More extensive collaboration will be the key to success |

During discussions on ATMPs, numerous interviewees cited the COVID-19 vaccine as an illustrative example of this technology's potential, particularly for the general public. Although the scientific groundwork is not new, the vaccine's profound impact on public awareness has spurred a surge in investments in the field. Additionally, an analysis of patient treatment data for 2023 reveals a notable 38% increase compared to 2022, underscoring the escalating interest in these therapies. Moreover, some interviewees posit that the field itself may be considered the future, given the substantial investments made over the past decade, demonstrating a consistent upward trend. With an influx of new drugs based on this technology entering the market, this heightened interest is unmistakable.

*"I have recently attended a meeting concerning competency development within ATMP, and the focus on delivery was not particularly emphasized. Nonetheless, there are several new training initiatives underway. Analysis of patient treatment data reveals a 38% increase in treated patients in 2023 compared to 2022, suggesting a steady upward trend."*

*- Industry expert*

Furthermore, most interviewees indicated that the Swedish market for ATMPs is considerably fragmented. This fragmentation poses a significant challenge as it fosters competition among the various centers currently operational. Despite substantial investments, the proliferation of initiatives underscores the necessity for greater alignment and enhanced collaboration. This sentiment reflects the overarching perspective within the industry.

*"I think that would be good for creating synergies, but I'm not sure how to do this in the best way. There are so many initiatives now, and for someone looking at this from the outside, it's all pretty much the same thing."*

*- Senior researcher*

### 4.2.2 **How Can The Center Leverage Its Existing Resources And Expertise To Stay Ahead In The Rapidly Evolving Field?**

Discussions during the interviews also delved into strategies for ensuring sustainability within the organization. Some stressed the critical importance of fostering close relationships with the scientific industry and researchers involved in ATMP. They highlighted the multifaceted significance of this aspect. Firstly, it ensures that the center maintains its position at the forefront of innovation. Additionally, they raised concerns about the risk of becoming obsolete if the center's values lag behind. To tackle this challenge, the proposal of establishing a network of scientists capable of anticipating future research trends was put forward, thereby enabling the center to proactively maintain relevance over time. Moreover, it was suggested that this approach would also bolster the technical credibility necessary for sustained relevance, thereby positioning the organization as a valuable asset in the eyes of the industry. Another interviewee stressed the importance of continually showcasing the center's value addition to the industry. This demonstration creates a demand for the center's survival, thereby incentivizing its continued existence.

*"You just need to stay on top of the science. And prove that you are adding value. That is the main thing, if you are not adding value you will never survive."*

*- International organization expert*

*"If you are building an organization within a specific technical area, it is important to remember that a lot of the credibility will come from technical expertise. (...) Building something through the university is a good way to do that, but again always think of these things from a network perspective. How are we building a network of expertise around highly connected individuals? You have to be seen as being very credible technically."*

*- International organization expert*

### 4.2.3 **How Flexible Is The Proposed Business Model In Adapting To Changes In The Nucleic Acid Therapies Landscape**

The flexibility of the proposed business model will be further elaborated in section 5.2.3 in the discussion.

# 5 Discussion

*This chapter consists of a discussion of the research findings in this thesis, in relation to previous research, as well as a critical examination of the proposed business model and payment model. The research findings and literature are compared in a gap analysis to find similarities and identify differences. Additionally, this section delves into the concept of generalizability, which explores the applicability of the insights and models developed in this project to other organizations within similar contexts.*

## 5.1 Gap Analysis

Upon completion of a literature review and interviews, several similarities and disparities have emerged concerning the ATMP industry, business models, and NPOs. Generally, many challenges identified in the literature review were echoed during the interviews. However, some challenges identified in the literature were not discussed in the interviews, while conversely, other challenges surfaced during the interviews that were not documented in the literature.

### 5.1.1 **The Future Of ATMPs**

This section conducts a gap analysis comparing the attitudes of interviewees towards ATMPs and the future landscape of the ATMP industry with insights gleaned from previous literature research. While the primary focus of the project revolves around business development and proposing a business model, it is crucial to assess whether the literature concerning ATMPs aligns with the perspectives shared by the interviewees, as the organization will operate within this landscape.

Notably, the overall attitude of the interviewees towards ATMPs was positive, mirroring the optimistic outlook presented in the literature review. Both sources suggest a bright future for the industry. However, despite this

alignment in positivity, there were nuanced differences in the viewpoints expressed. While the literature provided a comprehensive overview of the potential benefits and advancements in ATMPs, the interviews offered firsthand insights into the practical challenges and opportunities within the industry.

Despite the overall positivity, major challenges and hurdles were highlighted both in the literature and during the interviews. One significant challenge discussed was the delivery of ATMPs, particularly nucleotide-based treatments. This aspect was also mentioned in several interviews, underscoring its importance. It was noted that mastering the chemistry required to precisely target these vehicles could open new doors for the industry. Additionally, polymer nanoparticles, which were not initially highlighted as primary delivery options in the literature, have emerged as promising vehicles for nucleotide-based therapies. In the context of nanoparticle delivery methods, research-origin respondents emphasized that while various delivery methods share the common goal of delivering these therapies, the required infrastructure for researching these methods varies significantly depending on their type.

While the literature primarily focused on the ATMPs themselves, interviewees also highlighted other challenges regarding the use of ATMPs. One interviewee emphasized the impact of regulatory authorities on ATMPs, suggesting that regulatory aspects will become even stricter in the next five to ten years. Another interviewee addressed the cost aspects of ATMPs, noting that these therapies may not have the desired impact if their prices are too high, regardless of their effectiveness.

Finally, a topic discussed during the interviews that was not extensively explored in the literature is the financial future of the industry. Considering the survival of the organization, it is crucial to assess whether the field appears promising enough to continue attracting investments. The interviewees suggested that the COVID-19 pandemic served as an important catalyst, increasing public awareness of the potential of this technology. Moreover, the increase in the number of patients treated with this technology over the last few years indicates a bright financial future for the industry.

### 5.1.2 **Business Models**

When examining the findings from the literature review and interviews regarding business models and their usage within the non-profit sector, some parallels could be found. One of these was the uncertainty surrounding the term business models. Not all interviewees had the same level of understanding of the concept, resulting in varied perspectives on what constitutes a business model and how it can be utilized. This observation aligns with the literature, which indicates a lack of universally accepted terminology known and employed by all parties. Moreover, this issue strengthens the importance of this thesis project, as it will clarify and delineate the term making it more tangible for future usage in the industry.

During discussions on business models, interviewees highlighted the complexity surrounding engagement with diverse stakeholders, which could enhance revenue generation. It was mentioned that NPOs typically draw revenue from various sources, aligning with existing literature. Given the diverse nature of revenue streams, each stakeholder naturally seeks to exert influence on aspects related to the value proposition, which is important to keep in mind.

Another commonality identified was the emphasis on constant refinement and continuous development of business models, as discussed in section 3.2.4. One interviewee highlighted the importance of flexibility in the value proposition for Chalmers Precision HealthTech Hub's business model. It was emphasized that this aspect of the business model must be adaptable to changes within the industry, including the integration of new technologies and breakthroughs, to effectively address customer needs. Achieving this requires personnel within Chalmers Precision HealthTech Hub to adopt a mindset that acknowledges the principle of "one size does not fit all." It is recognized that a business model that addresses current needs may not necessarily address future needs. This sentiment is supported by the findings of a study mentioned in the literature review, which suggested that a one-size-fits-all non-profit business model may prove to be insufficient.

Despite the numerous similarities between the literature and the interview findings, several differences were observed. One notable difference pertained to the alignment of industry practitioners' understanding of what constitutes a business model. Almost all interviewees asked to present their organization's business model showcased vastly different interpretations.

Additionally, none of the interviewees presented a standardized framework. This is contrary to the literature, which suggests that frameworks are commonly used by industry practitioners. However, during the interviews conducted for this thesis project, this was not the case. There could be several reasons for this disparity; however, it is possible that non-profit organizations do not perceive these frameworks as adaptable to their organizational needs due to their non-profit nature, thus aligning with the literature.

Another notable aspect concerning perceptions of business models is the literature's suggestion that both internal and external sources should be included. However, the majority of interviewees who presented their business models only considered either internal or external resources. This further highlights a gap between the literature and practical applications in the field.

### 5.1.3 **NPOs**

In this section, the focus shifts toward NPOs, where the objective is to compare the findings obtained from the literature review with the viewpoints expressed by interviewees.

While definitions of NPOs were explored in Section 3.3.1, it became apparent that a uniform understanding of what constitutes an NPO remains elusive. This was also apparent during some interviews, where interviewees were unsure of what type of NPO Chalmers Precision HealthTech Hub was intended to be, when the one-pager was shown (figure A.1 Appendix A.3). This further supports the literature's assertion that the terminology surrounding NPOs and the non-profit sector can be somewhat ambiguous.

Another parallel identified between the literature and the interview responses was the recognition that NPOs endeavor to address needs that the business sector may not effectively serve, often due to the challenge of doing so profitably, as mentioned in section 3.3.5. This sentiment was echoed by an international interviewee. In addition to this, the literature review highlights a noteworthy trend in section 3.3.6: sustainability efforts within the non-profit sector are relatively recent compared to their counterparts in the for-profit sector. This observation was echoed by an interviewee affiliated with an NPO, who indicated that their organization's sustainability endeavors are still in their early stages. Despite this, all relevant interviewees established

the importance of addressing these sustainability questions, which aligns with the findings in the literature.

When reviewing the literature focused on NPOs, one aspect that was heavily focused on was the constant involvement of various stakeholders, and addressing all of these simultaneously can be challenging. This observation aligns with the insights gleaned from an interview with an international actor, who also emphasized the complexities associated with managing diverse stakeholder interests within non-profit organizations.

Despite the similarities, several topics emerged during the interviews that were not addressed in the literature. Firstly, it was noted that being a non-profit organization could be considered advantageous in the scientific industry. An international interviewee emphasized that the organization's goals should determine its profit status. Considering that the scientific industry is not highly profitable, and the primary objective of the organization is to promote research and collaboration, profit generation is not its main focus. Therefore, operating as a non-profit may be more sustainable in the long term.

Furthermore, in addition to the industry's lack of profitability, the non-profit characteristics of Chalmers Precision HealthTech Hub can offer significant advantages. Firstly, it can enhance motivation among scientists to join the organization. An international interviewee, drawing from experience within the scientific community, highlighted that a for-profit status might be viewed negatively by scientists. This is because they may question the organization's objectives if profit generation is its primary goal. Moreover, this increased motivation extends to collaborators, as they perceive the organization not as a competitor, but as a collaborator. This not only benefits the organization in terms of resources but also facilitates the achievement of one of its fundamental goals: increasing collaborations between academia and industry.

## 5.2 Examination of Proposed Business Model

The following section provides a detailed overview of the process involved in developing the proposed business model for Chalmers Precision HealthTech Hub. Following this, a comprehensive analysis of the advantages

and disadvantages of the proposed business model is presented. Finally, the section examines the adaptability and sustainability of the business model, addressing the second research question of the thesis project.

### 5.2.1 **Development Process Of Business Model For Chalmers Precision HealthTech Hub**

RQ1 of the thesis project focused on developing a suitable business model for Chalmers Precision HealthTech Hub, aligning it with the interests of various stakeholders both internally and externally to the organization.

An essential part of this process involved reviewing available frameworks designed for both for-profit organizations and NPOs. The initial framework assessed was the RCOV framework. However, as discussed in Section 3.2.3, this framework lacked certain crucial components necessary for a comprehensive business model. Consequently, the RCOV framework was deemed unsuitable for this project.

The second framework evaluated was the OP-BMC framework. Despite its comprehensive coverage of essential aspects, it did not fully encompass all the requirements for establishing a business model tailored to an NPO. Therefore, the authors decided to work with the framework intended for NPOs, presented in Section 3.3.6. This framework delineated the multifaceted aspects of an NPO, particularly separating funding activities from programmatic activities. This differentiation is crucial in the context of NPOs, as stakeholders have varied needs, requirements, and expectations. Following interviews and observations of other NPOs within the industry, this framework was chosen.

The subsequent step in developing the business model involved filling out different sections to encompass various aspects of Chalmers Precision HealthTech Hub. This was carried out after careful consideration of the needs, requirements, and expectations of different stakeholders, as discussed during the interview process. By the conclusion of this process, the programmatic section of the business model had been completed. As previously mentioned, the fundraising section of the business model was not within the scope of the thesis project. Consequently, these sections were filled in collaboratively with the project leader of Chalmers Precision

HealthTech Hub to ensure the usability of the business model beyond the project's conclusion.

It is noteworthy that before completing the various sections of the business model, an interview was scheduled with a representative from Chalmers University. The aim was to gain a better understanding of their expectations and criteria for the operations of Chalmers Precision HealthTech Hub. This meeting was considered successful and further ensured the usability of the business model beyond the project's conclusion.

### 5.2.2 **Segmented Payment Model: Tailoring Financial Support For Different Customer Segments**

As previously explained, the payment model is divided into three separate segments. This segmentation was done based on different beneficiaries' ability to pay for services provided by the organization.

The first segment comprises researchers in academia. Given the generally limited funds available to researchers, it was proposed that project requests from this group would be funded by external financiers. Consequently, these researchers would receive full cost coverage for their projects through both the organization and external funders, thus facilitating research as the primary goal of the organization. The second customer segment consists of start-up companies. Similar to researchers, start-up companies have limited budgets for projects beyond their core activities. Therefore, it was decided to maximize external funding for these projects. However, Chalmers Precision HealthTech Hub would not act as a direct funder for these projects, distinguishing them from the first researcher segment. The third customer segment encompasses SMEs and Big Pharma companies. Given their substantial financial resources, compared to researchers and start-ups, these companies were deemed not to require additional support for project requests. As a result, a full-cost-for-service model was implemented for this segment.

Regarding pricing for specific instruments, it will be determined based on the selection of instruments acquired by the organization. Each instrument will incur a unique cost, necessitating determination prior to the organization's launch in 2026. However, insights into this decision-making process are

provided in the Results section (4.1.5), where organizational aspects of three other lab core facilities are examined.

### 5.2.3 **Advantages & Disadvantages Of The Proposed Business Model**

An integral aspect of analyzing the business model involves evaluating its strengths and weaknesses. This section is dedicated to discussing the advantages and disadvantages of the proposed model, providing a comprehensive overview of its key attributes. Understanding both the advantages and disadvantages is crucial for making informed decisions regarding the implementation and effectiveness of the business model.

*Advantages*
One significant advantage to consider is that the proposed business model effectively addresses the inherent complexity of NPOs. Typically, capturing this complexity within a business model is challenging. However, the proposed model mitigates this difficulty by organizing it into distinct categories based on programmatic activities and fundraising efforts. This segmentation simplifies the complexity, rendering it more comprehensible and actionable for industry practitioners.

Furthermore, despite the initially intricate framework employed, once comprehended, it not only becomes user-friendly and accessible but also easy to work with continuously. This ongoing ease of use is a critical aspect to consider regarding the organization's sustainability. It provides managers with a comprehensive overview of the organization, facilitating easy adjustments as the industry evolves. This adaptability ensures that the organization remains responsive to changes, thereby enhancing its long-term viability and effectiveness. This ease of use is beneficial for both internal personnel and external industry practitioners, providing them with a clear understanding of the organization and its underlying business model. Moreover, by encapsulating the business model within a framework, it becomes more tangible for stakeholders beyond the organization, facilitating broader comprehension and engagement.

Additionally, an advantage of this framework, particularly relevant to the non-profit sector, is its inclusion of the organization's vision and impact. By articulating these elements clearly, it not only communicates the non-profit nature of the organization but also elucidates its overarching purpose. This

clarity enhances stakeholders' understanding of the organization's mission, potentially fostering increased motivation for participation and collaboration.

Another advantage of the business model is the inclusion of an additional payment model. By detailing customer segmentation, it provides a clearer understanding of how different customers will be targeted and funded before project commencement. This clarification is crucial as it enhances both customer comprehension and internal alignment within the organization regarding primary objectives. In the case of Chalmers Precision HealthTech Hub, this segmentation ensures transparency regarding the primary objective, which is to promote research. Therefore, it is essential to prioritize funding for researchers.

*Disadvantages*
One significant disadvantage of the proposed business model is its complex appearance. Due to its composition of multiple segments, it may appear overwhelming and difficult to understand at first glance. This complexity could potentially discourage industry practitioners from utilizing it. Moreover, a complex framework may require a considerable amount of time and effort to fully comprehend and implement. This could result in a reluctance among industry practitioners to adopt the model, especially if they perceive it as time-consuming or resource intensive. Furthermore, a complex framework may also pose challenges in terms of scalability and adaptability. As the organization grows or as industry dynamics change, the complexity of the framework may make it difficult to modify or update the business model accordingly. Overall, while the proposed business model may offer comprehensive insights and functionality, its complexity could potentially limit its effectiveness and adoption within the industry.

### 5.2.4 **Adaptability & Sustainability**

As emphasized in the literature review (Section 3.2.4), the continuous development of a business model is vital for ensuring the sustainability of any organization. Considering this, the authors opted to develop a framework that would be easily adaptable over time. Utilizing a framework provides managers with the ability to assess and modify various components of the business model, such as the value proposition, as necessary.

When considering the adaptability and sustainability of the proposed payment model, several factors merit attention. Firstly, the concept of trial and error is significant. Implementing the proposed payment model within a specific time frame allows the organization to validate its strategy and segmentation of customer segments. Furthermore, testing the cost structure and user margin among each customer segment enables the organization to assess alignment with Chalmers Precision HealthTech Hub's requirements. If adjustments are deemed necessary, the model can be readily modified over time to ensure sustainability.

Furthermore, considering the dynamic and evolving nature of the industry, it is essential to maintain a flexible business model. The value proposition, being a fundamental component of the business model, must also be adaptable. This recognition of the importance of flexibility in the business model, especially regarding the value proposition, further influenced the decision to prioritize the development of a framework that could be easily adjusted over time.

## 5.3 Generalizability

This subsection delves into the broader applicability of the findings and insights presented in this report, extending beyond the confines of the specific organization under study. It assesses the relevance of the project's outcomes for professionals engaged in business development and business model formulation across both non-profit and for-profit sectors. The comprehensive spectrum of interviewees, encompassing diverse national and international perspectives, enriches the depth of the analysis. Furthermore, the examination of the proposed business model's adaptability to varied organizational contexts, coupled with insights gained from stakeholders within and outside the non-profit sector, underpins the discussion on generalizability. Additionally, this subsection explores how the identified strategies and recommendations may resonate with international actors navigating similar challenges and opportunities in the evolving landscape of ATMPs and related sectors.

### 5.3.1 Coverage & Quality Of Interview Study: Analysis And Improvement Options

The 22 interviews that were held during this project covered many different areas such as the ATMP industry, NPOs, business models, payment models, and the needs, requirements and expectations of potential stakeholders. However, the main focus during various interviews differed, depending on the actor that was interviewed. The coverage and quality of the findings from the interview study could be relevant to other interested readers since a variety of different actors were interviewed. From CEOs (both national and international) within the life science industry, to well renowned senior researchers across Sweden, regional initiatives, SMEs within life science, and actors within big pharmaceutical companies. This diversity of perspectives provided a thorough understanding of the subject matter and enriched the insights gathered, increasing the chances of this being suitable for others.

However, for this coverage to be even more comprehensive, some considerations could be made. Firstly, the quantity of interviews. The time frame of this project limited the number of interviews to 22. In pursuance of increasing the applicability of these findings, one could increase the number of interviews. Especially with start-ups, SMEs, and big pharmaceutical companies, since these are crucial stakeholders for an organization such as Chalmers Precision HealthTech Hub. Both from a partnership perspective (collaborating on projects) as well as a customer perspective. More insights gained from these actors could be beneficial as an important aspect to consider when implementing a business model is how to address and adapt to the customers' needs. The coverage of this aspect was seen as successful, although interviews with more surrounding actors could be even more beneficial. Furthermore, involving secondary stakeholders mentioned earlier in the report, such as regulatory bodies and healthcare professionals, would broaden the scope of this project segment.

Although Chalmers Precision HealthTech Hub will not only be active within the region of Gothenburg, it is important to understand and address the surrounding initiatives, organizations, and persons that potentially could be crucial actors or stakeholders to the organization. Several interviewees were actively involved within the Gothenburg region, stemming from academia to industry. Understanding the general attitude towards the organization from these interviewees was imperative, both from the perspective of potential

customers and potential collaborators and partners. When implementing a business model for this organization, it is crucial to discern which components overlap with other initiatives and which do not, where collaborations can create a win-win scenario for both parties.

Looking at the international scope, interviews were held with three international interviewees from three different organizations, all within the life science industry. Since the main topics that were discussed with these actors included business models, the ATMP industry, and sustainability within NPOs, the findings gained are suitable for both national and international actors. This is because many of the topics and insights are not country or continent-specific, making the insights of the national interviewees also applicable. Despite this, an even more in-depth view could have been gained if the number of international interviewees had increased. However, this was not possible, given the time frame of the project. One important note is that some topics could be country-specific, such as regulatory and governmental aspects. However, this was not the core focus of this project.

Regarding the coverage of potential stakeholders, it is essential to emphasize that the identification process concerning stakeholders for Chalmers Precision HealthTech Hub was conducted by the authors in collaboration with project leaders from Chalmers and by synthesizing responses from interviewees. Consequently, there may be additional stakeholders, highly relevant to the organization, who have not been included in this report. Therefore, it is recommended that future managers undertake further stakeholder analysis to ensure all significant stakeholders are identified and included.

### 5.3.2 **Applicability Of Business Model**

While the primary focus of the project was to develop a suitable business model for Chalmers Precision HealthTech Hub, it also aimed to enhance understanding of business model implementation for NPOs, particularly within the life science sector. As such, the discussion will extend beyond the specifics of Chalmers Precision HealthTech Hub's business model to explore its broader applicability within the NPO landscape.

Although the contents of the business model are specific for the intended organization, the broader mindset of differentiating the programmatic and financial operations can be applied by other NPOs, both Swedish and international. For organizations involved with the same types of operations as Chalmers Precision HealthTech Hub, the payment model can be used as inspiration for how to differentiate the different customer segments and their respective prices and margins. Lastly, all insights gained from the interview study that were utilized when developing the business model can aid other organizations in their organizational work. This applies both for organizations within the ATMP sector as well as organizations in other sectors, as not all interview insights concern ATMPs and the life science sector.

# 6 Roadmap And Final Recommendations

*This section delineates additional recommendations that are based on insights gained through the interview study. However, the recommendations are not directly linked to the project's research questions and are therefore not brought up in the result section. Recognizing the constraints imposed by the project's timeline and the overarching goal of launching the organization in 2026, it is acknowledged that certain aspects addressed herein extend beyond the immediate scope of developing a viable business model for the center. Nonetheless, the inclusion of these recommendations is warranted by their prominence during the interview phase, underscoring their relevance to the organization's broader objectives. By incorporating these supplementary recommendations, the organization can proactively anticipate and address potential challenges, capitalize on emerging opportunities, and cultivate a culture of adaptability and resilience. Moreover, leveraging these insights enables the organization to refine its value proposition, enhance stakeholder engagement, and strengthen its long-term sustainability and impact within the industry.*

## 6.1 Continuous Development Of The Business Model

It is important for organizations to recognize that maintaining a static business model can prove detrimental. Just as the industry in which an organization operates evolves, so must the organization itself. Therefore, continuously updating the business model becomes not only critical for the organization's survival but also for its long-term sustainability. A key insight gleaned from interviews underscores the necessity of aligning the value proposition of a developing organization with the evolving needs of its customers. Particularly in a research context, these needs are subject to change over time. Thus, it is essential to proactively anticipate and adapt to

these shifts, ensuring that the value created for customers remains at the forefront of innovation.

### 6.1.1 **Key Performance Indicators**

Within the framework of ongoing business model evolution, it becomes critical for the organization to establish Key Performance Indicators (KPIs). These KPIs serve as quantifiable metrics of organizational performance, enabling the assessment of growth and development [93]. They provide a means to gauge the organization's efficacy in meeting customer needs and identify areas necessitating adaptation. Moreover, KPIs serve as a yardstick for evaluating the flexibility of the business model in response to the dynamic landscape of nucleotide therapy.

Numerous quantifiable KPIs exist. As discussed earlier, FoRmulaEx was assessed based on metrics such as published articles, patents, and the establishment of new companies. Given that the upcoming organization is a continuation of FoRmulaEx within the Chalmers Precision HealthTech Hub, it is important to examine and refine these indicators to align with the objectives of the hub. Among the potential KPIs for consideration are the following:

*Research Output Metrics*
Since one of the primary objectives of the organization will be to promote research within the field of delivery and characterization of nucleotide-based therapies research output metrics can be an important KPI. However, there are different aspects of metrics within this context that can be measured.

1.1 Number of research papers published in peer-reviewed journals
1.2 Impact factors of the published research
1.3 Number of patents filed or granted
1.4 Citations of the organization’s research outputs
1.5 Collaboration agreements or partnerships established with other research institutions or industry players

*Research Funding And Grants*
Another important aspect that will be important to attain the survival of the organization will be funding. In this context funding and grants can be measured, both in terms of donations to the organization itself, but also in

terms of funding that were granted for the research within the organization. Some of the examples of KPIs that can be set for this context are.

2.1 Total research funding secured from grants, contracts, and collaboration
    2.1a) For the organization
    2.1b) For the research within the organization
2.2 Success rate of grant applications
2.3 Diversity of funding (government grants, private funding, industry partnerships etc.)

*Talent Development And Retention*

Several interviewees emphasized the significance of competence supply. While securing funding is crucial for organizational sustainability, having the requisite expertise within the organization is equally imperative. Without credibility in terms of expertise, financial resources alone may not suffice. Thus, talent development and retention emerge as pivotal factors in ensuring organizational survivability and should be regarded as KPIs.

3.1 Number of students, PHDs, postdoctoral researchers, and research staff that are recruited and retained
3.2 Success rate of attracting top talents
3.3. Employee satisfaction and engagement surveys
3.4 Training and professional development opportunities were provided to the researchers

*IP-management*

Another important aspect to consider is IP. Tracking the number of new inventions or discoveries, patent growth portfolio, and revenue from licensing indicates the organization's innovation and its ability to protect and monetize its IP, crucial for sustainability and competitiveness. In this way, the organization develops an ability to track the imprint onto the research environment and increase credibility.

4.1 Number of new discoveries generated
4.2 Portfolio of patents owned or licensed by the researchers within the organization

*Research Impact And Influence*

Similarly to the first point regarding research output metrics, another important aspect that will be important to include is the research impact and influence. Assessing the organization's presence in the scientific community through metrics like presentations, media coverage, and awards demonstrates the reach and influence that the organization brings to the community. This further contributes to reputation building, credibility, attracting talent, and fostering collaborations.

5.1 Number of keynote speeches, invited talks, or conference presentations by organizational members
5.2 Media coverage and visibility of organizations' research findings
5.3 Participations in community gatherings concerning the industry
5.4 Recognitions and awards received for the research contributions

*Collaboration And Networking*

The last category of collaborations and networking is also highlighted by several interviewees as a key factor for success. In this context monitoring collaborative projects, partnerships, and participation in research networks reflect the organization's ability to leverage external expertise, access resources, and foster interdisciplinary collaboration, essential for addressing complex research challenges and maximizing the impact.

6.1 Number of collaborative research projects initiated with external partners
6.2 Quality of partnerships and collaborations (measured by outcomes, publications or joint funding)
6.3 Participations in research consortia, networks, or interdisciplinary initiatives
6.4 Feedback from collaborators and important stakeholders on the organization's contributions to joint efforts

These KPIs provide a comprehensive overview of the organization's performance in key areas such as research productivity, funding sustainability, talent management, IP-management, research impact, and collaboration effectiveness.

## 6.2 Future Financial Opportunities

Ensuring financial sustainability is paramount for the organization's long-term viability, as discussed previously. There are three primary avenues to achieve this objective.

Firstly, seeking funding through grants necessitates continuous efforts in securing grants, which can be challenging and time-consuming. However, solely relying on grant funding may lead to concerns of over-reliance and a perception of being dependent on external sources. This sentiment was echoed by many interviewees, who expressed reservations about this approach.

The second option involves self-sustaining the organization by developing fee-for-service concepts, enabling the reinvestment of earnings into the organization. However, given the nature of the industry targeted by Chalmers Precision HealthTech Hub and the activities of the organization, generating sufficient revenue to cover both organizational expenses and research endeavors may prove impractical. Hence, this alternative appears unfeasible.

The third and potentially most viable option involves a hybrid approach, combining funding from various sources, including donations and fee-for-service offerings. This strategy not only diversifies funding streams but also provides opportunities for both sustaining and expanding the organization. Consequently, the combination of these approaches is likely to yield the greatest success for the Chalmers Precision HealthTech Hub.

Throughout discussions with international stakeholders, a fourth potential avenue emerged. This entails establishing an in-house funding mechanism, wherein the organization cultivates a self-sustaining funding ecosystem. This framework would enable customers to access funding for their research endeavors through Chalmers Precision HealthTech Hub. While this option holds promise, it is essential to acknowledge that developing such a system requires a significant investment of time and resources, making it a prospect for future consideration. Given the current organizational context, the hybrid approach remains the recommended alternative.

## 6.3 Potential Risks And Barriers To The Center’s Continued Relevance, And How They Can Be Mitigated

During the interview sessions, thorough discussions were conducted regarding potential barriers and risks that could impede the sustained relevance of the center. These deliberations underscored various facets necessitating careful consideration to ensure that the center remains unaffected by adverse impacts.

### 6.3.1 **Navigating Regulatory Challenges: Ensuring Continued Relevance**

One vital aspect that emerged prominently was the regulatory landscape. As the industry undergoes continual evolution and the scope of research expands, it is foreseeable that regulatory authorities will impose increasingly stringent limitations on permissible practices. Despite the extensive duration of research in pharmaceutical delivery methods, the mode under consideration remains relatively novel, entailing numerous yet undiscovered facets that may surface with industry evolution.

Mitigating the risk of regulatory hurdles becoming a significant impediment for the center requires proactive measures. It is imperative to designate dedicated personnel who will consistently engage with regulatory bodies. This proactive engagement will enable not only compliance with current regulations but also anticipation of forthcoming regulatory boundaries. This strategic approach is indispensable to prevent research projects from being ensnared in prolonged regulatory scrutiny, thereby safeguarding the momentum of the center's initiatives.

Within this context, it is essential to closely align with key regulatory authorities. As explained further in Appendix A.2, pivotal entities such as the European Medicines Agency (EMA), and NT-rådet in Sweden hold paramount significance. Establishing and maintaining robust relationships with these authorities will foster transparency, facilitate timely adherence to regulatory changes, and foster collaborative efforts in navigating the evolving regulatory landscape.

### 6.3.2 **Strategic Approaches To IP-management**

During the interviews with start-up companies, another critical topic that emerged for discussion was IP rights. Despite being brought up by interviewees connected to start-up companies, this topic will become of importance in every customer segment. Across research organizations, the question of IP ownership looms large, prompting deliberation on the most appropriate approach. The handling of IP varies among different organizations in Sweden, with no universally applicable solution, rendering it a hurdle necessitating careful consideration.

Within this context, several potential solutions were explored. One approach entails the organization retaining full ownership of the IP. However, this approach could engender significant resistance among customer segments, as it restricts researchers and collaborating companies from advancing with the research post-project completion. Conversely, assigning the entirety of the IP to the customer poses its own set of challenges, as it relinquishes organizational control over project outcomes.

The recommended solution, which emerged from the discussions and aligns with best practices, involves developing a range of contract options, each tailored to different IP ownership criteria. This nuanced approach enables the organization to customize contracts according to the unique needs of each customer. Such flexibility not only enhances the organization's credibility and appeal but also serves as a key facilitator in accommodating diverse customer segments, as proposed in the business and payment models.

By adopting this approach, the organization demonstrates adaptability and responsiveness to client needs while retaining a measure of control over its intellectual assets. This strategic maneuver not only fosters collaborative relationships but also positions the organization as a trusted partner capable of navigating complex IP considerations with finesse.

## 6.4 Facilitating Important Partnerships

Another critical aspect of establishing Chalmers Precision HealthTech Hub as a credible industry partner over time is by forming strategic partnerships. However, it is essential to recognize that a successful partnership requires

more than just an initial connection; it must be actively facilitated. Therefore, this section highlights two key aspects of partnerships that will be of importance in this context: engagement with hospitals, and collaboration with other national and international entities within the industry.

### 6.4.1 **Involving The Healthcare Sector**

An aspect highlighted by interviewees underscores the pivotal role of hospital engagement in the context of advancing nucleotide-based therapies. As these therapies evolve, their accessibility to patients via hospitals is expected to rise significantly [17]. Beyond scientific breakthroughs, the organization aims to ensure that its achievements translate into tangible patient benefits through therapies administered in medical facilities. Thus, fostering close ties with hospitals becomes essential to facilitate collaboration and maximize the organization's impact on patient treatment outcomes. This strategic partnership not only enhances the organization's credibility but also accelerates the integration of innovative therapies into standard clinical practice, ultimately benefiting patients and advancing healthcare delivery.

### 6.4.2 **National And International Partnerships**

As the organization will be deeply rooted in the research community, remaining at the forefront of innovation is paramount. This necessitates not only cultivating relationships with esteemed researchers, but also fostering connections with other national and international organizations, donors, industry experts, and key stakeholders within the field. By engaging with individuals and entities who bring diverse perspectives and expertise, the organization can enhance its capacity for growth and development. Moreover, actively facilitating the expansion of this network not only bolsters the organization's survival but also positions it for continued success in an ever-evolving research landscape.

Moreover, expanding the organization's network to include individuals from various backgrounds and expertise, not only bolsters its internal capabilities but also enhances its credibility among those who are not yet engaged. When reputable researchers, industry experts, and influential figures within the field are associated with the organization, it signals to external stakeholders, potential collaborators, and the broader community that the organization is a

trusted and reputable entity. This increased credibility can attract new opportunities for collaboration, funding, and partnerships, ultimately contributing to the organization's long-term success and impact.

## 6.5 Competence Development

In every industry, the expertise of individuals regarding various organizational activities is paramount for the organization's sustenance. The absence of individuals possessing adequate knowledge poses significant challenges to any organization's viability. Chalmers Precision HealthTech Hub is no exception to this rule. Given the dynamic nature of the industry and the center's ongoing evolution, the composition of personnel within the organization is subject to change. Consequently, it is imperative to ensure a seamless transition by recruiting individuals with robust industry knowledge to replace departing personnel. This statement was echoed during interviews with several industry experts who listed competence development as a key factor for the success of Chalmers Precision HealthTech Hub.

Furthermore, the organization must prioritize the promotion of education specific to its context, particularly in the delivery and characterization of nucleotide-based therapies. Recognizing this need, several initiatives within the ATMP industry have established specialized programs at various universities in Sweden to address this challenge [94]. However, it is essential to underscore that, similar to other aspects, competence development is an ongoing process that necessitates continual effort.

Despite the advantage of being closely connected to the university, Chalmers Precision HealthTech Hub must guard against complacency and remain vigilant in addressing this ongoing challenge. Proactive measures, such as fostering collaborations with educational institutions outside of Gothenburg, implementing internal training programs, and incentivizing professional development opportunities, are essential to ensure a knowledgeable workforce capable of driving the organization's mission forward. By remaining steadfast in its commitment to competency development, the organization can effectively navigate industry dynamics and position itself for sustained success in the long term.

# 7 Conclusion

*In this concluding section, the results addressing the research questions are presented. Additionally, the reliability and limitations of these findings are discussed, alongside suggestions for future research.*

## 7.1 Concluding Results

The goal of the thesis project was to answer the two questions presented in section 1.4. The first question concerned the development of a suitable business model for Chalmers Precision HealthTech Hub that was adapted to the requirements, characteristics and needs of different stakeholders. In the results section of the report a business model and an additional payment model were presented. The project can thereby be determined successful. In addition to these two finalized models, important insights from interviewees relevant to the organization in question were given. These insights covered topics such as the stakeholders' needs and requirements as well as important aspects to think about when operating within an NPO and when implementing a business model.

The second research question regarded how the center can ensure continued relevance and a suitable business model over time, considering the rapidly evolving field that the organization will operate within. To answer this question Section 6 presented a roadmap and final recommendation for the project leaders of Chalmers Precision HealthTech Hub. This section aims to provide a guide for the organization, including several important aspects to consider for future operations to ensure sustainability. One aspect includes several suggested KPIs that Chalmers Precision HealthTech Hub can apply and analyze during their work, as quantifiable metrics of their organizational performance, enabling the assessment of growth and development. In addition to this, three different financial routes were given, where the third option seemed the most viable option. This involves a hybrid approach, combining funding from various sources, including donations, with fee-for-

service offerings. Potential risks and barriers regarding regulatory aspects and IP are important factors for Chalmers Precision HealthTech Hub to consider. Therefore, the same section also brings up several ways in how to manage these aspects. Lastly, facilitating important partnerships and the importance of having constant competence development were also highlighted.

Besides the future recommendations, the results section covering RQ2 contains valuable information regarding how to maintain relevance and sustainability within the organization. Interviewees addressed their views on the future of ATMPs, both from a scientific point of view, as well as from a financial perspective.

## 7.2 Reliability And Limitations

The procedures undertaken to ensure research quality are outlined in section 2.1.7, and are based on the criteria of credibility, transferability, dependability, and confirmability. However, like any research endeavor, this thesis has its limitations, which are addressed in this section.

The *credibility* of the conclusions can be examined concerning data collection and scope. This thesis analyzed a relatively broad scope with a limited number of interviews, which may affect credibility. Conducting a larger number of interviews or narrowing the scope could have yielded more precise conclusions from the data.

Regarding *transferability*, the researchers aimed to encompass a diverse array of experts, industry organizations, and researchers within the field. However, despite the representation of different interviewees, there was an imbalance in the distribution between nations, with a majority of interviews conducted with Swedish entities. This imbalance may affect the transferability of conclusions and pose a risk that they may not apply as effectively to similar organizations outside of Sweden. To enhance the representativeness of data collection, more interviews with representatives from other countries should be conducted.

Another facet of transferability concerns how the research results can extend beyond the intended audience and offer value to external actors. This thesis

primarily targeted decision-makers and stakeholders within the life science sector, particularly those involved in nucleic acid therapies. They can leverage these findings to inform their decision-making processes and collaborations with complex organizations like non-profit research centers. However, other entities in the industry might make use of the findings. Researchers in ATMPs and related therapeutic areas can leverage the insights regarding ATMPs and its future outlined in this study. This can enhance their understanding of industry operations and dynamics, facilitating adaptation to the evolving landscapes.

Regarding *dependability* and *confirmability*, a potential weakness lies in the degree of subjectivity in the analysis. For instance, the qualitative interview questions were open to interpretation by interviewees, introducing the possibility of misinterpretations and bias. Another limitation concerns the potential for biased perspectives on ATMPs among the interviewees, as all participants either research in this area or actively work within the life science sector with a genuine interest. Consequently, this group may hold an overly positive view that does not reflect broader perspectives. While it is challenging to address this issue since all interviewees volunteered to take part in this project, it can be important to bear in mind.

When considering the reliability and delimitations surrounding the finalized business model, several aspects come to light. Primarily, it's important to note that the organization for which the business model is intended has not yet been fully established. This means that aspects of the business model may need to be adjusted and tailored to fit the organization. Moreover, as the organization takes shape, new key topics and considerations may emerge, necessitating further refinement of the business model to ensure its relevance and effectiveness. Lastly, the business model has not undergone testing against real-world conditions or historical data. This lack of validation and testing introduces uncertainties about the model's applicability and effectiveness in practice.

## 7.3 Contribution To Future Research

This master thesis has focused on proposing a business model tailored for a specific non-profit research center specializing in delivery methods for ATMPs. The implementation of business models for NPOs remains a

relatively new area of study, with limited existing research available. Therefore, this thesis contributes to the expansion of knowledge within this field.

The insights presented in this thesis are the culmination of interviews conducted with 22 distinguished researchers, CEOs, and other industry experts. Their collective expertise and experience have significantly enriched the depth of knowledge within this field, ensuring a comprehensive understanding of the subject matter. However, as highlighted in section 5.3, the depth of knowledge could be further enhanced in future research endeavors by expanding the scope of interviews to include a more diverse range of experts, particularly those outside of Sweden.

Furthermore, the proposed business model and payment model presented in this study offer valuable insights that extend beyond the scope of the non-profit research center that was examined. These models can serve as valuable resources for other initiatives within the life science sector and beyond, particularly those with organizational structures similar to the focal organization. While the applicability of these models extends to both Swedish and international contexts, it is essential to acknowledge that variations in regulations and policies across different countries may pose limitations in some cases.

Although the primary focus of this thesis is on non-profit organizations, the findings and recommendations hold relevance for for-profit research centers as well. Various aspects of the proposed models, as well as insights from the various interviews, can be adapted and implemented by for-profit entities to enhance their operational efficiency and sustainability. Therefore, this study contributes not only to the understanding of business model development in the non-profit sector but also provides valuable insights applicable to diverse organizational contexts within the life science industry and further.

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# Appendix A

*This appendix provides supplementary information for the interested reader. It includes details about the interview formats used during the research, additional insights into the subcategories of ATMPs, and relevant regulatory aspects. Additionally, figures relevant to the project are included for further clarity and understanding.*

## A.1 Interview Questions

The interviews conducted for this study were semi-structured and open-ended, designed to gather comprehensive insights from the participants. Each interview was uniquely tailored to the background knowledge and experiences of the interviewee. To ensure relevance and depth in the discussions, a rough division was made depending on the primary discussion point of each interview. For instance, if the participant was a researcher and an employee at a similar initiative, the primary topics discussed focused on the researcher's perspective from a stakeholder point of view, but with additional insights concerning business models also brought up. This approach ensured that topics such as business models were addressed. While the discussions varied based on the expertise and perspectives of the participants, the following questions served as a grounding for the topics discussed:

### A.1.1 Interview Guide, Researchers / Principle Investigators

The following interview format was used when the primary objective of the interview was to gain insights into researchers, who could potentially be involved in Chalmers Precision HealthTech Hub, point of view. The interviewees had the opportunity to express their demands and expectations

from the organization if they would be involved in its operations. In addition to this, the interviewees had the chance to talk freely about their general attitude towards the proposed organizational structure, when the one-pager was shown (figure A.1 in Appendix A.3), as well as their view on the current ATMP industry, and its future.

Introduction

1. Start by introducing ourselves and our project.
2. Who are you? Tell us a bit about yourself.
3. How long have you been working in the industry?

Stakeholders' Needs, Requirements and Expectations

1. Present and explain the one-pager with the preliminary structure of the organization.
2. Since the primary purpose of the organization is to promote research on deliveries and characterization of these drugs, it is important that the researchers involved in the organization can continue to make this their primary task. Since you have a lot of experience as a researcher, we wonder how you would like the setup to be to ensure that research remains your primary task?
3. How would you like the setup to be in general? (Number of days per week / Criteria you wish to include?)
    a) With your experience of working with researchers and PIs previously, how do you think others would prefer it?
4. What would be required for you to want to participate as a PI in an advisory board?
    a) With your experience of working with researchers and PIs previously, how do you think the interest would be for others?
5. What do you consider reasonable requirements that the organization could have asked of you as a PI?
6. What do you see as your personal gain from being involved?

Sustainability and Relevance

1. How do you view the industry around ATMPs, will this be a relevant area in a long-term perspective?
2. How do you keep XX competitive and sustainable from a long-term perspective? (if involved in a company).

3. Considering your experiences and expertise, do you have any tips or important aspects for us to consider when proposing a business model for this organization?

Closing points

1. Is there anything you would like to add that we may have missed?
2. Do you have other individuals in your network whom you believe we should contact?
3. Any other general tips?

### A.1.2 Interview Guide, National Industry Experts

This interview format was used during interviews where the primary objective was to gain insights from national industry experts within the life science sector. The main focus of these interviews was on business models, and these interviewees were pin pointed because of their knowledge of business development, innovation, and leadership. Because of this, many of the interviewees were CEOs of their respective companies. Some of the interviewees were also involved in non-profit organizations, which also guided the focus towards important aspects and strategies to think of when implementing a business model for a non-profit organization.

Introduction

1. Begin by introducing ourselves and our project.
2. Who are you? Tell us a bit about yourself.
3. How long have you been working in the industry?

Business Model

1. Present and explain the one-pager.
    a) What do you consider the most important parts to include and consider in a business model for this type of organization?
2. When considering non-profit organizations, beyond financing, are there any other specific aspects or general tips you believe we should focus on in the business model and overall development of the organization, given your experience in advancing organizational initiatives?
3. Would you be able to briefly describe your business model?
    a) Who are your primary stakeholders?
    b) What are their needs, demands, and expectations?

4. Are there any specific areas that you have focused more on, compared to if you were a for-profit organization? (If non-profit organization)

Sustainability and Relevance

1. How do you view the industry around ATMPs, will this be a relevant area in a long-term perspective?
2. Sustainability is an important part of business model creation, especially in the sense of non-profit organizations. How do you keep yourselves competitive and sustainable at XX from a long-term perspective?
    a) Is it important to have a flexible and adaptable business model, considering this rapidly evolving field? How can we address this?

Closing Remarks

1. Is there anything you would like to add that we may have missed?
2. Do you have other individuals in your network whom you believe we should contact?
3. Any other general tips?

### A.1.3 Interview Guide, Lab Core Facilities

The following interview format was used when interviews were held with actors involved in laboratory core facilities, offering instruments, expertise, and infrastructure for research. The focus in these interviews was primarily on their payment models, for example, their margins for academia versus industry. However, other topics were also discussed.

Introduction

1. Begin by introducing ourselves and our project.
2. Who are you? Tell us a bit about yourself.
3. How long have you been working in the industry?

Business model

1. Present and explain the one-pager.
2. What do you consider to be the most important aspects to include and consider in a business model for this type of organization?
3. Given your background from XX, do you feel there is a part of the organization where XX would like to or could contribute?

4. We are a bit uncertain if these questions are relevant to you or if you would prefer to refer us to someone else, but we are curious about your business model.
    a) Do you have a clear and defined business model that you operate from?
    b) What does it look like?
    c) How do you ensure that everyone involved works based on your business model?
    d) What is the structure of your organization?
    e) What is your Unique Selling Point (USP)?
    f) What different types of actors do you work with?
    g) What do you consider to be the most important aspects to include in a business model for this type of organization?
    h) Are there any specific areas that you have focused more on, compared to if you were a for-profit organization? (If non-profit organization)

Payment Model

1. As we understand it, you offer laboratory equipment to academia and industry?
    a) What are your thoughts on the margin for academia versus industry?
    b) Do you have different prices and payment models for different customer segments? (For example, start-ups, SMEs, big pharma companies)
    c) Do you have your own lab, or do you rent space elsewhere?
    d) What types of instruments do you offer? (basic range / specialized)
    e) Can individuals rent space and work in your labs themselves, or is it a service they purchase with operators handling the measurements?

Sustainability and Relevance

1. How do you stay competitive and sustainable in the long term?
    a) For example, if there is a scenario where you offer an instrument that is no longer relevant?
2. Considering your experience and expertise, do you have any tips or important aspects that would be good for us to consider when proposing a business model for this organization?

Closing Remarks

1. Is there anything you would like to add that we may have missed?
2. Do you have other individuals in your network whom you believe we should contact?
3. Any other general tips?

### A.1.4 Interview Guide, International Industry Experts

This interview format was used during interviews with international industry experts within the life science sector. In this sense, three different international actors were interviewed. Similarly to the national industry experts, the main focus of these interviews was on business models. These interviewees were thereby pin pointed because of their knowledge of business development, innovation, and leadership. Because of this, the interviewees were CEOs, CTOs, or CSOs of their respective companies. All interviewees were also involved in non-profit organizations, which also guided the focus towards important aspects and strategies to think of when implementing a business model for a non-profit organization. Another noteworthy distinction between these interviews and the national industry expert interviews is the time constraint. As all of these interviewees are exceptionally busy individuals, the interviews were limited to 30 minutes, necessitating a slight adjustment to the setup.

Introduction

1. Begin by introducing ourselves and our project.
2. Who are you? Tell us a bit about yourself.
3. How long have you been working in the industry?

Business Model

1. When considering non-profit organizations, beyond financing, are there any other specific aspects or general tips you believe we should focus on in the business model and overall development of the organization, given your experience in advancing organizational initiatives?
2. Could you briefly describe your business model?
    a) Who are your primary stakeholders?
    b) What are their needs, demands, and expectations?
    c) How do you address these in your business model?

d) Are there any specific parts of your business model that you think could be of importance to us?
e) Are there any parts that you consider to be not applicable to this organization?

Sustainability and Relevance

1. Sustainability is an important part of business model creation, especially in the sense of non-profit organizations. How do you keep yourselves competitive and sustainable at XX from a long-term perspective? (Given this rapidly evolving industry)
    a) Is it important to have a flexible and adaptable business model, considering this rapidly evolving field? How can we address this?
    b) Have you changed anything regarding your business and business model over time, due to the fact that you are operating within such a rapidly evolving industry?
    c) For example, are you working with technology-scanning, and if so, do you have a designated employee for this?

Closing Remarks

1. Is there anything you would like to add that we may have missed?
2. Do you have other individuals in your network whom you believe we should contact?
3. Any other general tips?

## A.2 Additional Insights Regarding ATMPs

*As previously mentioned, ATMPs serve as an umbrella term encompassing GTMPs, sCTMPs, TEPs, and combined products. While the primary focus of this study concerns GTMPs, as detailed in the literature review, the subsequent section provides additional insights into the remaining subcategories for interested readers. Furthermore, although regulatory and legal aspects of ATMPs were beyond the scope of this project, they remain crucial considerations. While mentioned throughout the report, they were not extensively covered in the literature review due to their exclusion from the project's scope. Therefore, this section further elaborates on and explains the authorities responsible for the legislations to provide readers with information for future decision-making regarding these regulatory and legal considerations*.

### A.2.1 sCTMPs & TEPs

Besides GTMPs two other subcategories go under the umbrella term of ATMPs: sCTMPs and TEPs. sCTMPs are biological products that contain or consist of cells or tissues that have been subject to substantial manipulation or that are not intended to be used for the same essential function(s) in the recipient and the donor; the recipient and the donor could, however, be the same person [95]. This biomedical technology and methodology aims at assisting and accelerating the regeneration and repairing of defective and damaged tissues based on the natural healing potentials of the patients themselves [96]. This technology has shown tremendous potential in eg. treating rare eye diseases [97]. TEPs are products that contain or consist of engineered cells or tissues and are presented as having properties for or are used in or administered to, human beings to regenerate, repair, or replace human tissue [95]. These treatments show immense potential in everything from "organs on a chip" to test drug candidates for toxicity, to "whole-organ transplants" [98].

### A.2.2 Regulatory Authorities Responsible For Legislations Concerning ATMPs

Besides being a scientific term, ATMP also functions as a legal term with several regulatory frameworks. This section presents a brief overview of the authorities responsible for providing these frameworks, both within the EU and within Sweden.

*EU-regulations For Commercial Use Of ATMPs*
In the European Union (EU), these frameworks were developed by the Committee for Advanced Therapies (CAT), and established by the EU Commission in 2007 (Regulation EC NO. 1394/2007), and were first applied in December of 2008. The framework itself is designed to ensure the free movement of these medicines within the EU, facilitate their access to the EU market, and foster the competitiveness of European pharmaceutical companies in the field while guaranteeing the highest level of health protection for patients. Besides providing the frameworks for ATMPs, CAT plays an important role in the regulatory oversight of these products: among other responsibilities, they are the main scientific committee in charge of evaluating market authorization and applications for these products [99].

*Swedish Regulations For Commercial Use Of ATMPs*

To get approval for any type of medicinal product in Sweden, it has to be approved by the new therapies' council (NT-rådet). The council is an expert group with representatives from Sweden's different regions and is mandated to provide recommendations to the country's regions regarding the use of certain new drugs, usually those used in hospitals. The council makes decisions on recommendations based on the ethical platform for prioritization in healthcare, as decided by the parliament. The end goal of this council is to achieve fair, equitable, and purposeful use of medications for all patients nationwide, ensuring that the collective resources are utilized optimally [100].

## A.3 One-pager For Chalmers Precision HealthTech Hub

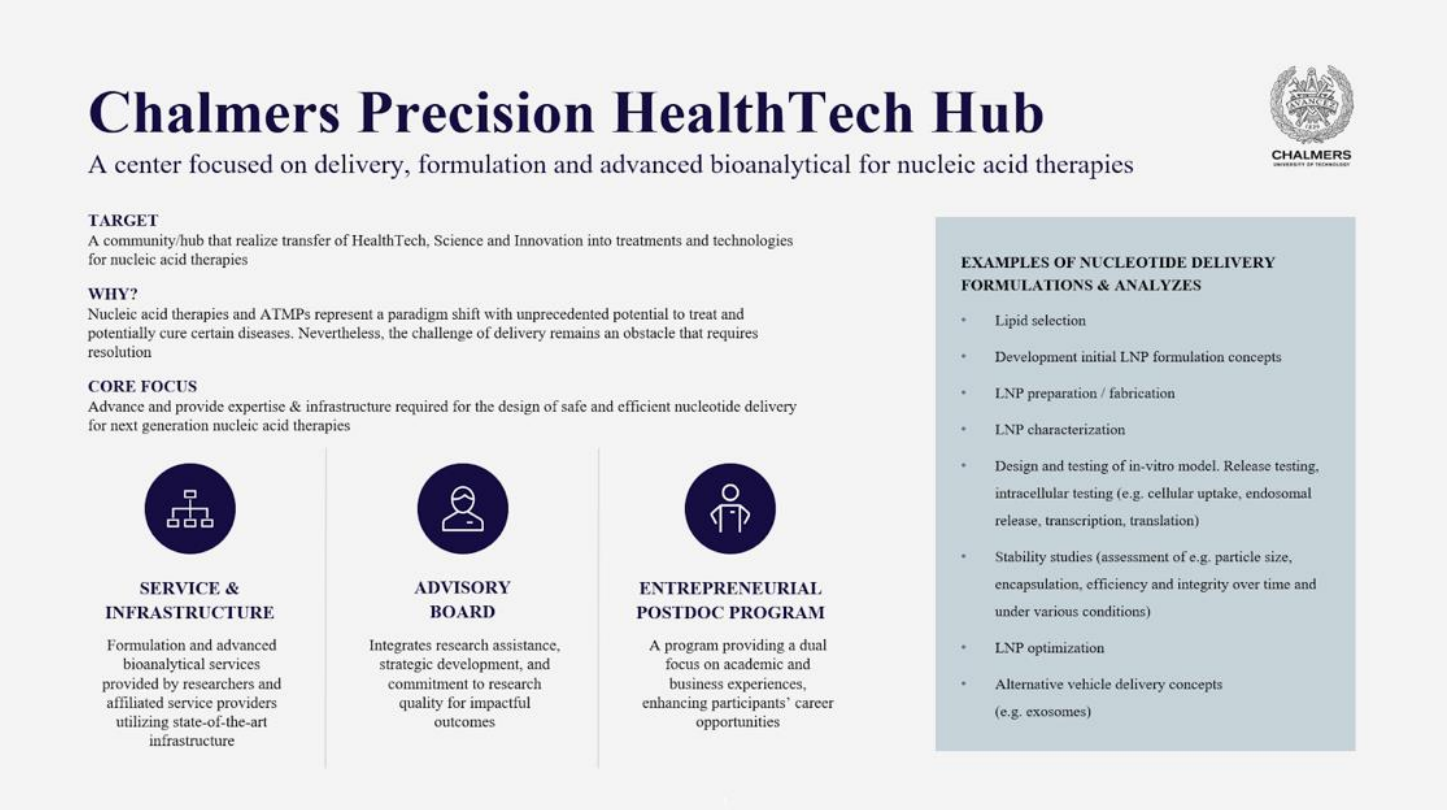


**Figure A.1. One-pager used during interviews to give interviewees a better understanding of the organization Chalmers Precision HealthTech Hub.**